COVID-19 VACCINE
Public Health Advice

Clinical Guidance for COVID-19 Vaccination

Comirnaty® (Pfizer BioNTech)

Spikevax® (COVID-19 Vaccine Moderna)

Vaxzevria® (AstraZeneca)

COVID-19 Vaccine Janssen®

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This document has been created and updated by the HSE National Immunisation Office

Seirbhís Sláinte Níos Fearr á Forbairt | Building a Better Health Service

Date of revision	**09/07/2021**
Revisions since last version (17.3)	<u>Section 6.</u> Contraindications amended for COVID-19 Vaccine Janssen® to include a history of capillary lean syndrome <u>Section 10.</u> Myocarditis and pericarditis added as very rare adverse events for Comirnaty® (Pfizer/BioNTech) and Spikevax®(Moderna) Text added regarding reports of Guillan Barré syndrome after Vaxzevria (no causal link established) Document amended throughout to reflect these changes

This guidance is intended for vaccinators administering COVID-19 vaccine.

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

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

1. Introduction

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

Purpose of the document

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

Indemnity for vaccinators

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

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

2. Vaccine priority groups

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

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

	Group	
1.	People aged 65 years and older who are residents of long-term care facilities (likely to include all staff and residents on site)	
2.	Frontline healthcare workers	
3.	People aged 70 and older	
4.	People aged 16-69 with a medical condition that puts them at very high risk of severe disease and death1	
5.	People aged 65-69 whose underlying condition puts them at a high risk of severe disease and death	
6.	Other people aged 65-69	Key workers essential to the vaccine programme
7.	People aged 16-64 who have an underlying condition that puts them at high risk of severe disease and death	
8.	Residents of long-term care facilities aged 16-64	
9.	People aged 64 years and younger in the following order: i.64-55 years ii.54-45 years iii.44-35 years iv.34-25 years v.24-16 years	People aged 16-64 living or working in crowded settings

[1]see Table overleaf

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

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

Medical condition[1]	Very high risk	High risk
Cancer	All cancer patients actively receiving (and/or within 6 weeks of receiving) systemic therapy with cytotoxic chemotherapy, targeted therapy, monoclonal antibodies or immunotherapies and surgery or radical radiotherapy for lung or head and neck cancer All patients with advanced/metastatic cancers	Haematological - within 1 year Haematological - within 1 - 5 years Non-haematological - within 1 year All other cancers on non-hormonal treatment
Chronic heart (and vascular) disease		e.g. heart failure, hypertensive cardiac disease
Chronic kidney disease	On dialysis, or eGFR <15 ml/min	With eGFR <30ml/min
Chronic liver disease		e.g. cirrhosis or fibrosis
Chronic neurological disease or condition	With evolving ventilatory failure (requiring non- invasive ventilation) e.g. motor neurone disease, spinal muscular atrophy	Significantly compromising respiratory function and/or the ability to clear secretions e.g. Parkinson's disease, cerebral palsy
Chronic respiratory disease	Severe e.g. severe cystic fibrosis, severe COPD, severe pulmonary fibrosis	Other e.g. stable cystic fibrosis, severe asthma (continuous or repeated use of systemic corticosteroids), moderate COPD
Diabetes Immunocompromise due to disease or treatment	HbA1c ≥58mmol/mol Severe e.g. Transplantation: - Listed for solid organ or haematopoietic stem cell transplant (HSCT) - Post solid organ transplant at any time - Post HSCT within 12 months Genetic diseases: - APECED2 - Inborn errors in the interferon pathway Treatment: - included but not limited to Cyclophosphamide, Rituximab, Alemtuzumab, Cladribine or Ocrelizumab in the last 6 months	All other diabetes (Type 1 and 2) Other e.g. High dose systemic steroids4 Persons living with HIV
Inherited metabolic diseases3	Disorders of intermediary metabolism/at risk of acute decompensation e.g. Maple Syrup Urine Disease	Disorders of intermediary metabolism not fulfilling criteria for very high risk
Intellectual disability3	Down syndrome	Intellectual disability excluding Down syndrome
Obesity	BMI >40 kg/m2	BMI >35 kg/m2
Severe mental illness3		e.g. Schizophrenia, bipolar disorder, severe depression
Sickle cell disease	Sickle cell disease	

1 may also include other people who have been classed as at very high risk, based on clinical judgement and an assessment of their needs

2 APECED - autoimmune polyendocrinopathy candidiasis ecto- dermal dystrophy

3 additional or updated medical conditions February 2021

4The following doses of prednisolone (or equivalent dose of other glucocorticoid) may increase the risk of severe COVID-19 disease:

≥10mg per day for more than 4 weeks with one other immunosuppressant

≥20mg per day for more than 4 weeks.

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

Read more at: https://www.gov.ie/en/publication/39038-provisional-vaccine-allocation-groups/#people-aged-16-64-who-have-an-underlying-condition-that-puts-them-at-high-risk-of-severe-disease-and-death

3. COVID-19 vaccines

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

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

mRNA Vaccines

The Pfizer BioNTech COVID-19 vaccine, marketed as Comirnaty® (Pfizer BioNTech) was authorised for use in the EU following a positive scientific recommendation by the European Medicines Agency (EMA) on 21 December 2020. Comirnaty® (Pfizer BioNTech) is licensed for active immunisation to prevent COVID-19 in individuals 16 years of age and older. https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty.

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

The Moderna COVID-19 vaccine, marketed as Spikevax® (COVID-19 Vaccine Moderna) was authorised for use in the EU following a positive scientific recommendation by the EMA on 06 January 2021. Spikevax® COVID-19 Vaccine Moderna is licensed for active immunisation to prevent COVID-19 in individuals 18 years of age and older https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna#product-information-section

Viral Vector Vaccines

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

Vaxzevria® (AstraZeneca) is licensed for active immunisation to prevent COVID-19 in individuals 18 years of age and older. https://www.ema.europa.eu/en/medicines/human/summaries-opinion/covid-19-vaccine-astrazeneca

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

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. https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-janssen

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

The following table summarisesthe vaccines in the HSE COVID-19 vaccination programme

	Comirnaty® (Pfizer BioNTech)	Spikevax® (COVID-19 Vaccine Moderna)	Vaxzevria® (AstraZeneca)	COVID-19 Vaccine Janssen®
Age 16 - <18	√	Unlicensed	Unlicensed	Unlicensed
18 - 49	√	√	Should be offered an mRNA vaccine People aged 18-34 may choose to be vaccinated with Vaxzevria® for earlier protection where mRNA vaccine supplies are limited and therefore they will not be vaccinated for some time **This is currently being operationalized by the HSE**	Should be offered an mRNA vaccine People aged 18-34 may choose to be vaccinated with COVID-19 vaccine Janssen® for earlier protection where mRNA vaccine supplies are limited and therefore they will not be vaccinated for some time
50-69	√	√	√	√
70 years and older	√	√	Should be offered an mRNA vaccine (but can receive the vaccine)	Should be offered an mRNA vaccine (but can receive the vaccine)

4. Infection Prevention and Control for the administration of COVID- 19 vaccines

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

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

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

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

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

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

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

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

Pre-drawn syringes of COVID-19 vaccines from multi-dose vials that are prepared within designated vaccine preparation areas may be available within the HSE centralised vaccination clinics (CVCs). When deviating from the protocols outlined in this guidance (to enable the use of pre-drawn syringes) national clinical guidance specific to CVC settings on this matter should be adhered to.

5.1 Comirnaty® (Pfizer BioNTech)

mRNA vaccines are fragile vaccines. Correct storage is essential to ensure the stability of the vaccine. Store vials upright. DO NOT store on their side as there is no stability data for vials stored on their side.

Table 1: Details of Comirnaty® (Pfizer BioNTech)

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

Comirnaty® (Pfizer BioNTech) vaccine efficacy and vaccine effectiveness

Data from the randomised Phase 3 trial demonstrated a two-dose vaccine efficacy of 95% (95% confidence interval of 90.3% to 97.6%) in those aged 16 and above. Efficacy was similar in all age groups.
A matched control study of over one million people from Israel showed vaccine effectiveness of 87% (95% CI, 55 to 100) against hospitalisation and 92% (95% CI, 75 to 100) against severe disease at 7 or more days after the second dose of vaccine.

Comirnaty® (Pfizer BioNTech) storage

- On arrival into the HSE National Cold Chain Service the vaccine is stored in an ultra-cold temperature (ULT) freezer at -80°C to -60°C.
- The vaccine is supplied to sites/clinics by the HSE National Cold Chain Service at +2 to +8°C with a shelf life of 1 month (31 days).
- The vaccine in each multi dose vial requires dilution with 1.8ml of 0.9% sodium chloride. This is supplied separately to the vaccine.
- Undiluted vials of Comirnaty® (Pfizer/BioNTech) have a shelf life of 1 month (31 days) when stored at +2 to +8°C and another 2 hours undiluted at room temperature.
- After dilution, the vaccine should be kept at +2°C to +30°C and used within 6 hours after which the vial should be discarded.

Table 2: Definitions of terms for expiry date and usage times of Comirnaty® (Pfizer BioNTech)

	Description
Expiry date	The date the vaccine expires if stored in an ultra-cold temperature (ULT) freezer at -80°C to -60°C. This is 6 months from the date of manufacture. The batch number on the side of each vial is recorded in the patient record. This is linked to the expiry date.
"*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	USE BEFORE date and time = 1 month (31 days) from the time vials are removed by HSE National Cold Chain from ULT and stored at +2°C to +8°C (must be recorded on patient's notes). Before the 1 month (31 days) has passed, vials must be removed from fridge.
Maximum time allowed from removal from storage at +2°C to+8°C fridge to dilution	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.
"*Discard*" date and time Maximum time allowed from dilution to expiry	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**: The labels on the first batches of vaccine have a space for date and time of dilution. These were printed before EMA authorisation. EMA has advised that "discard" date and time i.e. **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.
Transportation time	**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.

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

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

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

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

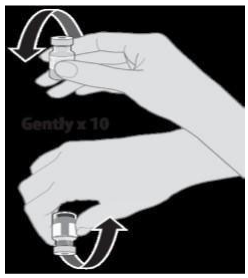
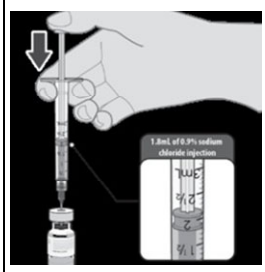
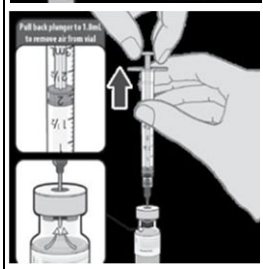
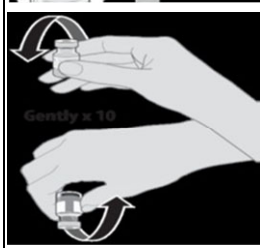
Table 3: interval between 2 doses

Interval between 1st and 2nd doses	Action required
Less than 17 days	This this is not considered a valid vaccine. A third dose should be given 28 days after the second (invalid) vaccine.
17 to 27 days	No further action needed (Evidence from trial data is that this is a valid vaccine).
Longer than 28 days	Give the 2nd dose at whatever interval. The course does not need to be restarted.

Dilution of Comirnaty® (Pfizer BioNTech)

Requirements for diluting the vaccine

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

STEP 1. PREPARING FOR DILUTION	
	• Check the "use before" date and time on the box containing the vials with a colleague • Remove the vial from the box in the fridge/ cool box • Gently invert vial 10 times prior to dilution. Do not shake • Inspect the liquid in the vial prior to dilution • Should be an off-white solution. It may contain white to off-white amorphous particles. • Remove cap • Clean with 70% alcohol swab and allow it to air dry fully
STEP 2. DILUTION	
  	• Twist to separate one ampoule of sodium chloride from other ampoules if attached • Check product and expiry date with colleague • Clean with a 70% alcohol swab • Open the ampoule by twisting the cap using standard aseptic technique • Connect syringe tightly to sodium chloride ampoule • Withdraw 1.8ml of Sodium Chloride 0.9% Solution for Injection • Cross check correct amount withdrawn with colleague • Discard the ampoule and any remaining diluent in it into waste bin • Using a 21 gauge green needle attached to the syringe, • insert diluent slowly into the vaccine vial. You may feel some pressure in the vial as you add the diluent. • Do not remove the needle from the vial. Keeping the needle above the level of the liquid, slowly withdraw 1.8 ml of air into the empty diluent syringe to equalise the pressure. • Remove needle and syringe from vial. • Dispose of the needle and syringe in a sharps bin. • Gently invert the diluted solution 10 times. Do not shake. • Diluted vaccine should be an off-white solution with no visible particles. Discard if particles present. • Discard the diluted vaccine if particulates or discolouration are present
STEP 3. LABELLING THE VIAL	
	• Label the diluted vial with the date and "discard time" (6 hours after time of dilution) using a 24 hour format. • Do not use the diluted vaccine after this date and time. • e.g. vial diluted at 10.00 01/01/2021. Discard time is 16.00 01/01/2021 • After dilution, the vial contains 6 doses* of 0.3 ml • Diluted vaccines can be stored at room temperature between +2°C and +30°C but must be used within 6 hours following dilution. • Bring the vial to your vaccination table/site for vaccine preparation and administration

**If more than six 0.3ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses*

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

Administration of Comirnaty® (Pfizer BioNTech)

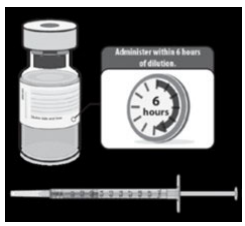
- Vaccine dose preparation and administration should be carried out at the point of administration i.e. beside the person to be vaccinated.
- The same needle and syringe should be used to draw up and administer the vaccine
- Each dose should be drawn up and immediately administered to the patient.
-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

Requirements for administration of up to 7 doses of vaccine

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

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).

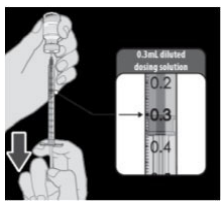


Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully

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

[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

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

Checklist before administering 2nd dose

- dose interval
- if diagnosis of COVID-19 since last dose - delay second dose until clinical recovery from COVID-19 and at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic
- if history of allergic reaction to the vaccine after first dose (or any new allergic reactions since first dose)
- if pregnant since first dose - delay second dose until at least 14 weeks of pregnancy.
- discuss very rare adverse event of myocarditis and pericarditis following vaccination and explain symptoms and to seek medical advice (see section 10)

5.2 Spikevax® (COVID-19 Vaccine Moderna)

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

Store vials upright. DO NOT store on their side as there is no stability data for vials stored on their side.

Table 4: details of Spikevax® (COVID-19 Vaccine Moderna)

Title	Description
Manufacturing process	mRNA
Name of vaccine	Spikevax® (COVID-19 Vaccine Moderna)
Constituents	• Lipid SM-102 Cholesterol • 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG) • Tromethamol • Tromethamol hydrochloride Acetic acid • Sodium acetate trihydrate Sucrose • Water for injections
Presentation	The vaccine is contained in a multidose clear glass vial.
Number of doses in each vial	Up to 10 doses If more than 10 (0.5 ml) doses can be safely and accurately withdrawn from a vial, they can be used as valid doses. There should be no pooling of vaccine from different vaccine vials
Dilution	**NOT REQUIRED**
Latex	No. The vial has a rubber stopper (chlorobutyl rubber) and a flip-off plastic cap with seal (aluminium seal). Chlorobutyl is a synthetic rubber – the vial stopper does not contain latex.
Preservatives	No
Dosage	0.5ml
Number of doses required	2
Interval between doses	28 days is the recommended interval between doses 24 days is the minimum interval
Transportation time	Within the 30 days storage of the unopened vaccine at +2°C to +8°C, up to 12 hours may be used for transportation.

Spikevax® (COVID-19 Vaccine Moderna) vaccine efficacy

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

High efficacy (≥86%) was observed across age, sex, and ethnicity categories and among persons with underlying medical conditions.

Spikevax® (COVID-19 Vaccine Moderna) storage

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

Store vials upright. DO NOT store on their side as there is no stability data for vials stored on their side.

The vaccine is transported to vaccination sites/clinics frozen at -25^{0}C to -15^{0}C. The vaccine must be thawed prior to administration.

The vaccine may be thawed as follows:

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

- **At room temperature** (Between +8°C and +25°C) for 1 hour

Never refreeze thawed vaccine.

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

Once a vial is punctured to draw up the first dose, there is a maximum time of 19 hours before the vial should be discarded. The "discard" date and time i.e. up to 19 hours after the vial is first punctured must be written on the vial using a 24 hour format. e.g. vial is first punctured 29/06/21 at 11.00. Discard date and time is 30/06/2021 at 06.00

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

Method of Vaccine Storage	Temperature	Duration
Frozen	**Between -25°C and -15°C**	**Until expiry date**
Refrigerator	**Between +2°C and +8°C**	**Up to 30 days (until "use before" date)**
Room Temperature	**Between +8°C and +25°C**	**Up to 24 hours**

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

Method of Vaccine Storage	Temperature	Duration
Refrigerator	**Between +2°C and +8°C**	**Up to 19 hours (until discard date and time)**
Room Temperature	**Between +2°C and +25°C**	**Up to 19 hours (until discard date and time)**

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

	Description
Expiry date	The date the vaccine expires if stored frozen at temperatures between -25C° 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.
"*Use before*" date and time **Maximum time from when vaccine is thawed to expiry**	The vaccine is transported by the HSE National Cold Chain service to vaccination sites/clinics frozen at -25°C and -15°C. At vaccination sites/clinics the vaccine is stored at +2°C and +8°C and thawed. If thawed and stored between +2°C and +8°C, the unopened vaccine has a shelf life of 30 days. This "use before" date and time is 30 days from date and time of delivery of vaccines by the NCCS van driver. The recipient must record the "use before" date and time on the vaccine box. The vials must be discarded when the "use before" date and time has been reached.
"*Discard*" date and time Maximum time allowed from when the vial is first punctured	Once the vaccine has been punctured for the first time it must be used within 19 hours (within the allowed use period of 30 days at +2°C to +8ºC and 24 hours at +8°C to +25ºC). The "discard" date and time i.e**. 19 hours after the vial is first punctured** must be written on the vial using a 24 hour format. **e.g. vial is first punctured 29/06/21 at 11.00. Discard date and time is 30/06/2021 at 06.00** Any unused or partially unused diluted vials must be discarded when this time has been reached.

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

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

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

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

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 24 days.

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

Table 8: Interval between 2 doses

Interval between 1st and 2nd doses	Action required
Less than 24 days	This is not considered a valid vaccine. A third dose should be given 28 days after the second (invalid) vaccine.
24-27 days	No further action needed (Evidence from trial data that this is a valid vaccine).
Longer than 28 days	Give the 2nd dose at whatever interval. The course does not need to be restarted.

Preparation of Spikevax® (COVID-19 Vaccine Moderna)

Thaw frozen vaccine prior to preparing.

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

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

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

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

NEVER refreeze thawed vaccine.

STEP 1. PREPARING THE VACCINE
• Check the "use before" <u>date and time</u> on the box containing the vials with a colleague • Ensure vaccine is thawed prior to preparation and administration • Allow thawed vaccine stored at +2°C to +8°C to come to room temperature for 15 minutes • DO NOT DILUTE THE VIAL • DO NOT SHAKE THE VIAL • Gently swirl the vaccine once thawed and before withdrawing subsequent doses.
STEP 2. LABELLING THE VIAL

• Label the thawed vial with the date and time vial was punctured and note "discard time" • (19 hours after first dose withdrawn when at room temperature between +2°C and +25°C) using a 24 hour format. • Bring the vial to the vaccination table

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

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

Requirements for administration of vaccine

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

STEP 1. Preparation and administration of one dose of vaccine

Unpunctured vials: Check the use before date and ensure the vaccine is still in date.
Punctured vials: Check the discard time. Never use vaccine after the discard time.
With the vial upright, gently swirl the vaccine. **Do NOT shake.** If the vial is shaken, contact the manufacturer.
Examine the vaccine. It should be white to off white in colour and may contain white or translucent coloured particulates. Do not use if discoloured or contains other particulate matter.
Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully
Attach 23 gauge blue needle to 1ml syringe
Withdraw 0.5ml of vaccine[2]
Make sure correct dose is drawn up as a smaller dose may not provide protection
Ensure all air bubbles have been removed before the needle is withdrawn
Do not change the needle between the vial and the patient unless the needle is contaminated or damaged or if indicated
Administer vaccine to the patient intramuscularly (see Appendix 1)
Dispose of used needle and syringe in a sharps bin

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

Checklist before administering 2nd dose

Check

- dose interval
- if diagnosis of COVID-19 since last dose - delay second dose until clinical recovery from COVID-19 and at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic
- if history of allergic reaction to the vaccine after first dose (or any new allergic reactions since first dose)
- if pregnant since first dose - delay second dose until at least 14 weeks of pregnancy.
- discuss very rare adverse event of myocarditis and pericarditis following vaccination and explain symptoms and to seek medical advice (see section 10)

[2] When vaccination is carried out in settings where this is practicable and feasible, best practice is for the volume of each dose to be checked by a colleague to ensure the correct volume has been withdrawn

5.3 Vaxzevria® (AstraZeneca)

People aged less than 50 years should be offered an mRNA vaccine. People aged 18-34 may choose to be vaccinated with Vaxzevria ® for earlier protection where mRNA vaccine supplies are limited and therefore they will not be vaccinated for some time with mRNA vaccines

Table 9: Details of Vaxzevria® (AstraZeneca)

Title	Description
Type of vaccine	Replication deficient adenovirus vector*
Name of vaccine	Vaxzevria® (AstraZeneca)
Constituents	One dose (0.5 ml) contains: COVID-19 Vaccine (ChAdOx1-S*recombinant) 5 × 1010 viral particles (vp) Produced in genetically modified human embryonic kidney (HEK) 293 cells.** The product contains genetically modified organisms (GMOs)** L-Histidine 9 L-Histidine hydrochloride monohydrate Magnesium chloride hexahydrate Polysorbate 80 Ethanol Sucrose Sodium chloride Disodium edetate dihydrate Water for injections Vaxzevria® (AstraZeneca) does not contain egg None of the vaccine ingredients are of human or animal origin
Presentation	Multidose clear glass vial
Number of doses in each vial	10 doses If more than ten doses of 0.5mls can be safely and accurately withdrawn from a vial, they can be used as valid doses. There should be no pooling of vaccine from different vials
Dilution	NO DILUTION REQUIRED
Latex	The multidose dose vial has a halobutyl rubber stopper and an aluminium overseal with a plastic flip-off cap. Halobutyl rubber is a synthetic rubber. There is no latex in the vial or stopper
Preservatives	The vaccine does not contain any preservative. Standard aseptic technique should be used for withdrawing the dose for administration.
Dosage	0.5 mls
Number of doses required	2
Interval between doses	4-12 weeks*** 4 weeks is preferred

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

**The result is a genetically modified organism (GMO) with a new combination of genetic material. These changes to the adenovirus allow the vaccine to deliver the spike protein genetic code to the cells without causing COVID-19. Please refer to FAQ section 14.21

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

People aged 18-34 may choose to be vaccinated with Vaxzevria® for earlier protection as mRNA vaccine supplies are limited and therefore, they will not be vaccinated for some time.
This has not yet been implemented by the HSE but will be soon.

Vaxzevria® (AstraZeneca) vaccine efficacy and effectiveness

Vaccine efficacy data presented to the EMA demonstrated a two-dose vaccine efficacy of 59.5% (95% confidence interval of 45.8% to 69.7%) in those aged 18 and above. There was insufficient clinical data to allow reliable calculation of efficacy in those aged 55 and older. However, as a similar immune response was shown in all age groups, including those aged 65 and older, the EMA authorised the vaccine for all adults.

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

Evidence shows that protection starts from approximately 3 weeks after the first dose of vaccine and persists up to 12 weeks. Studies show 76% protection overall against symptomatic COVID-19 disease in the first 90 days. Modelling showed no evidence of waning of protection in the first three months after vaccination. This level of protection may not be the same for all COVID-19 variants.

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

It was generally recommended the two doses are given 8-12 weeks apart because there is evidence which shows that higher efficacy of 82% was reported when the second dose was given after 12 weeks. The threat of new variants in circulation and evidence of suboptimal protection against the delta variant after one dose of Vaxzevria® means that a shorter 4-8 week interval is preferable to ensure earlier protection, if practicable.

Vaxzevria® (AstraZeneca) storage

The vaccine will be delivered by the National Cold Chain Service at +2°C to +8°C.

Unopened (unpunctured) multidose vials

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

Opened multidose vial

After first opening, chemical and physical in-use stability has been demonstrated from the time of vial puncture to administration for no more than 6 hours at room temperature (of up to +30°C). The product should not be returned to the refrigerator after this time[3]

[3] The SmPC states:. Alternatively, an opened vial may be stored in a refrigerator (2°C – 8°C) for a maximum of 48 hours if it is immediately returned to the refrigerator following each puncture. From a microbiological point of view, after first opening the vaccine should be used immediately. If the vaccine is not used immediately, in-use storage times and conditions are the responsibility of the user. BEST PRACTICE IS THAT ALL VACCINE IS USED WITHIN 6 HOURS OF FIRST PUNCTURE

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

	Description
Expiry date	The date the vaccine expires if stored at +2°C to +8°C This is 6 months from the date of manufacture. The batch number and expiry date on the side of each vial should be recorded in the patient record.
"Discard" date and time Maximum time allowed from first puncture to expiry	When the vaccine is first punctured it must be used within 6 hours. Do not return to the refrigerator after this time. The "discard" date and time i.e. **6 hours from first puncture**[4] of the vial should be written on the vial using a 24 hour format. This should be written on the vial **e.g. Vial is first punctured on 01/01/2021 at 10.00. Discard time is 01/01/2021 at 16.00. This is the date and time that should be written on the vial.** Any unused or partially used vials must be discarded when this time has been reached.

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

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

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

A single dose of vaccine is 0.5 ml
A vaccine course started with Vaxzevria® (AstraZeneca) should be completed with this product.
COVID-19 vaccines are not interchangeable.
Two doses of Vaxzevria® (AstraZeneca) are required.
The vaccine should be administered intramuscularly (IM). The preferred site of administration is the deltoid muscle.

[4] The SmPC states: Alternatively, an opened vial may be stored in a refrigerator (2°C – 8°C) for a maximum of 48 hours if it is immediately returned to the refrigerator following each puncture. From a microbiological point of view, after first opening the vaccine should be used immediately. If the vaccine is not used immediately, in-use storage times and conditions are the responsibility of the user. BEST PRACTICE IS THAT ALL VACCINE IS USED WITHIN 6 HOURS OF FIRST PUNCTURE

Recommended intervals between doses of Vaxzevria® (AstraZeneca)

Individuals who have already received one dose of Vaxzevria® (AstraZeneca) should receive their second dose of Vaxzevria® 4-12 weeks after the first dose. A shorter 4 week interval is preferable because of the threat of new variants in circulation and evidence of suboptimal protection against the delta variant after one dose of Vaxzevria® .
There is no evidence of an increased risk of Thrombosis and Thrombocytopenia Syndrome (TTS) after the second dose of Vaxzevria® (current evidence suggests the risk is much lower after the second dose).

Table 11: Interval between 2 doses

Interval between 1st and 2nd doses	Action required
Less than 24 days	This is not considered a valid vaccine. A third dose should be given 28 days after the second (invalid) vaccine.
24 to 27 days	No further action needed (evidence from trial data is that this is a valid vaccine).
Longer than 12 weeks (84 days)	Give the 2nd dose at whatever interval. The course does not need to be restarted.

Preparation and administration of Vaxzevria® (AstraZeneca)

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

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

Requirements for administration of vaccine

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

Preparation and administration of 1 dose of Vaxzevria® (AstraZeneca)

STEP 1. Preparation and administration of one dose of vaccine
Check the vial **Unpunctured vials:** Check the expiry date. Never use expired vaccine. **Punctured vials:** Check the discard time. Never use vaccine after the discard time**.** The vial should not be shaken but the vaccine can still be used if it has been shaken. **Examine the vaccine** It should be a colourless to slightly brown, clear to slightly opaque suspension The vaccine should be inspected visually prior to administration. Discard the vial if the suspension is discoloured or visible particles are observed. **Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully** **Attach 23 gauge blue or 25 gauge orange needle to a 1ml syringe** Withdraw 0.5ml of vaccine[55] Make sure the correct dose is drawn up as a smaller dose may not provide protection Ensure all air bubbles have been removed before the needle is withdrawn **Withdraw the needle from the vial** **Administer vaccine to the patient intramuscularly (see Appendix 1)** **Dispose of used needle and syringe in a sharps bin**

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

Check

- dose interval
- if history of allergic reaction to the vaccine after first dose (or any new allergic reactions since first dose)
- all vaccine recipients should be informed of very rare complicated thromboembolic events that have been reported in a small number of people who have recently received Vaxzevria® and of the very rare risk of capillary leak syndrome (see relevant section of the vaccine for details)
  A decision aid is available to support decision-making by vaccine recipients aged 18-34 in relation to AstraZeneca vaccine
  https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/covid-19-vaccines-for-18-34-yr-olds.pdf
- Recipients of Vaxzevria® should be advised to seek immediate medical attention if they develop symptoms suggestive of thromboembolic events or capillary leak syndrome (see section 11.2)

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

5.3 COVID-19 Vaccine Janssen®

People aged less than 50 years should be offered an mRNA vaccine. People aged 18-34 may choose to be vaccinated with COVID-19 vaccine Janssen® for earlier protection where mRNA vaccine supplies are limited and therefore they will not be vaccinated for some time with mRNA vaccines.

Table 12. Details of COVID-19 Vaccine Janssen®

Title	Description
Type of vaccine	Adenovirus vector vaccine*
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

COVID-19 Vaccine ® Janssen vaccine efficacy

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

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

COVID-19 Vaccine Janssen® storage

The vaccine will be delivered by the National Cold Chain Service at +2°C to +8°C.

Unopened (unpunctured) multidose vial should be stored in a pharmaceutical grade refrigerator (+2°C to +8°C) until the expiry date

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

Vials may be stored at be stored between 9°C to 25°C for up to 12 hours

Opened multidose vial

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

Table 13: Definitions of terms for expiry date and usage times of COVID-19 Vaccine Janssen®

	Description
Use before date	Is 3 months from date the vials were removed from the freezer and stored refrigerated at +2°C to +8°C, The use before date will be written on the vaccine box.
"Discard" date and time Maximum time allowed from first puncture to expiry	When the vaccine is first punctured it must be used within 3 hours[6] 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.

For General Practice, please return any unused/expired vials to the National Cold Chain Service by giving at your next delivery. Further regulatory information on COVID-19 vaccines can be found in the approved product information (Summary of Product Characteristics (SmPC) for health care professionals, and Package Leaflet (PL) for the public), is available via the EMA website:
https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-janssen

[6] 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

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

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

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

COVID-19 vaccines are not interchangeable.

Preparation and administration of COVID-19 Vaccine Janssen®

Vaccine dose preparation and administration should be carried out at the point of administration ie 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 manufacturers instructions
- Each dose should be drawn up and immediately administered to the patient
- There should be no pooling of vaccine from different vials.

Requirements for administration of vaccine

- One COVID-19 Vaccine Janssen® multidose vial (up to 6 doses)
- x 70% alcohol swabs
- x 23 gauge blue needles or 25 gauge orange needles
- 6 x 1ml syringes

STEP 1. Preparation and administration of one dose of vaccine

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

Examine the vaccine.
It should be a colorless to slightly yellow, clear to very opalescent.

The vaccine should be inspected visually prior to administration. Discard the vial if the suspension is discoloured or visible particles are observed.

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

Attach 23 gauge blue or 25 gauge orange needle to a 1ml syringe
Withdraw 0.5ml of vaccine[7]
Make sure the correct dose is drawn up as a smaller dose may not provide protection Ensure all air bubbles have been removed before the needle is withdrawn.

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

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

Repeat for each dose

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

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[7]When vaccination is carried out in settings where this is practicable and feasible, best practice is for the volume of each dose to be checked by a colleague to ensure the correct volume has been withdrawn

6. Contraindications and precautions to COVID-19 vaccines

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

Contraindications See Table 12 for more details

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

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 which should be given after an interval of at least 28 days and should be given in a specialized setting.

Precautions See Table 12 for more details

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

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

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

For more information see Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions www.rcpi.ie

Table 12: Vaccination of those due an mRNA COVID-19 vaccine

	History	Action
Contraindication	• Anaphylaxis after a previous dose of Comirnaty® or Spikevax ® (COVID-19 vaccine Moderna®) • Anaphylaxis after polyethylene glycol (PEG)e.g. some bowel preparations for endoscopy, certain laxatives such as Movicol®)	Consider vaccination with Vaxzevria® or COVID-19 vaccine Janssen® in a suitable facility Observe for 30 minutes or Discuss with allergist/immunologists
	• Anaphylaxis after Trometamol®: Spikevax®(COVID-19 vaccine Moderna) is contraindicated	Vaccinate with alternative vaccine
Special precautions	• Anaphylaxis after multiple, different drug classes, with no identified allergen (may indicate PEG allergy) • Anaphylaxis after a vaccine, or a medicine which contained PEG • Idiopathic anaphylaxis (may indicate PEG allergy)	Clarify if PEG is tolerated (see FAQs) Discuss with allergist or immunologist Consider vaccination with Vaxzevria® or COVID-19 vaccine Janssen® Observe for 30 minutes
	• Mastocytosis • Anaphylaxis after food, venom or medication	Vaccinate as scheduled Observe for 30 minutes
Not a contraindication or a precaution	• 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

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

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

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polysorbate 80) (see table 13)
- A second dose of Vaxzevria® should not be given to anyone who developed Thrombosis with Thrombocytopenia Syndrome (TTS) after a first dose of Vaxzevria®
- Previous history of capillary leak syndrome.
- Those with a contraindication to one viral vector COVID-19 vaccine should not receive another authorised viral vector vaccine. Consideration may be given to mRNA vaccination which should be given after an interval of at least 28 days

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

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

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

- Patients with planned immunosuppressive therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used. Specialists should consider the individual's risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of the patient's immune status and likely immune response to vaccination.
- Those aged under 50 years including those with medical conditions with very high or high risk of severe COVID-19 disease should be offered an mRNA vaccine, unless they have received one dose of Vaxzevria®; in that case they should receive their second dose as scheduled. People aged 18-34 may choose to be vaccinated with Vaxzevria® for earlier protection as mRNA vaccine supplies are limited and therefore they will not be vaccinated for some time with mRNA vaccines. This has not yet been operationalized by the HSE but will be soon.

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

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

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

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

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

- Patients with planned immunosuppressive therapy should ideally receive vaccination two weeks before treatment. 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.

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

People aged 18-34 may choose to be vaccinated with COVID-19 Vaccine Janssen® for earlier protection as mRNA vaccine supplies are limited and therefore they will not be vaccinated for some time with mRNA vaccines.

Table 13: Vaccination of those due a viral vector vaccine

	History	Action
Contraindication	• Anaphylaxis after a previous dose of Vaxzevria® • Anaphylaxis after Polysorbate 80	Consider vaccinationwith Comirnaty® or Spikevax ®(COVID-19 vaccine Moderna®) in a suitablefacility Observe for 30 minutes OR Discuss with allergist/immunologist
Special precautions	• Anaphylaxis after a vaccine, injected antibody preparation, or a medicine known to contain Polysorbate 80 • Unexplainedanaphylaxis (may indicate polysorbate 80 allergy)	Clarify if polysorbate 80 is tolerated (see FAQs)[8] Discuss with allergist/immunologist Consider vaccination with Comirnaty ®or Spikevax® (COVID-19 vaccine Moderna) Observe for 30 minutes
	• Mastocytosis 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 injury from fainting.

[8] https://rcpi-live-cdn.s3.amazonaws.com/wp-content/uploads/2021/06/FAQs-about-COVID19-Vaccines-and-Allergies_29June2021.pdf

6.3 Vaccination after COVID-19

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

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

For people aged under 65 years, vaccination may be deferred for those who are not immunocompromised for up to six months after diagnosis, symptom onset, or from the first PCR or antigen positive specimen.

Those who have had laboratory confirmed COVID-19 infection within 9 months after a first dose of COVID-19 vaccine should complete the course.

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®) between 14- and 36-weeks' gestation following an individual benefit/risk discussion with their obstetric care giver.

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

There is evidence of an increase in premature delivery and in the stillbirth rate in Ireland and the UK in 2021. Pregnant women were not included in the initial clinical trials of the COVID-19 but trials are now taking place in pregnant women, and results are expected in the coming months.

Animal reproductive toxicology studies of the mRNA and COVID-19 Vaccine Janssen® vaccines did not identify any safety concerns. A preliminary animal reproductive toxicity study of Vaxzevria® (AstraZeneca) did not show toxicity. There is no evidence that any COVID-19 vaccine affects the fetus or fertility.

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

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

There is no evidence that any COVID-19 vaccine affects fertility or the fetus. No unexpected pregnancy or infant outcomes have been observed related to COVID-19 vaccination during pregnancy.

NIAC and the Institute of Obstetricians and Gynaecologists have developed materials to support healthcare workers and pregnant women in decision making about COVID-19 vaccination[9].

[9] The NIAC and the Institute of Obstetricians and Gynaecologists have developed decision aids, Q and A and an infographic to support women and their healthcare providers in decision making. These are being updated to reflect the most recent NIAC recommendations https://www.rcpi.ie/policy-and-advocacy/national-immunisation-advisory-committee/

Second dose of Vaxzevria® (AstraZeneca) in pregnancy

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

- They should complete the vaccination course with Vaxzevria® (AstraZeneca).
- The second dose can be given at the shorter interval of 4[10] after the first dose to enable them to complete the vaccination schedule by 36 completed weeks of gestation.

COVID-19 vaccines are:

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

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

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 thrombocytopoenia (platelet count <50 x 103/ml) consult the supervising consultant. People with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra®) do not require haemostatic cover for vaccination. Details of haemostatic cover for all others can be found in the Patient Information tab at http://www.stjames.ie/services/hope/nationalcoagulationcentre

Those with inherited coagulopathies receiving factor replacement therapy should receive it on the day of vaccination, prior to the IM vaccination.
If there is uncertainty about the need for cover, contact the patient's Comprehensive Care Centre.

7.5 Individuals taking anticoagulants

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

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

[10] The threat of new variants in circulation and evidence of suboptimal protection against the delta variant after one dose of Vaxzevria® means that a shorter 4-week interval is preferable to ensure earlier protection, if practicable.

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

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

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

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

7.8 Immunosuppression due to disease or treatment

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

People, for whom immunosuppressive therapy is planned, should ideally complete vaccination 2 weeks before treatment begins. The recommended minimum interval may be used. This also applies to individuals aged <50 who received a 1st dose of Vaxzevria® (AstraZeneca) and are awaiting their second dose. Specialists should consider the individual's risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of the patient's immune status and likely immune response to vaccination.

7.9 People being treated with chemotherapy for cancer

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

7.10 People under 18 years of age

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

7.11 Children

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

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

8. Duration of protection of COVID-19 vaccines

Vaccine recipients may not be protected until:

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

Clinical trial follow-up is on-going to determine the length of protection from COVID-19 vaccines.

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

9. Post vaccination

9.1 Recording vaccination

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

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

Table 14. Recording vaccine details

Comirnaty® (Pfizer BioNTech)	Spikevax® (COVID-19 Vaccine Moderna)	Vaxzevria® (AstraZeneca)	COVID-19 Vaccine Janssen®
Use before date and time of vaccine	Use before date of vaccine	Expiry date of vaccine	Use before date of vaccine
Batch number of vaccine	Batch number of vaccine	Batch number of vaccine	Batch number of vaccine
Batch number of Sodium Chloride diluent			

Comirnaty® (Pfizer BioNTech)

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

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

Spikevax® (COVID-19 Vaccine Moderna)

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

Vaxzevria® (AstraZeneca)

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

COVID-19 Vaccine Janssen®

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

9.2 Observation period

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

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

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

10. Adverse reactions

10.1 Adverse reactions of COVID-19 vaccines

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

Table 15: Adverse reactions of COVID-19 vaccines from clinical trials and post authorisation experience

Type of Reaction	Comirnaty® (Pfizer BioNTech)	COVID-19 Vaccine Moderna®	Vaxzevria® (AstraZeneca)	COVID-19 Vaccine Janssen®
Very Common (≥ 1/10)	Local: injection site swelling and erythema	Local: injection site pain, injection site swelling, lymphadenopathy (axillary swelling and tenderness of the vaccination arm)	Local: injection site tenderness, pain, warmth, pruritus, bruising	Local: injection site pain
	General: arthralgia, fatigue, fever, headache, myalgia diarrhoea	General: fatigue, headache, myalgia, arthralgia, fever, chills, nausea and vomiting	General: fatigue, malaise, feverishness, chills, myalgia, arthralgia, nausea, headache	General: headache, nausea, myalgia, fatigue
Common (≥ 1/100 to < 1/10)	Local: injection site erythema, injection site urticarial, injection site rash	Local: injection site swelling,	Local: injection site erythema	Local: Injection site erythema, injection site swelling
	General: nausea, vomiting	General: rash	General: vomiting, diarrhoea, fever (measured fever ≥38°C) thrombocytopenia*	General: cough, fever, chills, joint pain,
Uncommon (≥ 1/1,000 to < 1/100)	Local: injection site pruritus	Local: injection site pruritus		
	General: insomnia, lymphadenopathy, malaise, extremity pain (refer to the vaccinated arm) Hypersensitivity reactions (e.g. rash, pruritus, urticaria, angioedema)		General: lymphadenopathy, decreased appetite, somnolence, dizziness, rash, pruritus, hyperhidrosis,	General: Tremor, sneezing, oropharyngeal pain, rash, hyperhidrosis, muscle pain, pain in extremities, back pain, asthenia, malaise

Rare (≥ 1/10,000 to < 1/1,000)	General: acute peripheral facial paralysis/Bell's Palsy, facial swelling in those who have had dermatological fillers	General: acute peripheral facial paralysis/Bell's Palsy, facial swelling in those who have had dermatological fillers		General: Hypersensitivity, urticarial,
Very rare (< 1/10,000)	Myocarditis and pericarditis***	Myocarditis and pericarditis***	Thrombosis in combination with thrombocytopenia** Capillary leak syndrome ***	Thrombosis in combination with thrombocytopenia** Capillary leak syndrome***
Not known, cannot be estimated from the available data	Anaphylaxis		Hypersensitivity Anaphylaxis	Anaphylaxis
*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. *** will be added to the licensed documentation by the EMA as a very rare adverse event				

- Events of anaphylaxis have been reported after COVID-19 vaccines. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine
- Very rare events of neuroinflammatory disorders have been reported following vaccination with COVID-19 vaccines. A causal relationship has not been established.
- Guillain-Barré syndrome (GBS) has been reported very rarely following vaccination with Vaxzevria®. A causal relationship has not been established. Healthcare professionals should be alert of GBS signs and symptoms to ensure correct diagnosis, in order to initiate adequate supportive care and treatment, and to rule out other causes.

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

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

	Comirnaty® (Pfizer BioNTech)	Spikevax® (COVID-19 Vaccine Moderna)	Vaxzevria® (AstraZeneca)	COVID-19 Vaccine Janssen®
Most frequent adverse reactions reports (percentage)	injection site pain (> 80%) fatigue (> 60%) headache (> 50%) myalgia and chills (> 30%) arthralgia (> 20%) pyrexia and injection site swelling (> 10%)	injection site pain (> 90%) fatigue (> 70%) headache (> 60%) myalgia (>60%) arthralgia (> 40%) chills (> 40%) nausea/vomiting (>20%) axillary swelling/ tenderness (>15%) pyrexia (>15%) injection site swelling and redness (>10%)	injection site tenderness (> 60%) injection site pain (>50%) fatigue (> 50%) headache (> 50%) myalgia (>40%) malaise (> 40%) pyrexia (>30%) chills (> 30%) arthralgia (>20%) nausea (>20%)	injection site pain (>40%) fatigue (>30%) headache (>30%) myalgia (>30%) nausea (>10%) fever (9%)

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

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

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

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

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

EMA's safety committee (PRAC) has concluded that myocarditis and pericarditis can occur in very rare cases following vaccination with Comirnaty® and Spikevax® (Moderna).

Myocarditis and pericarditis are now listed as very rare side effects in the product information for these vaccines.

These cases are very rare: an in-depth review by the EMA of 145 cases of myocarditis in the European Economic Area (EEA) among people who received Comirnaty and 19 cases among people who received Spikevax. PRAC also reviewed reports of 138 cases of pericarditis following the use of Comirnaty and 19 cases following the use of Spikevax. As of 31 May 2021, around 177 million doses of Comirnaty and 20 million doses of Spikevax were given in the EEA.

In addition the EMA also looked into cases received worldwide.

The committee concluded that the cases primarily occurred within 14 days after vaccination, more often after the second dose and in younger adult men. In five cases that occurred in the EEA, people died. They were either of advanced age or had concomitant diseases. Available data suggest that the course of myocarditis and pericarditis following vaccination is similar to the typical course of these conditions, usually improving with rest or treatment.

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.

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

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

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

For Vaxzevria® (AstraZeneca), the EMA estimates the risk of TTS after vaccination to be around 1 in 100,000 in people aged 50 and older and 2/100,000 in people <50 years. Preliminary UK evidence suggests that the risk of TTS may not be higher and is possibly substantially lower (1.6/ million) after the second dose.

For COVID-19 Vaccine Janssen®, based on recent data from the United States, the estimated risk of TTS after vaccination is 1 in 312,000. The risk of this rare condition is higher in younger people. It is not yet known if there is a sex difference

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

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

been reported in men.

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

As the risk/benefit of these vaccines is different in different age groups NIAC recommends that these vaccines should be given to people aged 50 years and older, and that younger people should be offered an mRNA vaccine.
People aged 18-34 may choose to be vaccinated with Vaxzevria® or COVID-19 Vaccine Janssen® for earlier protection as mRNA vaccine supplies are limited and therefore they will not be vaccinated for some time with mRNA vaccines
(the option to be vaccinated with Vaxzevria® has not yet implemented by the HSE)
.
The National Immunisation Office has developed a decision aid to support people in their decision regarding vaccination in this situation. This is available from
https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/covid-19-vaccines-for-18-34-yr-olds.pdf

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

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

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

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

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

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

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

The EMA concluded that people who have previously had a very rare syndrome called capillary leak syndrome, must not be vaccinated with Vaxzevria® vaccine (AstraZeneca) or COVID-19 Vaccine Janssen®. The Committee also concluded that capillary leak syndrome should be added to the product information as a new side effect of the vaccine, together with a warning to raise awareness among healthcare professionals and patients of this very rare risk.
(Refer to Section 6 for contraindications and precautions to Vaxzevria® and COVID-19 Vaccine Janssen®).

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

- Individuals who have already received one dose of Vaxzevria® (AstraZeneca) should receive their second dose of Vaxzevria® as scheduled. There is no evidence of an increased risk of Thrombosis and Thrombocytopenia Syndrome (TTS) after the second dose of Vaxzevria® compared with a first dose (current evidence suggests the risk is much lower with the second dose 1.6/million).
- The interval between the first and second dose should be reduced to no less than 4 weeks if practicable to provide earlier protection against the Delta COVID-19 variant.
- Healthcare professionals and vaccine recipients should be informed that very rare, complicated thromboembolic events have occurred in a small number of people who have recently received Vaxzevria®.
- Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia and report any suspected adverse reactions to the Health Products Regulatory Authority.
- Healthcare professionals should be aware of the signs and symptoms of capillary leak syndrome
- Healthcare professionals should tell people receiving the vaccine that they must seek medical attention if they have the following symptoms in the days after vaccination, which may be associated with feeling faint (due to low blood pressure):
    - oedema in the extremities
    - sudden weight gain.

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

10.5 Reporting adverse reactions

The Health Products Regulatory Authority (HPRA) is responsible for managing the national pharmacovigilance system. The HPRA reports nationally occurring adverse reactions to the EMA. Adverse reaction reporting is an important part of the EMA intensive monitoring plan for COVID-19 vaccines, so that any changes in benefit risk balance can be promptly detected and acted upon. This enables the EMA to continue to safeguard public health safety.

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

Healthcare professionals and members of the public are encouraged to report any suspected adverse reactions to the HPRA following the instructions available on the HPRA website www.hpra.ie. As much information as is known should be provided, and where possible, the vaccine batch number should be included.

10.6 Reporting of incidents during the vaccination session to HSE

In the case of medication errors that directly involve the vaccine recipient, i.e. wrong medication/dose/route being administered or another medication error, the vaccinator must remain with the person and closely monitor them for any adverse reactions. Vital signs should be recorded and the vaccine recipient should be reviewed by a medical practitioner.

The incident must be reported to the relevant line manager/person in charge as soon as possible.

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

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

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

11. 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.

12. Effect of COVID-19 vaccines on COVID-19 tests

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

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

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

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

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

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

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

Asymptomatic individuals who have undergone testing for COVID-19 and who are residents in a long-term care facility should also proceed with vaccination while awaiting the results of their tests. This applies also to healthcare staff who have undergone serial testing.

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

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

- Hand hygiene
- Put on Personal Protective Equipment (PPE). Check HPSC guidance for latest advice regarding PPE https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/ppe/
- 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/hseinfectio npreventionandcontrolguidanceandframework/

14. Frequently asked questions about Covid-19 vaccines

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

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

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

Those who have had laboratory confirmed COVID-19 infection within 9 months after a first dose of COVID-19 vaccine should complete the course.

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

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

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

Those who have had laboratory confirmed COVID-19 infection within 9 months after a first dose of COVID-19 vaccine should complete the course

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

Comirnaty® (Pfizer BioNTech)

- If a dose is given at an interval of less than 17 days, this this is not considered a valid dose. A third dose should be given 28 days after the second (invalid) vaccine.
- If a dose is given between 17 and 27 days, this is considered a valid dose.

Spikevax® (COVID-19 Vaccine Moderna)

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

Vaxzevria® (AstraZeneca)

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

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

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

14.5 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.

14.6 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.

14.7 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.

14.8 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.

14.9 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.

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

The vaccine is currently licensed by the EMA for those aged 12-15 however it is not currently routinely recommended by the National Immunisation Advisory Committee for this age group. However as it is licensed in this age group, the person and parent/guardians should be informed. A HSE incident form should be completed but this does not require reporting to HPRA.

14.11 What if a person under 18 years is given COVID-19 Vaccine Moderna® or Vaxzevria®(AstraZeneca) or COVID-19 Vaccine Janssen® inadvertently?

If a person under the age of 18 years receives the vaccine inadvertently, this should be reported to the HPRA and an incident form completed. The person (and their parents/guardians if less than 16 years old) should be advised regarding the common adverse events expected after vaccination. If Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen® is given inadvertently, they should be advised of 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. For Vaxzevria®, they should also be advised of the very rare reported adverse event of capillary leak syndrome and of the symptoms to be aware of.

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

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

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

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

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

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

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

It is not necessary to leave any interval after having the vaccine and becoming pregnant. If a woman becomes pregnant following the first dose, they should wait until 14 weeks or after to get the second dose and should discuss the risks and benefits with their Obstetrician or GP.

14.15 What if someone has a history of anaphylaxis or severe allergic reaction to a type of food - can they receive a COVID-19 vaccine?

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

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

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

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

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

If someone has had a reaction to the first dose of a vaccine but it is not a contraindication to vaccination, iIt is not currently recommended to give a vaccine from a different platform (i.e., mRNA or viral vector) as a second dose.
Please refer to Section 6 for more details and to the Immunisation Guidelines for Ireland Chapter 5a.

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

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

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

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

(As an example, the quadrivalent inactivated influenza flu vaccine that is licensed and used in Ireland and in Europe comes in a prefilled syringe with a fixed needle attached, and the needle is not the longer 40mm in length).

14.19 Can mRNA vaccines like Comirnaty® (Pfizer BioNTech) and Spikevax® (COVID-19 Vaccine Moderna) interact with a person's DNA?

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

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

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

14.21 Can COVID-19 vaccines affect fertility?

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

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

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

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

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

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

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

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

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

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

The Irish Catholic Bishops Conference has released a statement that it is morally permissible for Catholics to accept a vaccine which involves the use of foetal cell-lines, especially if the potential risk to life or health is significant, as in the case of a pandemic. For full statement see https://www.catholicbishops.ie/2020/12/09/bishops-conference-statement-welcoming-vaccines-for-the-common-good/

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

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

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

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

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

The Irish Catholic Bishops Conference has released a statement that it is morally permissible for Catholics to accept a vaccine which involves the use of foetal cell-lines, especially if the potential risk to life or health is significant, as in the case of a pandemic. For full statement see https://www.catholicbishops.ie/2020/12/09/bishops-conference-statement-welcoming-vaccines-for-the-common-good/

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

Yes, they can still have the Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen® if they have recently had a blood clot[11] or are on blood thinning treatments. There is no reason to delay vaccination.
Like anyone who has received Vaxzevria® or COVID-19 Vaccine Janssen®, they should be aware of the symptoms to look out for and to seek urgent medical attention in the few weeks after receiving the vaccine if they experience any of the following:

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

[11] The only exception to this is if they developed TTS after a previous dose of Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen®

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

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

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

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

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

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

They should receive their second dose of Vaxzevria® (AstraZeneca) as scheduled. There is no evidence of an increased risk of TTS after the second dose of Vaxzevria® (current evidence suggests the risk may be much lower after the second dose 1.6/million).

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

No. There is currently not sufficient evidence regarding safety and efficacy to recommend the use of a heterologous vaccination strategy (using a different vaccine for the first and subsequent doses of a multi-dose schedule). NIAC will continue to review the evidence as it becomes available.

14.30 Would you recommend taking paracetamol before being vaccinated?

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

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

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

15. Useful links

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

Immunisation Guidelines for Ireland: Chapter 5a Covid-19.
https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf

Information for women who are pregnant or breastfeeding and their doctors about Covid-19 vaccine
https://www.rcpi.ie/news/releases/information-for-women-who-are-pregnant-or-breastfeeding-about-the-covid-19-vaccine-update/

Information for 18-34 year olds considering getting the COVID-19 vaccine and their pharmacists
https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/covid-19-vaccines-for-18-34-yr-olds.pdf

HSE Management of cold chain guidance (2-8 °C)
https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf

HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes
https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02.pdf

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 (https://www.ema.europa.eu/en).

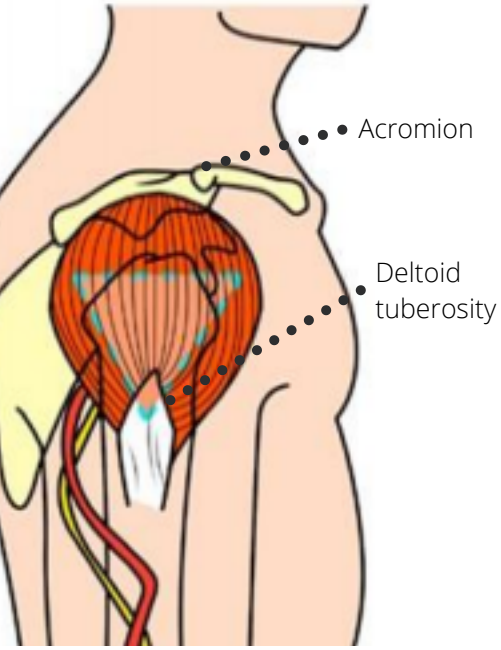
Health Products Regulatory Authority. Human Medicines Adverse Reaction Report
https://www.hpra.ie/homepage/about-us/report-an-issue/covid-19-vaccine-adverse-reaction

HPSC COVID-19 guidance www.hpsc.ie

Appendix 1. Intramuscular injection technique

ntramuscular (IM) Injection Technique

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

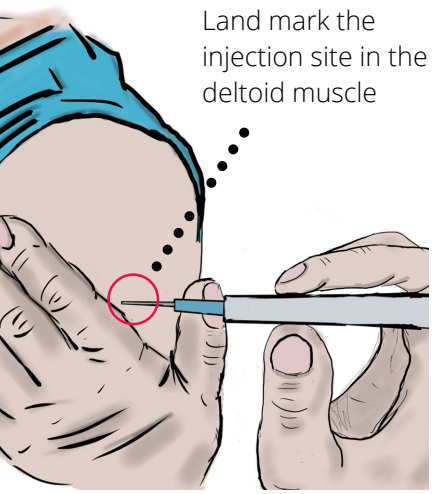


1. **Land mark the injection site in the deltoid muscle:**
   - Two finger widths down from the acromion process; the bottor edge is at an imaginary line drawn from the axilla
   - Injection site: 5cms below acromion process

NOTE: The recommended site is in the middle of the triangle. To av causing an injury, do not inject too high or too low. Vaccinators sho 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 <u>NOT</u> 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 ensure 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 bal gauze. Do not massage the injection site.

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

Swift needle entry

Slow injection of medication

Swift needle withdrawal

Less pain

<u>AC recommendations:</u>
is not necessary to use gloves for vaccine injections, unless contact with potentially infectious body fluids is ssible, or unless the health care worker has an infected lesion on the hand. If gloves are worn they should be anged for each patient. If the skin at the injection site is visibly dirty it should be cleaned with soap and water. ere is no need to use a disinfectant e.g. alcohol swabs. If an alcohol swab is used, injection should be delayed r ≥30 seconds, to ensure the alcohol will have evaporated".

<u>Read the guidelines</u>

Appendix 2. SOP

Management of Comirnaty® (Pfizer/BioNTech) COVID-19 vaccine Guidance at Vaccination Clinics

This document is under regular review and will be updated when relevant new information becomes available. Please check www.immunisation.ie 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 NationalCold Chain Service (NCCS) to the site. The site will take ownership of the vaccine upon delivery.

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

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

2. Responsibilities

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

3. Scope

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

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:

- 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 referencesources 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:
https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf

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

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

4.2 Vaccine decommissioning

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

4.3 Safe handling

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

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

DO NOT pool excess vaccines from multiple vials.

Undiluted vial

An **undiluted vial** of Comirnaty® (Pfizer/BioNTech) COVID-19 vaccine may be stored for up to one month (31 days) at temperatures between +2°C and +8°C. Boxes will be labeled by the NCCS with the **USE BEFORE date and time** reflecting this new extended storage shelf life. This date should be recorded in the patient's record. Prior to use, the unopened vaccine can be stored for up to 2 hours at room temperature up to 30°C.

The following information is intended to guide healthcare professionals only in case of temporary temperature excursion.
Stability data indicate that the unopened vial is stable for up to:

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

Diluted medical product

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

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

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

To note:

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

4.4 Transportation of vaccines

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

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

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

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

For additional information the following document may be consulted:

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

4.5 Stock Reconciliation

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

- Comirnaty® -Vaccine Reconciliation Form for GP practices Version 1.0 19 January 2021
- Comirnaty® -Vaccine Reconciliation Form for clinic settings Version 1.0 4 March 2021

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

These will be delivered in advance by HSE in the required quantities to match the quantity of vaccine ordered/supplied. A national distribution service will provide all necessary supplies, to handle, prepare and

administer the vaccine including PPE and critical clinical and non-clinical consumables. These are not includedin this SOP.

Other Equipment includes:

- **Anaphylaxis Kits**

Refer to National Immunisation Advisory Committee Guidelines
https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/protocols/anaphylaxis2016.pdf
The epinephrine will be purchased and FMDed by a pre-determined community/ hospital pharmacyas 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 alarmsshould take into account the need to maintain the temperature above +2 °C to prevent freezing and remain less than +8 °C. The temperature should be set to maintain +5 °C +/- 3 °C.

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

6. Stock Control, Security & Monitoring of Wastage

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

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

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

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

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

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

7. Health & Safety

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

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

Management of Spikevax® COVID-19 Vaccine Moderna Guidance at Vaccination Clinics

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

1. Background

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

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

Spikevax® (Moderna) was granted conditional marketing authorisation by the EC on 6 January 2021. https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna

2. Responsibilities

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

3. Scope

The scope of this document is to set a standardised protocol of procedures to be followed in the provision of Spikevax® (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 thawing and first puncture of the vial
- Transportation
- Vaccines decommissioning
- Stock reconciliation

The document provided may be used as 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

Spikevax® (Moderna) will be delivered frozen between -25°C and -15°C to each vaccination clinic. Receipt delivery of stock 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, for maximum 30 days. The temperature in your fridge may suddenly deepen into negative temperatures (freezing) depending on the size of the shipment being placed into the fridge as this product is at temperature between -25°C and -15°C. Monitor the fridge and take action if this happens.

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

Each box of vaccine has 10 multidose vials (MDV). One dose (0.5 mL) of Spikevax® (Moderna) contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles).

When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for additional dose(s).

The National Immunisation Advisory Committee advises that if more than ten doses can be safely and accurately withdrawn from a vial they can be used as valid doses. There should be no pooling of excess vaccine volume from multiple vials.

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

Where ScanVax is available (Hospitals, HSE Central Vaccination Clinics) Spikevax® (Moderna) ***USE BEFORE*** *date and time* will automatically recalculate once scanned. This should be done at the time of arrival. When a printer is available, print a new ***USE BEFORE*** label and apply it on the box. If a printer is not available, manually record the ***USE BEFORE*** *date and time* displayed on the screen onto the box.

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

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

  OR
- ✓ Room temperature: Between + 15°C and + 25°C for 1 hour.

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

Unopened vials may be kept between +8°C and +25°C for up to 24 hours after which the product must be discarded.

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

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.

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

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

SpikeVax® (Moderna) Reconciliation Forms can be found at the links below. Please note they are editable PDF.

- Moderna® - Vaccine Reconciliation Form for GP practices Version 1.0 https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/modernavaccinereconciliationf orm.pdf

- Moderna® - Vaccine Reconciliation Form for clinic settings Version 1.0 https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/modvaccrecnongp.pdf

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

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^{O}C to prevent freezing and remain less than +8^{O}C. The temperature should be set to maintain +5^{O}C +/- 3^{O}C.
Fridges should be validated and monitored in accordance with existing local procedures.

6. Stock Control, Security & Monitoring of Wastage

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

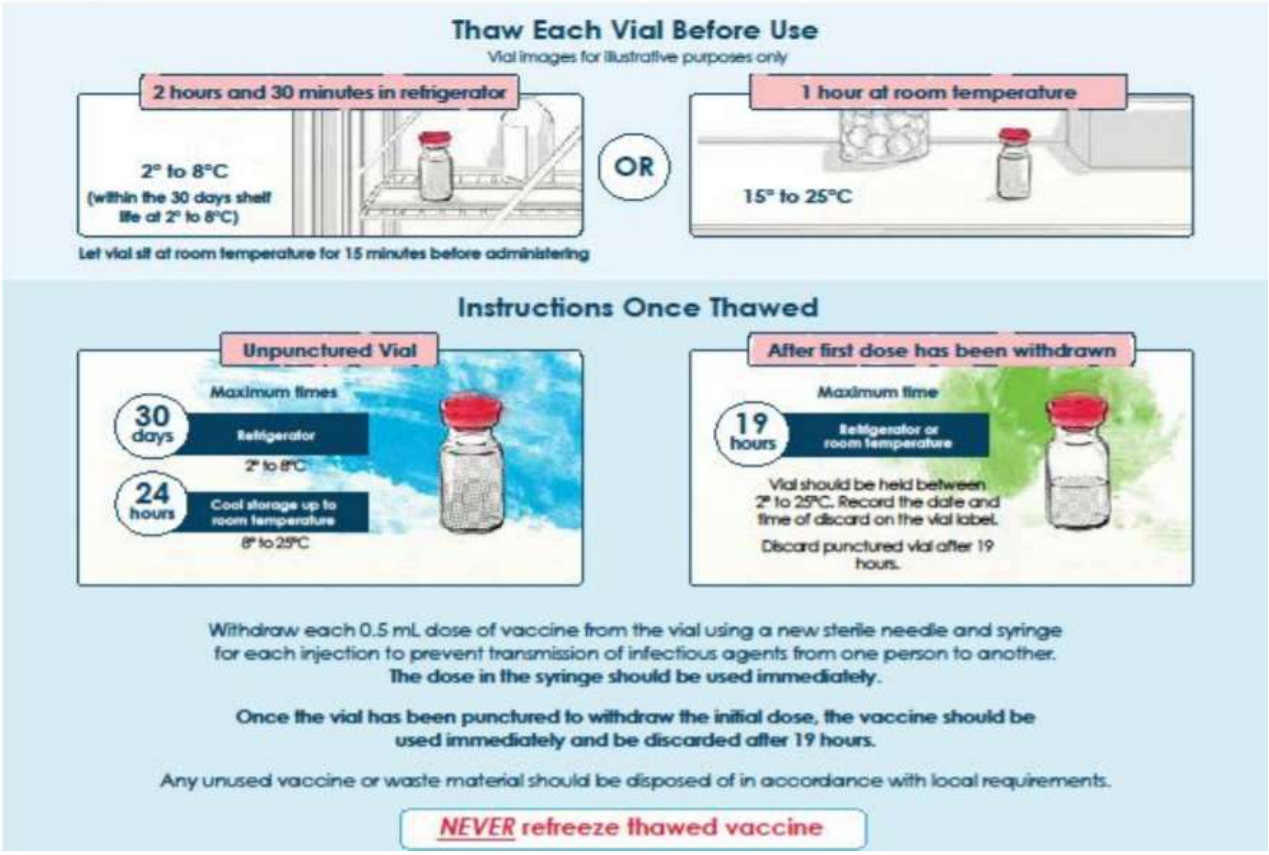
Original cartons must have their labels defaced using permanent black marker pens, and placed into appropriate waste sack for incineration, as soon as possible after they become empty.

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.


Thaw Each Vial Before Use
Vial images for illustrative purposes only
2 hours and 30 minutes in refrigerator
2° to 8°C
(within the 30 days shelf life at 2° to 8°C)
OR
1 hour at room temperature
15° to 25°C
Let vial sit at room temperature for 15 minutes before administering
Instructions Once Thawed
Unpunctured Vial
Maximum times
30 days
Refrigerator
2° to 8°C
24 hours
Cool storage up to room temperature
8° to 25°C
After first dose has been withdrawn
Maximum time
19 hours
Refrigerator or room temperature
Vial should be held between 2° to 25°C. Record the date and time of discard on the vial label.
Discard punctured vial after 19 hours.
Withdraw each 0.5 mL dose of vaccine from the vial using a new sterile needle and syringe for each injection to prevent transmission of infectious agents from one person to another.
The dose in the syringe should be used immediately.
Once the vial has been punctured to withdraw the initial dose, the vaccine should be used immediately and be discarded after 19 hours.
Any unused vaccine or waste material should be disposed of in accordance with local requirements.
NEVER refreeze thawed vaccine

Management of COVID-19 Vaccine Vaxzevria® (AstraZeneca) Guidance at Vaccination Clinics

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

1. Background

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

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

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

https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-astrazeneca-product-information-approved-chmp-29-january-2021-pending-endorsement_en.pdf

2. Responsibilities

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

3. Scope

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

4. Purpose

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

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

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

4.1 Safe and temperature controlled storage

Upon arrival at your vaccination centre:

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

For additional information the following document may be consulted:
https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf Vaxzevria® (AstraZeneca) will be delivered at a temperature of +2 °C to +8 °C
Each box will contain 10 multidose vials (MDV). Receipt delivery of stock and scan stock onto the system as you unpack the delivery

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

4.2 Safe handling

Vaxzevria® (AstraZeneca) comes ready to use, and each vial contains at least 10 doses. One dose (0.5 mL) contains not less than 2.5 x 10^8 infectious units (Inf. U).

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

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

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

4.3 Vaccine decommissioning

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

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

Vaxzevria is serialised and must be decommissioned.

4.4 Stock Reconciliation

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

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

- Vaxzevria® (AstraZeneca) -Vaccine Reconciliation Form for GP practices Version 1.0

https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/astrazenecavaccinereconciliationfor m.pdf

- Vaxzevria® (AstraZeneca) - Vaccine Reconciliation Form for clinic settings Version 1.0

https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/azvaccrecnongp.pdf

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

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

Other Equipment includes:

- **Anaphylaxis Kits**

Refer to National Immunisation Advisory Committee Guidelines
https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf

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

- **Storage Equipment**

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

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

6. Stock Control, Security & Monitoring of Wastage

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

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

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

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

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

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

7. Health & Safety

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

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

Management of COVID-19 Vaccine Janssen®

Guidance at vaccination Clinics

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

1. Background

COVID-19 vaccine Janssen® was granted conditional marketing authorisation by the European Commission on 11th March 2021. https://www.ema.europa.eu/en/medicines/human/EPAR/COVID-19-vaccine-janssen

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

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

2. Responsibilities

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

3. Scope

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

4. Purpose

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

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

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:
https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf

4.2 Vaccines decommissioning

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

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

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

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

Initially some boxes may not be serialised and therefore will not require to be decommissioned:

If BLACK = DO NOT SCAN for DECOMMISSIONING

If WHITE+LINES = SCAN for DECOMMISIONING

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

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

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

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

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

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

Place the stock immediately in the fridge at a temperature of +2°C to +8°C. The vials should remain in their original box to be protected from light, for maximum of 3 months (and within original expiry date).

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

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

4.4 Stock Reconciliation

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

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

GP form: https://www.hse.ie/eng/health/immunisation/hcpinfo/COVID19vaccineinfo4hps/janssen/janssen-vaccine-reconciliation-form-gp.pdf

Clinic form: https://www.hse.ie/eng/health/immunisation/hcpinfo/COVID19vaccineinfo4hps/janssen/janssen-vaccine-reconciliation-form-clinic-form.pdf

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:

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

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 3. Checklist for Clinics

SAMPLE CHECKLIST FOR COVID-19 VACCINATION CLINICS

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

Before the Vaccine clinic		
		Physical Environment / Layout of the Vaccine clinic
YES	NO	A designated space for registration
YES	NO	Awaiting area for patients to be called for vaccination
YES	NO	A designated clean area for vaccine storage and preparation in the clinic.
YES	NO	A designated area for vaccine administration
YES	NO	Area for post vaccine observation for 15-30 minutes with adequate space for physical distancing and also a private space for medical emergencies (anaphylaxis management)
		Documentation **(Check for most up to date version of documents www.immunisation.ie)**
YES	NO	Clinical and administrative guidance for Vaccinators
YES	NO	National immunisation Advisory Committee Immunisation Guidelines for Ireland. https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf
YES	NO	Copy of a relevant COVID-19 vaccine medicine protocol (for nurse/midwife vaccinators only)
YES	NO	Anaphylaxis management in the community- Copy of an algorithm https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf
YES	NO	Copy of information on Cold chain management or access to the same https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/
YES	NO	Vaccination record cards and HSE advice leaflets for after vaccination for the recipients (if hard copies are available)
YES	NO	Current up to date copies of : HSE vaccine information leaflets and European Medicines Agency Patient Information Leaflets (please see www.ema.eu/en for most up to date version)
		Infection Prevention & Control Precautions:
YES	NO	Posters in relation to COVID-19 o Do NOT visit if you have symptoms of COVID-19 o Physical distancing o Cough etiquette/respiratory hygiene Posters are available from the HSE website
YES	NO	Hand Sanitiser (alcohol gel/foam sanitiser) for staff and patients
YES	NO	PPE for the vaccinator i.e. adequate stocks of surgical face masks
YES	NO	Disposable tissues available for patients and a foot pedal bin for disposal
YES	NO	Disinfectant wipes for worktops and other areas

YES	NO	Signs and floor markers to instruct patients to remain 2 metres apart from other patients and clinic staff have been set up before the clinic.
YES	NO	Appropriate seating arrangements with physical distancing markings displayed
YES	NO	Sharps waste bin, Clinical & Non clinical risk waste bins
		Clinical equipment
YES	NO	Access to pharmaceutical fridge or validated cool box with external display of current temperature and data logger
YES	NO	An anaphylaxis medical kit as per Guidelines (https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf)
YES	NO	Gloves □ Sharps boxes □ Alcohol Gel □ Clinical Tray □ Cotton wool □ Tape □ Clinical waste bags □ 70% Alcohol swabs □needles □syringes
After the vaccination		
YES	NO	Post-vaccination monitoring (recommended for 15-30 minutes): Allocation of staff for post vaccine observation for 15 -30 minutes
YES	NO	Post vaccine documentation Vaccinations administered recorded in HSE Covid-19 Vaccination Management System
YES	NO	All patient medical information placed in a secured storage location for data protection.
YES	NO	Session report form completed

Useful resources & links:

1) Immunisation Guidelines for Ireland https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/
2) Anaphylaxis management https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf
3) HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio01.pdf
4) HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool box https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/sopnio02.pdf
5) Reporting adverse reactions to the Health Products Regulatory Authority (HPRA). Details of the brand name and batch number of the vaccine must be included)
   - Online reporting at www.hpra.ie
   - Using a downloadable report form also accessible from HPRA website, which may be completed manually and submitted to the HPRA via "freepost" available from the HPRA website https://www.hpra.ie/homepage/about-us/report-an-issue/covid-19-vaccine-adverse-reaction.
6) Summary of Product Characteristics (SmPC) for the Covid -19 vaccine used in the HSE COVID-1 vaccination programme available at https://www.ema.europa.eu/en
7) In the event of a sharps injury the local procedure must be followed. This will require immediate first aid and follow-up. For further information on sharps injury please see http://www.hpsc.ie/AZ/EMIToolkit/EMIToolkit.pdf

Appendix 4. Advice from the National immunisation Advisory Committee regarding fever after COVID-19 vaccination

ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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.