Clinical Guidance for COVID-19 Vaccination

Comirnaty® (Pfizer BioNTech)
Spikevax® (COVID-19 Vaccine Moderna)
COVID-19 Vaccine Janssen®
Comirnaty® 10 mcg/dose for children 5-11 years (Pfizer BioNTech)

Version 36 17/02/2022

This document has been created and updated by the HSE National Immunisation Office
<table>
<thead>
<tr>
<th>Date of revision</th>
<th>18/02/2022</th>
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</table>
| Revisions and additions | Observation period after vaccination changed in line with latest recommendations from the National immunisation Advisory committee  
Addition of FAQ 14.21 in section 17 |
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This guidance is intended for vaccinators administering COVID-19 vaccine.

This guidance is intended for vaccinators who are trained and competent in immunisation practice. Vaccinators should have undergone training in the administration of COVID-19 vaccine(s), recognition and management of anaphylaxis, and basic life support and intramuscular injection technique. They should also be familiar with the anaphylaxis protocol outlined in the Immunisation Guidelines for Ireland (see useful links section).

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

1. Introduction

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

Purpose of the document

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

Indemnity for vaccinators

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

Registered medical practitioners (including GPs), nurses, pharmacists, physiotherapists, dentists, dental hygienists, optometrists, radiographers and radiation therapists, paramedics, advanced paramedics, emergency medical technicians and relevant healthcare students (as per the Statutory Instruments for the administration of COVID-19 vaccines), in receipt of relevant training with regard to administration of the vaccines, who are administering vaccines on the direction of, or on behalf of, the 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. It provided the provisional sequencing for groups to be vaccinated based on clinical priorities and an ethical framework. This was updated on March 31st 2021.

<table>
<thead>
<tr>
<th>Group</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>
</tr>
<tr>
<td>2. Frontline healthcare workers</td>
</tr>
<tr>
<td>3. People aged 70 and older</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>
</tr>
<tr>
<td>5. People aged 65-69 whose underlying condition puts them at a high risk of severe disease and death</td>
</tr>
<tr>
<td>6. Other people aged 65-69 Key workers essential to the vaccine programme</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>
</tr>
<tr>
<td>8. Residents of long-term care facilities aged 16-64</td>
</tr>
<tr>
<td>9. People aged 64 years and younger in the following order:</td>
</tr>
<tr>
<td>i. 64-55 years</td>
</tr>
<tr>
<td>ii. 54-45 years</td>
</tr>
<tr>
<td>iii. 44-35 years</td>
</tr>
<tr>
<td>iv. 34-25 years</td>
</tr>
<tr>
<td>v. 24-16 years</td>
</tr>
</tbody>
</table>

People aged 16-64 living or working in crowded settings

**Additional groups included in the programme**

- Pregnant women and adolescents from 12 years of age should be offered COVID-19 vaccination at any stage in pregnancy
- Vaccination of children aged 12-15 years
- Vaccination of children aged 5-11 years

*see Table overleaf*
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 at the time of vaccination, require an additional dose of vaccine for their primary vaccination course (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>Receiving or within 6 weeks of receiving systemic cytotoxic chemotherapy, targeted therapy, monoclonal antibodies or immunotherapies</td>
<td>Haematological - within 5 years of treatment</td>
</tr>
<tr>
<td></td>
<td>Receiving treatment or pending treatment for a haematological cancer</td>
<td>Non haematological cancer within 1 year following immunomodulating treatment</td>
</tr>
<tr>
<td></td>
<td>Undergoing or within 6 weeks of surgery or radical radiotherapy for lung or head and neck cancer</td>
<td>All other cancers being treated (excluding hormonal treatment)</td>
</tr>
<tr>
<td></td>
<td>Advanced/ metastatic cancer</td>
<td></td>
</tr>
<tr>
<td>Chronic heart (and vascular) disease</td>
<td></td>
<td>e.g. heart failure, hypertensive cardiac disease</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>On dialysis, or eGFR &lt;15 ml/min</td>
<td>With eGFR &lt;30ml/min</td>
</tr>
<tr>
<td>Chronic liver disease</td>
<td></td>
<td>e.g. cirrhosis or fibrosis</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: - APECED - 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 steroids HIV, not on treatment or CD4 count &lt;200 x10^9/L for adults</td>
</tr>
<tr>
<td>Inherited metabolic diseases3</td>
<td>Disorders of intermediary metabolism/at risk of acute decompensation e.g. Maple Syrup Urine Disease</td>
<td>Disorders of intermediary metabolism not fulfilling criteria for very high risk</td>
</tr>
<tr>
<td>Intellectual disability3</td>
<td>Down syndrome</td>
<td>Intellectual disability excluding Down syndrome</td>
</tr>
<tr>
<td>Obesity</td>
<td>BMI &gt;40 kg/m2</td>
<td>BMI &gt;35 kg/m2</td>
</tr>
<tr>
<td>Severe mental illness3</td>
<td></td>
<td>e.g. Schizophrenia, bipolar disorder, severe depression</td>
</tr>
<tr>
<td>Sickle cell disease</td>
<td>Sickle cell disease</td>
<td></td>
</tr>
</tbody>
</table>

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

There are currently four COVID-19 Vaccines authorised for use in Ireland.

mRNA Vaccines


- Comirnaty® is authorised by the EMA for use as a booster dose in those aged 18 and over. (The National immunization Advisory Committee (NIAC) recommends a booster dose in people aged 16 years and older which should be given after a minimum interval of three months).

  Comirnaty® 10 micrograms is licenced by the EMA for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus in children aged 5-11 years. For the primary immunisation course, the dose and schedule of Comirnaty® for this age group is 10 micrograms, two doses given three weeks apart. NIAC have recommended that Comirnaty® 10 micrograms be offered to all children aged 5-11 years. Children aged 5 to 11 years who are severely immunocompromised should be given a third dose of Comirnaty® (10 micrograms) at least 28 days after the second dose to complete the primary series. There are no recommendations for booster does in those aged 5-11 years. Vaccination of those aged 5-11 years is discussed in a separate chapter within this document.


- On 29th October Spikevax® was authorised by the EMA for use as a booster dose in those aged 18 and over. The booster dose is 0.25mls which is half the dose used for the primary series. (NIAC recommends a booster dose of Spikevax® only for people aged 30 years and older which should be given after a minimum interval of three months)

Both Comirnaty® and Spikevax® are authorized by the EMA for use as an extra dose for people with severely weakened immune systems, as an extension of the primary vaccination course. The National Immunisation Advisory Committee recommends that an extended primary vaccination course should be given to those aged 12 years and older with immunocompromise associated with a suboptimal response to vaccines at the time of vaccination, who have completed their primary course. The additional vaccine should be given after a minimum interval of two months following the last dose of an EMA authorized COVID-19 vaccine. Spikevax® is recommended for people aged 30 years and older only (people less than 30 should receive Comirnaty®). Those aged 16 years and older with immunocompromise associated with a suboptimal response to vaccines who have completed a three dose primary series, should be given an mRNA booster vaccine after a minimum interval of three months. Comirnaty® is recommended for those aged 16 years and older and Spikevax® is recommended only for those aged 30 years and older.
Viral Vector Vaccines

COVID-19 Vaccine Janssen® (The Johnson and Johnson/Janssen COVID-19 Vaccine) was authorised for use following a positive scientific recommendation by the EMA on 11th March 2021. 

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

This vaccine is currently used in the COVID-19 vaccination programme only for individuals aged 18 years and older who cannot receive an mRNA vaccine, as a primary course, booster dose or additional dose for immunocompromised.

Please refer to the National Immunisation Advisory Committee guidelines for details of recommendations.

Comirnaty 10 micrograms/dose for children aged 5-11 years was authorised for use following a recommendation by the EMA on the 25th of November.

The vaccine is recommended by the National immunization Advisory Committee for this age group. Please refer to Section 16 for details.

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


Vaxzevria® was last distributed in July 2021 and all remaining stocks were donated and therefore there is no stock currently in Ireland. Vaxzevria® is therefore no longer used in the COVID-19 vaccination programme in Ireland.
Vaccine used in the COVID-19 immunisation programme for those aged 12 years and older (details are in relevant sections of this document)

**Quick Reference Guide to COVID-19 Vaccines**

This is a summary of information, the full clinical guidance and NIAC guidelines should be consulted at [www.immunisation.ie](http://www.immunisation.ie)

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Comirnaty* (Children’s formulation)</th>
<th>Comirnaty* (Pfizer BioNTech)</th>
<th>Spikevax* (Moderna)</th>
<th>COVID-19 Vaccine Janssen* (only if cannot receive an mRNA vaccine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>5-11 years</td>
<td>≥12 years</td>
<td>≥30 years</td>
<td>≥18 years</td>
</tr>
<tr>
<td>Dose</td>
<td>0.2mL</td>
<td>0.3mL</td>
<td>0.5mL</td>
<td>0.5mL</td>
</tr>
<tr>
<td>Interval between dose 1 and dose 2</td>
<td>21 days</td>
<td>21-28 days</td>
<td>28 days</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Timing since COVID-19 infection</td>
<td>4 weeks</td>
<td>4 weeks</td>
<td>4 weeks</td>
<td>4 weeks</td>
</tr>
</tbody>
</table>

Additional dose for immunocompromised (recommended for people aged 5 years and older)

| Age     | 5-11 years                         | ≥12 years                    | ≥30 years           | ≥18 years                                                    |
| Dose    | 0.2mL                              | 0.3mL                        | 0.5mL               | 0.5mL                                                       |
| Interval since finishing primary vaccination course | 28 days                         | 2 months                    | 2 months           | 2 months                                                    |
| Timing since COVID-19 breakthrough infection | At least 3 months             | At least 3 months           | At least 3 months   | At least 3 months                                           |

**Booster dose for eligible groups**

| Age     | Not recommended                    | ≥16 years                    | ≥30 years           | ≥18 years                                                    |
| Dose    | -                                  | 0.3mL                        | 0.25mL              | 0.5mL                                                       |
| Interval since finishing primary vaccination course | -                              | At least 3 months           | At least 3 months   | At least 3 months                                           |
| Timing since COVID-19 breakthrough infection | -                              | At least 3 months           | At least 3 months   | At least 3 months                                           |

*Recommended for people aged 16 years and older, including pregnant women (see Chapter 5a, Immunisation Guidelines).

For any questions regarding deviation in practice from that recommended in the guidance please contact the National Immunisation Office.

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*NIAC does not recommend a second dose, therefore not used for the primary immunization course in this age-group*
4. Infection Prevention and Control for the administration of COVID-19 vaccines

- Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the "WHO five moments of hand hygiene" with emphasis on:
  - Before vaccine preparation
  - Before drawing up and administering the vaccine
  - Before and after each recipient contact

Check HPSC website for latest guidance on infection prevention and control for healthcare workers:
https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/

- PPE should be worn as per HPSC guidance for healthcare staff.
- It is not necessary to use a skin disinfectant prior to injection. If the skin at the injection site is visibly dirty, clean with soap and water. If an alcohol swab is used, delay injection for ≥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/
5. Vaccine details, storage and instructions for preparation and administration.

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

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

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

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

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

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

Contacts for National immunization Office Pharmacists include:
- Cliona Kiersey: mobile 087 9915452
- Mariangela Toma: mobile 087 7575679
- Achal Gupta: mobile 087 4064810

Email the immunisation inbox

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

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

Table 1: Details of Comirnaty® (Pfizer BioNTech) for the primary vaccination course for those aged 12 years and older

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing process</td>
<td>mRNA</td>
</tr>
<tr>
<td>Name of vaccine</td>
<td>Comirnaty® (Pfizer BioNTech)</td>
</tr>
</tbody>
</table>
| Constituents                 | Polyethylene glycol/macrogol (PEG) as part of ALC-0159.  
ALC-0315 = (4-hydroxybutyl) azanediyli)bis (hexane-6,1-diyl) bis (2-hexyldecanoate),  
ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide  
1,2-Distearoyl-sn-glycero-3-phosphocholine  
Cholesterol  
Potassium chloride  
Potassium dihydrogen phosphate  
Sodium chloride  
Disodium hydrogen phosphate dihydrate  
Sucrose  
Water for injections |
| Presentation                 | Concentrated solution of vaccine is contained in a multidose clear glass vial. |
| Number of doses in each vial | Post dilution 6 doses.  
If a seventh dose of 0.3ml can be safely and accurately withdrawn from a diluted vial, it is a valid dose. No more than 7 valid doses are available. |
| Dilution                     | Yes with 0.9% Sodium Chloride (supplied separately)  
Latex                       | No. The vial has a synthetic rubber (bromobutyl) stopper– the vial stopper does not contain latex. |
| Preservatives                | No                                                                         |
| Dosage                       | 0.3ml                                                                     |
| Number of doses required     | 2                                                                          |
| Interval between doses       | The recommended interval between doses is 21 to 28 days  
The minimum interval between doses is 17 days. |

Comirnaty® (Pfizer BioNTech) storage
- The vaccine is delivered from the manufacturer to the HSE National Cold Chain Service (NCCS) at -90°C to -60°C and this storage condition is continued as the vaccine is stored in an ultra-cold temperature (ULT) freezer at -90°C to -60°C.
- The vaccine is supplied 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
Clinical Guidance for COVID-19 Vaccination

(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.

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>Expiry date</td>
<td>The date the vaccine expires when stored in an ultra-cold temperature (ULT) freezer at -90°C to -60°C. This is 9 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>“Use before” date and time Maximum time from removal from ultra-low temperature (ULT) freezer to expiry, when stored at +2°C to +8°C</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 allowed from removal from storage at +2°C to +8°C fridge to dilution</td>
<td>Once the vaccine is removed from the fridge it must be diluted within 2 hours. It must be discarded, if not diluted within 2 hours.</td>
</tr>
<tr>
<td>“Discard” date and time Maximum time allowed from dilution to expiry</td>
<td>When the vaccine is diluted it must be used within 6 hours. The “discard” date and time i.e. 6 hours after dilution must be written on the vial using a 24 hour format. Note: 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. e.g. 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>Transportation time</td>
<td>Undiluted vial maximum of 12 hours - 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. Diluted vial: 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>

For General Practice and Pharmacies, please return any unused and unusable vials to the National Cold Chain Service (NCCS) for destruction. Please give these damaged or unusable vaccines to the NCCS van-driver at your next vaccine delivery. See https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/vaccreturn.pdf
Clinical Guidance for COVID-19 Vaccination

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

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

- Two doses of 0.3mls Comirnaty® 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, if possible 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® (dose 1) and Comirnaty® (dose 2).

<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 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) for those aged 12 years and older

Requirements for diluting the vaccine
- One Comirnaty® (Pfizer BioNTech) multidose vial
- One 10ml ampoule of Sodium Chloride 0.9% solution for injection (Stored at room temperature/should not be kept in a fridge)
- Two 70% alcohol swabs
- One 21 gauge green needle
- A 2.5ml, 3ml or 5ml syringe
### STEP 1. PREPARING FOR DILUTION

[Image showing a step-by-step guide on 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

[Images showing steps of 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

[Image showing a label on the vial]

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

*If a seventh 0.3ml dose can be safely and accurately withdrawn from a diluted vial, then it can be used as valid doses
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 be diluted in advance as per best practice and the manufacturer’s instructions that diluted vials should be used immediately.
- There should be no pooling of vaccine solution from different vials.

Requirements for administration of up to 7 doses of vaccine

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

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

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

Should 8 doses be obtained from a vial the following steps should be considered:
- Identify stage of the process where the error happened e.g. dilution, dose draw up
- Add extra in-process and finished product checking steps
- Retrain personnel involved
- Audit the process regularly

Should 8 doses be administered, in addition to the above steps, the following steps should also be considered:
- Discuss the incident at management level-this is a clinical decision and must be taken locally
- Consider the need for open disclosure
Coring issues with Comirnaty® reconstitution

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

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

The needle used for reconstitution should be 21G or narrower. The presence of rubber stopper particles inside the solution may be due to incorrect technique used during product administration.

STEP 1. Preparation and administration of one dose of vaccine

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

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

\(^1\) 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 in their original carton in a fridge at temperature between +2°C and +8°C. DO NOT store on their side.

Table 4: Details of Spikevax® (COVID-19 Vaccine Moderna) for the primary vaccination course

<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 (DPC) 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>
<tr>
<td>Number of doses in each vial</td>
<td>Up to 10 doses² If more than 10 (0.5 ml) doses can be safely and accurately withdrawn from a vial, they can be used as valid doses. There should be no pooling of vaccine from different vaccine vials As per SmPC the bung must not be punctured more than 20 times</td>
</tr>
<tr>
<td>Dilution</td>
<td>NOT REQUIRED</td>
</tr>
<tr>
<td>Latex</td>
<td>No. The vial has a synthetic rubber stopper (chlorobutyl rubber)– the vial stopper does not contain latex.</td>
</tr>
<tr>
<td>Preservatives</td>
<td>No</td>
</tr>
<tr>
<td>Dosage</td>
<td>0.5ml (PLEASE NOTE THAT IF ADMINISTERING A BOOSTER DOSE, THE DOSE IS 0.25ml. Refer to section 8.0)</td>
</tr>
<tr>
<td>Number of doses required</td>
<td>2</td>
</tr>
<tr>
<td>Interval between doses</td>
<td>28 days is the recommended interval between doses 21 days is the minimum interval</td>
</tr>
<tr>
<td>Transportation time</td>
<td>Within the 30 days storage of the unopened vaccine at +2°C to +8°C, up to 12 hours may be used for transportation.</td>
</tr>
</tbody>
</table>

² Up to 20 doses if booster doses. Refer to Section 8 for details of booster doses
Spikavax® (COVID-19 Vaccine Moderna) storage

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

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

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

Never refreeze thawed vaccine.

**DISCARD date and time**

Once a vial is punctured to draw up the first dose, a “DISCARD” date and time must be written on the vial. The maximum time after which the vial should be discarded is 19 hours. The “DISCARD” date and time is calculated by adding 19 hours to the time the vial is first punctured. The “DISCARD” date and time must be written on the vial using a 24 hour format. e.g. vial is first punctured 29/06/21 at 11.00. Discard date and time is 30/06/2021 at 06.00.

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

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

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

<table>
<thead>
<tr>
<th>Method of Vaccine Storage</th>
<th>Temperature</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerator or Room Temperature</td>
<td>Between +2°C and +25°C</td>
<td>Up to 19 hours (until discard date and time)</td>
</tr>
</tbody>
</table>
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Table 7: Definitions of terms for expiry date and usage times of Spikevax® (COVID-19 Vaccine Moderna)

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

For General Practice and Pharmacies, please return any unopened and unusable vials to the National Cold Chain Service for destruction. Please give damaged or unusable vaccines to the NCCS van-driver at your next vaccine delivery. [https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/vacreturn.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/vacreturn.pdf)

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

**Spikevax® (COVID-19 Vaccine Moderna) dosage, scheduling for the primary vaccination course**

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

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

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3 Please refer to section 8 for details of booster doses
4 The 4 day rule does not apply to the 21 days
Note that Spikevax® is not recommended in people aged <30 years.

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

Table 8: Interval between 2 doses for the Primary Vaccination Course

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

Preparation of Spikevax® (COVID-19 Vaccine Moderna)

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

NEVER refreeze thawed vaccine

**STEP 1. PREPARING THE VACCINE**

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

**STEP 2. LABELLING THE VIAL**

- Label the vial with the “discard” time which is 19 hours after initial puncture using a 24 hour format. Store the vial at temperature between +2°C and +25°C.
- Bring the vial to the vaccination table
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Spikevax® (COVID-19 Vaccine Moderna) dose preparation and administration

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

Requirements for administration of vaccine (IF ADMINISTERIN BOOSTER DOSES, APPROPRIATE NUMBER OF SUPPLIES WILL BE NEEDED FOR EACH VIAL)

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

STEP 1. Preparation and administration of one dose of vaccine

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

Punctured vials: Check the DISCARD time. Never administer the vaccine after the discard time.

With the vial upright, gently swirl the vaccine. Do NOT shake. If the vial is shaken, contact the manufacturer.

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

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

Attach 23 gauge blue needle to 1ml syringe

Withdraw 0.5ml of vaccine

PLEASE NOTE FOR A BOOSTER DOSE, THE VOLUME REQUIRED IS 0.25mls refer to Section 8

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

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5 When vaccination is carried out in settings where this is practicable and feasible, best practice is for the volume of each dose to be checked by a colleague to ensure the correct volume has been withdrawn
Clinical Guidance for COVID-19 Vaccination

Transportation

Within the USE BEFORE date & time, up to 12 hours may be used for transportation. This must include the transportation duration from NCCS to the vaccination site/clinic, which has been recorded on the delivery box.
5.3 COVID-19 Vaccine Janssen®

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

Table 9: Details of COVID-19 Vaccine Janssen® for the primary vaccination course

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of vaccine</td>
<td>Adenovirus vector vaccine*</td>
</tr>
</tbody>
</table>
| Name of vaccine              | COVID-19 Vaccine Janssen  
Ad26.COV2.S                                                                                                                                                                                                                                                                                                                               |
| Constituents                 | 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                                                                                                                                                                                                                                                                 |
| Presentation                 | Multidose clear glass vial  
The vaccine is a colourless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection                                                                                                                                                                                                                                                  |
| Number of doses in each vial | Up to 5 doses  
If more than 5 doses of 0.5mls can be safely and accurately withdrawn from a vial, they can be used as valid doses. There should be no pooling of vaccine from different vials                                                                                                                                                                                                 |
| Dilution                     | NO DILUTION REQUIRED                                                                                                                                                                                                                                                                                                                         |
| Latex                        | No, the vaccine is latex free  
The vial contains a rubber stopper (chlorobutyl with fluoropolymer coated surface), aluminum crimp, and blue plastic cap                                                                                                                                                                                                         |
| Preservatives                | The vaccine does not contain any preservative.                                                                                                                                                                                                                                                                                                 |
| Dosage                       | 0.5 mls                                                                                                                                                                                                                                                                                                                                     |
| Number of doses required     | 1                                                                                                                                                                                                                                                                                                                                            |
| Interval between doses       | No interval – single dose schedule                                                                                                                                                                                                                                                                                                           |

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

**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 Use Before Date.
Clinical Guidance for COVID-19 Vaccination

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 10: Definitions of terms for expiry date and usage times of COVID-19 Vaccine Janssen**

<table>
<thead>
<tr>
<th><strong>Use before date</strong></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is 4.5 months from date the vials were removed from the freezer and stored refrigerated at +2°C to +8°C, The use before date will be on the label on the vaccine box.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>“Discard” date and time</strong></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maximum time allowed from first puncture to expiry</strong></td>
<td>When the vaccine is first punctured it must be used within 3 hours&lt;sup&gt;6&lt;/sup&gt; Do not return to the refrigerator after this time. The “discard” date and time i.e. 3 hours from first puncture of the vial, should be written on the vial using a 24 hour format. E.g. Vial is first punctured on 01/01/2021 at 10.00. Discard date and time is 01/01/2021 at 13.00. This is the date and time that should be written on the vial. Any unused or partially used vials must be discarded when this time has been reached.</td>
</tr>
</tbody>
</table>

**COVID-19 Vaccine Janssen** dosage, scheduling and site of vaccination for the primary vaccination course

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

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

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

<sup>6</sup> 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

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

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

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

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

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

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

Administer vaccine to the patient intramuscularly (see Appendix 1)
Dispose of used needle and syringe in a sharps bin

Repeat for each dose
Once all doses have been administered, discard the vial and record the time and date of discard.

6. Contraindications and precautions to COVID-19 vaccines

When vaccination is carried out in settings where this is practicable and feasible, best practice is for the volume of each dose to be checked by a colleague to ensure the correct volume has been withdrawn.
6.1 mRNA Vaccines Comirnaty® (Pfizer BioNTech) and Spikevax® (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 (COVID-19 vaccine Janssen®) for anyone 18 and older including pregnant women. This should be given after an interval of at least 28 days.

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

Precautions: See Table 12 for more details

- All those aged 16-29 should not receive Spikevax® as a 2nd or subsequent dose, they should receive Comirnaty® instead
- 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.
- A history of pericarditis after a previous dose of an mRNA vaccine: (seek specialist advice before vaccination).

- Consider adenoviral vector vaccination for those aged 18 years and older, including pregnant women, with:
  - Anaphylaxis after multiple, different drug classes, with no identified allergen (may indicate PEG allergy)
  - Anaphylaxis after a vaccine, or a medicine which contained PEG
  - Unexplained anaphylaxis (may indicate PEG allergy)

- Patients with planned immunosuppressive therapy should ideally complete vaccination 2 weeks before treatment. The recommended minimum interval may be used. Specialists should consider the individual’s risk and provide advice based on the person’s immune response and likely immune response to vaccination.

For more information see Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions www.rcpi.ie
## Table 11: Vaccination of those due an mRNA COVID-19 vaccine

<table>
<thead>
<tr>
<th>History</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contraindication</strong></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></td>
<td>If aged ≥18 year consider vaccination with COVID-19 vaccine Janssen® in a suitable facility. Observe for 30 minutes or Discuss with allergist/immunologists</td>
</tr>
<tr>
<td>• Anaphylaxis after polyethylene glycol (PEG) e.g. some bowel preparations for endoscopy, certain laxatives such as Movicol®)</td>
<td></td>
</tr>
<tr>
<td>• Anaphylaxis after Trometamol®: Spikevax® (COVID-19 vaccine Moderna) is contraindicated</td>
<td>Vaccinate with alternative vaccine</td>
</tr>
<tr>
<td><strong>Special precautions (people &lt;30 years)</strong></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)</td>
</tr>
<tr>
<td></td>
<td>If 12-17 years, discuss with allergist/immunologist</td>
</tr>
<tr>
<td>• Anaphylaxis after a vaccine, or a medicine which contained PEG</td>
<td></td>
</tr>
<tr>
<td>• Unexplained anaphylaxis (may indicate PEG allergy)</td>
<td>If aged ≥18 years, consider vaccination with COVID-19 vaccine Janssen®</td>
</tr>
<tr>
<td></td>
<td>Observe for 30 minutes</td>
</tr>
<tr>
<td>All those aged 16-29 years should receive Comirnaty® as a second or subsequent dose unless contraindicated</td>
<td></td>
</tr>
<tr>
<td>• Mastocytosis</td>
<td>Vaccinate as scheduled</td>
</tr>
<tr>
<td>• Idiopathic anaphylaxis</td>
<td>Observe for 30 minutes</td>
</tr>
<tr>
<td>• Anaphylaxis after food, venom or medication</td>
<td></td>
</tr>
<tr>
<td><strong>Not a contraindication or a precaution</strong></td>
<td></td>
</tr>
<tr>
<td>• Non-anaphylactic food allergy</td>
<td>Vaccinate as scheduled</td>
</tr>
<tr>
<td>• Family history of allergy, including anaphylaxis</td>
<td>Observe for 15 minutes</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>• Underlying asthma</td>
<td></td>
</tr>
<tr>
<td>• Hay fever</td>
<td></td>
</tr>
<tr>
<td>• NSAID allergy</td>
<td></td>
</tr>
<tr>
<td>• Chronic spontaneous urticarial</td>
<td></td>
</tr>
</tbody>
</table>

1 including pregnant women
6.2 Viral vector vaccines COVID-19 Vaccine Janssen®

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
  - unexplained anaphylaxis (may indicate polysorbate 80 allergy)

If an individual has a history of thrombocytopenic disorder, the risk of developing low platelet levels such as Immune thrombocytopenia (ITP) as a very rare side effect to COVID-19 Vaccine Janssen® should be considered before vaccination. Therefore platelet monitoring is recommended after COVID-19 Vaccine Janssen vaccination in an individual who has a past history of ITP.

Please refer to the National immunization Advisory Committee’s guidelines for details.

Table 12: Vaccination with COVID-19 vaccine Janssen

<table>
<thead>
<tr>
<th>Contraindication</th>
<th>History</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaphylaxis after a previous dose of a viral vector vaccine (Vaxzevria®)</td>
<td>Discuss with allergist/immunologist</td>
<td></td>
</tr>
<tr>
<td>Anaphylaxis after Polysorbate 80</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Special precautions</th>
<th>History</th>
<th>Action</th>
</tr>
</thead>
</table>
| Anaphylaxis after a vaccine, injected antibody preparation, or a medicine known to contain Polysorbate 80 | Clarify if polysorbate 80 is tolerated (see FAQs)
| Unexplained anaphylaxis (may indicate polysorbate 80 allergy) | Discuss with allergist/immunologist
| Mastocytosis | Observe for 30 minutes |
| Idiopathic anaphylaxis | |
| Anaphylaxis after food, venom or medication | Vaccinate as scheduled
| | Observe for 30 minutes |
## Not a contraindication or a precaution

- Non-anaphylactic food allergy
- Family history of allergy, including anaphylaxis
- Previous local reaction to any vaccine
- Hereditary angioedema
- Contact dermatitis to PEG containing cosmetic product
- Patients with stable asthma on biologic therapy
- NSAID allergy

Vaccinate as scheduled
Observe for 15 minutes

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

### 6.3 Vaccination after COVID-19 (primary vaccination course)

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

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

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

See section 8 for details on booster vaccination and section 7.8.1 for guidance on the additional dose in immunocompromised people.
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 this includes the additional mRNA vaccine dose recommended for immunocompromised individuals and the booster vaccine dose.

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 of stillbirth 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 — 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, 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 on-going. Please note that women aged less than 30 years should receive Comirnaty®, rather than Spikevax ® as a second, booster or additional dose.

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. Visit www.rcpi.ie

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

Please refer to Section 8.0 for details of Booster vaccination and section 7.8.1 for details of additional dose for immunocompromised individuals.

COVID-19 vaccine Janssen may be considered for pregnant women who cannot receive an mRNA vaccine because of a contraindication or precaution.
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 the treatment on the day of vaccination, prior to the IM vaccination.

If there is uncertainty about the need for cover, contact the patient’s Comprehensive Care Centre. If an individual has a history of thrombocytopenic disorder, the risk of developing low platelet levels such as Immune Thrombocytopenia (ITP) should be considered before vaccination with virus vector COVID-19 Vaccine Janssen®, and platelet monitoring is recommended after vaccination with in an individual who has a history of ITP.

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 for those aged over 12 years

Other vaccines may be administered with COVID-19 vaccines at the same time or at any interval before or after a Covid-19 vaccine. If other vaccines are being given at the same time as COVID-19 vaccines it is preferable to give them in separate limbs.

7.8 Immunosuppression due to disease or treatment

Individuals with immunsupression due to disease or treatment should be vaccinated if they have no contraindications. Patients with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used. Specialists should consider the individual’s risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of the patient’s immune status and likely immune response to vaccination.

7.9 Extended Primary Course for those with immunosuppression due to disease or treatment

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

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

People less 30 years of age should receive Comirnaty® and not Spikevax®. This is as a precaution, due to the reports of higher risk of myocarditis or pericarditis following vaccination with Spikevax®, when compared with Comirnaty®.

The additional vaccine should be given after a minimum interval of two months following the last dose of an authorised COVID-19 vaccine. If the vaccine is given before the minimum interval, there is no evidence of the safety and efficacy of administering further doses of vaccine, and therefore additional vaccine doses should not be administered.

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

Vaccination after breakthrough infection

For those who have had laboratory confirmed COVID-19 breakthrough infection since full vaccination with an

---

9 The EMA’s human medicines committee (CHMP) has concluded that an extra dose of the COVID-19 vaccines Comirnaty® (Pfizer BioNTech) COVID-19 mRNA Vaccine and SpikeVax® (COVID-19 Vaccine Moderna) may be given to people with severely weakened immune systems, at least 28 days after their second dose.

However, in Ireland we follow the interval recommended by the National Immunization Advisory Committee (i.e. a minimum interval of two months following the last dose of an authorised COVID-19 vaccine)
Clinical Guidance for COVID-19 Vaccination

authorized COVID-19 vaccine, the additional dose should be deferred until at least 3 months from diagnosis. If it is not possible to establish if an individual had laboratory confirmed breakthrough infection during that timeframe, they may be vaccinated.

**Contraindication to mRNA vaccines:**
A viral vector vaccine (COVID-19 Vaccine Janssen®) may be considered as an additional dose in those with a contraindication or precaution to an mRNA vaccine, including pregnant women. For those aged <18 years with a contraindication to an mRNA vaccine, the advice of an immunologist should be sought.

There is more limited data regarding the safety of an additional dose of mRNA COVID-19 vaccine. However, evidence to date has not indicated any safety concerns. The adverse event profile appears similar to that of the primary vaccination series.

**7.10 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).

**7.11 People aged 12 to 18 years of age**
Comirnaty® 30 micrograms (Pfizer BioNTech) is recommended for active immunisation to prevent COVID-19 in individuals 12 years of age and older. Those aged 16 years and older may give their own consent.

People aged 16-29 years should not receive Spikevax® as a primary course as a precaution because of reports of more frequent cases of myocarditis and pericarditis following a second dose of Spikevax®, compared with a second dose of Comirnaty®. COVID-19 Vaccine Janssen® is not licensed for active immunisation to prevent COVID-19 in individuals under 18 years of age. There is insufficient data on the safety and efficacy in children of COVID-19 Vaccine Janssen® in individuals less than 18 years. Vaccination for children aged 5-11 years is discussed in a separate chapter within this guidance document.
8. Booster COVID-19 Vaccines

Booster doses are recommended for everyone aged 16 years and older including pregnant women who have completed a primary vaccination course and for those with immunocompromise associated with a suboptimal response to vaccines who have completed an extended primary course. Booster should be administered after a minimum interval of three months in order of priority as per NIAC guidance.


The following vaccines are recommended:

People aged 16-29
Comirnaty® 0.3mls (Spikevax® should not be administered).
This is as a precaution because of reports of an increased frequency of myocarditis and pericarditis from a 2nd dose of Spikevax®, when compared with Comirnaty®

People aged 30 years and older:
- Comirnaty® 0.3mls
- Spikevax® 0.25mls (NOTE THIS IS HALF THE DOSE FOR THE PRIMARY VACCINATION COURSE)

Immunocompromise associated with suboptimal response to vaccines
Those aged 16 years and older with immunocompromise associated with a suboptimal response to vaccines who have completed a primary series and received an additional dose of an mRNA vaccine, should also be given an mRNA booster vaccine after a minimum interval of three months. The booster dose is Comirnaty® 30 micrograms (0.3mls) for those aged 16-29 years or Spikevax 50 micrograms (0.25mls) for those aged 30 years and older.

Please refer to section 5.1 for details of preparation and reconstitution, transport and storage of vaccine

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of vaccine</td>
<td>Comirnaty® (Pfizer-BioNTech)</td>
</tr>
<tr>
<td>Number of doses in each vial</td>
<td>Post dilution 6 doses. If a seventh dose of 0.3ml can be safely and accurately withdrawn from a diluted vial, it is a valid dose. No more than 7 valid doses are available. There should be no pooling of vaccine from different vaccine vials.</td>
</tr>
<tr>
<td>Dosage of booster dose</td>
<td>0.3mls</td>
</tr>
<tr>
<td>Number of doses required</td>
<td>1</td>
</tr>
<tr>
<td>Interval between booster dose and last dose of an authorised COVID-19 vaccine</td>
<td>A booster dose of vaccine should be given after a minimum interval of three months regardless of which vaccine was given for the primary immunisation course.</td>
</tr>
<tr>
<td>Interval between laboratory confirmed breakthrough COVID-19 infection and booster dose</td>
<td>At least 3 months</td>
</tr>
</tbody>
</table>
Please refer to section 5.2 for details of preparation, transport and storage of vaccine

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of vaccine</td>
<td>Spikevax® (Moderna)</td>
</tr>
<tr>
<td>Number of doses in each vial</td>
<td>Up to 20 booster doses</td>
</tr>
<tr>
<td></td>
<td>As per SmPC, the bung must not be punctured more than 20 times</td>
</tr>
<tr>
<td>Dosage Of booster dose</td>
<td>THE DOSE IS 0.25ml(^{11})</td>
</tr>
<tr>
<td>Number of doses required</td>
<td>1</td>
</tr>
<tr>
<td>Interval between doses of booster dose and last dose of</td>
<td>A booster dose of vaccine should be given after a minimum interval of three</td>
</tr>
<tr>
<td>an authorised COVID 19 vaccine</td>
<td>months regardless of which vaccine was given for the primary immunisation</td>
</tr>
<tr>
<td></td>
<td>course.</td>
</tr>
<tr>
<td>Interval between laboratory confirmed breakthrough</td>
<td>At least 3 months</td>
</tr>
<tr>
<td>COVID-19 infection and booster dose</td>
<td></td>
</tr>
</tbody>
</table>

**Rationale for booster programme**

- The primary aim of the booster campaign is to protect against severe breakthrough infection.
- Age and underlying conditions are the most important determinants of risk of severe breakthrough infection. Pregnancy is a risk factor for severe illness and adverse outcomes related to COVID-19.
- Booster vaccination is associated with a substantial reduction in the rate of severe illness in those aged 40 years and older and also a reduction in confirmed infection across the age groups.
- Booster doses of mRNA vaccines have not shown any unexpected short term safety concerns. The risk of myocarditis or other rare adverse reaction following an mRNA booster dose has yet to be characterised and will be closely monitored.
- Recent data shows that primary COVID-19 vaccine protection against the Omicron variant is not as robust as that against the Delta variant. Neutralising antibodies against the Omicron variant, which are a known correlate of protection, can be significantly increased by booster vaccination.
- Reducing the interval between the primary course and the booster dose should facilitate earlier protection. Therefore, NIAC have recommended shortening the interval between the primary course and the booster to three months.
- Data on a fourth dose of a COVID-19 vaccine in those with immunocompromise associated with a suboptimal response to vaccines are limited. However, they are at a higher risk of severe outcomes of COVID-19 and also at increased risk of decreasing protection over time since vaccination, thus a booster dose at a shorter interval is recommended.

\(^{11}\)Note this is the volume for the booster dose. For people who are immunocompromised and receiving an additional dose to complete the primary vaccination course, a full dose of 0.5mls should be given.
For those who are immunocompromised and receiving a booster dose following an extended primary course, a 0.25mls booster dose should be given.
Recommended interval

- The booster dose should be given after an interval of three months following the last dose of any authorised COVID-19 vaccine and can be given at the same time or at any interval before or after seasonal influenza vaccine or other vaccines.

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.

If a booster dose was given in error before the 2 month minimum interval, this is not considered a valid vaccine. However, there is no evidence of the safety and efficacy of any additional doses. Revaccination is not recommended.

Vaccination after COVID-19 breakthrough infection
For those who have had laboratory confirmed COVID-19 breakthrough infection since full vaccination with an authorized COVID-19 vaccine, the booster dose should be deferred until at least 3 month from diagnosis. If it is not possible to establish if an individual had laboratory conformed breakthrough infection during that timeframe, they may be vaccinated.

Adverse events
There is more limited data regarding the safety of a booster dose of COVID-19 vaccine. However, evidence to date has not indicated any safety concerns. The adverse event profile appears similar to that of the primary vaccination series. The risk of myocarditis or other rare adverse reactions following an mRNA booster dose has yet to be characterized and are being closely monitored.

Vaccination in pregnancy
Pregnant women are recommended to receive a booster dose of an mRNA vaccine. The booster dose can be given at any time during pregnancy.

Contraindications to mRNA vaccines
A viral vector vaccine (COVID-19 Vaccine Janssen®) may be considered as a booster dose in those with a contraindication or precaution to an mRNA vaccine. This includes pregnant women.
9. Protection from COVID-19 vaccines after a primary vaccination course

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

- 7 days after the second dose of Comirnaty® (Pfizer BioNTech)
- 14 days after second dose of Spikevax® (COVID-19 Vaccine Moderna).
- 15 days after the second dose of Vaxzevria® (AstraZeneca) (vaccine no longer available in Ireland)
- 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 duration of protection from COVID-19 vaccines.

Duration of protection after a booster COVID-19 vaccination has not yet been determined.

Vaccinated persons should be informed that they should continue to follow all current public health guidance to protect themselves and others.
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 13: Recording vaccine details**

<table>
<thead>
<tr>
<th>Comirnaty® (Pfizer BioNTech)</th>
<th>Spikevax® (COVID-19 Vaccine Moderna)</th>
<th>COVID-19 Vaccine Janssen®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use before date and time of vaccine</td>
<td>Use before date of vaccine</td>
<td>Use before date of Vaccine</td>
</tr>
<tr>
<td>Batch number of vaccine</td>
<td>Batch number of vaccine</td>
<td>Batch number of Vaccine</td>
</tr>
<tr>
<td>Batch number of Sodium Chloride diluent</td>
<td></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 Use Before date supersedes the expiry date on the vial.

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.

**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:

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

10.2.1 Observation after administration of booster doses

NIAC recommends that the 15 minute observation period following administration of a homologous or heterologous booster COVID-19 mRNA vaccine can be temporarily waived.

The reasons for this recommendation are:

- The risk of a serious allergic reaction after mRNA vaccination is very rare (1-10 per million).
- Removing the 15 minute post observation requirement will enable more people to be vaccinated.

If people are receiving another vaccine (e.g. flu vaccine) at the same time as the booster, do not waive the observation period.

This recommendation does not apply to those:

- receiving a primary COVID-19 vaccine course, who should be observed for 15 minutes.
- with a history of mastocytosis receiving a booster vaccine, who should be observed for at least 30 minutes.

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

11.1 **Adverse reactions of COVID-19 vaccines**

The adverse events are listed below in Table 15 according to the following frequency: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to < 1/1,000), Very rare (< 1/10,000).

**Table 14: Adverse reactions of COVID-19 vaccines from clinical trials and post authorisation experience**

<table>
<thead>
<tr>
<th>Type of Reaction</th>
<th>Comirnaty® (Pfizer BioNTech)</th>
<th>Spikevax® (Moderna)</th>
<th>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 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: 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, injection site swelling</td>
</tr>
<tr>
<td></td>
<td>General: nausea, vomiting</td>
<td>General: rash</td>
<td>General: cough, fever, chills, joint pain,</td>
</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: Tremor, sneezing, oropharyngeal pain, rash, hyperhidrosis, muscle pain, pain in extremities, back pain, asthenia, malaise, diarrhea, paresthesia</td>
</tr>
<tr>
<td></td>
<td>General: insomnia, lymphadenopathy, extremity pain (refer to the vaccinated arm), hyperhidrosis (night sweats), decreased appetite, asthenia and lethargy Hypersensitivity reactions (e.g. rash, pruritus, urticaria, angioedema)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

12 Refer to Appendix A for details of Vaxzevria®
## Clinical Guidance for COVID-19 Vaccination

<table>
<thead>
<tr>
<th>Rare (≥ 1/10,000 to &lt; 1/1,000)</th>
<th>Very rare (&lt; 1/10,000)</th>
<th>Not known (cannot be estimated from the available Data)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General: acute peripheral facial paralysis</td>
<td>Myocarditis and pericarditis***</td>
<td>Anaphylaxis</td>
</tr>
<tr>
<td>General: acute peripheral facial paralysis/Bell’s Palsy, facial swelling in those who have had dermatological fillers</td>
<td>Thrombosis in combination with thrombocytopenia**</td>
<td>Facial swelling in those who have had dermatological fillers</td>
</tr>
<tr>
<td>General: Hypersensitivity, urticarial, hypoesthesia, lymphadenopathy, vomiting and tinnitus</td>
<td>Capillary leak syndrome, Guillain-Barré syndrome</td>
<td>Extensive swelling of the vaccinated limb</td>
</tr>
<tr>
<td>Venous Thromboembolism</td>
<td></td>
<td>Myocarditis and pericarditis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Erythema Multiforme</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Erythema Multiforme</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 15 lists the most frequent adverse reactions reported during clinical trials.

**Table 15: Details of most frequent adverse reactions reported during clinical trials of COVID-19 Vaccines**

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

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

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

The cases occurred particularly in males aged under 30 years, and following the second dose of Spikevax. In the US, reported rates in males were 1 case per 100,000 after a first dose, and 6.7 per 100,000 after a second dose.

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

Studies have shown that after the second dose of Comirnaty there were about 2.6 extra cases of myocarditis per 100,000 males aged 12 - 29 years after seven days and 5.7 extra cases of myocarditis per 100,000 males.
aged 16 - 24 years after 28 days. The rates for Spikevax were three to five times higher.

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

- breathlessness,
- palpitations and
- chest pain.

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

Please refer to section 8 for details of booster doses.

### 11.3 Adverse events following COVID-19 Vaccine Janssen® and very rare cases of Thrombosis and Thrombocytopenia Syndrome (TTS)

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

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

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.

The clinical features of TTS include cerebral venous sinus thrombosis (CVST), splanchnic vein thrombosis and thrombosis at other sites, arterial ischaemia 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 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.

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 COVID-19 Vaccine Janssen should be given to people aged 50 years and older, and that younger people should be offered an mRNA vaccine. In Ireland, COVID-19 vaccine Janssen is offered to individuals from the age of 18 who cannot receive an mRNA vaccine due to a contraindication or precaution.
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Early recognition and prompt treatment are important in the management of TTS. Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia.

- Recipients of COVID-19 Vaccine Janssen® should be advised to seek immediate medical attention if they develop the following symptoms in the weeks after vaccination:
  - shortness of breath
  - chest pain
  - leg swelling
  - persistent abdominal pain
  - severe or persistent headaches (particularly 3 or more days after vaccination)
  - blurred vision
  - confusion (or mental status change)
  - seizures
  - petechiae or ecchymoses beyond the site of vaccination

- Healthcare professionals should seek early expert advice from the National Coagulation Centre about the specialised testing and treatment options for patients presenting with thromboembolic events that are associated with thrombocytopenia, (including Disseminated Intravascular Coagulation (DIC) or Cerebral venous sinus thrombosis (CVST)) occurring within weeks following vaccination with COVID-19 Vaccine Janssen. Furthermore, the EMA has recommended that healthcare professionals who diagnose thrombocytopenia post vaccination should check for any thrombosis and vice versa (i.e. if they have a diagnosed thrombosis to check for thrombocytopenia).

11.4 Adverse events following COVID-19 Vaccine Janssen® and Rare cases of Venous Thromboembolism (VTE)

VTE (which is different from TTS or Thrombosis with Thrombocytopenia syndrome) was added a rare (frequency >1/10,000 to <1/1,000) side effect of COVID-19 vaccine Janssen based on data from clinical trials and post marketing surveillance. Healthcare professionals and individual receiving the vaccine should be aware of this risk, especially in those who may have an increased risk of VTE.

11.5 Adverse events following COVID-19 vaccine Janssen® and very rare cases of Capillary Leak Syndrome (CLS)

On the 9th of July 2021, the EMA’s safety committee (PRAC) 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
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syndrome, must not be vaccinated with 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 COVID-19 Vaccine Janssen®).

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

- There may be circumstances where a person has received a first dose of Vaxzevria® but has not received 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® and are considering receiving an mRNA vaccine as their second dose should be informed that:
  - The National immunisation Advisory Committee have recommended that a heterologous schedule can be used
  - The EMA have issued recommendations that a heterologous vaccination approach can be used. However this option is not yet licensed by the EMA and so is “off-label”.


- 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.

**11.6 COVID-19 Vaccine Janssen® and very rare cases of Guillain-Barre Syndrome**

**Information for vaccinated people**

Guillain-Barre syndrome (GBS) has occurred very rarely in people who have had COVID-19 Vaccine Janssen®. GBS is a rare neurological disorder in which the body's immune system mistakenly attacks nerves located outside the brain and spinal cord. Symptoms of GBS range from mild weakness to more severe paralysis. Most people eventually fully recover even from the most severe symptoms, while some may continue to have some degree of weakness.

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

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

Healthcare professionals should be alert to signs and symptoms of GBS to ensure correct diagnosis, to initiate adequate supportive care and treatment and to rule out other causes.
11.7 **Immune Thrombocytopenia (ITP) with COVID-19 Vaccine Janssen®**

ITP is a condition in which the immune system mistakenly targets blood cells called platelets that are needed for normal blood clotting. It can cause bleeding and can sometimes be fatal. Very few cases of ITP have occurred after COVID-19 Vaccine Janssen. It has usually occurred within 4 weeks of vaccination and will be added as a side effect for both vaccines (frequency unknown).

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

11.8 **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](http://www.hpra.ie). As much information as is known should be provided, and where possible, the vaccine batch number should be included.

11.9 **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/](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.

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**

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

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

**Primary vaccination:**
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 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. Healthcare staff in LTCFs should follow public health and occupational health guidance. www.hpsc.ie

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/
15. Frequently asked questions (FAQs) about COVID-19 vaccines

Please refer to Section 16 for FAQs on the vaccination of children aged 5-11 years

15.1 Should unvaccinated 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.

The primary vaccination course 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.

15.2 What if somebody is diagnosed with COVID-19 infection after a first dose of vaccine of the primary vaccination course?
Vaccination with the second dose 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.

Please refer to sections 15.22 and 15.23 for details of timing of booster and immunocompromised additional doses of vaccination after breakthrough infection.

15.3 What if the second dose of COVID-19 vaccine in the primary vaccination course is administered at less than the recommended interval for those aged 12 years and older?
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.

15.4 For the primary vaccination course, 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 settings 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) vaccine inadvertently?
The vaccine formulation used for adults is 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 30 years is given Spikevax® inadvertently?
If a person under the age of 30 years receives the vaccine inadvertently, an incident form should be 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 also be advised of the very rare reported adverse event of myocarditis and pericarditis and the symptoms to be aware of. If the person who received the vaccine is less than 12 years of age, the incident should also be reported to the HPRA (the vaccine is not licensed for this age-group).

15.12 What if a person under 18 years is given 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. They should also be advised of the very rare adverse event of Guillain-Barré syndrome and of the symptoms to be aware of.

15.13 What if a woman becomes pregnant between the first and second dose of a COVID-19 vaccine?
Women may complete the primary vaccination course 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.

15.15 Can COVID-19 vaccines affect fertility?
There is no biologically plausible reason why the vaccines would affect fertility. The vaccines cannot interact with a person’s DNA. The European Medicines Agency licensed documentation states that animal studies do not indicate direct or indirect harmful effects on fertility.
15.16  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.

15.17  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).

15.18  Should a person who has already received a first dose of Vaxzevria® (AstraZeneca) be offered a different vaccine for their second dose?
If a person has received a single dose of Vaxzevria® and did not receive a second dose, they may receive an mRNA vaccine as their second dose. They must be informed that:
  o The National Immunisation Advisory Committee have recommended that a heterologous schedule can be used
  o The EMA have issued recommendations that a heterologous vaccination approach can be used. However this option is not yet licensed by the EMA and so is “off-label”.
  o The rate of side effects following the administration of a heterologous vaccination schedule may be higher

15.19  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.

15.20  Can other vaccines be co-administered with COVID-19 vaccines for those aged 12 years and older?
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.

15.21  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

15.22 Who is recommended to receive a COVID-19 booster dose?
NIAC recommends people aged 16 years and over should be offered a booster dose of a COVID-19 vaccine. See Section 8 for more details.

15.23 What is the advice for timing of a booster dose in someone who has had a breakthrough infection since completing their primary vaccination course?
If a person has had laboratory confirmed (PCR) breakthrough COVID-19 infection since completion of their primary course, the booster dose should be deferred for at least 3 months after diagnosis. If it is not possible to establish if a person had breakthrough COVID-19 infection in this timeframe, they may be vaccinated.

15.24 What is the advice for timing of an additional dose of vaccine for an immunocompromised person who has had a breakthrough infection since completing their primary vaccination course?
If a person has had laboratory confirmed (PCR) breakthrough COVID-19 infection since completion of their primary course, the additional dose should be deferred for at least 3 months after diagnosis. If it is not possible to establish if a person had breakthrough COVID-19 infection in this timeframe, they may be vaccinated.

15.25 What if an additional dose for immunocompromised people is given before the minimum interval? Is there a need to repeat the dose?
If the vaccine is given before the recommended interval (2 months), there is no evidence as to the safety and efficacy of giving a further dose under these circumstances to complete the primary course. The dose should not be repeated. However, a booster vaccine should still be given after a minimum interval of three months.
Clinical Guidance for COVID-19 Vaccination

The person (and their parents/guardians if less than 16 years old) should be advised regarding the error and the incident reported. The error should be reported to the HPRA.

15.26 What if a booster dose is given before the minimum interval? Is there a need to repeat the dose?
If the vaccine is given before the minimum interval (2 months), there is no evidence as to the safety and efficacy of giving a further dose under these circumstances. The dose should not be repeated.

The person should be advised regarding the error and the incident reported. The error should be reported to the HPRA.

15.27 What if a person is given a booster dose of 0.5mls dose of Spikevax®/Moderna instead of the recommended and licensed 0.25ml dose?
The person should be informed of the error. The error should be reported to the HPRA, and an incident form completed. The person should be informed of the risks of very rare side effects from the vaccine including myocarditis and pericarditis, and the symptoms to be aware of.

15.28 What if a person less than 30 years of age is given a booster or an additional dose of Spikevax®?
The person should be informed of the error. An incident form completed. The person should be informed of the risks of very rare side effects from the vaccine including myocarditis and pericarditis and the symptoms to be aware of.

15.29 What should I do if a person who is immunocompromised and is receiving an additional dose of Spikevax® receives a 0.25ml dose (a booster dose) in error?
If the error is discovered on the same day a further 0.25ml dose can be given and these two doses can be considered as a valid vaccine.

If the error is discovered later, they should receive the correct 0.5ml dose as soon as possible (no minimum time interval required).

The subsequent booster dose of 0.25ml should be given at the recommended interval i.e. at least 3 months after the correct dose (or the two 0.25mls doses) is administered.

The person should be informed of the error and an incident form completed. The error should be reported to the HPRA if the person experiences an adverse event as a result. Vaccination of children aged 5-11 years
16. Vaccination of children aged 5-11 years

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

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

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

16.1 National Immunisation Advisory Committee recommendation

Following approval of Comirnaty® formulation for children by the European Medicines Agency (EMA) in November 2021, the National Immunisation Advisory Committee (NIAC) has made the following recommendations:

- COVID-19 vaccination is strongly recommended for those aged 5 to 11 years:
  - With underlying conditions
  - Living with a younger child with complex medical needs
  - Living with a person who is immunocompromised

- COVID-19 vaccination should be offered to all other children aged 5 to 11 years
  - This is because of the favourable benefit risk profile of the vaccine, to protect them from severe disease and from the consequences that can follow infection e.g., multisystem inflammatory syndrome in children (MISC), long COVID as well as psychosocial and developmental impacts

- Children aged 5 to 11 years who are severely immunocompromised should be given a third dose of Comirnaty® at least 28 days after the second dose to complete the primary series

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

The decision to accept, defer or refuse vaccination for a child should be respected.

16.2 Vaccine storage

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

- The vaccine is supplied to sites/clinics by the HSE National Cold Chain Service at +2 to +8°C with a shelf life of 10 weeks. This new “use before” time and date is labelled by NCCS once vials are removed from ULT.

- The vaccine in each multi-dose vial requires dilution with 1.3ml of 0.9% sodium chloride.

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

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

  After dilution, the vaccine must be kept at +2°C to +30°C and used within 12 hours after which the vial must be discarded.
### Summary of Comirnaty 10 micrograms/dose

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

### 16.3 Vaccine dose

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

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

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

*This image overleaf shows the children's formulation*
16.4 Interval between doses
The recommended interval between doses is 21 days. If the interval between doses is longer than 21 days, the second dose should be given as soon as possible. The course does not need to be restarted. The minimum interval is 19 days. This is a different minimum interval compared to the minimum interval for those aged ≥12 years. The date of administration of the 1st dose is to be calculated as Day 0. If the second dose is given between 19 and 20 days after the first dose, it is a valid dose. If the second dose is given before 19 days, this is not considered a valid dose. A third dose should be given 21 days after the second (invalid) dose.

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

16.5 Interchangeability of vaccines
The same vaccine should be used for both doses.

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

Note that the day the 1st dose of vaccine is given is day 0
16.6  Infection prevention and control

- Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the “WHO five moments of hand hygiene” with emphasis on:
  - Before vaccine preparation
  - Before drawing up and administering the vaccine
  - Before and after each recipient contact
- PPE should be worn as per Health Protection Surveillance Centre (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.
- Gloves are not routinely recommended for vaccine preparation and administration
- There is no need to routinely check temperature either at registration or before vaccination.
- Follow HPSC standard precautions (sharps management, healthcare waste management etc.)
  
  https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectionpreventionandcontrolguidanceandframework/

- Check HPSC website for latest guidance on infection prevention and control for healthcare workers:
  
  https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/

16.7  Vaccine Dilution and Preparation for Administration

Prior to dilution

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

Preparation for dilution

Prepare the equipment needed for dilution:

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

Check the use before date and time on the box containing the vials i.e., that the vial has NOT been stored in the fridge for more than 10 weeks. Before dilution mix by inverting vaccine vial gently 10 times, do not shake. Inspect the liquid in the vial prior to dilution, the liquid is a white to off-white suspension and may contain opaque amorphous particles. Do not use if the liquid is discoloured or if other particles are observed.
Clinical Guidance for COVID-19 Vaccination

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

- Do not remove the needle and syringe from the vial until you have equalised the vial pressure by slowly withdrawing 1.3 ml of air into the empty diluent syringe before removing the needle from the vial
Clinical Guidance for COVID-19 Vaccination

- Gently invert the diluted solution 10 times, do not shake

Gently × 10

- Inspect the vial
- The diluted vaccine should be an off-white suspension
- Do not use if vaccine is discoloured or contains particulate matter

Labelling the diluted vial

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

Vaccine Dose Preparation

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

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

16.8.1 Method of IM Vaccine Administration

- Intramuscular injection technique for children aged 5-11 is the same as for older children and adults
- Vaccine to be given Intramuscularly into the deltoid muscle
- The light triangle in figure indicates site for IM injection into the deltoid muscle
Clinical Guidance for COVID-19 Vaccination

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

16.8.2 Positioning for vaccination

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

Source: Immunisation guidelines of the National Immunisation Advisory Committee

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

Source: Australian Immunisation handbook
For older/bigger children

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

16.8.3 Techniques for vaccinating children

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

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

- Only one person should hold the child for vaccination at any time (to avoid risk of needle stick injury)
- If the child cannot be held/positioned by the parent/carer so that vaccination is possible, then the child should not be vaccinated
- Repeated attempts to vaccinate the child are unlikely to help
- Check with your clinical lead for advice
- It may be better to bring the child back another time
- With the parent if parent was not present.
- They may benefit from vaccination during quiet times

Prevention and Management of Syncope in Vaccination Clinics

- Syncope is rare in younger children, it is more common in adolescents
- Syncope episodes mostly occur within 15 minutes of vaccine administration
- Reassurance about the procedure may help to prevent fainting
- Recipients should be seated (or lying down - if past history of fainting) when being administered their vaccines in case of an immediate faint
- There should be facilities in place in case of fainting
  - So that the person can be placed in a recumbent position/lie down or sit with head between knees for several minutes if lying down is not possible
- It may be helpful to loosen any tight clothing and apply cool, damp cloths to the person’s face and neck
- Further information is available on the [www.immunisation.ie](http://www.immunisation.ie) and at [https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/](https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/)
16.9 Contraindications and precautions to COVID-19 vaccination in children

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

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

Precautions
- Acute severe febrile illness; defer until recovery
- Pericarditis after a previous dose of Comirnaty® (seek specialist advice)
- Vaccination should be postponed in children with a previous history of MIS-C, until clinical recovery or until 90 days or more since diagnosis, whichever is the longer.

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

16.10 Post-vaccination Procedures

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

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

Advice following vaccination
- Give the parent/carer the after-care leaflet information
Clinical Guidance for COVID-19 Vaccination

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

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

The most frequent adverse reactions in children 5 to 11 years of age were
• Injection site pain (>80%)
• Fatigue (>50%)
• Headache (>30%)
• Injection site redness and swelling (>20%)
• Myalgia and chills (>10%)

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

Myocarditis and pericarditis
Myocarditis and pericarditis are inflammatory conditions of the heart. Symptoms can vary but often include breathlessness, palpitations and chest pain. A European Medicines Agency (EMA) review listed Pericarditis and Myocarditis as a very rare side effect of Comirnaty® vaccine. The risk is highest in younger males and is more often observed after the second dose. Two European studies have estimated the risk of myocarditis after the second dose of the vaccine:
• One additional case for every 38,000 men aged 12 to 29 (within 7 days)
• One additional case for every 17,500 men aged 16-24 (within 28 days)

Data are very limited on those 5 to 11 years of age.
Myocarditis has also been associated with COVID-19 infection and these events can also occur in all age groups unrelated to vaccines or to COVID-19. Available data suggest that the course of myocarditis and pericarditis following vaccination is similar to the typical course of these conditions and in most individuals, symptoms resolved with conservative management. The long-term follow-up of these cases is ongoing.
Clinical Guidance for COVID-19 Vaccination

Reporting of adverse events following immunisation

16.12 Clinical considerations

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

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

16.12.2 Co-administration with other vaccines
Until there is more evidence, it is prudent to separate COVID-19 vaccine administration in children aged 5-11 years from any other vaccine for a period of 14 days before and after vaccination.

This advice differs to that for people aged ≥ 12 years

16.12.3 Children who are immunocompromised
Children who are immunocompromised due to disease or treatment may be vaccinated if they have no contraindications. Data indicates that those with severe immunocompromise do not have adequate protection following a primary COVID-19 vaccine course. There is evidence that protection can be enhanced by an additional mRNA vaccine dose, representing an extension of the primary vaccination series. See Table 5a.2 of the NIAC guidelines for conditions that may be associated with a suboptimal response to vaccines. An additional Comirnaty® dose (10 micrograms 0.2ml) should be given to those aged 5-11 years with immunocompromise associated with a suboptimal response to vaccines at the time of vaccination, who have completed their primary course. This is an extended primary vaccination course.

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

- For all those aged 12 years or more with immunocompromised an interval of 2 months is still advised

Serological testing prior to giving an additional dose is not recommended.

Children with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used. Specialists should consider the child’s risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of their immune status and likely immune response to vaccination.
Clinical Guidance for COVID-19 Vaccination

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

For those with thrombocytopenia (platelet count <5 x 10⁹/L consult the supervising consultant. People with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra) do not require haemostatic cover for vaccination.

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

Those receiving long-term anticoagulation with either Warfarin or heparin are not considered to be at higher risk of bleeding complications following vaccination. There is no reason to expect that there is a greater risk of bleeding complications with the oral anticoagulants or antiplatelet agents, than with other anticoagulants. See Chapter 2 of the NIAC guidelines, sections 2.4.6 and 2.4.7 for further information, including technique for IM injection, in this patient group.

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

16.13 Booster vaccinations
There are no recommendations for booster vaccinations in this age group.

16.14 Frequently asked questions: Comirnaty (10 micrograms/dose concentrate) for children aged 5-11

16.14.1 Which COVID-19 vaccine is approved for children aged 5-11?
For children aged 5 to 11 years Comirnaty (10 micrograms/dose concentrate) is currently the only vaccine approved and licensed by the EMA for this age group. The European Medicines Agency (EMA) recommended extending the indication for Comirnaty to include use in children aged 5 to 11 years of age on 25th of November 2021.

**Note the vaccine for children aged 5-11 is a different vaccine formulation to the one used in persons aged 12 and over i.e Comirnaty (30 micrograms/dose concentrate).**

16.14.2 Why is the COVID-19 vaccine recommended for children aged 5-11?
COVID-19 vaccines are strongly recommended by the National Immunisation Advisory Committee (NIAC) for children aged 5 to 11 years who:

- live with underlying conditions
Clinical Guidance for COVID-19 Vaccination

- living with a younger child with complex medical needs
- living with a person who is immunocompromised

For all children in this age group, the recommendation of NIAC is that the benefits of vaccination are greater than the risks from the vaccine.

This is because of the favourable benefit risk profile of the vaccine, to protect them from severe disease, the consequences that can follow infection e.g. multisystem inflammatory syndrome in children (MIS-C), long COVID, psycho-social and developmental impacts.

16.14.3 What is the dose of Comirnaty for children aged 5-11 years?
The dose of vaccine for those aged 5 to 11 years is 0.2 ml intramuscularly (IM) into the deltoid muscle. Each dose contains 10 micrograms. Note that the dose volume, and the vaccine dose is different to that for ≥12 years (0.3mls and 30 micrograms per dose)

16.14.4 What volume of 0.9% saline should be used to dilute a vaccine vial?
The vaccine requires dilution with 1.3ml of 0.9% sodium chloride. After dilution, the vaccine should be kept at +2°C to +30°C and used within 12 hours. Note that the dilution volume and the discard time is different.

16.14.5 How many doses of 0.2mls are in a diluted vial of the vaccine?
If more than ten 0.2ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses. There are a maximum of 12 doses in each vial.

16.14.6 What is the recommended Interval between doses?
The day that the first dose of vaccine is given is day 0.

The recommended interval is 21 days.
- If the interval between doses is longer than 21 days, the second dose should be given as soon as possible. The course does not need to be restarted.
- If the second dose is given between 19 and 20 days after the first dose, it is a valid dose.
- The minimum interval is 19 days. If the second dose is given before 19 days, this is not considered a valid dose. A third dose should be given 21 days after the second (invalid) dose.

**Note this is a different minimum interval compared to that for those aged ≥12 years**

16.14.7 When is an additional dose recommended for children aged 5-11?
NIAC have recommended that children aged 5 to 11 years who are severely immunocompromised at time of vaccination should be given a third dose of Comirnaty (10 micrograms/dose) at least 28 days after the second dose to complete the primary series in line with the licensed documentation.

** Note for people aged 12 years and over who are immunocompromised an additional dose is
Clinical Guidance for COVID-19 Vaccination

recommended 2 months after their COVID-19 vaccination course.**

16.14.8 Is a booster dose recommended for children aged 5-11?
A booster dose for children aged 5-11 has not been recommended by NIAC or approved by the EMA currently.

16.14.9 Which Comirnaty vaccine dose should a child receive if they are 11 years of age, but will turn 12 years old before they can receive a second dose?
The dose of Comirnaty® depends on the age of the child at the time of the first vaccine i.e., an 11 year old child who receives the first dose of 10 micrograms Comirnaty and who then becomes 12 years of age should receive a further dose of 10 micrograms Comirnaty as their second dose.

16.14.10 Which Comirnaty® vaccine dose should a child receive if they are immunocompromised and 11 years of age when receiving their 1st and 2nd dose, but will turn 12 years old before they can receive an additional/third dose?
If the child has turned 12 at the time they are due the additional/3rd dose of Comirnaty®, they should receive the 30 microgram Comirnaty® dose.

16.14.11 Can other vaccines be co-administered with Comirnaty® 10 micrograms/dose in children aged 5-11?
No. As a precaution, it is advised to separate COVID-19 vaccine administration in children aged 5 - 11 years from any other vaccine for a period of 14 days. Before or after COVID-19 vaccine

** Note this is different from advice for vaccination of those aged 12 years and older.**

16.14.12 Should unvaccinated children aged 5-11 who have had COVID-19 infection be offered the COVID-19 vaccine?
Vaccination should be deferred until clinical recovery from COVID-19 infection and for at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic.

Those with persistent symptoms post COVID-19 may be vaccinated unless there is evidence of recent clinical deterioration.

Serological testing prior to vaccination is not recommended.

16.14.13 What if a child aged 5-11 is diagnosed with COVID-19 infection after a first dose of vaccine?
Vaccination with the second dose 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.
16.14.14 What if a child with immunocompromised aged 5-11 is diagnosed with breakthrough COVID-19 infection after their 2nd dose of vaccine?
If a child is immunocompromised and has had a laboratory-confirmed breakthrough infection following their 2nd vaccine dose, the additional/third dose should be delayed for at least 3 months.

16.14.15 What are contraindications to vaccination with a Comirnaty® (10 micrograms/doseconcentrate)?
- Anaphylaxis following a previous dose of the vaccine or following any of its constituents including polyethylene glycol (PEG) and Trometamol (found in gadolinium- containing contrast dyes).
- Myocarditis after a previous dose of Comirnaty®

16.14.16 What precautions to vaccination with a Comirnaty® Vaccine?
- Acute severe febrile illness; defer until recovery
- Pericarditis after a previous dose of Comirnaty® (seek specialist advice)
- Vaccination should be postponed in children with a previous history of MIS-C, until clinical recovery or until 90 days or more since diagnosis, whichever is the longer.

For more information see Frequently Asked Questions about COVID-19 vaccines for children with pre-existing allergic conditions.

16.14.17 What if only the diluent of Comirnaty® is administered?
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 their parent/guardian and a correctly diluted dose of the vaccine should be given as soon as possible. This should be reported to HPRA if this is associated with an adverse event and an incident report form completed.

16.14.18 What if an over-diluted 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 parent or guardian and a correctly diluted dose of the vaccine should be given as soon as possible (i.e. no minimal interval). This should be reported to HPRA if this is associated with an adverse event and an incident report form completed.

In settings where doses may be prepared in advance, if thirteen doses have been obtained from a vial, each of the syringes must be examined by another person to identify the syringe with less than 0.2ml. If all syringes contain 0.2ml then more than 1.3ml must have been added and the vial has been over-diluted.
16.14.19 What if an under-diluted vaccine or the whole multi-dose vial of vaccine is administered instead of the recommended dose?
In clinical trials where a small number of children were given higher doses of a similar vaccine was not associated with serious adverse events during the observation period but most local reactions were mild to moderate and short lived.

If the error was made with the first dose, the child is given their second dose of vaccine according to the recommended schedule. The parents 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.

This vaccine error should be reported to HPRA if associated with an adverse event and an incident report form completed.

16.14.20 What if a 10mcg dose of children’s Comirnaty is inadvertently given to a person aged 12 and over?
In this case, the error should be explained to the parent or person (if aged 16 and over). The actions will depend on the person’s age:

<table>
<thead>
<tr>
<th>Person aged 12-17 years</th>
<th>Error</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Given lower 1\textsuperscript{st} dose</td>
<td>Do not repeat. Give correct second dose</td>
</tr>
<tr>
<td></td>
<td>Given lower 2\textsuperscript{nd} dose</td>
<td>Do not repeat</td>
</tr>
<tr>
<td></td>
<td>Given lower 1\textsuperscript{st} and 2\textsuperscript{nd} dose</td>
<td>Give correct dose 21 days after incorrect second dose</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Person aged 18 years and older</th>
<th>Error</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Given lower 1\textsuperscript{st} dose</td>
<td>Give correct dose immediately (no minimum interval) and correct second dose 21 days later</td>
</tr>
<tr>
<td></td>
<td>Given lower 2\textsuperscript{nd} dose</td>
<td>Give correct dose immediately (no minimum interval)</td>
</tr>
</tbody>
</table>

This should be reported to HPRA if this is associated with an adverse event and an incident report form completed.

16.14.21 Comirnaty\textsuperscript{®} vaccine for children aged 5-11 years (orange cap) contains 10 micrograms of mRNA vaccine in each dose. The vaccine for people aged 12 years and older contains 30 micrograms in each 0.3ml dose. Can I use 0.1 mls of the purple cap vaccine to vaccinate a child who is aged 5-11 years?
No. You cannot use the vaccine for people aged 12 years and older (purple cap) to vaccinate children aged 5-11 years. Although it might appear that 0.1ml of the purple cap formulation would be equivalent to a 10 microgram dose of the orange cap formulation, the correct concentration of mRNA vaccine cannot be guaranteed in such a small volume of vaccine.

16.14.22 What if a 30mcg dose of Comirnaty\textsuperscript{®} if given in error to a child aged 5-11?
In clinical trials where a small number of children were given higher doses of a similar vaccine was not
associated with serious adverse events during the observation period and most local reactions were mild to moderate and short lived.

If the error was made with the first dose, the child is given their second dose of vaccine according to the recommended schedule. The parents 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. This vaccine error should be reported to HPRA if associated with an adverse event and an incident report form completed.

16.14.23 How can you ensure the right formulation of Comirnaty is given to the appropriate age group?

The following checks are routinely recommended before COVID-19 vaccination:

- Is this a primary course, an additional dose for a person who is immunocompromised or a booster dose?
- What is the age of the person?
- What is the recommended vaccine for this age group?
- What is the recommended dose?
- What is the recommended interval since the last dose?
- Has the person had COVID-19 infection? What is the recommended interval since laboratory-confirmed COVID-19 infection?

In addition, NIAC recommends consideration should be given to establishing separate child friendly vaccination clinics for children aged 5 - 11 years. This would minimise distress in young children and reduce likelihood of vaccine error by avoiding having the adult and paediatric formulations of Comirnaty at the same venue.

16.14.24 What if someone in the child’s pod or classroom has recently tested positive for COVID-19?

Follow the public health guidance provided. If the child has been advised to restrict their movements they should not attend for vaccination at this time. Provided the child is well they can receive the vaccine after they have completed the period of restricted movements.
17. 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
Appendix A: Intramuscular injection technique
Intramuscular (IM) Injection Technique

All vaccinators must be competent in IM injection technique. Below is a reminder of IM injection technique.

Note: COVID-19 vaccine should be given IM only.

1. **Land mark the injection site in the deltoid muscle:**
   - Two finger widths down from the acromion process; the bottom edge is at an imaginary line drawn from the axilla
   - Injection site: 5cms below acromion process
   
   **NOTE:** The recommended site is in the middle of the triangle. To avoid causing an injury, do not inject too high or too low. Vaccinators should landmark the injection site and use correct injection technique to prevent shoulder injuries.

2. **At the injection site spread the skin taut between the thumb and forefinger with the non-dominant hand.**
   - **Do NOT bunch up the skin** as this leads to administering the vaccine into subcutaneous tissue inadvertently.
   
   **NOTE:** COVID-19 vaccine should be given by IM only.

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

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

5. Insert the needle smoothly and swiftly.

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

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

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

<table>
<thead>
<tr>
<th>Swift needle entry</th>
<th>Slow injection of medication</th>
<th>Swift needle withdrawal</th>
<th>Less pain</th>
</tr>
</thead>
</table>

NIAC recommendations:

“It is not necessary to use gloves for vaccine injections, unless contact with potentially infectious body fluids is possible, or unless the health care worker has an infected lesion on the hand. If gloves are worn they should be changed for each patient. If the skin at the injection site is visibly dirty it should be cleaned with soap and water. There is no need to use a disinfectant e.g. alcohol swabs. If an alcohol swab is used, injection should be delayed for ≥30 seconds, to ensure the alcohol will have evaporated”.

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

1. Background

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

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

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

2. Responsibilities

The Responsible Person should ensure that this SOP is followed.

3. Scope

The scope of this document is to set a standardised protocol of procedures in the provision of the Comirnaty® (Pfizer/BioNTech) COVID-19 Vaccine. Separate documents are available for other COVID-19 vaccines.

4. Purpose

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

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

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

4.1 Safe and temperature controlled storage

Upon arrival at your vaccination centre:

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

For additional information the following document may be consulted:

NCCS will deliver Comirnaty® at a temperature of +2 °C to +8 °C in their original carton, or pre-packed into labelled cartons. Receipt delivery of stock and scan stock onto the system as you unpack the delivery.

Place the stock immediately in the fridge at a temperature of +2 °C to +8°C. The vials should remain in an upright position and in the box in order to protect from light. The vials should not be refrozen.

4.2 Vaccine decommissioning

The vaccines will be decommissioned by the NCCS for the Article 23 locations e.g., GPs and HSE locations including Vaccination Clinics.

4.3 Safe handling

Comirnaty® comes in a multi dose vial and **before use, must be diluted with 1.8ml of sodium chloride (0.9%) solution for injection**. Each vial contains 0.45ml antigen and after dilution will contain 2.25 ml and therefore up to 7 doses of 0.3mL may be available. One dose (0.3mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for a seventh dose. The National Immunisation Advisory Committee (NIAC) advises that if more than six doses can be safely and accurately withdrawn from a vial they can be used as valid doses.

**DO NOT** pool excess or residual vaccine solution from multiple vials.

**Undiluted vial**

An **undiluted vial** of Comirnaty® (Pfizer/BioNTech) COVID-19 vaccine may be stored for up to one month (31 days) at temperatures between +2°C and +8°C. Boxes or cartons will have a label created by the NCCS displaying the **USE BEFORE date and time**. The **USE BEFORE date** is the date that should be recorded in the patient's record. The **USE BEFORE date and time** is the time by when the vaccine must be taken out from +2°C and +8°C for dilution.

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

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

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

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

**Diluted medical product**

Once diluted a “**DISCARD time**” is applied and written on the vial which is 6 hours from the time of dilution.

Chemical and physical in-use stability, has been demonstrated for 6 hours at 2 °C to 30 °C **after dilution**.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

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

**To note:**

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

The total or cumulative duration of transit of the undiluted product at temperatures between +2 °C and +8°C, must not exceed 12 hours. The 12 hours must include all travel time commencing at time of departure from NCCS to the vaccination centre and all other transportation of the undiluted vaccine thereafter. These times must be taken within the USE BEFORE dates and time. Each delivery box is over labelled with time of departure label which is stamped when leaving NCCS and is completed by driver at time of handover to recipient.

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

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

For additional information the following document may be consulted:

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

4.5 Stock Reconciliation

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

Comirnaty® -Vaccine Reconciliation Form for clinic settings Version 2.0 13 October 2021
Comirnaty® -Vaccine Reconciliation Form for Long Term Care Facilities Version 1.0 12 October 2021
Please note both forms are in an editable PDF format

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

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

- **Anaphylaxis Kits**

  Refer to National Immunisation Advisory Committee Guidelines

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

- **Storage Equipment**

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

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

6. **Stock Control, Security & Monitoring of Wastage**

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

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

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

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

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

  Records of vaccine dose reconciliation should be maintained at the site.
7. Health & Safety

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

Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.
Management of Covid-19 vaccine Comirnaty® children 5 to 11 years
Guidance at vaccination clinics

1. Background

COVID-19 vaccine Comirnaty® children 5 to 11 years will be delivered at a temperature of +2°C to +8°C by the National Cold Chain Service (NCCS) to the site. The vaccine will have a 10 weeks shelf –life. The site will be responsible for the vaccine upon delivery.

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


2. Safe Handling

Comirnaty® children 5 to 11 years comes in a multi dose vial and must be diluted before use. 10-vial packs of the vaccine will be available and one vial (1.3 mL) contains 10 doses of 0.2 mL after dilution.

Each vial contains 1.3ml concentrate for dispersion. Dilute with 1.3 ml of sodium chloride (NaCl 0.9%) solution for injection.

After dilution the vial will contain 2.6 ml.

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

When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for 12 doses. The National Immunisation Advisory Committee (NIAC) advises that if more than 10 doses can be safely and accurately withdrawn from a vial they can be used as valid doses.

- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
- Do not pool excess vaccine from multiple vials.
3. Thawed and Unopened vial

An unopened vial of Comirnaty® children 5 to 11 years can be stored and transported at +2°C to +8°C for up to 10 weeks within the 6-month shelf life.

The vaccine is delivered at +2°C to +8°C and it should be stored at +2°C to +8°C. The relevant date is the USE BEFORE date and time and the original expiry date should have been crossed out. The vials should not be refrozen.

The outer carton or original box will have an HSE SCAN ME label containing the updated USE BEFORE date and time label affixed by the NCCS. The USE BEFORE date is the date that should be recorded in the child’s record. The USE BEFORE date and time is the time by when the vaccine must be taken out from +2°C and +8°C for dilution.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between +8°C and +30°C. This is within the 10 week shelf life.

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

Stability data indicate that the unopened vial is stable:

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

Note:

- The USE BEFORE dates and time of the vaccine must be recorded in the IT system (as per the HSE SCAN ME label on the vaccine box delivered by the HSE National Cold Chain Service).
- The batch number of the vaccine must be recorded, to be selected on Scanvax.
- The batch number of the 0.9% Sodium Chloride solution must be recorded, to be selected on Scanvax.

4. Diluted vial

Once diluted with sodium chloride 9 mg/mL (0.9% NaCl) solution for injection a DISCARD Date and Time is calculated as 12 hours after dilution. DISCARD Date and Time is written on the vial which is stored at +2°C to +30°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.
The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.

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

5. Reconciliation

It is a requirement that vaccines delivered are tracked and any vaccine “wastage” i.e. not used for any reason are accounted for. For sites using Trackvax, TrackVax will perform an automatic reconciliation at the end of the day.

6. Summary

- Shelf Life of delivered vaccine = 10 weeks
- 10 vials per pack
- 10 doses per vial
- Dilute each vial with 1.3ml 0.9% NaCl
- Each dose = 0.2ml
- Discard Time = 12 hours
Vaccination Clinics

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

1. Background

Spikevax® (Moderna) will be delivered by the National Cold Chain Service (NCCS) at temperature of +2°C and +8°C to the site therefore it will be thawed and labelled with the “USE BEFORE” time and date. (if Time is not included on the label, “USE BEFORE” time is 23:59 of the preceeding day, ie “USE BEFORE” date 28/01/2022 is 11:59 pm on 27/01/2022.)

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

Spikevax® (Moderna) was granted conditional marketing authorisation by the EC on 6 January 2021.

2. Responsibilities

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

3. Scope

The scope of this document is to set a standardised protocol of procedures to be followed in the provision of Spikevax® (Moderna). Separate documents are available for other COVID-19 vaccines.
4. Purpose

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

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

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

4.1 Safe and temperature controlled storage

Upon arrival at your vaccination centre:

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

Spikevax® (Moderna) will be thawed and delivered at temperatures between +2°C and +8°C to each vaccination clinic. Receipt and scan stock onto the system as you unpack the delivery.

Place in the fridge at a temperature of +2°C to +8°C, in original boxes to protect vials from light. Note and retain details of the transportation label affixed to the delivery box.
4.2 **Safe vaccine handling including management of shelf life reduction processes following first puncture of the vial**

Each box of vaccine presents as multi-dose vials (MDV).

The unopened vaccine may be stored refrigerated at +2°C to +8°C, protected from light, for maximum 30 days.

Spikevax boxes will have a label affixed by the NCCS displaying the *USE BEFORE* date and time. The *USE BEFORE* date is the date that should be recorded in the patient's record.

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

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

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

24 hours when kept between +8°C and +25°C after which the product must be discarded.

The *DISCARD* date and time should be recorded on the vial after the initial puncture. Chemical and physical in-use stability has been demonstrated for 19 hours (see Note 1) at +2°C to +25°C after initial puncture (within the allowed use period of 30 days at +2°C to +8°C and 24 hours at +8°C to +25°C).

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

Ten (10) doses (of 0.5 mL each) or a maximum of twenty (20) doses (of 0.25 mL each) can be withdrawn from each vial.

Pierce the stopper preferably at a different site each time.

Do not puncture the vial more than 20 times.

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

Within 30 days storage of the unopened vaccine at +2°C to +8°C, up to 12 hours may be used for transportation. The delivery box will have a transportation label affixed which will indicate the time of the dispatch from NCCS and the time of delivery at the site. This duration must be taken into consideration for any onward transportation.

4.4 Vaccine decommissioning

Serialised boxes of Spikevax must be decommissioned by Hospitals and by Retail Pharmacies. NCCS will decommission for other locations as per Art.23.

4.5 Stock reconciliation

TrackVax (v24) has been updated for labelling and stock management. Stock is booked out and labelled in either

Booster mode (0.25ml dose) OR Standard mode (0.5ml dose).

There is no clinical reason why both (0.25ml and 0.5ml doses) cannot be withdrawn from the same vial. TrackVax cannot facilitate a combination of 0.25ml and 0.5ml doses from one vial, therefore the number of doses administered on Covax will not reconcile with the number of doses issued from TrackVax. This discrepancy must be reconciled at the end of day or session.

For example in Booster Mode, 20 labels will be generated but if some standard doses are administered, then Covax will record less than 20 vaccinated people. When such discrepancies arise, complete the comment section on TrackVax end of session report, specifying how many standard (0.5ml) doses were withdrawn from that vial while operating in Booster Mode.
5. **Consumables, record cards and other equipment**

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

**Note 1:** For sites using TrackVax, the system can accept 19 hours or midnight whatever is the first to be reached.

- **Anaphylaxis Kits**
  Refer to National Immunisation Advisory Committee Guidelines

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

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

6. **Stock control, security and monitoring of wastage**

A physical stock count of COVID-19 vaccine vials should be performed. The physical stock count of SpikeVax® (Moderna) should match the stock count recorded on the IT system.

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

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

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

Records of vaccine dose reconciliation should be maintained at the site.
7. **Health & Safety**

There are no special handling requirements for routine handling and dealing with SpikeVax® (Moderna).

Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.

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**Instructions Once Thawed**

- **Unpunctured Vial**
  - Maximum time: 30 days in refrigerator, 2°C to 8°C.
  - Maximum time: 24 hours in cool storage up to room temperature, 8°C to 25°C.

- **After first dose has been withdrawn**
  - Maximum time: 19 hours in refrigerator or room temperature.

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

Once the vial has been punctured to withdraw the initial dose, the vaccine should be used immediately and be discarded after 19 hours.

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

*NEVER* refreeze thawed vaccine.
Guidance at vaccination Clinics

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

1. Background


COVID-19 vaccine Janssen® will be delivered stored at -25°C to -15°C in freezers in the National Cold Chain Service (NCCS). Once removed from the freezers and transferred to fridge conditions of +2°C to +8°C, a label will be applied to the box with a “use before” date and time calculated at 4.5 months from removal from freezer. The box will be labelled prior to dispatch.

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

2. Responsibilities

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

3. Scope

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

4. Purpose

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

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

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

4.1 Safe and temperature controlled storage

Upon arrival at your vaccination centre:

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

For additional information the following document may be consulted:

4.2 Vaccines decommissioning

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

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

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

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

Initially some boxes may not be serialised and therefore will not require to be decommissioned:
Management of COVID-19 Vaccine Janssen® Guidance at vaccination Clinics

If boxes are NOT serialised (black rectangle) they will not need to be decommissioned. While if boxes are serialised (white with lines rectangle), they will need to be decommissioned.

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

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

Prior to delivery to vaccination sites by NCCS the boxes will have been thawed and stored at +2°C to +8°C. The NCCS will label the vaccine box with the new storage condition and **USE BEFORE date and time**: this is 4.5 months after thaw (and within original expiry date). This should be recorded in the patient record.

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

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

Place the stock immediately in the fridge at a temperature of +2°C to +8°C. The vials should remain in their original box to be protected from light, for maximum of 4.5 months (and within original expiry date).

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

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

### 4.4 Stock Reconciliation

- It is a requirement that vaccines delivered are tracked and any vaccine “wastage” i.e. not used for any reason are accounted for. Central Vaccination Clinics using Trackvax will perform a daily and automatic vaccine vials/ doses reconciliation.
5. **Consumables, Patient Information Leaflet (PIL), Record Cards & other equipment**

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

- **Anaphylaxis Kits**

Refer to National Immunisation Advisory Committee Guidelines:


In the HSE central vaccination clinics settings, the epinephrine will be purchased and decommissioned by a pre-determined community/hospital pharmacy as agreed by the lead governance organization CHO/HG.

- **Storage Equipment**

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

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

6. **Stock control, Security & Monitoring of Wastage**

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

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

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

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

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

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

There are no special handling requirements for routine handling of COVID-19 Vaccine Janssen®. Should a spillage occur this should be disinfected with an appropriate antiviral disinfectant (active on adenovirus).

Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.
Appendix C: Advice from the National immunisation Advisory Committee regarding fever after COVID-19 vaccination
National Immunisation Advisory Committee

29 December 2020

Statement on fever following COVID-19 vaccination

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

Post immunisation fever

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

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