Protocol for the Administration of COVID-19 Vaccine by Registered Radiographers and Radiation Therapists under S.I. 245/2021

(This document is to be read in conjunction with the Master Medicine Protocol published by National Immunisation Office for administration of each COVID-19 vaccine)

<table>
<thead>
<tr>
<th>Name of Organisation where this protocol applies</th>
<th>Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE), non-HSE healthcare facilities and vaccination clinic centres. This protocol applies to CORU registered Radiographers and Radiation Therapists involved in the administration of COVID-19 Vaccine to vaccine recipients under this protocol.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date this protocol comes into effect</td>
<td>June 2021</td>
</tr>
<tr>
<td>Date for review of this protocol</td>
<td>June 2022</td>
</tr>
<tr>
<td>Document prepared by:</td>
<td>The Office of the Chief Clinical Officer (OoCCO) in collaboration with the National Health and Social Care Professions Office (HSCP) Office, The Irish Institute of Radiographers and Radiation therapists (IIRRT), and the National Immunisation Office (NIO). Clinical governance provided by the Clinical Lead appointed by the Chief Clinical Officer.</td>
</tr>
</tbody>
</table>
| Names and Signatures of the officers authorising the implementation of this protocol | Name: Dr David Hanlon, National Clinical Advisor and Group Lead Primary Care, HSE  
Signature: __  

Name: Ms Jackie Reed, National Lead, National Health and Social Care Professions Office, HSE  
Signature: _  

"On behalf of the HSE as the approving authority of the COVID-19 vaccination training programme for CORU registered Radiographers and Radiation therapists, I have read this protocol and authorise its implementation"  

Protocol for the Administration of COVID-19 Vaccine by Registered Radiographers and Radiation Therapists 2021/2022 – Version 1 (16/06/21)
Background Context:
CORU registered Radiographers and Radiation Therapists were listed in law (Statutory Instrument S.I. 245 of 2021) to legally administer vaccines during the 2021/2022 HSE COVID-19 Vaccination Programme. The National Health and Social care Professions (HSCP) Office was requested by the New Vaccinators working group to support development of the COVID-19 vaccination training programme for Radiographers and Radiation Therapists. A working group consisting of Radiographers and Radiation Therapists with relevant expertise was formed to review an existing vaccination training programme and to develop content for the training programme specific to Radiographers and Radiation Therapists. Clinical Governance to this work was provided by the clinical lead appointed by the Chief Clinical Officer. As stated in S.I. No 245 of 2021, this training programme is approved by the HSE following consultation CORU, the regulatory body for registered Radiographers and Radiation Therapists.

The Office of the Chief Clinical Officer (OoCCO) in collaboration with the National HSCP Office, the Irish Institute of Radiographers and Radiation therapists (IIRRT), and the National Immunisation Office (NIO) developed this Protocol for the administration of COVID-19 vaccines by registered Radiographers and Radiation Therapists. This protocol is specifically for the administration of COVID-19 Vaccine to vaccine recipients by registered Radiographers and Radiation Therapists. This protocol is valid for the 2021/2022 HSE COVID-19 Vaccination Programme.

This document sets out the specific requirements for Radiographers and Radiation Therapists to vaccinate using the COVID-19 vaccines, and the master medicine protocol published by NIO sets out the detail in relation to administration of each individual vaccine. Each Radiographer and Radiation Therapist participating in the COVID-19 vaccination programme must be familiar with and meet the requirements set out in this profession specific protocol as well as the vaccine specific master medicine protocol for each covid-19 vaccine to be administered.

This Protocol was adapted from the Office of Nursing and Midwifery Services Director (ONMSD) and NIO Medicine Protocol template for the Administration of COVID-19 Vaccine to vaccine recipients by registered nurses and registered midwives.

Legislation and related documentation:


2. S.I. No. 698 of 2020 MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 7) REGULATIONS 2020 4F(vi) - available online at S.I. No. 698/2020 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 (irishstatutebook.ie)


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**Definitions** (as it applies in this protocol)
- Registered Radiographers and Radiation Therapists means any Radiographers and Radiation Therapists registered with the Radiographers Registration Board of CORU.

**Professional qualifications, training, experience and competence required:**

- Must be registered with the Radiography Registration Board Register of Radiographers and Radiation Therapists as maintained by CORU.
- Must have completed all of the following (which will be provided, #5 will be provided if not undertaken in last 2 years)
  1. HSE approved (in accordance with Statutory Instrument No. 245 of 2021) COVID-19 vaccine education programme for registered Radiographers and Radiation Therapists (via HSELand). The module on the protocol for the administration of COVID-19 vaccine by registered radiographers and radiation therapists includes relevant links to the master medicine protocols on the NIO website for the administration of each COVID-19 vaccine to vaccine recipients. They must familiarise themselves to the content in the master medicine protocols for each COVID-19 vaccine and be aware of updates to the master medicine protocols.
  2. Intramuscular injection skills including medicine preparation online programme, followed by classroom-based workshop, and have been deemed competent in administering *COVID-19 Vaccines*.
  3. A number of recorded supervised episodes in administering the COVID-19 vaccines and deemed competent by the clinical lead of the vaccination center or by an appointed nominee (Appendix II).

Protocol for the Administration of COVID-19 Vaccine by Registered Radiographers and Radiation Therapists 2021/2022 – Version 1 (16/06/21)
4. Initial anaphylaxis programme ("National Anaphylaxis Education Programme for Health Care Professionals") via HSELand followed by classroom-based skills workshop. (Must complete subsequent updates every two years via HSELand Anaphylaxis e-learning programme available at www.hse.ie).

5. An accredited Basic Life Support training course within the last two years. This includes either the Irish Heart Foundation (IHF) HeartSaver AED or Pre-Hospital Emergency Care Council (PHECC) Cardiac First Responder courses. This Certificate should be valid for the duration of your role as vaccinator. It is imperative that you update these skills if the expiry date is during the period in which you are vaccinating. Failure to hold a valid basic life support certificate will make you ineligible to vaccinate.

   - Must complete and sign the Competency Assessment Form (Appendix I) for each COVID-19 Vaccine to be administered.

Details on the HSE Approved COVID-19 Vaccination Training Programme for Radiographers and Radiation therapists:

**Training Requirements:**

- Basic Life Support
  - theory and practical – External Provider
- Anaphylaxis Management Programme
  - theory - HSELand
  - practical – External Provider
- Intramuscular injection delivery including medicine preparation
  - theory and practical – External Provider
- COVID-19 vaccination education programme for registered Radiographers and Radiation Therapists (HSELand)
- Hand Hygiene for Clinical Staff - (HSELand)
- Aseptic Non Touch Technique - (HSELand)
- GDPR guidelines- (HSELand)

In addition to the above mentioned training, you must be familiar with:

- The HSE National policy on Consent 2019 and how to obtain consent from a vaccine recipient
- The law in relation to Assisted Decision-making (Capacity) and the principles of decision making how to deal with a person who has not given consent
- Guidance on consent for Vaccination for Covid-19

**Slide Presentations:**

COVID-19 vaccination education programme for registered Radiographers and Radiation Therapists (HSELand)

- Introduction to COVID-19 Education Programme
- Protocol for the administration of COVID-19 vaccine by registered Radiographers and Radiation Therapists 2021/2022 – Version 1 (16/06/21)
Radiation Therapists to vaccine recipients

- Professional and Legal Aspects of Vaccinations
- Immunisation Process
  - COVID-19 vaccine authorisation process (HPRA)
  - COVID-19 vaccine suspected adverse reactions reporting to HPRA
  - Clinical Trial Data and Vaccine Recommendation
  - Vaccine Storage and Handling
  - Preparing for Vaccination
  - Communicating about COVID-19 vaccine
  - MCQ Assessment

Documents (found on NIO website):
1. Master medicine protocol for the administration of Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA vaccine to vaccine recipients.
2. Master medicine protocol for the administration of COVID-19 Vaccine Moderna to vaccine recipients.
3. Master medicine protocol for the administration of COVID-19 Vaccine AstraZeneca to vaccine recipients.
4. Master medicine protocol for the administration of COVID-19 Vaccine Janssen to vaccine recipients.
5. Protocol for the administration of COVID-19 vaccine by registered Radiographers and Radiation Therapists to vaccine recipients.

Information on Medicine Protocol:

Medicine protocols are specific written instructions for administering a named medicine in a specific clinical situation, in this case the 2021/2022 HSE COVID-19 Vaccination Programme. The medicine protocol enables registered radiographers and radiation therapists employed as vaccinators in the COVID-19 vaccination programme who have undertaken the required HSE approved education and training programmes to administer COVID-19 Vaccine to vaccine recipients, with reference to and guidance from the HSE National Health and Social Care Professions (HSCP) Office, the IIRRT and the National Immunisation Advisory Committee (NIAC), the National Immunisation Office (NIO) and in accordance with the Summary of Product Characteristics for COVID-19 Vaccine as detailed by the European Medicines Agency (EMA).

Registered radiographers and radiation therapists operating within this medicine protocol are included under the state clinical indemnity scheme for the duration of the 2021/2022 HSE COVID-19 Vaccination Programme.

A medicine protocol has the following structure

- Critical elements
- Clinical criteria
- Name of medicine
- Information for vaccine recipient

Elements that require particular attention under some of these headings are listed below.

a. Clinical Criteria:
It is imperative that you familiarise yourself with the clinical criteria specific to COVID-19 Vaccine on the master COVID-19 Vaccine medicine protocol. This can be found via these links
You must be familiar with the following for COVID-19 Vaccine

- Clinical Condition for use of the medicine protocol
- Circumstances in which the medicine protocol applies
- Exclusion criteria for vaccine recipient using the medicine protocol
- Inclusion criteria for vaccine recipient using the medicine protocol
- Actions to be taken for those who are excluded from the medicine protocol
- Action to be followed for vaccine recipients who do not wish to receive the vaccine
- Description of circumstances and referral arrangements when further advice or consultation is required
- Documentation required to support implementation of the medicine protocol

b. Name of Medicine – a COVID-19 Vaccine:
It is imperative that you familiarise yourself with the clinical procedures specific to COVID-19 Vaccine on the master COVID-19 Vaccine medicine protocol. This can be found via these links

Comirnaty

Moderna

Please be aware that it is your responsibility to be aware of any updates in regards to these medicine protocols via NIO website
https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/

If you have any doubt or concern about this medicine protocol or the clinical criteria for the use of this vaccine you must highlight this and seek support from a senior member of the vaccination team

AstraZeneca

Janssen

Please be are aware that it is your responsibility to be aware of any updates in regards to these medicine protocols via NIO website
https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/

If you have any doubt or concern about this medicine protocol or the process in administrating your duties you must highlight this and seek support from a senior member of the vaccination team.

You must be familiar with the following in relation to COVID-19 Vaccine

- Dose and Route of administration.
- Ability to access the COVID –19 Vaccine product information and other data including instructions for supply and administration via the European medicine agency.
- The potential adverse reactions and procedures for treatment of same during the administration of COVID-19 vaccine.
- The Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA).
- The procedure for the reporting and documentation of errors and near misses involving COVID-19 Vaccine
- The resources and equipment required to administer COVID-19 Vaccine
- The Audit process to identify appropriate use of the medicine protocol or unexpected outcomes whilst administering COVID-19 Vaccine

Personal Protective Equipment (PPE) Requirements:
The vaccinator is expected to wear a surgical mask. Other PPE such as gloves are not usually recommended as administering vaccine is considered as a clean low contact clinical activity (however clinical judgement to be applied in each scenario). Infection control procedures such as hand hygiene and appropriate use of disinfectant wipes to clean surfaces are to be applied. PPE to be removed and safely disposed into healthcare risk waste bin (yellow bag) followed by hand hygiene.

For any further information please refer to
- the Infection prevention Control (IPC) standard precautions found in the NIO clinical guidance document
- the HPSC guidance for latest advice regarding PPE https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/ppe/
c. Information for vaccine recipient:
It is imperative that you familiarise yourself with the information for vaccine recipient specific to COVID-19 Vaccine on the master COVID-19 Vaccine medicine protocol. This can be found via these links

Comirnaty

Moderna

AstraZeneca

Janssen

Please be aware that it is your responsibility to be aware of any updates in regards to these medicine protocols via NIO website
https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/

You must be familiar with the following for COVID-19 Vaccine

- Be familiar with the Advice to be given to the vaccine recipient before and after treatment including common and uncommon local and general side effects of COVID – 19 Vaccine.
- Be able to explain to the vaccine recipient the process of follow-up, action and referral arrangements should local or systemic side effects occur following administration of COVID-19.

Consent:

- You must check before administering the vaccine that the person has given consent to receive the vaccine
- If a person has not already given consent, you must go through the consent process with the person, in accordance with the HSE Policy on Consent.
- You must assume that a person has the capacity to make the decision about taking, or not taking, the vaccine unless the opposite has been demonstrated.
- You must be aware that no other person such as a family member, friend or carer (and no organisation) can give or refuse consent on behalf of an adult who lacks capacity to consent
- Where a person is shown not to have capacity to consent, they may be vaccinated if it has been determined that vaccination is to their benefit and in accordance with their will and preference. See
In order to give valid consent, the potential vaccine recipient must:

- Receive sufficient information,
- Be communicated to clearly in plain English, in a comprehensible manner about the
  - Nature,
  - Purpose,
  - Benefits and
  - Risks of vaccination including any alternatives.
- Be acting voluntarily (that is, not under undue duress from anyone)
- Have the mental capacity (be ‘competent’) to make a particular decision at that time (HSE, 2019).

The individual must be informed of the best current information on:

1. The vaccine to be administered and against which disease it provides protection;
2. Benefits and risks of the vaccine and the risk of the disease;
3. Possible side effects of vaccination, when might they occur and how they should be treated (as per the protocol for the specific vaccine);
4. Common - even if minor - side effects and rare but serious/adverse outcomes;
5. The failure of an intervention to achieve the desired aim;
6. Risks associated with not taking the vaccine or taking an alternative approach; and
7. Must be given the opportunity to ask questions, before agreement to proceed or not with vaccination

Consent for vaccination may have been documented prior to meeting the vaccinator but the vaccinator should confirm this with the person prior to vaccination.

**Where the person does not have capacity**

Refer to the National consent policy and associated guidance. In the case of a person who has been assessed as lacking capacity to make a specific decision about vaccination for Sars-CoV-2, HSE National Consent Policy currently notes (5.6): “Irish case law, national and international guidelines suggest that in making decisions for those who lack capacity, the health and social care professional should determine what is in their best interests, which is decided by reference to their values and preferences if known”.

The Policy (5.6.3) notes that even if the individual lacks decision-making capacity in relation to this decision, the expressed views of the individual nonetheless carries great weight. If someone cannot express an opinion: “Decisions should be made in the best interests of the [person] bearing in mind the principles outlined above. It is good practice to inform those close to the [person] of the planned interventions and to seek their agreement if possible. However, it is important to remember that the primary duty of the health and social care professional is to the [person themselves]”. If an individual who lacks capacity can express a preference to receive or forgo an intervention, “[s]uch preferences should in general be respected.”

People who do not wish to have the vaccine should not be given against their will.
The vaccinator can proceed with vaccination when satisfied that such a determination has been conducted and documented, if the vaccine recipient is compliant to vaccination. Appropriate measures to relieve situational anxiety in the vaccine recipient may be used however the vaccinator should not proceed with vaccination if the recipient is actively resisting or refusing the vaccine. The vaccinator should seek senior assistance if in doubt whether to proceed.

As those aged 16-18 years old can give consent to a medical procedure, refusing to receive the vaccine should also be respected.

Links to useful information on supporting the consent process for the vaccination programme against Sars-CoV-2 (COVID-19) can be found via


References


S.I. No. 698/2020 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020 (irishstatutebook.ie)

S.I. No. 245 of 2021 Medicinal Products (Prescription and Control of Supply) (Amendment) (No.7) Regulations 2021. Dublin: Department of Health pdf (irishstatutebook.ie)


Acknowledgements

• The Irish Institute of Radiographers and Radiation Therapists for professional and clinical input in reviewing and developing content in this training programme

• The Association of Optometrists Ireland (AOI) for sharing of content in developing this training programme

• The Irish Society of Chartered Physiotherapists (ISCP) for sharing of content in developing this training programme

• The Office of Nursing and Midwifery Services Director (ONMSD) for sharing of content and for expert guidance in developing this training programme and for the support to upload the education programme on HSELand

• The National Health and Social Care Professions (HSCP) Office as the lead for developing the training programme for registered radiographers and radiation therapists

• The National Immunisation Office (NIO) for sharing of content and for expert guidance in developing this training programme
### Appendix I: Competency Assessment Form

**Self-Assessment of Competency to Administer COVID-19 Vaccine** 

<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 radiography and radiation therapy practice in relation to:  
  - RRB Code of Professional Conduct and Ethics, CORU  
  - NIAC Immunisation Guidelines for Ireland. | | | |
<p>| 2                  | I practice within my scope of practice to undertake administration of COVID-19 Vaccine under the medicine protocol | | | |
| 3                  | I have undertaken the education programme for registered radiographers and radiation therapists on the use of medicine protocol for the administration of COVID-19 Vaccine | | | |
| 4                  | I hold a valid Basic Life Support (Irish Heart Foundation or Pre-Hospital Emergency Care Council approved) Certificate | | | |
| 5                  | I have completed the injection skills training workshop, and been deemed competent following this training. | | | |
| 6                  | I have completed supervised administration of COVID-19 Vaccine and been deemed competent by the clinical lead of the vaccination centre or by an appointed nominee (Appendix II to be used) | | | |
| 7                  | I have attended the approved anaphylaxis education programme and I am familiar with the current medicine protocol on the administration of epinephrine by registered radiographers and radiation therapists. | | | |
| 8                  | I can outline the inclusion/exclusion criteria for administering COVID-19 Vaccine under the named medicine protocol. | | | |
| 9                  | 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. | | | |
| 10                 | I am familiar with the documentation required to support implementation of the medicine protocol to ensure safe administration of COVID-19 Vaccine. | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th>Description</th>
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<tbody>
<tr>
<td>11</td>
<td>In assessing suitability for vaccination I can undertake a clinical assessment of individuals within the scope of the medicine protocol.</td>
</tr>
<tr>
<td>12</td>
<td>I can provide information regarding COVID-19 Vaccine, benefits and side effects to vaccine recipients.</td>
</tr>
<tr>
<td>13</td>
<td>I am aware of the procedure for treatment and reporting of potential adverse reactions.</td>
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<td>14</td>
<td>I understand the procedure for reporting and documentation of medicine errors/near misses.</td>
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<td>15</td>
<td>I dispose of all equipment and sharps in accordance with guidance for Healthcare Risk Waste HSE (2010).</td>
</tr>
<tr>
<td>16</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>
</tr>
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</table>
| 17| 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 read  HSE National Consent Policy 2019 and Assisted Decision-Making (capacity) Act 2015 and understand its implications as applicable to COVID-19 vaccination |

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

Registered Radiographer/Radiation Therapist Signature:

__________________________________________

Date: ______________

RRB Registration Number: _________________
### Appendix II

**Sheet for recording supervised administration of intramuscular injection Skills Peer Review of competency to Administer COVID-19 Vaccine ----------- (Name of vaccine) under Medicine Protocol**

<table>
<thead>
<tr>
<th>Date</th>
<th>Age of Vaccine Recipient</th>
<th>Insertion site (Arm/Thigh) (Right/Left)</th>
<th>Reflection</th>
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(Note: A minimum of two should be given either on the right or the left side)

I have completed my supervised injection vaccinations ☐ Yes ☐ No

I feel confident in my abilities to perform injection vaccinations ☐ Yes ☐ No

Signature of registered radiographer/radiation therapist:

_______________________________________________________                  Date: ____________________

RRB Registration No. ________________

Signature of clinical lead of vaccination centre or appointed nominee:

_______________________________________________________                  Date: ____________________

If any deficits in theory and/or clinical practice are identified, the registered radiographer/radiation therapist must discuss with the relevant clinical lead of vaccination centre or appointed nominee and implement an 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 Injection skills competency:

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

Date to be achieved: ........................................

Supporting evidence of measures taken to achieve competency:

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

Signature of registered radiographer/radiation therapist:

_______________________________________________________                  Date: _________________
Protocol for the Administration of COVID-19 Vaccine by Registered Radiographers and Radiation Therapists 2021/2022 – Version 1 (16/06/21)

RRB Registration No. ________________

Signature of clinical lead of vaccination centre or appointed nominee:

______________________________________________________________________________ Date: ________________