Clinical Guidance for COVID-19 Vaccination

Version 9.0

25th February 2021
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<th>25/02/2021</th>
</tr>
</thead>
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<tr>
<td>Addition since last version (version 8.0) under precautions</td>
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This guidance is intended for vaccinators administering COVID-19 vaccine.

This guidance is intended for vaccinators who are already 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. They should also be familiar with the anaphylaxis protocol outlined in the Immunisation Guidelines for Ireland (see useful links section).

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

1. Introduction

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

Purpose of the document

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

Indemnity for vaccinators

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

Registered medical practitioners (including GPs); nurses; pharmacists; and other health professionals in receipt of relevant training with regard to administration of the vaccine, who are administering vaccines on the direction of, or on behalf of, the HSE will be indemnified with regard to any adverse product liability-related events arising from their administration of the vaccine. GPs, GP Practice Nurses and retail pharmacists however, will not be indemnified in respect of malpractice events occurring during the administration of the vaccine. Such malpractice events will be indemnified by their professional insurers.
2. Vaccine priority groups

The Government has agreed and published a COVID-19 vaccination strategy and implementation plan developed by the High-Level Task Force on COVID-19 Vaccination with input on priority groupings 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.

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.

<table>
<thead>
<tr>
<th>Group</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults aged ≥65 years who are residents of long-term care facilities.</td>
<td>At greatest risk of severe illness and death</td>
</tr>
<tr>
<td>Consider offering vaccination to all residents and staff on site.</td>
<td>In Ireland, in the first wave of COVID-19, 56% of deaths occurred in this setting</td>
</tr>
<tr>
<td>Frontline HCW* in direct patient contact roles or who risk exposure</td>
<td>At very high or high risk of exposure and/or transmission. In the first</td>
</tr>
<tr>
<td>to bodily fluids or aerosols</td>
<td>wave over 30% of cases were in healthcare workers</td>
</tr>
<tr>
<td>Aged 70 and older in the following order:</td>
<td>At higher risk of hospitalisation and death</td>
</tr>
<tr>
<td>85 and older</td>
<td></td>
</tr>
<tr>
<td>80-84</td>
<td></td>
</tr>
<tr>
<td>75-79</td>
<td></td>
</tr>
<tr>
<td>70-74</td>
<td></td>
</tr>
<tr>
<td>Other HCWs not in direct patient contact</td>
<td>Provide essential health services, protect patients</td>
</tr>
<tr>
<td>Aged 65-69. Prioritise those with medical conditions** which put them</td>
<td>At higher risk of hospitalisation and death</td>
</tr>
<tr>
<td>at high risk of severe disease</td>
<td></td>
</tr>
<tr>
<td>Key workers (to be further refined)</td>
<td>Providing services essential to the vaccination programme</td>
</tr>
<tr>
<td>Aged 16-64 years with medical conditions** which put them at high</td>
<td>At higher risk of hospitalisation</td>
</tr>
<tr>
<td>risk of severe disease</td>
<td></td>
</tr>
<tr>
<td>Residents of long-term care facilities aged 16-64</td>
<td>High risk of transmission</td>
</tr>
<tr>
<td>Aged 16-64 years living or working in crowded settings where</td>
<td>Disadvantaged socio demographic groups more likely to experience a higher</td>
</tr>
<tr>
<td>self-isolation and social distancing may be difficult to maintain</td>
<td>burden of infection</td>
</tr>
</tbody>
</table>
Key workers in essential jobs who cannot avoid a high risk of exposure to COVID-19. They include workers in the food supply system, public and commercial transport and other vital services | High risk of exposure as unable to work without physical distancing

Those who are essential to education and who face disease exposure - primary and second level school staff, childcare workers, maintenance workers, school bus drivers etc. | To maintain the opening of full-time education of all children who have been disproportionately impacted from the pandemic

Aged 55-64 years | Based on risk of hospitalisation

Those in occupations important to the functioning of society, e.g., third level institutions, entertainment and goods-producing industries who work in settings where protective measures can be followed without much difficulty | Moderate risk of exposure

Aged 16-54 years who did not have access to the vaccine in prior phases | If evidence demonstrates the vaccine(s) prevent transmission, those aged 18-34 should be prioritised due to their increased level of social contact and role in transmission

Children, adolescents up to 16 years (to be refined) | If evidence demonstrates safety and efficacy

* HCW who work in and out of all healthcare settings including vaccinators

** see below

Pregnant women who are healthcare workers or who have medical conditions which put them at high risk of severe disease are included in the respective priority groups. The priority for other pregnant women will be determined when more evidence is available

** At risk medical conditions

- Cancer
- Cardiovascular disease (e.g., cardiomyopathy, chronic heart failure, congenital heart disease, coronary artery disease)
- Chronic kidney disease (receiving dialysis, or eGFR <15ml/min)
- Chronic liver disease
- Chronic neurological disease compromising clearance of respiratory secretions
- Chronic respiratory disease e.g., chronic obstructive pulmonary disease (COPD), cystic fibrosis, severe asthma (BTS/SIGN>4)
- Down syndrome
### 3. COVID-19 vaccines

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

The vaccines are **not** interchangeable. The same vaccine should be used for both doses.

<table>
<thead>
<tr>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunocompromised due to disease or treatment</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Obesity (Body Mass Index ≥ 40)</td>
</tr>
<tr>
<td>Organ transplant history</td>
</tr>
<tr>
<td>Type 1 or 2 diabetes mellitus</td>
</tr>
<tr>
<td>Sickle cell disease</td>
</tr>
</tbody>
</table>


Comirnaty® is licensed for active immunisation to prevent COVID-19 in individuals 16 years of age and older.


COVID-19 Vaccine Moderna® is licensed for active immunisation to prevent COVID-19 in individuals 18 years of age and older.


COVID-19 Vaccine AstraZeneca® is licensed for active immunisation to prevent COVID-19 in individuals 18 years of age and older.

The Department of Health policy is that people aged 70 years and older should be offered an mRNA vaccine (Comirnaty® or COVID-19 Vaccine Moderna®)
4. Vaccine details, storage and instructions for preparation and administration.

4.1. Comirnaty® (Pfizer/BioNTech) vaccine

Table 1 Details of Comirnaty® (Pfizer/BioNTech) vaccine

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing process</td>
<td>mRNA</td>
</tr>
<tr>
<td>Name of vaccine</td>
<td>Comirnaty®                                                                                                           Note: This vaccine was called COVID-19 mRNA BNT162b2 (Pfizer/BioNTech) before authorisation. This name will be on early batches of the vaccine.</td>
</tr>
</tbody>
</table>
| Constituents                               | • Polyethylene glycol/macrogol (PEG) as part of ALC-0159.  
• ALC-0315 = (4-hydroxybutyl) azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate),  
• ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide  
• 1,2-Distearoyl-sn-glycero-3-phosphocholine  
• Cholesterol  
• Potassium chloride  
• Potassium dihydrogen phosphate  
• Sodium chloride  
• Disodium hydrogen phosphate dihydrate  
• Sucrose  
• Water for injections  
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  
NB smaller dosage than routine vaccines                                                                                                                                                                                                                               |
| 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.                                                                                                             |
Clinical Guidance for COVID-19 Vaccination

Comirnaty® vaccine efficacy

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.

Comirnaty® vaccine storage

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

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

- On arrival into the HSE National Cold Chain Service the vaccine is stored in an ultra-cold temperature (ULT) freezer at -80°C to -60°C.
- The vaccine is supplied to sites/clinics by the HSE National Cold Chain Service at +2 to +8°C with a limited shelf life of 120 hours.
- 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® have a shelf life of 120 hours 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) vaccine

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expiry date</strong></td>
<td>The date the vaccine expires if stored in an ultra-cold temperature (ULT) freezer at -80°C to -60°C. This is 6 months from the date of manufacture. The batch number on the side of each vial is recorded in the patient record. This is linked to the expiry date.</td>
</tr>
<tr>
<td><strong>“Use before” date and time</strong></td>
<td>USE BEFORE date and time = 120 hours 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 120 hours have passed, vials must be removed from fridge.</td>
</tr>
<tr>
<td><strong>Maximum time allowed from removal from ultra-low temperature (ULT) freezer to expiry, when stored at +2°C to +8°C</strong></td>
<td>Once the vaccine is removed from the fridge it must be diluted within 2 hours. It must be discarded, if not diluted within 2 hours.</td>
</tr>
<tr>
<td><strong>Maximum time allowed from removal from storage at 2-8°C fridge to dilution</strong></td>
<td></td>
</tr>
<tr>
<td><strong>“Discard” date and time</strong></td>
<td>When the vaccine is diluted it must be used within 6 hours. The “discard” date and time i.e. 6 hours after dilution must be written on the vial</td>
</tr>
</tbody>
</table>
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from dilution to expiry

| Note: | using a 24 hour format. |
| 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 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 120-hour 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. |

Any unused vials need to be stored at +2 to +8°C and 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 (PL) for the public), is available via the EMA website www.ema.europa.eu

Comirnaty® dosage, scheduling and site of vaccination

A single dose of vaccine is 0.3 ml (30 mcgs).

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

Two doses of 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.

Table 3: interval between 2 doses

<table>
<thead>
<tr>
<th>Interval between 1st and 2nd doses</th>
<th>Action required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 17 days</td>
<td>Evidence on efficacy for a dose interval of less than 17 days is lacking but currently the recommendation is that a 3rd dose is not indicated.</td>
</tr>
<tr>
<td>17 to 20 days</td>
<td>No further action needed (evidence from trial data is that this is a valid vaccine).</td>
</tr>
<tr>
<td>Longer than 28 days</td>
<td>Give the 2nd dose at whatever interval. The course does not need to be restarted.</td>
</tr>
</tbody>
</table>

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4.1.2 Preparation and Administration of Comirnaty® (Pfizer/BioNTech) vaccine

Infection Prevention and Control

- Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the “WHO five moments of hand hygiene” with emphasis on:
  - Before vaccine preparation
  - Before drawing up and administering the vaccine
  - Before and after each recipient contact
- 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.)
- Check HPSC website for latest guidance on infection prevention and control for healthcare workers: [https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/](https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/)
- Information should be available to those attending clinics that they should not attend if they feel unwell or have any symptoms suggestive of COVID-19 (see sample clinical checklist in Appendix 5).

Dilution of Comirnaty® vaccine

Requirements for diluting the vaccine

- One Comirnaty® 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® vaccine

- 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® multidose vial (up to 7 doses)
- 7 x 70% alcohol swabs
- 7 x 23 gauge blue needles
- 7 x 1ml syringes
STEP 1. Preparation and administration of one dose of vaccine

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

Once all doses have been administered, discard the vial and record the time and date of discard (see session report form/vial traceability form www.immunisation.ie).
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)
- no other vaccines have been given within the last 14 days
- if pregnant since first dose - delay second dose until at least 14 weeks of pregnancy.
## 4.2 COVID-19 Vaccine Moderna®

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing process</td>
<td>mRNA</td>
</tr>
<tr>
<td>Name of vaccine</td>
<td>COVID-19 Vaccine Moderna®</td>
</tr>
</tbody>
</table>
| 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          | Once thawed, COVID-19 Vaccine Moderna® cannot be moved from one site to another. Within the same site or campus, it can only be hand carried once with shaking and vibration minimised. The duration of this single journey must not exceed 1 hour. |
COVID-19 Vaccine Moderna® Vaccine efficacy

Data from the randomised Phase 3 trial demonstrated a two-dose vaccine efficacy for COVID-19 Vaccine Moderna® of 94.1% (95% confidence interval of 89.3% to 96.8%) in those aged 18 and above. Efficacy was similar in all age groups. High efficacy (≥86%) was observed across age, sex, and ethnicity categories and among persons with underlying medical conditions.

COVID-19 Vaccine Moderna® Vaccine 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 -25º to -15ºC.

The vaccine must be thawed prior to administration.

The vaccine may be thawed as follows:

- **In the refrigerator** (Between +2 ºC and +8 ºC) 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 ºC and +25 ºC) 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 by” date is 30 days from this date if the vaccine is thawed and stored at +2 to+8 ºC. The “use by” date should be recorded on the vaccine box.

Once a vial is punctured to draw up the first dose, there is a maximum time of 6 hours before the vial should be discarded. The “discard” date and time i.e. 6 hours after the vial is first punctured must be written on the vial using a 24 hour format. e.g. vial is first punctured 20/01/2021 at 11.00. Discard date and time is 20/01/2021 at 17.00

Table 3: Storage of unopened vials of COVID-19 Vaccine Moderna®

<table>
<thead>
<tr>
<th>Method of Vaccine Storage</th>
<th>Temperature</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen</td>
<td>Between -25 ºC and -15 ºC</td>
<td>Until expiry date</td>
</tr>
<tr>
<td>Refrigerator</td>
<td>Between +2 ºC and +8 ºC</td>
<td>Up to 30 days (until “use by” date)</td>
</tr>
<tr>
<td>Room Temperature</td>
<td>Between +8 ºC and +25 ºC</td>
<td>Up to 12 hours</td>
</tr>
</tbody>
</table>
Clinical Guidance for COVID-19 Vaccination

Table 4: Storage of opened (needle punctured) vials of COVID-19 Vaccine Moderna®

<table>
<thead>
<tr>
<th>Method of Vaccine Storage</th>
<th>Temperature</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerator</td>
<td>Between +2 ºC and +8 ºC</td>
<td>Up to 6 hours (until discard date and time)</td>
</tr>
<tr>
<td>Room Temperature</td>
<td>Between +2 ºC and +25 ºC</td>
<td>Up to 6 hours (until discard date and time)</td>
</tr>
</tbody>
</table>

Table 5: Definitions of terms for expiry date and usage times of COVID-19 Vaccine Moderna®

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

Any unused vials need to be stored at +2 to +8ºC and 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 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](https://www.ema.europa.eu/en)
COVID-19 Vaccine Moderna® dosage, scheduling and site of vaccination

A single dose of vaccine is 0.5 ml (100 mcgs).

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

Two doses of COVID-19 Vaccine Moderna® are required with an interval of 28 days between doses.

The minimum interval between the first and second dose is 24 days.

The vaccine should be administered intramuscularly (IM)

The preferred site of administration is the deltoid muscle

Table 6: Interval between 2 doses

<table>
<thead>
<tr>
<th>Interval between 1st and 2nd doses</th>
<th>Action required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 24 days</td>
<td>Evidence on efficacy for a dose interval of less than 24 days is lacking but currently the recommendation is that a 3rd dose is not indicated.</td>
</tr>
<tr>
<td>24-28 days</td>
<td>No further action needed (evidence from trial data that this is a valid vaccine).</td>
</tr>
<tr>
<td>Longer than 28 days</td>
<td>Give the 2nd dose at whatever interval. The course does not need to be restarted.</td>
</tr>
</tbody>
</table>

Preparation and Administration of COVID-19 Vaccine Moderna®

Infection Prevention and Control

- For the 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 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.)
Clinical Guidance for COVID-19 Vaccination

https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseeinfectionpreventionandcontrolguidanceandframework/

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

- Information should be available to those attending clinics that they should not attend if they feel unwell or have any symptoms suggestive of COVID-19 (see sample clinical checklist in Appendix 5).

Preparation of COVID-19 Vaccine Moderna®

Thaw frozen vaccine prior to preparing.

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

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

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

**STEP 1 PREPARING THE VACCINE**

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

**STEP 2. LABELLING THE VIAL**

- Label the thawed vial with the date and time vial was punctured and note “discard time” (6 hours after first dose withdrawn when at room temperature between 2°C and 25°C) using a 24 hour format.
- Bring the vial to the vaccination table
COVID-19 Vaccine Moderna® dose preparation and administration

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

Requirements for administration of vaccine

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

STEP 1. Preparation and administration of one dose of vaccine

- **Unpunctured vials**: Check the use before. 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. **Do NOT shake.** If the vial is shaken, contact the manufacturer.
- Examine the vaccine. It should be white to off white in colour and may contain white or translucent coloured particulates. Do not use if discoloured or contains other particulate matter.
- Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully
- Attach 23 gauge blue needle to 1ml syringe
- Withdraw 0.5ml of vaccine
- Make sure correct dose is drawn up as a smaller dose may not provide protection
- Ensure all air bubbles have been removed before the needle is withdrawn
- Do not change the needle between the vial and the patient unless the needle is contaminated or damaged or if indicated
- Administer vaccine to the patient intramuscularly (see Appendix 3)
- Dispose of used needle and syringe in a sharps bin

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

Once all doses have been administered, discard the vial and record the time and date of discard (see session report form/vial traceability form [www.immunisation.ie](http://www.immunisation.ie)).
Checklist before administering 2nd dose

Check
- dose interval - at least 24 days for COVID-19 Moderna (4 day rule may be applied)
- if diagnosis of COVID-19 since last dose - delay second dose until clinical recovery from COVID-19 and at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic
- if history of allergic reaction to the vaccine after first dose (or any new allergic reactions since first dose)
- no other vaccines have been given within the last 14 days
- if pregnant since first dose - delay second dose until at least 14 weeks of pregnancy.
# 4.3 COVID-19 Vaccine AstraZeneca®

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of vaccine</strong></td>
<td>Replication deficient adenovirus vector*</td>
</tr>
<tr>
<td><strong>Name of vaccine</strong></td>
<td>COVID-19 Vaccine AstraZeneca</td>
</tr>
<tr>
<td><strong>Constituents</strong></td>
<td>One dose (0.5 ml) contains:</td>
</tr>
<tr>
<td></td>
<td>COVID-19 Vaccine (ChAdOx1-S* recombinant) 5 × 1010 viral particles (vp)</td>
</tr>
<tr>
<td></td>
<td>Produced in genetically modified human embryonic kidney (HEK) 293 cells.**</td>
</tr>
<tr>
<td></td>
<td>The product contains genetically modified organisms (GMOs)***</td>
</tr>
<tr>
<td></td>
<td>L-Histidine 9</td>
</tr>
<tr>
<td></td>
<td>L-Histidine hydrochloride monohydrate</td>
</tr>
<tr>
<td></td>
<td>Magnesium chloride hexahydrate</td>
</tr>
<tr>
<td></td>
<td>Polysorbate 80</td>
</tr>
<tr>
<td></td>
<td>Ethanol Sucrose</td>
</tr>
<tr>
<td></td>
<td>Sodium chloride</td>
</tr>
<tr>
<td></td>
<td>Disodium edetate dihydrate</td>
</tr>
<tr>
<td></td>
<td>Water for injections</td>
</tr>
<tr>
<td></td>
<td>COVID-19 Vaccine AstraZeneca does not contain egg</td>
</tr>
<tr>
<td></td>
<td>None of the vaccine ingredients are of human or animal origin</td>
</tr>
<tr>
<td><strong>Presentation</strong></td>
<td>Multidose clear glass vial</td>
</tr>
<tr>
<td><strong>Number of doses in each vial</strong></td>
<td>10 doses</td>
</tr>
<tr>
<td></td>
<td>If more than ten doses of 0.5mls can be safely and accurately withdrawn from a vial, they can be used as valid doses. There should be no pooling of vaccine from different vials</td>
</tr>
<tr>
<td><strong>Dilution</strong></td>
<td>NO DILUTION REQUIRED</td>
</tr>
<tr>
<td><strong>Latex</strong></td>
<td>The multidose dose vial has a halobutyl rubber stopper and an aluminium overseal with a plastic flip-off cap.</td>
</tr>
<tr>
<td></td>
<td>Halobutyl rubber is a synthetic rubber. There is no latex in the vial or stopper</td>
</tr>
<tr>
<td><strong>Preservatives</strong></td>
<td>The vaccine does not contain any preservative.</td>
</tr>
<tr>
<td></td>
<td>Standard aseptic technique should be used for withdrawing the dose for administration.</td>
</tr>
<tr>
<td><strong>Dosage</strong></td>
<td>0.5 mls</td>
</tr>
<tr>
<td><strong>Number of doses required</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>Interval between doses</strong></td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>(The National immunisation Advisory Committee Recommends an interval of 8-12 weeks between doses)</td>
</tr>
</tbody>
</table>

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

**Please refer to FAQ section 12.21

***COVID-19 Vaccine AstraZeneca contains a genetically modified adenovirus. Two genetic alterations have been made in order to make the vaccine:
- Genes essential for adenovirus replication have been deleted.
- The coronavirus (SARS-CoV-2) spike protein gene has been added.
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.

**COVID-19 Vaccine AstraZeneca® efficacy**

The EMA licensed documentation states that pooled analysis of the randomised Phase 2/3 trials demonstrated a two-dose vaccine efficacy for COVID-19 Vaccine AstraZeneca® 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 COVID-19 Vaccine AstraZeneca® efficacy in those aged 55 and older. However, as a similar immune response was shown in all age groups, it is expected that reduction in COVID-19 disease will be achieved in this age group. The EMA stated that the vaccine can be used in older adults.

Evidence shows that protection starts from approximately 3 weeks after 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.

Higher efficacy of 82% after the second dose was found if the booster dose was given at 12 weeks.

**COVID-19 Vaccine AstraZeneca® storage**

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

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

Vials must not be frozen

Vials must be stored in 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.1

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1 The SmPC states: If stored in a refrigerator (+2°C to +8°C) chemical and physical in-use stability have been demonstrated from the time of vial opening (first needle puncture) to administration for no more than 48 hours. If the vial is removed from the refrigerator and punctured, then it has to be used within 6 hours or discarded and cannot be returned to the fridge.

The stability data for opened vials in a refrigerator at (+2°C to +8°C) applies ONLY if the vial is punctured and doses withdrawn while in a refrigerator (i.e. a walk-in refrigerator).

BEST PRACTICE IS THAT ALL VACCINE IS USED WITHIN 6 HOURS OF FIRST PUNCTURE.
Table 6: Definitions of terms for expiry date and usage times of COVID-19 Vaccine AstraZeneca

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

Any expired vials need to be stored at +2°C to +8°C and sent back to the National Cold Chain Service in the original box.

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

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

A single dose of vaccine is 0.5 ml

A vaccine course started with COVID-19 Vaccine AstraZeneca® should be completed with this product.

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

Two doses of COVID-19 Vaccine AstraZeneca are required with an interval of 12 (84 days) weeks between doses. (The National Immunisation Advisory Committee recommends an interval of 8-12 weeks between doses)

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

The minimum interval between the first and second dose is 24 days

Table: Interval between 2 doses
Preparation and administration of COVID-19 Vaccine AstraZeneca®

Infection Prevention and Control

➢ Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the “WHO five moments of hand hygiene” with emphasis on:
  • Before vaccine preparation
  • Before administering the vaccine
  • Before and after each recipient contact
  • Surgical mask should be worn as per HPSC guidance for healthcare staff.
  • There is no need to routinely check temperature either at registration of before vaccination.

➢ 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.

➢ Follow HPSC standard precautions (sharps management, healthcare waste management etc.)
  [https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectiop
 npreventionandcontrolguidanceandframework/](https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectiop
 npreventionandcontrolguidanceandframework/) Check HPSC website for latest guidance on infection prevention and control for healthcare workers: [https://www.hpsc.ie/a-
  z/respiratory/coronavirus/novelcoronavirus/](https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/)

➢ Information should be available to those attending clinics that they should not attend if they feel unwell or have any symptoms suggestive of COVID-19 (see sample clinical checklist in Appendix 5).

➢ Vaccine spills should be disinfected with an appropriate antiviral disinfectant.

---

<table>
<thead>
<tr>
<th>Interval between 1st and 2nd doses</th>
<th>Action required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 24 days</td>
<td>No further action needed</td>
</tr>
<tr>
<td>24 to 27 days</td>
<td>No further action needed</td>
</tr>
<tr>
<td>(evidence from trial data is that this is a valid vaccine).</td>
<td></td>
</tr>
<tr>
<td>Longer than 12 weeks (84 days)</td>
<td>Give the 2nd dose at whatever interval.</td>
</tr>
<tr>
<td>The course does not need to be restarted.</td>
<td></td>
</tr>
</tbody>
</table>
Preparation and administration of COVID-19 Vaccine AstraZeneca®

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

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

Requirements for administration of vaccine

- One COVID-19 Vaccine 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 one dose of vaccine

1) **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.

2) **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

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

4) **Attach 23 gauge blue or 25 gauge orange needle to a 1ml syringe**

   Withdraw 0.5ml of vaccine

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

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

5) **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

6) **Administer vaccine to the patient intramuscularly (see Appendix 3)**

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

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

(see session report form/vial traceability form [www.immunisation.ie](http://www.immunisation.ie)).
Checklist before administering 2nd dose of COVID-19 Vaccine AstraZeneca

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)
- no other vaccines have been given within the last 14 days
- if pregnant since first dose - delay second dose until at least 14 weeks of pregnancy.
5.0 Contraindications to COVID-19 vaccines

Comirnaty® and COVID-19 Vaccine Moderna®

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

COVID-19 Vaccine AstraZeneca®

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

6.0 Precautions to COVID-19 vaccines

- Acute severe febrile illness; defer until recovery.

  NIAC guidance states

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

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

- Advice from a relevant specialist should be sought for a person with a history of an immediate allergic reaction to any other vaccine or injectable therapy or, if administering COVID-19 mRNA vaccines to polysorbate 80 (because of the possibility of cross reactivity with PEG). The risks should be weighed against the benefits of vaccination. They should be observed for 30 minutes after vaccination.

- 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.

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

**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.**
7.0 Clinical considerations for COVID-19 vaccines

7.1 Pregnancy - Comirnaty®, COVID-19 Vaccine Moderna® and COVID-19 Vaccine AstraZeneca®

There is limited experience with use of COVID-19 mRNA vaccines in pregnant women. For mRNA vaccines, animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development.

For COVID-19 Vaccine AstraZeneca®, animal reproductive toxicity studies have not yet been completed. Based upon results from the preliminary study, no effects are expected on development of the foetus.

Although the available safety data do not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy.

Administration of COVID-19 vaccines in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus. Pregnant women at high risk of severe disease and healthcare workers should be referred to their obstetrician or GP to discuss the risks and benefits of COVID-19 vaccine.

NIAC has recommended COVID-19 vaccine where it is decided that the risk/benefit is favourable. The two dose schedule should not commence before 14 weeks gestation and should be completed by 33 weeks gestation. This is a precaution to minimise any possible association with miscarriage or pre term birth.

Women attending for vaccination will be asked if they are pregnant when consenting to vaccination. Women who are between 14 weeks and 33 weeks gestation, will be asked to confirm that they have consulted their obstetric care giver (Obstetrician or GP) and decided to receive the vaccine. Vaccination should be deferred if they are less than 14 weeks pregnant. If they are more than 33 weeks pregnant, vaccination should be deferred until after birth.

There is no need to check a pregnancy test prior to administration of COVID-19 vaccines.

When COVID-19 Vaccine AstraZeneca® is being administered in pregnancy, the two dose schedule should be given 12 weeks apart if possible. However, as the two dose schedule should be given between 14 and 33 completed weeks of gestation, a shorter interval can be used, 4-12 weeks apart.

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2 The Institute of Obstetricians and Gynaecologists and the National Immunisation Advisory Committee have developed Questions and Answers, a decision aid and an infographic for pregnant or breastfeeding women and their doctors about COVID-19 vaccination https://www.rcpi.ie/news/releases/information-for-women-who-are-pregnant-or-breastfeeding-and-their-doctors-about-the-covid-19-vaccine-update/
COVID-19 vaccines are:

- recommended for pregnant women (as per their priority group) between 14 and 33 weeks gestation provided they have confirmed that they have consulted their obstetric care giver (obstetrician or GP) and decided to have the vaccine
- not recommended for pregnant women at less than 14 weeks gestation.
- not recommended for pregnant women at more than 33 weeks gestation.

7.2 Breastfeeding

There is no known reason to avoid breastfeeding. COVID-19 vaccines (Comirnaty®, COVID-19 Vaccine Moderna® and COVID-19 AstraZeneca®) can be given to healthcare workers who are breastfeeding.

7.3 Individuals with a bleeding disorder

Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopenia (platelet count <50 x 10^3/ml) consult the supervising consultant. People with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra®) do not require haemostatic cover for vaccination. Details of haemostatic cover for all others can be found in the Patient Information tab at http://www.stjames.ie/services/hope/nationalcoagulationcentre

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.

7.4 Individuals taking anticoagulants

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

People on Warfarin® should follow their usual schedule for international normalised ratio (INR) testing and can be vaccinated if it is less than 4.0. If the INR is 4.0 or more, follow the advice of the clinic/practice managing Warfarin® and wait until the INR is less than 4.0 to be vaccinated.
7.5 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.

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

Co-administration with other vaccines has not been studied.

It is advised to leave an interval of 14 days between a COVID-19 vaccine and other vaccines.

7.7 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.

7.8 Healthcare workers under 18 years of age

Comirnaty® is licensed for active immunisation to prevent COVID-19 in individuals 16 years of age and older so the vaccine is recommended for healthcare worker from 16 years of age. Those of 16 years and older may give their own consent. COVID-19 Vaccine Moderna® and COVID-19 Vaccine AstraZeneca® are not licensed for active immunisation to prevent COVID-19 in individuals under 18 years of age.

7.9 Children

There is no data on the safety and efficacy of Comirnaty® in children less than 16 years and of COVID-19 Vaccine Moderna® or COVID-19 Vaccine AstraZeneca® 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®
- 14 days after second dose of COVID-19 Vaccine Moderna®.
- 15 days after the second dose of COVID-19 Vaccine AstraZeneca (protection starts three weeks after the first dose)

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

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

9. Post vaccination

9.1 Recording vaccination

For Comirnaty® vaccine

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.

For COVID-19 Vaccine Moderna®

The use before date and time of the vaccine must be recorded in the IT system (The use before date and time will 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.

For COVID-19 Vaccine AstraZeneca®

The expiry date and batch number of the vaccine must be recorded on the IT system
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 from clinical studies

The adverse events are listed below in Table 7 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 7 Adverse reactions of COVID-19 vaccines.

<table>
<thead>
<tr>
<th>Type of Reaction</th>
<th>Name of Vaccine</th>
<th>Name of Vaccine</th>
<th>Name of Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Comirnaty®.</td>
<td>COVID-19 Vaccine Moderna®</td>
<td>COVID-19 Vaccine AstraZeneca®</td>
</tr>
<tr>
<td>Very Common (≥ 1/10),</td>
<td>Local: Injection site swelling and erythema</td>
<td>Local: injection site pain, injection site swelling, lymphadenopathy (axillary swelling and tenderness of the vaccination arm) General: fatigue, headache, myalgia, arthralgia, fever, chills, nausea and vomiting</td>
<td>Local: Injection site tenderness, pain, warmth, pruritus, bruising General: fatigue, malaise, feverishness, chills, myalgia, arthralgia, nausea, headache</td>
</tr>
<tr>
<td></td>
<td>General: arthralgia, fatigue, fever, headache, myalgia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common (≥ 1/100 to &lt; 1/10),</td>
<td>Local: injection site pain, erythema General: nausea</td>
<td>Local: injection site erythema, injection site urticarial, injection site rash General: Rash</td>
<td>Local: Injection site swelling, injection site erythema General: Vomiting diarrhoea, fever (measured fever ≥38°C)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncommon (≥ 1/1,000 to &lt; 1/100),</td>
<td>Local: injection site pruritus General: insomnia, lymphadenopathy, malaise, extremity pain</td>
<td>Local: injection site pruritus</td>
<td>General: lymphadenopathy, decreased appetite, somnolence, dizziness, rash, pruritus, hyperhidrosis,</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rare (≥ 1/10,000 to &lt; 1/1,000),</td>
<td>Local: General: acute peripheral facial paralysis/Bell’s Palsy</td>
<td>Local: General: acute peripheral facial paralysis/Bell’s Palsy Facial swelling in those who have had dermatological fillers</td>
<td></td>
</tr>
</tbody>
</table>

Events of anaphylaxis have been reported. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.
Very rare events of neuroinflammatory disorders have been reported following vaccination with COVID-19 vaccines. A causal relationship has not been established.

Table 8 lists the most frequent adverse reactions reported during clinical trials.

Table 8 Details of most frequent adverse reactions reported during clinical trials of COVID-19 Vaccines

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

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

A higher rate of pyrexia (after Comirnaty®) and local and systemic adverse events (after 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 COVID-19 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

The vaccine recipient should be informed of possible adverse events, given the HSE advice leaflet for after vaccination and advised to seek medical advice if unwell.
10.2 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.

Comirnaty®, COVID-19 Vaccine Moderna® and COVID-19 AstraZeneca® 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.

10.3 Reporting of incidents during the vaccination session to HSE

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

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

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

The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day. (National Incident Report Form (NIRF 01 – V11)) (2020) available at: https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf

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

Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.
11. 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 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 mass vaccination clinics, 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
- After vaccination, the seating area to be cleaned with disinfectant wipes
- PPE to be removed and safely dispose into a healthcare risk waste bin (yellow bag) followed by hand hygiene.
12. Frequently asked questions about Covid-19 vaccines (Comirnaty®, COVID-19 Vaccine Moderna® and COVID-19 Vaccine AstraZeneca®)

12.1 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, as the level and duration of immunity after natural infection is unknown. 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.

12.2 What is 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.

12.3 What if the second dose of COVID-19 vaccine is administered at less than the recommended interval?
12.3.1 Comirnaty®
The advice of the National Immunisation Advisory Committee is that evidence of efficacy of doses given before 17 days is lacking. However there is also no safety and efficacy date in relation to repeating vaccination in this situation (giving a total of 3 doses). Therefore a further dose is not required. This should be reported to HPRA and an incident report form completed.
If a dose is given between 17 and 21 days, this is considered a valid dose.

12.3.2 COVID-19 Vaccine Moderna®
The advice of the National Immunisation Advisory Committee is that evidence of efficacy of doses given before 24 days is lacking. However there is also no safety and efficacy date in relation to repeating vaccination in this situation (giving a total of 3 doses). Therefore a further dose is not required. This should be reported to HPRA and an incident report form completed.
If a dose is given between 24 and 27 days, this is considered a valid dose.
12.3.3 COVID-19 Vaccine AstraZeneca®

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

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

12.4 What if the second dose of 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.

12.5 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.

12.6 What if a vaccine is given after the expiry date or 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.

12.7 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.
12.8 What if only the diluent of Comirnaty® is given?

The diluent for Comirnaty® 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.

12.9 What if an over-diluted Comirnaty® 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.

12.10 What if a person under 16 years is given Comirnaty® vaccine inadvertently?

If a person under the age of 16 years receives the vaccine inadvertently, this should be reported to the HPRA and an incident form completed. The person and their parents/guardians should be advised regarding the common adverse events expected after vaccination.

12.11 What if a person under 18 years is given the COVID-19 Vaccine Moderna® or COVID-19 Vaccine AstraZeneca® 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.

12.12 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 are recommended at this time.

12.13 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
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 Obstetrician (or GP) regarding the risks and benefits of receiving the second dose of COVID-19 vaccine, once they are at or over 14 weeks gestation. The second COVID-19 vaccine dose should not be given while less than 14 weeks gestation.

12.14 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.

12.15 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.

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

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

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

12.17 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
12.18 Can mRNA vaccines like Comirnaty® and COVID-19 Vaccine Moderna® interact with a person’s DNA?

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

12.19 Can viral vector vaccines like COVID-19 Vaccine AstraZeneca® 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.

12.20 Can COVID-19 vaccines like Comirnaty®, COVID-19 Vaccine Moderna®, and COVID-19 Vaccine AstraZeneca® affect fertility?

As explained in section 12.18 and 12.19 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.

12.21 Does COVID-19 Vaccine AstraZeneca® contain genetically modified organisms?

Yes. COVID-19 Vaccine AstraZeneca contains a genetically modified adenovirus. Two genetic alterations have been made in order to make the vaccine:

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

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.
12.22 Does COVID-19 Vaccine AstraZeneca® contain cells of human embryonic origin

No. The cell-lines used in COVID-19 Vaccine Astra Zeneca 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 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 aborted foetus cells to develop the vaccine.

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

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

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

Vaccinated individuals should be advised that COVID-19 mRNA 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 5 for a statement from the National Immunisation Advisory Committee.

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

COVID-19 Vaccine AstraZeneca contains 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.

15. Recording Vaccine Administration

Vaccine administration should be recorded in the HSE COVID-19 vaccination management system. 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.
Useful links

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


Information for women who are pregnant or breastfeeding and their doctors about the mRNA Covid-19 vaccine

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

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


Health Products Regulatory Authority. Human Medicines Adverse Reaction Report

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

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

1. **Apply standard aseptic technique throughout the procedure.**
2. **It is not necessary to use gloves** if the vaccinator's and patient's skin is intact.
3. **It is not necessary to use a skin disinfectant e.g. alcohol swabs.**
   - If the skin at the injection site is visibly dirty, clean with soap and water.
   - If an alcohol swab is used, delay injection for ≥30 seconds, to ensure the alcohol will have evaporated.
4. **Land mark the injection site in the deltoid muscle:**
   - Two finger widths down from the acromion process; the bottom edge is at an imaginary line drawn from the axilla.
   - Injection site: 5cms below acromion process.
5. **At the injection site spread the skin taut between the thumb and forefinger with the non-dominant hand.**
   - **Do NOT bunch up the skin** as this leads to administering the vaccine into subcutaneous tissue inadvertently.
   NOTE: COVID-19 vaccine should be given by IM only.
6. **Use the dominant hand to inject the medication.** This ensures control of the needle and syringe during the procedure.
7. Hold the syringe firmly between thumb and forefinger, with heel of hand resting on the thumb of the non-dominant hand. This ensures a 90-degree angle is achieved and the correct site is targeted.
8. Insert the needle smoothly and swiftly.
9. Inject at a 90-degree angle, to ensure the medication reaches the muscle. Inject medication over 1-2 seconds.
10. After removing the needle, use gentle pressure with a cotton ball or gauze. Do not massage the injection site.
11. If there is a leakage at the injection site after withdrawal of needle: apply light pressure with gauze.

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

**Swift needle entry**

**Slow injection of medication**

**Swift needle withdrawal**

Less pain
Appendix 2. SOP
Management of Comirnaty® (Pfizer/BioNTech) COVID-19 Vaccine
Guidance Vaccination Centre

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

The vaccine supply chain is managed by the National Immunisation Office (NIO) and The HSE National Cold Chain Service (NCCS). The HSE will take ownership of the vaccine upon delivery by the manufacturer to the HSE National Cold Chain Service. Onward delivery to the hubs or points of administration will at temperature of +2°C to +8°C.

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:

2 Scope & Purpose

The scope of this document is limited to the Comirnaty® (Pfizer/BioNTech) COVID-19 Vaccine. Separate documents will be specially prepared for other COVID-19 vaccines.

The purpose of this document is to outline the medicines management responsibilities at local vaccination centre, and to provide supporting guidance and resources in relation to:

- Safe storage and distribution, including temperature controlled storage, safe handling, stock control, and stock reconciliation
- Oversight of vaccine handling and preparation, including management of shelf life reduction processes following reconstitution

It aims to promote consistency of practice by providing flow diagrams outlining a stepwise approach to implementing processes to receive, store and issue vaccines, and to oversee vaccine handling processes by clinical staff.

The documents provided may be used as templates to be adapted for local use, or may be used as reference sources to check that existing local procedures are robust and comprehensive.
3 Operating at the Vaccination Centre

At the time of writing it is known that an undiluted vial of Comirnaty® (Pfizer/BioNTech) COVID-19 vaccine may be stored for up to 120 hours at temperatures between +2°C and +8°C, followed by an additional 2 hours at room temperature. Boxes delivered by NCCS will be labelled with a USE BEFORE date and time. This should be recorded in the patient record.

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 the travel time from NCCS in Dublin to the vaccination centre and all other transportation thereafter. These times are to be taken within the 120 hour shelf life. The models in this document are designed to minimise movement of the vaccine once it has been thawed. 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.

After dilution in sodium chloride (0.9%) it should be used as soon as practically possible and within 6 hours of dilution.

The vaccine vials will come in their original carton, or pre-packed into smaller labelled cartons and they should remain between +2°C and +8°C until the point of vaccination. An appropriate container should be used to minimize the potential for vials to be jostled. If vials are inadvertently bumped, they should be righted, however the risk to the product is minimal and vials, which are temporarily knocked over, may still be used.

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

Implementation of effective process control is essential to ensure that vaccines are stored correctly and appropriate “use before” and “discard” dates and times are allocated.

4 Vaccines, Consumables & Other Equipment

4.1 Vaccines

NCCS will deliver Comirnaty® to the point of administration or the designated Hub requiring storage between +2°C and +8°C.

The vaccine comes in a multi dose vial and must be diluted before use. Each vial contains 0.45ml antigen and contains up to 7 doses of 0.3mL after dilution. One dose (0.3mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
5 Consumables, Patient Information Leaflet & Record Cards

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 will be delivered in advance by HSE in the required quantities to match the quantity of vaccine ordered. These are not included in this SOP.

5.1 Anaphylaxis Kits

Refer to National Immunisation Advisory Committee Guidelines

5.2 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.

6 Safe Storage & Distribution

6.1 Stock Control, Security & Monitoring of Wastage

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. Waste vaccines and empty vials must be disposed of 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. Records of vaccine dose reconciliation should be maintained at the site. Covid-19 Vaccine Pfizer Vaccine Traceability Form should be emailed to immunisation@hse.ie

6.2 Validation & Monitoring of Cold Chain

Comirnaty® vaccine requires storage at +2°C to +8°C.

Fridges and cool boxes should be validated and monitored in accordance with existing local procedures.
6.3 Health & Safety

Pfizer/BioNTech reports that neither special handling requirements for either routine handling nor dealing with spillages is necessary.

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

7 Vaccine Handling & Preparation

Each step of this process changes the vaccine characteristics and therefore each step will require a reduction in the shelf life. A diligent process is necessary to ensure the correct end date/time is adhered to, and that the vaccine is safe and effective at the point of use.

Process flow 1 shows a process of packing thawed vials at a hub and transport to vaccination locations or points of administration

Process flow 2 shows an overview of the vaccine pathways during vaccination sessions. This is supported by a SOP, a work instruction for syringe preparation, and a sessional checklist for supervision of the vaccine handling during the vaccination session.

Transportation time: Vaccines should be moved in compliance with the requirement for a maximum of 12 hours transportation time.

Transportation time: a maximum of 12 hours - cumulative time from the start of when the thawed vaccine is moved from the NCCS to the delivery location and any subsequent movement of the vaccine until the time of vaccine administration.
Process Flow 1: Transportation of Vaccines

1. **Prepare a cool box for transport at 2-8°C**

2. **Position the coolbox in or as close as possible to the assembly**

3. **Choose the relevant prepacked box for the Clinic vaccination clinic**

4. **ENSURE the box is in the correct position with vials upright**

5. **Secure the box into the coolbox**

6. **Transport to the vaccination location**

---

**Cool boxes must be suitable for the duration of use and mode of transport. Consider the volume of vaccines carried compared to normal vaccination clinics and adjust the number of cold chain packs appropriately. Consider the duration for which the cool box will be required.**

**Ideally assembly will be performed inside a cold store if issuing from fridge:**

- Work quickly to minimise exposure of the vaccines to room temp. Consider working in pairs
- Avoid frequent fridge door openings and allow fridge temperature to recover between openings
- Place a temperature monitoring probe into the cool box.

**The vials must be securely held in an upright position to minimise movement in transport, and should be protected from light.**

**The coolbox packing pattern should be defined locally to**

- Minimise movement of the vials
- Maintain temperature between +2°C and +8°C.

**The thawed, packed vaccine may be transported for up to 12 hours during the 120 hour post-thaw shelf life. It must take into account any journeys the vaccine may have already taken in its thawed state.**

Agitation of the vials should be minimised throughout this time.
Process Flow 2: Overview of the Vaccine Pathways during Vaccination Sessions

1. Remove vaccine vial from coolbox or adjacent pharmaceutical fridge,

2. Dilute one vial at a time and write the discard date and time on the label.

   - The vial must be used as soon as practically possible, and within 6 hours of dilution.

3. 0.3 ml dose should be drawn up into each syringe and administered as soon as possible.

   - Each diluted vial contains up to 7 doses. These should be drawn up and administered immediately. Filled syringes must never be left unattended.

4. Discard any part-used or un-used vials as it occurs and document.

   - Unused or partially used vials must not be returned to the fridge. All remaining liquid in vial must be discarded in the vial into a sharps bin.
## COVID-19 Vial Traceability Session Form

<table>
<thead>
<tr>
<th>Vial number</th>
<th>Vaccinator</th>
<th>Batch number</th>
<th>Dilution date and time</th>
<th>Discard date and time (Max 6 hours after dilution)</th>
<th>Date and time vial was discarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>e.g. 1</td>
<td>NS</td>
<td>e.g. EM4076</td>
<td>07/01/2021 10:05</td>
<td>07/01/2021 16:05</td>
<td>07/01/2021 11:32</td>
</tr>
</tbody>
</table>

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

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

1. Background

The vaccine supply chain is managed by the National Immunisation Office (NIO) and the HSE National Cold Chain Service (NCCS). COVID-19 Vaccine Moderna® will be delivered frozen between -25°C and -15°C 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.

COVID-19 Vaccine Moderna® was granted conditional marketing authorisation by the EC on 6 January 2021.

2. Scope & Purpose

The scope of this document is limited to the COVID-19 Vaccine Moderna®. Separate documents will be specially prepared for other COVID-19 vaccines.

The purpose of this document is to outline the medicines management responsibilities at local vaccination centre, and to provide supporting guidance and resources in relation to:

- Safe storage including temperature controlled storage, safe handling, stock control, and stock reconciliation
- Oversight of vaccine handling and preparation, including management of shelf life reduction processes following thawing.

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.
3. Operating at the Vaccination Clinic

- Upon arrival at your vaccination centre:
  - Read the temperature of the fridge/s
  - Record maximum, minimum, and current temperature
  - Reset after recording.

- COVID-19 Vaccine Moderna® will be delivered frozen between -25°C and -15°C to each vaccination clinic.
  - Unpack the boxes immediately upon arrival. Each box of vaccine has 10 multidose vials.
  - Receipt delivery of stock and scan stock onto the system.
  - Record the **USE BEFORE date and time** on the vaccine box by adding 30 days from **date and time of arrival of the vaccines**

- Place immediately in the fridge at a temperature of +2°C to +8°C, in original boxes to protect vials from light, for maximum 30 days.

- 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 refrozen.

- Unopened vials should be kept in the fridge/cool box until the time for usage i.e. 15 minutes before usage to reach the room temperature.

- Vials that have **not been punctured** may be kept between +8°C and +25°C for up to 12 hours after which the product must be discarded.

- Once the vial is **punctured** for drawing up the vaccine the **DISCARD date and time** should be recorded on the vial. It is to be calculated by adding 6 hours to the time of first puncture.
  - Once punctured, the vaccine vial can be kept between 2°C to 25°C until the discard time.
Implementation of effective process control is essential to ensure that:

- vaccines are stored correctly
- appropriate “USE BEFORE” and “DISCARD” dates and times are recorded and adhered to

4. Vaccines, Consumables & Other Equipment

COVID-19 Vaccine Moderna® vials are multidose. The vaccine comes ready to use once thawed and kept at 15 minutes at room temperature. One dose (0.5 mL) 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 an additional dose. 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.

5. Consumables, Patient Information Leaflet & Record Cards

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

- 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.

6. Safe Storage & Distribution

- Stock Control, Security & Monitoring of Wastage

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. Waste vaccines and empty vials must be disposed of 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. Covid 19 Vaccine Moderna Vial Traceability Form should be emailed to immunisation@hse.ie

- Validation & Monitoring of Cold Chain

COVID-19 Vaccine Moderna® requires storage between temperatures of +2°C to +8°C once delivered to vaccination centres.

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

- Health & Safety

The manufacturer of COVID-19 Vaccine Moderna® reports that neither special handling requirements for either routine handling nor dealing with spillages is necessary.

Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.
Short Duration Transport on a Vaccination site

The vaccine can be transported as a hand-carry (walked, no running) for a cumulative time of one hour between +2°C to +25°C.

COVID-19 Vaccine Moderna® storage and handling
# COVID-19 Vaccine Moderna® Vial Traceability Session Form

<table>
<thead>
<tr>
<th>Vial number</th>
<th>Vaccinator</th>
<th>Batch number</th>
<th>First puncture of vial date and time</th>
<th>Discard date and time (max 6 hours after first puncture)</th>
<th>Actual date and time the vial was discarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>e.g. 1</td>
<td>NS</td>
<td>e.g. EM4076</td>
<td>07/01/2021 10:05</td>
<td>07/01/2021 16:05</td>
<td>07/01/2021 11:32</td>
</tr>
</tbody>
</table>
Management of COVID-19 Vaccine 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

The vaccine supply chain is managed by the National Immunisation Office (NIO) and the HSE National Cold Chain Service (NCCS). COVID-19 Vaccine AstraZeneca® will be delivered at a temperature of +2 °C to +8 °C 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 COVID-19 Vaccine AstraZeneca on the 29th January 2021. The product information approved by the CHMP contains prescribing information for healthcare professionals can be found below:


2. Scope & Purpose

The scope of this document is limited to the COVID-19 Vaccine AstraZeneca®. Separate documents are available for other COVID-19 vaccines.

The purpose of this document is to outline the medicines management responsibilities at vaccination centre level, and to provide supporting guidance and resources in relation to:

- Safe storage, including temperature controlled storage, safe handling, stock control, and stock reconciliation
- Oversight of vaccine handling and preparation, including management of shelf life reduction processes following first puncture of the vial.

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.
Management of COVID-19 Vaccine AstraZeneca® Guidance at Vaccination Clinics

3. Operating at the Vaccination Clinic

Upon arrival at your vaccination centre:

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

COVID-19 Vaccine AstraZeneca® will be delivered at a temperature of +2 °C to +8 °C

Unpack the boxes immediately. Each box will contain 10 multidose vials. Receipt delivery of stock and scan stock onto the system.

Place immediately in the fridge at a temperature of +2 °C to +8°C in original boxes to protect vials from light.

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. Vaccines, Consumables and Other Equipment

COVID-19 Vaccine AstraZeneca® comes in multidose vials and contain at least 10 (ten) doses. The vaccine comes ready to use. One dose (0.5 mL) contains not less than 2.5 x 10⁸ 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. 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 different vaccine vials.

5. Consumables, Patient Information Leaflet & Record Cards

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

- 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.

6. Safe storage and Distribution

- Stock Control, Security & Monitoring of Wastage

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.

Covid-19 Vaccine AstraZeneca Vial Traceability Form should be emailed to immunisation@hse.ie

- Validation & Monitoring of Cold Chain

COVID-19 Vaccine AstraZeneca® requires storage between temperatures of +2°C to +8°C.

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

- Health & Safety

There are no special handling requirements for routine handling of COVID-19 Vaccine AstraZeneca®. However, COVID-19 Vaccine 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.
Appendix 3. Medicine Protocol
Medicine Protocol for the Administration of Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine to Vaccine Recipients

This medicine protocol is a specific written instruction for the administration of Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine to vaccine recipients by registered nurses and registered midwives. This medicine protocol is valid for the 2020/2021 HSE COVID-19 Vaccination Programme. This medicine protocol enables registered nurses and registered midwives employed in the voluntary and statutory services of the Health Service Executive (HSE) who have undertaken the required education and training programmes to administer Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine to vaccine recipients, with reference to and guidance from the Nursing & Midwifery Board of Ireland (NMBI), National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics for Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine as detailed by the European Medicines Agency (EMA).

- Health Service Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or Suspected Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive
- National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College of Physicians Ireland (Online Update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/)
- Nursing and Midwifery Board of Ireland (2014) Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) Practice Standards for Midwives. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) Recording Clinical Practice. Guidance to Nurses and Midwives. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland

The Nursing and Midwifery Board of Ireland defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect” (An Bord Altranais, 2007) (See Appendix III NMBI Statement of Support 2020).
**Medicine Protocol for the Administration of Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine to vaccine recipients**

<table>
<thead>
<tr>
<th>Document reference number:</th>
<th>16 ONMSD 2020</th>
</tr>
</thead>
</table>

### 1.0 Critical Elements

<table>
<thead>
<tr>
<th>Name of Organisation where medicine protocol applies</th>
<th>Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE), non-HSE healthcare facilities and mass vaccination clinic venues. This Medicine Protocol applies to: Registered nurses and registered midwives involved in the administration of Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine to vaccine recipients under this medicine protocol.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date the medicine protocol comes into effect</td>
<td>December 2020</td>
</tr>
<tr>
<td>Date for review of medicine protocol</td>
<td>January 2022</td>
</tr>
<tr>
<td>Document prepared by:</td>
<td>Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the National Immunisation Office (NIO)</td>
</tr>
</tbody>
</table>
| Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol | Name: **Dr. Lorraine Doherty**, National Clinical Director Health Protection, HSE  
[Signature]

**On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation**

Name: **Dr Colm Henry**, Chief Clinical Officer, HSE  
[Signature]

Name: **Dr Geraldine Shaw**, Nursing and Midwifery Services Director, HSE  
[Signature]
2.0 Clinical Criteria

<table>
<thead>
<tr>
<th>Clinical Condition for use of the medicine protocol</th>
<th>The clinical condition for which this medicine protocol has been developed is for the immunisation of vaccine recipients (see Inclusion Criteria) against COVID-19.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circumstances in which the medicine protocol applies</td>
<td>Targeted immunisation programme for vaccine recipients against COVID-19 as identified in the DOH policy based on the NIAC recommendations. The World Health Organisation declared COVID-19 outbreak as a pandemic on 11th March 2020 which is still ongoing.</td>
</tr>
<tr>
<td>Inclusion criteria for vaccine recipient using the medicine protocol</td>
<td>Note: Vaccine Recipients who have received Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine as a first dose MUST be advised that the second dose is ALSO Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine ONLY.</td>
</tr>
</tbody>
</table>

**Inclusion Criteria:**
- Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older.

**Precautions**
- Acute severe febrile illness defer until recovery
- Advice from a relevant specialist should be sought for a person with a history of an immediate allergic reaction to any other vaccine or injectable therapy. The risks should be weighed against the benefits of vaccination. They should be observed for 30 minutes after vaccination.
- Vaccination should be deferred until clinical recovery from COVID-19 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 those with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration
- Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM (intramuscular) injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopenia (platelet count <50 x 10⁹/ml) consult the supervising consultant
- Co-administration with other vaccines has not been studied. It is prudent to leave 14 days between administering COVID-19 vaccine and administering another vaccine.

**Pregnancy:**
- Women who are at less than 14 weeks or more than 33 weeks of gestation should not receive the vaccine
- Pregnant women who are between 14 weeks and 33 weeks of gestation and wish to receive the vaccine should confirm they have consulted with their obstetric care giver (Obstetrician or GP) and decided to receive the vaccine.

**Breastfeeding:**
There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping.
Exclusion criteria for vaccine recipient using the medicine protocol

Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine should not be given under this medicine protocol if the vaccine recipient has:
- a confirmed anaphylactic reaction to a previous dose of the same COVID-19 vaccine
- a confirmed anaphylactic reaction to any components of the COVID-19 vaccine including polyethylene glycol.

Actions to be taken for those who are excluded from the medicine protocol

- Refer to/discuss with the relevant Medical Practitioner for an individual medical assessment
- Document action in clinical notes
- Where Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine is prescribed following medical assessment, the nurse or midwife may administer the vaccine within his/her scope of practice.

**Note:** In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).

Action to be followed for vaccine recipients who do not wish to receive the vaccine

Advise of the risks of not having the vaccine, including risk of possible severe COVID-19 disease. Advice regarding minimization of risk.

Description of circumstances and referral arrangements when further advice or consultation is required

Refer to/discuss with relevant Medical Practitioner if the vaccine recipient had previous adverse reaction or other clinical concerns as outlined in Exclusion Criteria.

Documentation required to support implementation of the medicine protocol

- Vaccine consent forms or check for and ensure online consent
- Vaccine Information Leaflets
- Patient held record cards if available
- Health Products Regulatory Authority Adverse Reaction Reporting forms

It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine which includes the following:
- Medicine Protocol for the Administration of Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine to vaccine recipients
- Clinical Guidance for Covid-19 Vaccination
<table>
<thead>
<tr>
<th><strong>3.0 Name of Medicine</strong></th>
<th>Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine.</th>
</tr>
</thead>
</table>
| **Dose & Route of administration** | • The dose is 0.3ml, 2 doses 21 - 28 days apart recommended.  
• Route of administration: IM  
• Site: The preferred site is the deltoid muscle  
• If the interval between doses is less than 21 days, a further dose is not required. However evidence of efficacy of doses given before 17 days is lacking.  
• If the second dose is given between 17 and 20 days after the first dose, it is a valid dose.  
• If the interval between doses is longer than 28 days, the second dose should still be given as soon as possible. The course does not need to be restarted.  
• There are no data available on the interchangeability of Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine with other COVID-19 vaccines to complete the vaccination series  
• Individuals who have received one dose of Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine should receive a second dose of Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine to complete the vaccination series  
• Do not inject the vaccine intravascularly, subcutaneously or intradermally |

<table>
<thead>
<tr>
<th><strong>Link to Medicine</strong></th>
<th>Details of product information and other data including instructions for supply and administration is available from the European Medicines Agency (EMA)</th>
</tr>
</thead>
</table>

| **Potential adverse reactions and procedures for treatment of same** | Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction  
• Those with no history of anaphylaxis from any cause: 15 minutes  
• Those with a history of anaphylaxis from any cause: 30 minutes  
• Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated  

The vaccine recipient should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine after the above period of observation. |

| **Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)** | The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out on line at http://www.hpra.ie or through use of the yellow card system which is available in a downloadable format from the HPRA website, or on request from the HPRA.  

The vaccine recipient’s General Practitioner should be informed of any reported adverse reaction.  

The incident and all actions taken must be promptly recorded in accordance with the Management of a Patient with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee 2019), available online at |
Procedure for the reporting and documentation of errors and near misses involving the medicine

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 registered nurse or midwife 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 the relevant medical practitioner or other appropriate physician.

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

The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day. (National Incident Report Form (NIRF 01 – V11) (2020) available at: https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf

The vaccine recipient and/or significant others should be informed of the incident.

An incident report form must be completed by the nurse or midwife 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.

<table>
<thead>
<tr>
<th>Resources and equipment required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine</td>
</tr>
<tr>
<td>Sodium Chloride 0.9% Solution for Injection</td>
</tr>
<tr>
<td>2ml/ 2.5ml / 3ml syringe and 21 gauge green needle for reconstitution</td>
</tr>
<tr>
<td>23 gauge needle for IM administration</td>
</tr>
<tr>
<td>Fridge/Cooler box with data logger with external temperature monitoring display to maintain cold chain temperature between +2° to +8°C</td>
</tr>
<tr>
<td>Disposable kidney dishes/trays</td>
</tr>
<tr>
<td>70% alcohol swabs (for sterilizing vials)</td>
</tr>
<tr>
<td>Gauze swabs, tape/plasters</td>
</tr>
<tr>
<td>Sharps bins, and bins for disposal of other hazardous material</td>
</tr>
<tr>
<td>Alcohol hand rinse</td>
</tr>
<tr>
<td>Access to telephone</td>
</tr>
<tr>
<td>Safe storage areas for medicines and equipment</td>
</tr>
<tr>
<td>Current medicine protocol</td>
</tr>
</tbody>
</table>

Audit process to identify appropriate use of the medicine protocol or unexpected outcomes

All documentation will be held for review and audit purposes as per local/national agreement.
### 4.0 Information for vaccine recipient

<table>
<thead>
<tr>
<th>Advice to be given to the vaccine recipient before treatment</th>
<th>Vaccine Information material must be supplied with the consent form to the vaccine recipient prior to administration of the vaccine.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before Treatment</strong></td>
<td></td>
</tr>
<tr>
<td>Check and confirm the online consent has been provided or obtain signed consent.</td>
<td></td>
</tr>
<tr>
<td>Discuss the Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine and the importance of protecting their health.</td>
<td></td>
</tr>
<tr>
<td>Discuss potential side effects. Individuals may not be protected until at least 7 days after their second dose of the vaccine.</td>
<td></td>
</tr>
<tr>
<td><strong>After Treatment</strong></td>
<td></td>
</tr>
<tr>
<td>Discuss potential side effects. Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction.</td>
<td></td>
</tr>
<tr>
<td>Events of anaphylaxis have been reported therefore NIAC recommends the following monitoring for the post-vaccination period:</td>
<td></td>
</tr>
<tr>
<td>- Those with no history of anaphylaxis from any cause: 15 minutes</td>
<td></td>
</tr>
<tr>
<td>- Those with a history of anaphylaxis from any cause: 30 minutes</td>
<td></td>
</tr>
<tr>
<td>- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated.</td>
<td></td>
</tr>
<tr>
<td>The vaccine recipient should not leave the healthcare facility if they are feeling unwell and must report any side effects to a member of the vaccination team.</td>
<td></td>
</tr>
</tbody>
</table>

**The vaccine recipient may be advised:**

Side effects may occur with following frequencies:

**Local:**
- Very common: injection site swelling and erythema
- Common: injection site pain, erythema
- Uncommon: injection site pruritus

**General:**
- Very common: arthralgia, fatigue, fever, headache, myalgia
- Common: nausea
- Uncommon: insomnia, lymphadenopathy, malaise, extremity pain
- Rare: acute peripheral facial paralysis


The vaccine recipient should be advised to report any side effects to the relevant medical practitioner.
If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol or ibuprofen-containing products) may be used. Ibuprofen is not recommended in pregnancy.

If more serious adverse or persistent effects occur, vaccine recipient should be advised to contact their GP/out of hours service.

<table>
<thead>
<tr>
<th>Details of any necessary follow-up, action and referral arrangements</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the event of an adverse reaction the vaccination team must ensure that all procedures are adhered to as outlined in Section 3.</td>
</tr>
</tbody>
</table>

### 5.0 Staff authorised to use this medicine protocol

<table>
<thead>
<tr>
<th>Professional qualifications, training, experience and competence required prior to using this medicine protocol / Professional Qualifications:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered nurse or registered midwife, maintained on the active register maintained by The Nursing and Midwifery Board of Ireland.</td>
</tr>
</tbody>
</table>

**Education programme for nurses and midwives on the use of COVID-19 Medicine Protocol for the Administration of Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine to vaccine recipients by registered nurses and registered midwives and any updates.**

Basic Life Support for Health Care Providers within the last two years.

Initial anaphylaxis programme (“National Anaphylaxis Education Programme for Health Care Professionals”) via HSELandD followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSELandD Anaphylaxis e-learning programme available at [www.hse.ie](http://www.hse.ie).

The nurse/midwife must complete the Competency Assessment Form (Appendix II) to administer the Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine.

**Recommended:**

*Storing and Managing Vaccines* [www.hseland.ie](http://www.hseland.ie)
References


Health Service Executive (2019) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or Suspected Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis.* Dublin: Health Service Executive


Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland, available at: http://www.nmbi.ie
Appendix I

Signature Sheet:

**Name of Protocol:** *Medicine Protocol for the Administration of Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine* to vaccine recipients by registered nurses and registered midwives.

I have read, understood & agreed to adhere to the attached medicine protocol.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Signature:</th>
<th>Occupation:</th>
<th>Pin No:</th>
<th>Date:</th>
</tr>
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<tbody>
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</table>

The above signed nurses and midwives are authorised by the signatories on page 2 to administer *Comirnaty© (Pfizer/BioNTech) COVID-19 mRNA Vaccine* in accordance with this medicine protocol.
## Appendix II: Competency Assessment Form

### Self-Assessment of Competency to Administer Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine under Medicine Protocol

<table>
<thead>
<tr>
<th>Domain of Practice</th>
<th>Critical Element</th>
<th>Competent Date/Initials</th>
<th>Needs Practice Date/Initials</th>
<th>Needs Theory Date/Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I understand the role and function of medicine protocols in the context of NMBI guidelines in relation to:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- The Code of Professional &amp; Ethical Conduct</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Scope of Nursing and Midwifery Practice</td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td>- Guidance to Nurses and Midwives on Medication Management</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- NIAC Immunisation Guidelines for Ireland.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>I practice within my scope of practice to undertake administration of Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine, under medicine protocol.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>I have undertaken the education programme for nurses and midwives on the use of medicine protocol for the administration of Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>I have attended Basic Life Support for Health Care Providers within the last two years.</td>
<td></td>
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<tr>
<td>5</td>
<td>I am competent in safe injection technique.</td>
<td></td>
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<tr>
<td>6</td>
<td>I have attended approved Anaphylaxis education programme and I am familiar with the current medicine protocol on the administration of Epinephrine by RNs/RMs.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>7</td>
<td>I can outline the inclusion/ exclusion criteria for administering Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine under the named medicine protocol.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>I can refer/to/discuss those that are meeting the exclusion criteria to the relevant medical practitioner for an individual medical assessment as per medicine protocol.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>I am familiar with the documentation required to support implementation of the medicine protocol to ensure safe administration of Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>In assessing suitability for vaccination I can undertake a clinical assessment of individuals within the scope of the medicine protocol.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>I can provide information regarding Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine, benefits and side effects to vaccine recipients.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>I am aware of the procedure for treatment and reporting of potential adverse reactions.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>I understand the procedure for reporting and documentation of medicine errors/ near misses.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>I dispose of all equipment and sharps in accordance with guidance for Healthcare Risk Waste HSE (2010).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I am aware of and comply with the guidance on vaccine storage and handling including the maintenance of the cold chain in accordance with national and local policies.</td>
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</tr>
<tr>
<td>---</td>
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</tr>
<tr>
<td>I have undertaken the following HSELand programmes:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| - “Hand Hygiene for HSE Clinical Staff”  
  [www.hseland.ie](http://www.hseland.ie) |
| - “Aseptic Non Touch Technique” (ANTT)  
  [www.hseland.ie](http://www.hseland.ie) |
| - GDPR guidelines  
  [www.hseland.ie](http://www.hseland.ie) |

I have sufficient theoretical knowledge and practice to undertake vaccination under this medicine protocol independently, and I acknowledge my responsibility to maintain my own competence in line with the Scope of Nursing and Midwifery Practice and current best evidence.

Registered Nurse/Midwife  
Signature: ________________________________  Date: ________________

If any deficits in theory and/or clinical practice are identified, the nurse/midwife must discuss with relevant Line Manager and implement appropriate action plan to achieve competency within an agreed time frame.

**Action Plan** (for use if needed to reach competencies outlined)

Action necessary to achieve competency:

.............................................................................................................................................................................
.............................................................................................................................................................................
.............................................................................................................................................................................

Date to be achieved: __________________________

Supporting evidence of measures taken to achieve competency:

.............................................................................................................................................................................
.............................................................................................................................................................................
.............................................................................................................................................................................

Nurse/Midwife signature:  
______________________________  Date: ________________

Line Manager signature  
______________________________  Date: ________________
Covid-19 vaccine(s) and registered nurses and midwives update

December 30, 2020

The Nursing and Midwifery Board of Ireland supports the administration of the Covid-19 vaccine(s) by registered nurses and registered midwives as provided for in SI 888 of 2020 and underpinned by medication protocols, developed, approved and signed off nationally by the Health Service Executive.

The Nursing and Midwifery Board of Ireland supports the administration of the Covid-19 vaccine(s) by registered nurses and registered midwives as provided for in SI 888 of 2020 (NMBI/media/NMBI/SI888.pdf) and underpinned by medication protocols, developed, approved and signed off nationally by the Health Service Executive.

This legal framework is supported by the Scope of Nursing and Midwifery Practice Framework (NMBI, 2015) and the Guidance to Nurses and Midwives on Medication Management (Section 4 Medication Protocol) (ABA, 2007).

Bord Altranais agus Cnámheachais na hÉireann, Nursing and Midwifery Board of Ireland (NMBI), 18/20 Carysfort Avenue, Blackrock, Co. Dublin, A94 R299, Ireland.

Customer Feedback (/customer-feedback-form)

- 013 353-1-639 8500 (tel:0035316398500)
- Faxes: 1890 200 116 (tel:1890200116)

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Medicine Protocol for the Administration of COVID-19 Vaccine Moderna to Vaccine Recipients

This medicine protocol is a specific written instruction for the administration of COVID-19 Vaccine Moderna to vaccine recipients by registered nurses and registered midwives. This medicine protocol is valid for the 2021/2022 HSE COVID-19 Vaccination Programme. This medicine protocol enables registered nurses and registered midwives employed in the voluntary and statutory services of the Health Service Executive (HSE) who have undertaken the required education and training programmes to administer COVID-19 Vaccine Moderna to vaccine recipients, with reference to and guidance from the Nursing & Midwifery Board of Ireland (NMBI), National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics for COVID-19 Vaccine Moderna as detailed by the European Medicines Agency (EMA).

- Health Service Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or Suspected Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive
- National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College of Physicians Ireland (Online Update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/)
- Nursing and Midwifery Board of Ireland (2014) Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) Practice Standards for Midwives. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) Recording Clinical Practice. Guidance to Nurses and Midwives. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland

The Nursing and Midwifery Board of Ireland defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect” (An Bord Altranais, 2007) (See Appendix III NMBI Statement of Support 2020).
## 1.0 Critical Elements

<table>
<thead>
<tr>
<th>Document reference number:</th>
<th>ONMSD 2021 002</th>
</tr>
</thead>
</table>

### Name of Organisation where medicine protocol applies

Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE), non-HSE healthcare facilities and mass vaccination clinic venues. This Medicine Protocol applies to:

Registered nurses and registered midwives involved in the administration of COVID-19 Vaccine Moderna to vaccine recipients under this medicine protocol.

### Date the medicine protocol comes into effect

January 2021

### Date for review of medicine protocol

January 2022

### Document prepared by:

Office of the Nursing and Midwifery Services Director (ONMSD) HSE in collaboration with the National Immunisation Office (NIO)

### Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol

**“On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation”**

- **Name:** Dr. Lorraine Doherty, National Clinical Director Health Protection, HSE
  - Signature: _______________________

- **Name:** Dr Colm Henry, Chief Clinical Officer, HSE
  - Signature: _______________________

- **Name:** Dr Geraldine Shaw, Nursing and Midwifery Services Director, HSE
  - Signature: _______________________
# 2.0 Clinical Criteria

<table>
<thead>
<tr>
<th><strong>Clinical Condition for use of the medicine protocol</strong></th>
<th>The clinical condition for which this medicine protocol has been developed is for the immunisation of vaccine recipients (see Inclusion Criteria) against COVID-19.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Circumstances in which the medicine protocol applies</strong></td>
<td>Targeted immunisation programme for vaccine recipients against COVID-19 as identified in the DoH policy based on the NIAC recommendations. The World Health Organisation declared COVID-19 outbreak as a pandemic on 11th March 2020 which is still ongoing.</td>
</tr>
</tbody>
</table>
| **Inclusion criteria for vaccine recipient using the medicine protocol** | Note: Vaccine Recipients who have received COVID-19 Vaccine Moderna as a first dose MUST be advised that the second dose is ALSO COVID-19 Vaccine Moderna ONLY.  
Inclusion Criteria:  
- Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 18 years of age and older.  

**Precautions:**  
- Acute severe febrile illness defer until recovery  
- Advice from a relevant specialist should be sought for a person with a history of an immediate allergic reaction to any other vaccine or injectable therapy. The risks should be weighed against the benefits of vaccination. They should be observed for 30 minutes after vaccination  
- Vaccination should be deferred until clinical recovery from COVID-19 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 those with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration  
- Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in intramuscular (IM) injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopoenia (platelet count <50 x 10⁹/ml) consult the supervising consultant  
- Co-administration with other vaccines has not been studied. It is prudent to leave 14 days between administering COVID-19 vaccine and administering another vaccine.  

**Pregnancy:**  
- Women who are at less than 14 weeks or more than 33 weeks of gestation should not receive the vaccine  
- Pregnant women who are between 14 weeks and 33 weeks of gestation and wish to receive the vaccine should confirm they have consulted with their obstetric care giver (Obstetrician or GP) and decided to receive the vaccine.  

**Breastfeeding:**  
There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping. |
| **Exclusion criteria for vaccine recipient using the medicine protocol** | COVID-19 Vaccine Moderna should not be given under this medicine protocol if the vaccine recipient has:  
- a confirmed anaphylactic reaction to a previous dose of the vaccine  
- a confirmed anaphylactic reaction to any components of the vaccine including polyethylene glycol. |
| --- | --- |
| **Actions to be taken for those who are excluded from the medicine protocol** | • Refer to/discuss with the relevant Medical Practitioner for an individual medical assessment  
• Document action in clinical notes  
• Where COVID-19 Vaccine Moderna is prescribed following medical assessment, the nurse or midwife may administer the vaccine within his/her scope of practice.  

**Note:** In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015). |
| **Action to be followed for vaccine recipients who do not wish to receive the vaccine** | Advise of the risks of not having the vaccine, including risk of possible severe COVID-19 disease.  
Advice regarding minimization of risk. |
| **Description of circumstances and referral arrangements when further advice or consultation is required** | Refer to/discuss with relevant Medical Practitioner if the vaccine recipient had previous adverse reaction or other clinical concerns as outlined in Exclusion Criteria. |
| **Documentation required to support implementation of the medicine protocol** | • Vaccine consent forms or check for and ensure online consent  
• Vaccine Information Leaflets  
• Patient held record cards if available  
• Health Products Regulatory Authority Adverse Reaction Reporting forms  
• National Incident Management System Form NIRF-01-v11 available at: https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf  

It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of COVID-19 Vaccine Moderna which includes the following:  

- Medicine Protocol for the Administration of COVID-19 Vaccine Moderna to vaccine recipients  
<table>
<thead>
<tr>
<th>3.0 Name of Medicine</th>
<th>COVID-19 Vaccine Moderna</th>
</tr>
</thead>
</table>
| **Dose & Route of administration** | • The dose is 0.5ml, 2 doses 28 days apart  
• Route of administration: IM  
• Site: The preferred site is the deltoid muscle  
• If the interval between doses is longer than 28 days, the second dose should still be given as soon as possible. The course does not need to be restarted  
• If the second dose was given between 24 and 27 days after the first dose, it is a valid dose  
• If the interval between doses is less than 24 days, a further dose is not required. Evidence of efficacy of doses given before 24 days is lacking  
• Do not inject the vaccine intravascularly, subcutaneously or intradermally |
| **Details of product information and other data including instructions for supply and administration is available from the European Medicines Agency (EMA)** | **Potential adverse reactions and procedures for treatment of same** |
| Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction  
• Those with no history of anaphylaxis from any cause: 15 minutes  
• Those with a history of anaphylaxis from any cause: 30 minutes  
• Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated  
The vaccine recipient should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the COVID-19 Vaccine Moderna after the above period of observation. |
| **Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)** | The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out on line at http://www.hpra.ie or through use of the yellow card system which is available in a downloadable format from the HPRA website, or on request from the HPRA.  
The vaccine recipient’s General Practitioner should be informed of any reported adverse reaction.  
The incident and all actions taken must be promptly recorded in accordance with the Management of a Patient with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee 2019), available online at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf |
| **Procedure for the reporting and documentation of errors and near misses involving the medicine** | 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 registered nurse or midwife 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 the |
relevant medical practitioner or other appropriate physician. The incident must be reported to the relevant line manager/person in charge as soon as possible.

The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day. (National Incident Report Form (NIRF 01 – V11)) (2020) available at:
https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf
The vaccine recipient and/or significant others should be informed of the incident.

An incident report form must be completed by the nurse or midwife 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.

<table>
<thead>
<tr>
<th>Resources and equipment required</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Each vial contains up to 11 doses of 0.5mL.</td>
</tr>
<tr>
<td>• Pack size: multidose vial</td>
</tr>
<tr>
<td>• 1 ml/2ml/2.5ml syringe, 23/25 gauge needle for IM administration</td>
</tr>
<tr>
<td>• Fridge/Cooler box with data logger with external temperature monitoring display to maintain cold chain temperature between +2° to +8°C</td>
</tr>
<tr>
<td>• Disposable kidney dishes/trays</td>
</tr>
<tr>
<td>• 70% alcohol swabs (for sterilizing vials)</td>
</tr>
<tr>
<td>• Gauze swabs, tape/plasters</td>
</tr>
<tr>
<td>• Sharps bins, and bins for disposal of other hazardous material</td>
</tr>
<tr>
<td>• Alcohol hand rinse</td>
</tr>
<tr>
<td>• Access to telephone</td>
</tr>
<tr>
<td>• Safe storage areas for medicines and equipment</td>
</tr>
<tr>
<td>• Current COVID-19 Vaccine Moderna medicine protocol</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Audit process to identify appropriate use of the medicine protocol or unexpected outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>All documentation will be held for review and audit purposes as per local/national agreement.</td>
</tr>
</tbody>
</table>

4.0 Information for vaccine recipient

<table>
<thead>
<tr>
<th>Advice to be given to the vaccine recipient before treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine Information material must be supplied with the consent form to the vaccine recipient prior to administration of the vaccine.</td>
</tr>
</tbody>
</table>

**Before Treatment**
Check and confirm the online consent has been provided or obtain signed consent. Discuss the COVID-19 Vaccine Moderna and the importance of protecting their health. Inform vaccine recipient that patient information leaflet is available online at


Discuss potential side effects.
<table>
<thead>
<tr>
<th>Advice to be given to the recipient healthcare worker after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals may not be protected until at least 14 days after their second dose of the vaccine.</td>
</tr>
</tbody>
</table>

**After Treatment**

Discuss potential side effects

Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction.

Events of anaphylaxis have been reported therefore NIAC recommends the following monitoring for the post-vaccination period:

- Close observation for at least 15 minutes is recommended following vaccination
- The second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of COVID-19 Vaccine Moderna.

The vaccine recipient should not leave the healthcare facility if they are feeling unwell and must report any side effects to a member of the vaccination team.

**The vaccine recipient may be advised:**

Side effects may occur with following frequencies:

**Local:**
- Very common: injection site pain and swelling
- Common: injection site erythema, rash and urticaria
- Uncommon: injection site pruritus.

**General:**
- Very common: arthralgia, axillary lymphadenopathy (on the side of injection), chills, fatigue, fever, headache, myalgia, nausea, vomiting
- Rare: acute peripheral facial paralysis, facial swelling (in those with dermatological fillers)

A full list of adverse reactions may be found in the Summary of Product Characteristics (SmPC), available at


The vaccine recipient should be advised to report any side effects to the relevant medical practitioner.

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

If more serious adverse or persistent effects occur, vaccine recipient should be advised to contact their GP/out of hours service.

<table>
<thead>
<tr>
<th>Details of any necessary follow-up, action and referral arrangements</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the event of an adverse reaction the vaccination team must ensure that all procedures are adhered to as outlined in Section 3.</td>
</tr>
</tbody>
</table>
### 5.0 Staff authorised to use this medicine protocol

<table>
<thead>
<tr>
<th>Professional qualifications, training, experience and competence required prior to using this medicine protocol</th>
<th>Registered nurse or registered midwife, maintained on the active register maintained by The Nursing and Midwifery Board of Ireland.</th>
</tr>
</thead>
<tbody>
<tr>
<td>/ Professional Qualifications:</td>
<td>Education programme for nurses and midwives on the use of <em>COVID-19 Medicine Protocol for the Administration of COVID-19 Vaccine Moderna</em> to vaccine recipients by registered nurses and registered midwives and any updates.</td>
</tr>
<tr>
<td>Training, Experience, Competence:</td>
<td>Basic Life Support for Health Care Providers within the last two years.</td>
</tr>
<tr>
<td></td>
<td>Initial anaphylaxis programme (“National Anaphylaxis Education Programme for Health Care Professionals”) via HSELandD followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSELandD Anaphylaxis e-learning programme available at <a href="http://www.hse.ie">www.hse.ie</a>.</td>
</tr>
<tr>
<td></td>
<td>The nurse/midwife must complete the Competency Assessment Form (Appendix II) to administer the COVID-19 Vaccine Moderna.</td>
</tr>
<tr>
<td>Recommended:</td>
<td><strong>Storing and Managing Vaccines</strong> <a href="http://www.hseland.ie">www.hseland.ie</a></td>
</tr>
</tbody>
</table>
References


Health Service Executive (2019) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or Suspected Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis.* Dublin: Health Service Executive


Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland, available at: http://www.nmbi.ie
Appendix I

Signature Sheet:

**Name of Protocol:** *Medicine Protocol for the Administration of COVID-19 Vaccine Moderna* to vaccine recipients by registered nurses and registered midwives.

I have read, understood & agreed to adhere to the attached medicine protocol.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Signature:</th>
<th>Occupation:</th>
<th>Pin No:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

The above signed nurses and midwives are authorised by the signatories on page 2 to administer *COVID-19 Vaccine Moderna* in accordance with this medicine protocol.
**Appendix II: Competency Assessment Form**

### Self-Assessment of Competency to Administer COVID-19 Vaccine Moderna under Medicine Protocol

<table>
<thead>
<tr>
<th>Domain of Practice</th>
<th>Critical Element</th>
<th>Competent Date/Initials</th>
<th>Needs Practice Date/Initials</th>
<th>Needs Theory Date/Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I understand the role and function of medicine protocols in the context of NMBI guidelines in relation to:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The Code of Professional &amp; Ethical Conduct</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Scope of Nursing and Midwifery Practice</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Guidance to Nurses and Midwives on Medication Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• NIAC Immunisation Guidelines for Ireland.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>I practice within my scope of practice to undertake administration of COVID-19 Vaccine Moderna under medicine protocol.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>I have undertaken the education programme for nurses and midwives on the use of medicine protocol for the administration of COVID-19 Vaccine Moderna</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>I have attended Basic Life Support for Health Care Providers within the last two years.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>I am competent in safe injection technique.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>I have attended an approved Anaphylaxis education programme and I am familiar with the current medicine protocol on the administration of Epinephrine by RNS/RMs.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>I can outline the inclusion/exclusion criteria for administering COVID-19 Vaccine Moderna under the named medicine protocol.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>I can refer/discuss those that are meeting the exclusion criteria to the relevant medical practitioner for an individual medical assessment as per medicine protocol.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>I am familiar with the documentation required to support implementation of the medicine protocol to ensure safe administration of COVID-19 Vaccine Moderna.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>In assessing suitability for vaccination I can undertake a clinical assessment of individuals within the scope of the medicine protocol.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>I can provide information regarding COVID-19 Vaccine Moderna, benefits and side effects to vaccine recipients.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>I am aware of the procedure for treatment and reporting of potential adverse reactions.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>I understand the procedure for reporting and documentation of medicine errors/near misses.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>I dispose of all equipment and sharps in accordance with guidance for Healthcare Risk Waste (HSE, 2010).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>I am aware of and comply with the guidance on vaccine storage and handling including the maintenance of the cold chain in accordance with national and local policies.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
I have undertaken the following HSELand programmes:

- “Hand Hygiene for HSE Clinical Staff”
  [www.hseland.ie](http://www.hseland.ie)

- “Aseptic Non Touch Technique” (ANTT)
  [www.hseland.ie](http://www.hseland.ie)

- GDPR guidelines
  [www.hseland.ie](http://www.hseland.ie)

I have sufficient theoretical knowledge and practice to undertake vaccination under this medicine protocol independently, and I acknowledge my responsibility to maintain my own competence in line with the Scope of Nursing and Midwifery Practice and current best evidence.

Registered Nurse/Midwife  Signature: _________________________________ Date: ________________

If any deficits in theory and/or clinical practice are identified, the nurse/midwife must discuss with relevant Line Manager and implement appropriate action plan to achieve competency within an agreed time frame.

**Action Plan** (for use if needed to reach competencies outlined)

Action necessary to achieve competency:

----------------------------------------------------------

----------------------------------------------------------

----------------------------------------------------------

Date to be achieved: _____________________

Supporting evidence of measures taken to achieve competency:

----------------------------------------------------------

----------------------------------------------------------

Nurse/Midwife signature:

_______________________________________________________ Date: ________________

Line Manager signature

_______________________________________________________ Date: ________________
NMBI statement on Covid-19 vaccinations

January 21, 2021

The Nursing and Midwifery Board of Ireland supports the administration of the Covid-19 vaccine(s) by registered nurses and registered midwives as provided for in legislation and underpinned by medicine protocols, developed, approved and signed off nationally by the Health Service Executive.
Medicine Protocol for the Administration of COVID-19 Vaccine AstraZeneca to Vaccine Recipients

This medicine protocol is a specific written instruction for the administration of COVID-19 Vaccine AstraZeneca to vaccine recipients by registered nurses and registered midwives. This medicine protocol is valid for the 2021/2022 HSE COVID-19 Vaccination Programme. This medicine protocol enables registered nurses and registered midwives employed in the voluntary and statutory services of the Health Service Executive (HSE) who have undertaken the required education and training programmes to administer COVID-19 Vaccine AstraZeneca to vaccine recipients, with reference to and guidance from the Nursing & Midwifery Board of Ireland (NMBI), National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics for COVID-19 Vaccine AstraZeneca as detailed by the European Medicines Agency (EMA).

- Health Service Executive (2019) Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or Suspected Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis. Dublin: Health Service Executive
- National Immunisation Advisory Committee Immunisation Guidelines for Ireland Dublin: Royal College of Physicians Ireland (Online Update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/)
- Nursing and Midwifery Board of Ireland (2014) Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) Practice Standards for Midwives. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) Recording Clinical Practice. Guidance to Nurses and Midwives. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework. Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland

The Nursing and Midwifery Board of Ireland defines medicine protocols as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect” (An Bord Altranais, 2007) (See Appendix III NMBI Statement of Support 2020).
**Medicine Protocol for the Administration of COVID-19 Vaccine AstraZeneca to vaccine recipients**

<table>
<thead>
<tr>
<th>Document reference number:</th>
<th>ONMSD 2021-003</th>
</tr>
</thead>
</table>

### 1.0 Critical Elements

<table>
<thead>
<tr>
<th>Name of Organisation where medicine protocol applies</th>
<th>Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE), non-HSE healthcare facilities and mass vaccination clinic venues. This Medicine Protocol applies to: Registered nurses and registered midwives involved in the administration of COVID-19 Vaccine AstraZeneca to vaccine recipients under this medicine protocol.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date the medicine protocol comes into effect</td>
<td>February 2021</td>
</tr>
<tr>
<td>Date for review of medicine protocol</td>
<td>February 2022</td>
</tr>
<tr>
<td>Document prepared by:</td>
<td>Office of the Nursing and Midwifery Services Director (ONMSD) HSE in collaboration with the National Immunisation Office (NIO)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation</td>
</tr>
<tr>
<td>Name: Dr. Lorraine Doherty, National Clinical Director Health Protection, HSE</td>
</tr>
<tr>
<td>Signature:</td>
</tr>
</tbody>
</table>

| Name: Dr Colm Henry, Chief Clinical Officer, HSE |
| Signature: |

| Name: Dr Geraldine Shaw, Nursing and Midwifery Services Director, HSE |
| Signature: |

---

**Medicine Protocol for the Administration of COVID-19 Vaccine AstraZeneca 2021/2022**
### 2.0 Clinical Criteria

<table>
<thead>
<tr>
<th>Clinical Condition for use of the medicine protocol</th>
<th>The clinical condition for which this medicine protocol has been developed is for the immunisation of vaccine recipients (see Inclusion Criteria) against COVID-19.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circumstances in which the medicine protocol applies</td>
<td>Targeted immunisation programme for vaccine recipients against COVID-19 as identified in the DoH policy based on the NIAC recommendations. The World Health Organisation declared COVID-19 outbreak as a pandemic on 11th March 2020 which is still ongoing.</td>
</tr>
<tr>
<td>Inclusion criteria for vaccine recipient using the medicine protocol</td>
<td>Note: Vaccine Recipients who have received COVID-19 Vaccine AstraZeneca as a first dose MUST be advised that the second dose is ALSO COVID-19 Vaccine AstraZeneca ONLY.</td>
</tr>
</tbody>
</table>

**Inclusion Criteria:**
- Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals \( \geq \) 18 years of age and older.

**Precautions:**
- 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 any other vaccine or injectable therapy and the risks should be weighed against the benefits of vaccination. The patient should be observed for 30 minutes after vaccination.
- Vaccination should be deferred until clinical recovery from COVID-19 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 those with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration
- Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM (intramuscular) injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopenia (platelet count <50 x 10^9/ml) consult the supervising consultant
- Those with inherited coagulopathies who require factor replacement therapy should receive it on the day of vaccination, prior to the IM vaccination. If there is uncertainty about the need for cover, contact the patient’s Comprehensive Care Centre
- Co-administration with other vaccines has not been studied. It is prudent to leave 14 days between administering COVID-19 vaccine and administering another vaccine.
**Pregnancy:**
- Women who are at less than 14 weeks or more than 33 weeks of gestation should not receive the vaccine
- Pregnant women who are between 14 weeks and 33 weeks of gestation and wish to receive the vaccine should confirm they have consulted with their obstetric care giver (Obstetrician or GP) and decided to receive the vaccine. When COVID-19 Vaccine AstraZeneca is being administered in pregnancy, the two dose schedule should be given 12 weeks apart if possible. However, as the two dose schedule should be given between 14 and 33 completed weeks of gestation, a shorter interval can be used, 4-12 weeks apart.

**Breastfeeding:**
- There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping.

**Exclusion criteria for vaccine recipient using the medicine protocol**
COVID-19 Vaccine AstraZeneca should not be given under this medicine protocol if the vaccine recipient has:
- anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polysorbate 80).

**Actions to be taken for those who are excluded from the medicine protocol**
- Refer to/discuss with the relevant Medical Practitioner for an individual medical assessment
- Document action in clinical notes
- Where COVID-19 Vaccine AstraZeneca is prescribed following medical assessment, the nurse or midwife may administer the vaccine within his/her scope of practice.

**Note:** In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).

**Action to be followed for vaccine recipients who do not wish to receive the vaccine**
Advise of the risks of not having the vaccine, including risk of possible severe COVID-19 disease.
Advice regarding minimisation of risk

**Description of circumstances and referral arrangements when further advice or consultation is required**
Refer to/discuss with relevant Medical Practitioner if the vaccine recipient had previous adverse reaction or other clinical concerns as outlined in Exclusion Criteria.

**Documentation required to support implementation of the medicine protocol**
- Vaccine consent forms or check for and ensure online consent
- Vaccine Information Leaflets
- Patient held record cards
- Health Products Regulatory Authority Adverse Reaction Reporting forms
- National Incident Management System Form NIRF-01-v11 available at:  
  [https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf](https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf)

It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of COVID-19 Vaccine AstraZeneca which includes the following:
- Medicine Protocol for the Administration of COVID-19 Vaccine AstraZeneca to vaccine recipients

### 3.0 Name of Medicine

COVID-19 Vaccine AstraZeneca

### Dose & Route of administration

- The dose is 0.5ml
- Route of administration: IM Site
- The preferred site is the deltoid muscle
- **For those aged less than 65 years**, two doses of COVID-19 Vaccine AstraZeneca are required with an interval of 12 weeks between doses.
  The National Immunisation Advisory Committee recommends an interval of 4-12 weeks apart, therefore the following applies;
  - If the interval between doses is longer than 12 weeks, the second dose should still be given as soon as possible. The course does not need to be restarted.
  - If the second dose was given between 24 and 27 days after the first dose, it is a valid dose.
  - If the interval between doses is less than 24 days, a further dose is not required.
- **For those aged 65 years and older**, an interval of 6 weeks is recommended.
  - If the interval between doses is longer than 6 weeks, the second dose should still be given as soon as possible. The course does not need to be restarted.
  - If the second dose was given between 24 and 27 days after the first dose, it is a valid dose.
  - If the interval between doses is less than 24 days, a further dose is not required.
- Do not inject the vaccine intravascularly, subcutaneously or intradermally

### Link to Medicine

**Details of product information and other data including instructions for supply and administration is available from the European Medicines Agency (EMA)**

### Link to Summary of Product Characteristics and Patient Information Leaflet


### Potential adverse reactions and procedures for treatment of same

Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction

- Those with no history of anaphylaxis from any cause: 15 minutes
- Those with a history of anaphylaxis from any cause: 30 minutes
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

The vaccine recipient should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the COVID-19 Vaccine AstraZeneca after the above period of observation.

### Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)

The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out on line at [http://www.hpra.ie](http://www.hpra.ie) or through use of the yellow card system which is available in a downloadable format from the HPRA website, or on request from the HPRA.

The vaccine recipient’s General Practitioner should be informed of any reported adverse reaction.

The incident and all actions taken must be promptly recorded in accordance with the *Management of a Patient with Anaphylaxis: Treatment in the Community* (National Immunisation Advisory Committee 2019), available online at [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf)

### Procedure for the reporting and documentation of errors and near misses involving the medicine

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 registered nurse or midwife 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 the relevant medical practitioner or other appropriate physician.

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

The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day. (National Incident Report Form (NIRF 01 – V11)) (2020) available at: [https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf](https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf)

The vaccine recipient and/or significant others should be informed of the incident. An incident report form must be completed by the nurse or midwife 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.

### Resources and equipment required

- A multidose vial of COVID-19 vaccine AstraZeneca
- 1 ml/2ml/2.5ml syringe, 23/25 gauge needle for IM administration
- Fridge/Cooler box with data logger with external temperature monitoring display to maintain cold chain temperature between +2° to +8°C
- Disposable kidney dishes/trays
- 70% alcohol swabs (for sterilizing vials)
- Gauze swabs, tape/plasters
- Sharps bins, and bins for disposal of other hazardous material
- Alcohol hand rinse
- Access to telephone
- Resuscitation equipment and drugs in accordance with *Anaphylaxis: Treatment*
<table>
<thead>
<tr>
<th>Advice to be given to the vaccine recipient before treatment</th>
<th>Vaccine Information material must be supplied with the consent form to the vaccine recipient prior to administration of the vaccine.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Discuss potential side effects. Evidence shows that protection starts from approximately 3 weeks after first dose of vaccine and persists up to 12 weeks. Modelling showed no evidence of waning of protection in the first three months after vaccination. Higher efficacy after the second dose was found if the booster dose was given at 12 weeks.</td>
</tr>
<tr>
<td><strong>After Treatment</strong></td>
<td>Discuss potential side effects Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction. Events of anaphylaxis have been reported therefore NIAC recommends the following monitoring for the post-vaccination period:</td>
</tr>
<tr>
<td></td>
<td>- Post vaccination observation period</td>
</tr>
<tr>
<td></td>
<td>- Those with no history of anaphylaxis from any cause: 15 minutes</td>
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<tr>
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<td>- Those with a history of anaphylaxis from any cause: 30 minutes</td>
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<tr>
<td></td>
<td>- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated</td>
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<tr>
<td></td>
<td>- The second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of COVID-19 Vaccine AstraZeneca or any of its constituents including Polysorbate 80</td>
</tr>
<tr>
<td></td>
<td>The vaccine recipient should not leave the healthcare facility if they are feeling unwell and must report any side effects to a member of the vaccination team.</td>
</tr>
</tbody>
</table>

**The vaccine recipient may be advised:**
Side effects may occur with following frequencies:
Local:
**Very common:** injection site bruising, pain, pruritus, tenderness, warmth
**Common:** injection site erythema, swelling
**Uncommon:** injection site haematoma

**General:**
**Very common:** arthralgia, chills, fatigue, feverishness, headache, malaise, myalgia, nausea
**Common:** diarrhoea, fever >38°C, vomiting
**Uncommon:** decreased appetite, dizziness, hyperhidrosis, lymphadenopathy, pruritus, somnolence, rash


The vaccine recipient should be advised to report any side effects to the relevant medical practitioner.

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

If more serious adverse or persistent effects occur, vaccine recipient should be advised to contact their GP/out of hours service.

<table>
<thead>
<tr>
<th>Details of any necessary follow-up, action and referral arrangements</th>
<th>In the event of an adverse reaction the vaccination team must ensure that all procedures are adhered to as outlined in Section 3.</th>
</tr>
</thead>
</table>

### 5.0 Staff authorised to use this medicine protocol

**Professional qualifications, training, experience and competence required prior to using this medicine protocol / Professional Qualifications:**

Registered nurse or registered midwife, maintained on the active register maintained by The Nursing and Midwifery Board of Ireland.

Education programme for nurses and midwives on the use of **COVID-19 Medicine Protocol for the Administration of COVID-19 Vaccine AstraZeneca** to vaccine recipients by registered nurses and registered midwives and any updates.

Basic Life Support for Health Care Providers within the last two years.

Initial anaphylaxis programme (“**National Anaphylaxis Education Programme for Health Care Professionals**”) via HSELaND followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme).

Subsequent updates every two years via HSELaND Anaphylaxis e-learning programme available at [www.hse.ie](http://www.hse.ie).

The nurse/midwife must complete the **Competency Assessment Form** (Appendix II) to administer the **COVID-19 Vaccine AstraZeneca**.
Recommended:

*Storing and Managing Vaccines* [www.hseland.ie](http://www.hseland.ie)
References


Health Service Executive (2019) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or Suspected Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis.* Dublin: Health Service Executive


Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland, available at: [http://www.nmbi.ie](http://www.nmbi.ie)
Appendix I

Signature Sheet:

**Name of Protocol:** Medicine Protocol for the Administration of COVID-19 Vaccine AstraZeneca to vaccine recipients by registered nurses and registered midwives.

I have read, understood & agreed to adhere to the attached medicine protocol.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Signature:</th>
<th>Occupation:</th>
<th>Pin No:</th>
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</table>

The above signed nurses and midwives are authorised by the signatories on page 2 to administer COVID-19 Vaccine AstraZeneca in accordance with this medicine protocol.
## Appendix II: Competency Assessment Form

### Self-Assessment of Competency to Administer COVID-19 Vaccine AstraZeneca under Medicine Protocol

<table>
<thead>
<tr>
<th>Domain of Practice</th>
<th>Critical Element</th>
<th>Competent Date/Initials</th>
<th>Needs Practice Date/Initials</th>
<th>Needs Theory Date/Initials</th>
</tr>
</thead>
</table>
| 1                  | I understand the role and function of medicine protocols in the context of NMBI guidelines in relation to:  
  - The Code of Professional & Ethical Conduct  
  - Scope of Nursing and Midwifery Practice  
  - Guidance to Nurses and Midwives on Medication Management  
  - NIAC Immunisation Guidelines for Ireland.                                                                                                      |                          |                              |                             |
| 2                  | I practice within my scope of practice to undertake administration of COVID-19 Vaccine AstraZeneca under medicine protocol.                                                                                                                                                                    |                          |                              |                             |
| 3                  | I have undertaken the education programme for nurses and midwives on the use of medicine protocol for the administration of COVID-19 Vaccine AstraZeneca.                                                                                                                                                                        |                          |                              |                             |
| 4                  | I have attended Basic Life Support for Health Care Providers within the last two years.                                                                                                                                                                                                                                                                   |                          |                              |                             |
| 5                  | I am competent in safe injection technique.                                                                                                                                                                                                                                                                                                               |                          |                              |                             |
| 6                  | I have attended an approved Anaphylaxis education programme and I am familiar with the current medicine protocol on the administration of Epinephrine by RNS/RMs.                                                                                                                                                                                               |                          |                              |                             |
| 7                  | I can outline the inclusion/exclusion criteria for administering COVID-19 Vaccine AstraZeneca under the named medicine protocol.                                                                                                                                                                                                                       |                          |                              |                             |
| 8                  | I can refer to/discuss those that are meeting the exclusion criteria to the relevant medical practitioner for an individual medical assessment as per medicine protocol.                                                                                                                                                                                      |                          |                              |                             |
| 9                  | I am familiar with the documentation required to support implementation of the medicine protocol to ensure safe administration of COVID-19 Vaccine AstraZeneca.                                                                                                                                                                     |                          |                              |                             |
| 10                 | In assessing suitability for vaccination I can undertake a clinical assessment of individuals within the scope of the medicine protocol.                                                                                                                                                                                                                   |                          |                              |                             |
| 11                 | I can provide information regarding COVID-19 Vaccine AstraZeneca, benefits and side effects to vaccine recipients.                                                                                                                                                                                                                                          |                          |                              |                             |
| 12                 | I am aware of the procedure for treatment and reporting of potential adverse reactions.                                                                                                                                                                                                                                                                  |                          |                              |                             |
| 13                 | I understand the procedure for reporting and documentation of medicine errors/near misses.                                                                                                                                                                                                                                                                     |                          |                              |                             |
| 14                 | I dispose of all equipment and sharps in accordance with guidance for Healthcare Risk Waste (HSE, 2010).                                                                                                                                                                                                                                                  |                          |                              |                             |
| 15                 | I am aware of and comply with the guidance on vaccine storage and handling including the maintenance of the cold chain in accordance with national and local policies.                                                                                                                                                                                      |                          |                              |                             |
I have undertaken the following HSEland programmes:

- “Hand Hygiene for HSE Clinical Staff”
  [www.hseland.ie](http://www.hseland.ie)
- “Aseptic Non Touch Technique” (ANTT)
  [www.hseland.ie](http://www.hseland.ie)
- GDPR guidelines
  [www.hseland.ie](http://www.hseland.ie)

I have sufficient theoretical knowledge and practice to undertake vaccination under this medicine protocol independently, and I acknowledge my responsibility to maintain my own competence in line with the Scope of Nursing and Midwifery Practice and current best evidence.

Registered Nurse/Midwife                      Signature: _______________________________ Date: ______________

If any deficits in theory and/or clinical practice are identified, the nurse/midwife must discuss with relevant Line Manager and implement appropriate action plan to achieve competency within an agreed time frame.

<table>
<thead>
<tr>
<th>Action Plan (for use if needed to reach competencies outlined)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action necessary to achieve competency:</td>
</tr>
<tr>
<td>...........................................................................................................</td>
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<td>Date to be achieved: .................................................................</td>
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<tr>
<td>Supporting evidence of measures taken to achieve competency:</td>
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<tr>
<td>Nurse/Midwife signature:</td>
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<td>........................................................................................................... Date: ______________</td>
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<tr>
<td>Line Manager signature</td>
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<tr>
<td>........................................................................................................... Date: ______________</td>
</tr>
</tbody>
</table>
NMBI statement on Covid-19 vaccinations

January 21, 2021

The Nursing and Midwifery Board of Ireland supports the administration of the Covid-19 vaccine(s) by registered nurses and registered midwives as provided for in legislation and underpinned by medicine protocols, developed, approved and signed off nationally by the Health Service Executive.
Appendix 4. Anaphylaxis Protocol
Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis

Incorporating

Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis

Document reference number: ONMSD 2016-004
Document prepared by: Office of the Nursing and Midwifery Services Director, Health Service Executive, in collaboration with the National Immunisation Office at the request of the Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation

Document approved by:
Name: Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE
Signature:

Name: Dr. Lynda Sisson, National Clinical Lead, Workplace Health and Wellbeing, HSE
Signature: [Signature]

Name: Ms Mary Wynne, Interim Nursing and Midwifery Services Director, HSE
Signature: [Signature]

Approval date: 9th April 2019
Responsibility for implementation: Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation,

Revision date: This is a controlled document and may be subject to change at any time.
Provisional date: March 2021

Categories of health professionals that may administer in accordance with these Directions and Medicine Protocol:
Registered Nurses and Midwives in the voluntary and statutory services of the Health Service Executive who are expected to deal with an anaphylaxis

Directions for nurses and midwives for the management of a patient who develops anaphylaxis and Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1,000 by IM Injection by registered nurses and registered midwives.
Version 3, 2019
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Purpose</td>
<td>3</td>
</tr>
<tr>
<td>2.0</td>
<td>Scope</td>
<td>3</td>
</tr>
<tr>
<td>3.0</td>
<td>Definition of Anaphylaxis</td>
<td>3</td>
</tr>
<tr>
<td>4.0</td>
<td>Recognition of Anaphylaxis: General Principles</td>
<td>3</td>
</tr>
<tr>
<td>5.0</td>
<td>Recognition of Anaphylaxis</td>
<td>5</td>
</tr>
<tr>
<td>6.0</td>
<td>Treatment of Anaphylaxis</td>
<td>6</td>
</tr>
<tr>
<td>7.0</td>
<td>Follow up</td>
<td>9</td>
</tr>
<tr>
<td>8.0</td>
<td>Storage of Epinephrine (Adrenaline)</td>
<td>9</td>
</tr>
<tr>
<td>9.0</td>
<td>Caution</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Medicine Protocol for the Administration of Epinephrine (Adrenaline)</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Injection 1:1,000 by IM injection by nurses and midwives for the</td>
<td></td>
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<tr>
<td></td>
<td>management of a patient with anaphylaxis or suspected anaphylaxis</td>
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</tr>
<tr>
<td></td>
<td>References</td>
<td>17</td>
</tr>
</tbody>
</table>

Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis and Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1,000 by IM injection by registered nurses and registered midwives. Version 3, 2019
Directions for nurses and midwives for the management of a patient who develops Anaphylaxis or suspected anaphylaxis

1.0 Purpose

The purpose of this direction is to provide information on the safe and effective management of anaphylaxis to ensure patients are promptly diagnosed, treated and managed after onset of symptoms of anaphylaxis.

2.0 Scope

This direction applies to registered nurses and registered midwives in the voluntary and statutory services of the HSE who are expected to deal with anaphylaxis.

3.0 Definition of Anaphylaxis

Anaphylaxis is a potentially life threatening allergic reaction to foreign protein antigens such as food and bee stings. It is a very rare complication of immunisation (0.4-2 per million doses) (Immunisation Guidelines for Ireland, National Immunisation Advisory Committee, available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/)

4.0 Recognition of anaphylaxis-General Principles

Anaphylaxis must be distinguished from fainting (vasovagal episode), anxiety and breath-holding episodes, which are significantly more common. See Table 1 below.

Table 1 Differentiating Vasovagal episode and Anaphylaxis

<table>
<thead>
<tr>
<th>Onset</th>
<th>Vasovagal episode</th>
<th>Anaphylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>Generalised pallor; cold, clammy skin</td>
<td>Itch, generalised erythema, urticaria or angio-oedema (localised swelling of face, mouth, etc.)</td>
</tr>
<tr>
<td>Respiratory</td>
<td>Normal or shallow, not laboured</td>
<td>Cough, wheeze, stridor, tachypnoea, recession, cyanosis</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Bradycardia but strong carotid pulse. Hypotension corrected when lying down</td>
<td>Tachycardia, weak/absent pulse. Sustained hypotension unless specific treatment</td>
</tr>
<tr>
<td>Neurological</td>
<td>Light-headed. Possible loss of consciousness, improves on lying down</td>
<td>Severe anxiety and distress, loss of consciousness</td>
</tr>
</tbody>
</table>

Source: http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/

Those experiencing an anxiety spell may appear fearful, pale and sweaty, and complain of light-headedness, dizziness and numbness or tingling of their hands or feet. Hyperventilation is usually present.

During a breath-holding episode an infant or child is suddenly silent but obviously agitated. Facial flushing or pallor can occur as breath-holding continues. Some episodes end with a resumption of crying, but others can be followed by a brief period of unconsciousness during which breathing resumes.
Swelling and an urticaria rash may appear at the injection site but are not always caused by an allergic reaction and may disappear without additional treatment. However, if any other symptoms occur, even if considered mild (sneezing, nasal congestion, coughing, etc.), Epinephrine (Adrenaline) should be given. There is little risk with the unnecessary use of Epinephrine (Adrenaline), whereas delay in its administration in anaphylaxis may result in severe anaphylaxis and death. The features of severe disease include obstructive swelling of the upper airway, marked bronchospasm and hypotension.
5.0 Recognition of anaphylaxis

5.1 Anaphylaxis is likely when all of the following 3 criteria are met:

5.1.1 a. Sudden onset

b. Rapid progression of symptoms
c. Involving two or more organ systems.

- The patient will feel and look unwell
- Most reactions occur within several minutes. Rarely, reactions may be delayed in onset
- The time of onset of anaphylaxis depends on the type of trigger
- The patient is usually anxious and can experience a “sense of impending doom”

5.1.2 Life-threatening Airway and/or Breathing and/or Circulation problems (Resuscitation Council (UK) 2008)

- Patients can have some or all of the following; (use the ABCDE approach to recognise these)

Airway problems:

- Airway swelling e.g. mouth, tongue and throat swelling (pharyngeal/laryngeal oedema). The patient has difficulty in breathing and swallowing and feels that the throat is closing up
- Shortness of breath – Hoarse voice
- Stridor (a high-pitched inspiratory noise caused by upper airway obstruction)

Breathing problems:

- Increased respiratory rate
- Wheeze
- Confusion caused by hypoxia
- Cyanosis (appears blue). This is usually a late sign.
- Respiratory arrest

Circulation problems:

- Signs of shock – pale, clammy
- Increased pulse rate (tachycardia)
- Low blood pressure (hypotension)
- Decreased conscious level or loss of consciousness
- Anaphylaxis can cause myocardial ischaemia and electrocardiograph changes even in patients with normal coronary arteries
- Cardiac arrest

The circulatory effects do not respond, or only respond transiently, to simple measures such as lying the patient down and raising the legs. Patients with anaphylaxis can deteriorate if made to sit or stand up.

Disability Problems
The above Airway, Breathing and Circulation problems can all alter the patient’s neurological status causing Disability problems because of decreased brain perfusion. There may be confusion, agitation and loss of consciousness.

Patients can also have gastro-intestinal symptoms (abdominal pain, incontinence, vomiting).

5.1.3 Skin and/or mucosal changes (flushing, urticaria, angioedema)

**Exposure**

- Skin and mucosal changes should be looked for
- They are often the first feature and are present in over 80% of patients with anaphylaxis
- They can be subtle or dramatic
- There may be just skin, just mucosal or both skin and mucosal changes
- There may be erythema (a patchy or generalised red rash)
- There may be urticaria, which may appear anywhere on the body
- Angioedema is similar to urticaria but involves swelling of deeper tissues, commonly in the eyelids and lips, and sometimes in the mouth and throat

Skin changes alone, without airway, breathing or circulation problems, do not signify anaphylaxis. Most patients who have skin changes caused by allergy do not go on to develop anaphylaxis.

5.2 The following supports the diagnosis:

5.2.1 Recent exposure to a known allergen for the patient. The patient should be observed for immediate adverse reactions.

5.2.2 Following administration of any vaccine the patient should be observed for 15 minutes to allow monitoring for any immediate reaction including possible anaphylaxis, as typically the onset of anaphylaxis occurs within minutes.

6.0 Treatment of Anaphylaxis

6.1 As soon as anaphylaxis is suspected, **call for help**. Get a member of the team to dial 999 or 112 and state that there is a suspected case of anaphylaxis.

6.2 Treating a patient with anaphylaxis in the community will not be the same as in an acute hospital. Out of hospital, an ambulance must be called immediately and the patient transported to an emergency department.

6.3 Patient positioning: The patient should be placed in a comfortable position. The following factors should be considered:

- The patient with Airway and Breathing problems may prefer to sit up as this may make breathing easier.
- Lying flat with or without leg elevation is helpful for the patient with low blood
pressure (Circulation problem). If a patient feels faint, do not sit or stand them up – this can cause cardiac arrest.

- The patient who is breathing and unconscious should be placed on their side (recovery position).

6.4 **Breathing**: If the patient stops breathing, mouth to mouth or preferably bag valve mask ventilation should be performed.

6.5 **Epinephrine (Adrenaline)**: If the patient has clinical signs of shock, airway swelling or breathing difficulties, they should be given Epinephrine (Adrenaline) 1:1,000 administered by intramuscular injection. See National Immunisation Advisory Committee *Anaphylaxis: Treatment in the Community* (available at [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf)

6.6 **Cardiac Arrest**: If the patient has a cardiac arrest discontinue administration of IM Epinephrine (Adrenaline), initiate CPR and continue it until medical assistance arrives.
Anaphylaxis: Treatment in the Community

Anaphylaxis is likely if a patient, who, within minutes of exposure to a trigger (allergen), develops a sudden illness with rapidly progressing skin changes and life-threatening airway and/or breathing and/or circulation problems.

1. Get help
2. Call ambulance
3. Assess airway, breathing, and circulation
4. Send, wheeze, respiratory distress or clinical signs of shock
5. Lie patient flat with legs raised (unless vomiting, or respiratory distress increases)
6. Epinephrine 1:1000 (1mg/ml) IM
   - 0-5 years: 0.15ml (150micrograms)
   - 6-12 years: 0.3ml (300micrograms)
   - > 12 years: 0.5ml (500micrograms)
   - Adult: 0.5 - 0.6ml (500 - 600micrograms)
7. Use 27-25g needle for those < 100kg
8. Repeat every 5-10 mins, up to 3 doses
   Remember urgency of hospital transfer

1. Ambulance will be equipped with oxygen, Salbutamol and fluids.
2. If profound shock judged immediately life- threatening, give CPR/BLS if necessary.
3. If respiratory distress present, elevate head.
4. IM into middle third of anterolateral thigh, max intravenous effect 10 minutes after IM injection.

NOTE: Immediate administration of adequate doses of epinephrine will decrease patient mortality and morbidity. All patients with signs of a systemic reaction, especially hypotension, airway swelling, or difficulty breathing, should receive immediate intramuscular (IM) epinephrine in the anterolateral thigh.

The anterolateral thigh is superior to IM administration in the deltoid or subcutaneous injection

Suggested Anaphylaxis Kit

The availability of protocols, equipment and drugs necessary for management of anaphylaxis should be checked before each vaccination session

- Copy of "Anaphylaxis: Treatment in the Community" from Immunisations Guidelines for Ireland
- 3 x 1ml ampoules of Epinephrine (1:1000, 1mg/ml)
- 6 x Epinephrine auto-injectors, 150 mcg, 300 mcg and/or 3 x 500 mcg* (depending on age of vaccinees)
- 3 x 1 ml syringes
- Needles 3 x 16mm, 3 x 25mm, 3 x 37 - 40mm
- 1 pocket mask
- Sphygmomanometer (optional)
- Stethoscope (optional)
- Pen and paper to record time of administration of Epinephrine

The kits should be kept closed to ensure the drugs are not exposed to light and stored at room temperature. The kits require regular checking to replace drugs before their expiry date.

*Ensure that 500mcg auto-injectors have 25mm needles
7.0 Follow up

7.1 Following immediate management, all patients must be referred to hospital for observation, even if it appears that they have made a good recovery. Biphasic or late phase reactions occur in up to 20% of cases. They can be more difficult to treat than the initial episode. Patients should therefore be observed in hospital for at least 12 hours after severe anaphylaxis.

7.2 Record all actions taken including drug, dose, route, time and site of administration in patient notes.

7.3 In Ireland the Health Product Regulatory Authority (HPRA) is responsible for monitoring adverse reactions to medicines and vaccines. Of particular importance are all suspected reactions to newly authorised products, serious reactions to established products and all suspected reactions to vaccines.

7.4 The incident and all actions taken must be promptly recorded and the relevant National Incident Management Report Form completed (National Incident Report Form (HC NIRF 01 – VO2)) (April 2017) (available at https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v10-person.pdf )

7.5 The HPRA must be informed using the Adverse Reaction Report (Yellow) Card System available at www.hpra.ie.

8.0 Storage of Epinephrine (Adrenaline)

8.1 Epinephrine (Adrenaline) is light sensitive and so should always be stored in its box until required. The carriage of loose ampoules of Epinephrine (Adrenaline) is not recommended. It should be protected from heat, but does not require storage in a fridge. Check expiry date.

9.0 Caution

9.1 Do not administer Epinephrine (Adrenaline) intravenously. The IV route should be reserved for specialist use in hospital.

9.2 Epinephrine (Adrenaline) is available in different strengths and preparations. Each ml of solution for IM injection contains 1 mg of Epinephrine (Adrenaline).
Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1000 concentrate by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis.

This medicine protocol is a specific written instruction for the administration of Epinephrine (Adrenaline) by intramuscular injection to groups of patients who may not be individually identified before presentation for treatment.

This medicine protocol enables registered nurses and midwives in the voluntary and statutory services of the HSE who have undertaken the relevant education programmes to administer Epinephrine (Adrenaline) 1:1000 with reference to the Nursing and Midwifery Board of Ireland professional guidance, National Immunisation Advisory Committee and National Immunisation Office, HSE and in accordance with Summary of Product Characteristics for Epinephrine (Adrenaline) 1:1,000 as detailed by the Health Product Regulatory Authority (HPRA) at www.hpra.ie.

- Health Services Executive (2018) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis*. Dublin: Health Service Executive
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Dublin: Royal College of Physicians Ireland (Online Update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/)
- Nursing and Midwifery Board of Ireland (2015) *Practice Standards for Midwives* Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Professional Guidance* Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework* Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2014) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Dublin: Nursing and Midwifery Board of Ireland

The Nursing and Midwifery Board of Ireland defines medicine protocols as "written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medicine when a medicine protocol is in effect" (An Bord Altranais, 2007, p35).
Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis

### 1.0 Critical Elements

<table>
<thead>
<tr>
<th>Name of Organisation where medicine protocol applies</th>
<th>Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date the medicine protocol comes into effect</td>
<td>March 2019</td>
</tr>
<tr>
<td>Date for review of medicine protocol</td>
<td>March 2021 This is a controlled document and may be subject to change at any time.</td>
</tr>
<tr>
<td>Document prepared by:</td>
<td>Office of the Nursing and Midwifery Services Director, Health Service Executive, in collaboration with the National Immunisation Office at the request of the Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE</td>
</tr>
</tbody>
</table>

### Names and Signatures of the employing authority who is authorising the implementation of the medicine protocol

"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"

<table>
<thead>
<tr>
<th>Name: Dr. Kevin Kelleher, Assistant National Director Public Health, National Office for Public Health/Child Health, Strategic Planning and Transformation, HSE</th>
<th>Name: [Signature] [MKN 19719]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Dr Colm Henry, Chief Clinical Officer, HSE</td>
<td>Name: [Signature]</td>
</tr>
<tr>
<td>Name: Dr. Lynda Sisson, National Clinical Lead, Workplace Health and Wellbeing, HSE</td>
<td>Name: [Signature] [MKN 12552]</td>
</tr>
<tr>
<td>Name: Ms Mary Wynne, Interim Nursing and Midwifery Services Director, HSE</td>
<td>Name: [Signature]</td>
</tr>
</tbody>
</table>

Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis and Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1,000 by IM Injection by registered nurses and registered midwives. Version 3. 2019
### 2.0 Clinical Criteria

| Clinical Condition for use of the medicine protocol (World Health Organisation 2009): | Epinephrine (Adrenaline) Injection is used to provide rapid relief of hypersensitivity reactions to drugs and other allergens, and in the emergency treatment of anaphylaxis. Anaphylaxis can be described as a severe, systemic (whole body) allergic reaction. Signs and Symptoms of anaphylaxis: Possible early warning signs:  
- Itching of skin, rash and swelling around the injection site  
- Dizziness and general feeling of warmth  
- Painless swelling in parts of the body e.g. face or mouth  
- Flushed, itchy skin, nasal congestion, sneezing, tears  
- Hoarseness,  
- Swelling of the face, difficulty breathing  
- Nausea, vomiting, abdominal pain  
Life threatening symptoms:  
- Wheezy, difficulty breathing, collapse, low blood pressure, weak pulse |

It is important that anaphylaxis is differentiated from other more common and less serious reactions to vaccination, e.g. simple faints (Vasovagal episode), anxiety attacks and breath holding episodes.

| Circumstances in which the medicine protocol applies | This medicine protocol applies in the management of a patient with anaphylaxis or suspected anaphylaxis. |
| Inclusion criteria for patient/service user treatment using the medicine protocol | This medicine protocol applies to treatment of:  
- Adults  
- Children |
| Exclusion criteria for patient/client treatment using the medicine protocol | None |
| Actions to be taken for those who are excluded from the medicine protocol | Not applicable |
| Referral arrangements if further advice or consultation is required | As soon as anaphylaxis is suspected, call for help. Get a member of the team to dial 999 or 112 and state that there is a case of anaphylaxis. |
3.0 Details of Medicine to be supplied

<table>
<thead>
<tr>
<th>Name of Medicine</th>
<th>Epinephrine (Adrenaline) Injection BP 1:1,000, 1ml ampoule (1mg)</th>
</tr>
</thead>
</table>

**Route/Method of Administration**: Intramuscular injection. The anterolateral thigh is superior to IM administration in the deltoid or subcutaneous injection.

**Dose and Frequency of Administration**

- **Dose by age**:
  - 0 – 5 years: 0.15ml (150micrograms)
  - 6 – 12 years: 0.3ml (300micrograms)
  - >12 years: 0.5ml (500 micrograms)
  - Adult: 0.5 – 0.6ml (500 – 600micrograms)

- Use 21G 37-40mm needle for those ≥ 100Kgs

*See Algorithm for Emergency Management of Anaphylaxis NIAC Guidelines*

<table>
<thead>
<tr>
<th>Potential adverse reactions.</th>
<th>Tachycardia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Palpitations</td>
</tr>
<tr>
<td></td>
<td>Dyspnoea</td>
</tr>
<tr>
<td></td>
<td>Tremor</td>
</tr>
<tr>
<td></td>
<td>Headache</td>
</tr>
<tr>
<td></td>
<td>Dizziness</td>
</tr>
<tr>
<td></td>
<td>Cold extremities</td>
</tr>
</tbody>
</table>

Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis and Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1,000 by IM Injection by registered nurses and registered midwives. Version 3, 2019
<table>
<thead>
<tr>
<th><strong>Procedure for reporting Adverse Reactions to the Health Product Regulatory Authority</strong></th>
</tr>
</thead>
</table>
| The RNP registered nurse or midwife should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out online at [http://www.hpra.ie](http://www.hpra.ie) ("Report an Issue" tab) or through use of the downloadable or post-paid yellow card options. Downloadable forms may be completed manually and submitted to the HPRA via "freepost". Yellow cards are available on request from the HPRA at **01 6764971**.

- Suspected adverse reactions must be reported in accordance with criteria outlined by the HPRA. This includes any suspected adverse reactions brought to the attention of the registered nurse or midwife. HPRA reporting of suspected adverse reactions may be carried out online at [http://www.hpra.ie](http://www.hpra.ie) or through use of the yellow card system which is available in a downloadable format from the HPRA website, or on request from the HPRA. You may request adverse reaction forms via
  - Telephone number +353-1-6764971
  - Fax number +353-1-6767836
  - Email: info@hpra.ie

The incident and all actions taken must be promptly recorded in accordance with the *Management of a Patient with Anaphylaxis: Treatment in the Community* (National Immunisation Advisory Committee 2019) – available online at [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf)

<table>
<thead>
<tr>
<th><strong>Procedure for the reporting and documentation of errors and near misses involving the medicine</strong></th>
</tr>
</thead>
</table>
| In the case of medication errors that directly involve the patient/service user, i.e. wrong medicine/patient/dose/route being administered or another medication error, the registered nursing/midwifery staff must remain with the patient and closely monitor the patient/service user for any adverse reactions. Vital signs should be recorded and the patient should be reviewed by the registered nurse/midwife and medical practitioner.

- 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 – V10)) (May 2018), available at [https://www.hse.ie/eng/about/gavd/incident-management/nirf-01-v10-person.pdf](https://www.hse.ie/eng/about/gavd/incident-management/nirf-01-v10-person.pdf)

- The incident must be reported to the relevant line manager as soon as possible.

- The incident and all actions taken must be promptly recorded in the patient’s documentation/notes.

- The patient/service user and/or significant others should be informed of the incident.

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

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Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis and Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1,000 by IM Injection by registered nurses and registered midwives. Version 3. 2019
### Mechanisms for storage of medicine
- Keep the container in the outer carton
- Epinephrine (Adrenaline) is light sensitive and so should always be stored in its box until required.
- Do not store above 25°C
- Keep out of reach of children
- Nature and Content of Container: 1ml, clear glass ampoules.
- Pack size: 10 x 1ml ampoules
- Single use only. If only part used, discard the remaining solution

Any waste material should be disposed of in accordance with the “Healthcare risk waste management segregation packaging and storage guidelines for healthcare risk waste” 4th edition November 2010, available at

### Resources and equipment required
- Disposable kidney dishes/trays
- Gauze swabs, tape/plasters
- Sharps bins, and bags for disposal of other hazardous waste materials
- Alcohol hand rinse
- Access to telephone

### Audit process to identify appropriate use of the medicine protocol or unexpected outcomes
- All documentation to be held for review and audit purposes.
- Team meetings are advisable to review the use of the medicine protocol.
4.0 Patient/service-user care information

| Advice to be given to the patient/service user and/or carer before and/or after treatment | - Patient should be transported to an emergency department as soon as possible  
- All who had anaphylaxis should be advised of the benefits of wearing a device such as a bracelet that will inform bystanders of their anaphylaxis history  
- Advise the patient to contact their General Practitioner for follow up. |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Details of any necessary follow-up, action and referral arrangements</td>
<td>- Patient is transferred to the nearest emergency department as soon as possible.</td>
</tr>
</tbody>
</table>

5.0 Staff authorised to use medicine protocol

| Professional qualifications, training, experience and competence relevant to this medicine protocol | Professional Qualifications:  
- Registered as a nurse or midwife on the live Register of the Nursing and Midwifery Board of Ireland  
Training, Experience, Competence:  
- Basic Life Support for Health Care Workers within the last two years  
- Approved Anaphylaxis Treatment Training programme initially, with updates as required to maintain individual competence  
- Education programme for nurses and midwives on the use of the following medicine protocol:  
  - Medicine Protocol for the administration of Epinephrine (Adrenaline) Injection 1:1000 by Intramuscular Injection by registered nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (2019). |

Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis and Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection 1:1000 by IM Injection by registered nurses and registered midwives. Version 3. 2019
References


Appendix 5. 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.

<table>
<thead>
<tr>
<th>Physical Environment / Layout of the Vaccine clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES  NO</td>
</tr>
<tr>
<td>YES  NO</td>
</tr>
<tr>
<td>YES  NO</td>
</tr>
<tr>
<td>YES  NO</td>
</tr>
<tr>
<td>YES  NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Check for most up to date version of documents <a href="http://www.immunisation.ie">www.immunisation.ie</a>)</td>
</tr>
<tr>
<td>YES  NO</td>
</tr>
<tr>
<td>YES  NO</td>
</tr>
<tr>
<td>YES  NO</td>
</tr>
<tr>
<td>YES  NO</td>
</tr>
<tr>
<td>YES  NO</td>
</tr>
<tr>
<td>YES  NO</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Infection Prevention &amp; Control Precautions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES  NO</td>
</tr>
<tr>
<td>YES  NO</td>
</tr>
<tr>
<td>YES  NO</td>
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<tr>
<td>YES  NO</td>
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<tr>
<td>YES  NO</td>
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<tr>
<td>YES</td>
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<tr>
<td>-----</td>
</tr>
<tr>
<td>YES</td>
</tr>
<tr>
<td>YES</td>
</tr>
</tbody>
</table>

**Clinical equipment**

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

**After the vaccination**

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

**Useful resources & links:**


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](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](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](http://www.hpra.ie)


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](http://www.hpsc.ie/AZ/EMIToolkit/EMIToolkit.pdf)
Appendix 6. Advice from the National immunisation Advisory Committee regarding fever after COVID-19 vaccination
National Immunisation Advisory Committee

29 December 2020

Statement on fever following COVID-19 vaccination

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

Post immunisation fever

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

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