

OPERATIONAL GUIDANCE FOR COVID-19 VACCINATION IN RESIDENTIAL CARE FACILITIES

Version 10.0
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Operational guidance for covid-19 vaccination in Residential Care Facilities		Document developed by:	Sub Group for Covid-19 Vaccine Process and Workflow for Residential Care Facility & The National Immunisation Office
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1) Scope and Context

This document outlines the Operational for the administration of the Covid-19 Vaccine for Adults aged ≥65 years and staff in Residential Care Facilities.

The Government has agreed and published a COVID-19 allocation strategy developed by the National Immunisation Advisory Committee (NIAC) and Department of Health, endorsed by the National Public Health Emergency Team (NPHE). It provides the provisional sequencing for groups to be vaccinated based on clinical priorities and ethical values. Adults aged ≥65 years who are residents of care facilities have been identified as at greatest risk of severe illness and death. In Ireland, in the first wave of COVID-19, 56% of deaths occurred in this setting. The sequencing model as set out in the National COVID-19 Vaccination Strategy suggests offering vaccination to all residents and staff in these sites.

The national model to provide Covid-19 vaccination to residents and staff is based upon the mobilisation of vaccination teams from each Community Health Organisation (CHO) with support from Residential Facility staff and other services (including the National Ambulance Service & Acute Hospital Services) to deliver vaccination for adults aged ≥65 years who reside in Residential Care Facilities and staff on site.

***Where there is a resident under 65 in a primarily older persons residential setting it is envisaged they will be vaccinated when the vaccination team is on site**

2) Clinical Guidance

Please see link for Clinical Guidance for Covid-19 Vaccination.

www.immunisation.ie

<https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf>

Glossary of Terms

EMA European Medicines Agency

HPRA HEALTH Products Regulatory Authority

NCCS National Cold Chain Service

NIAC National immunisation Advisory Committee

NIO National Immunisation Office

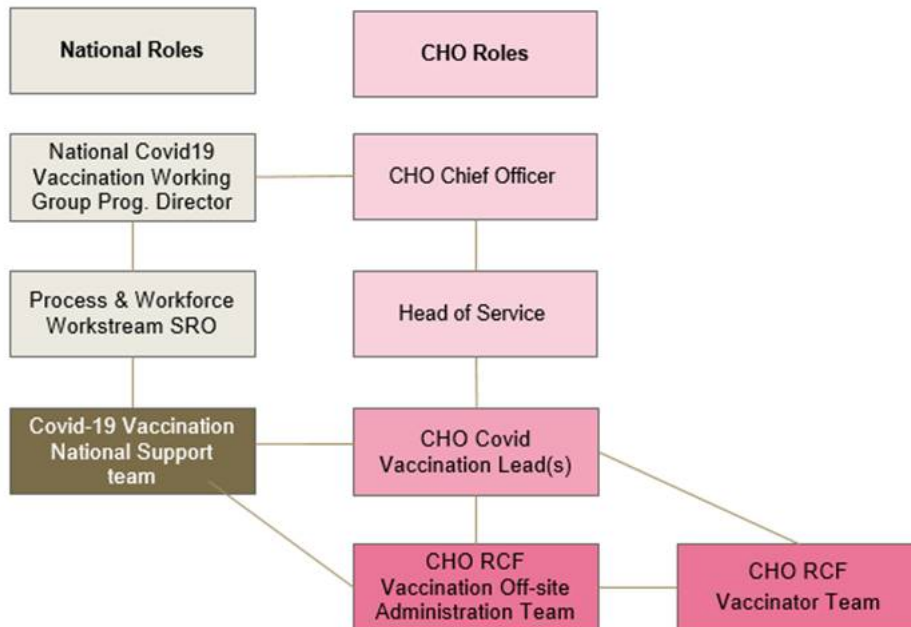
RCF Residential Care Facility

CHO Community Health Organisation

NAS National Ambulance Service

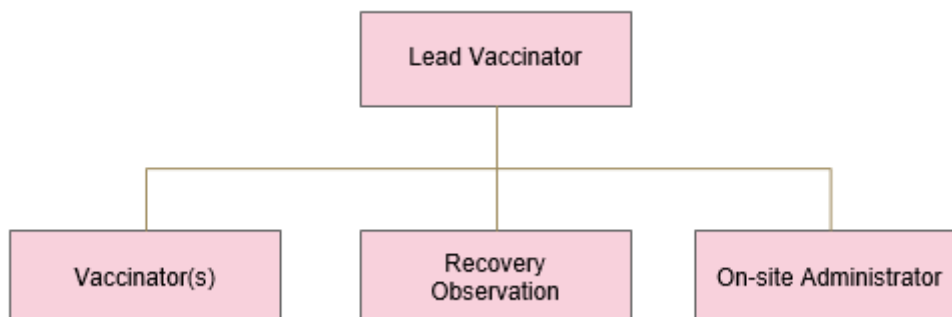
3) Governance and Communication Structures

A communication structure for vaccination in Residential Care Facilities is outlined in the diagram below



Clinical governance of the Vaccination team members will remain with their existing clinical management structure.

The proposed roles within the vaccinator team are:



4) Workforce

a. Role of Residential Care Facility Staff

- To liaise with members of the HSE Covid-19 Vaccination team and provide any information that may be required to ensure the safe delivery of the Covid-19 vaccine to staff and residents in their facility.
- To identify and delegate persons responsible for liaising with the HSE Covid-19 vaccination team
- To identify a person responsible for accepting delivery of the Covid-19 vaccine into their facility and maintaining the cold chain until the arrival of the HSE Covid-19 vaccination team, only in the event that the site has direct deliveries of vaccines from the National Cold Chain Service and has a monitored vaccine fridge in operation. Otherwise HSE staff should arrive with the vaccine in appropriate cool boxes.
- To liaise with members of the HSE Covid-19 vaccination team to ensure the readiness and preparation required for facilitating the vaccine in their facility – this may require liaising with the HSE Covid-19 vaccination team and arranging a site visit
- To ensure that their site and vaccinations areas are suitable and accessible to the HSE Covid-19 vaccination team
- To register all residents on the IBM Salesforce Platform
- To liaise with the HSE Covid-19 vaccination team in relation to any difficulties they have in relation to registering residents or staff on the IBM Salesforce Platform
- To ensure an adequate number of staff are working in their facility on the day the vaccination team visit.
- To ensure they prepare and review the rostering of staff in the days following vaccinations to ensure an adequate amount of staff available. The Residential Care Facility staff should be aware and familiar with any expected side effects following administration of a vaccine.
- Ensure that all Residential Care Facility staff are familiar with the processes following a vaccination
 - ✓ Who to contact in the event a resident becomes unwell following vaccination
 - ✓ The reporting process for any adverse side effects
- To liaise with the HSE Covid-19 vaccination team in planning the scheduling of residents and the order in which they will attend for the vaccine
- To prepare residents on the day of the vaccination by;
 - ✓ Ensuring they are appropriately dressed
 - ✓ Ensuring they are aware of the arrival of the vaccination team
 - ✓ Ensuring they have had something to eat before having their vaccination
 - ✓ Ensuring they have an appropriate person if needed accompany them for their vaccination
- It is requested that the Residential Care Facility ensure that any additional supports residents may require following vaccinations are in place, e.g. activities to enable them to stay in the observation area for 15 minutes post vaccination
- To ensure they liaise with the Covid-19 vaccination team in relation to dates the follow up vaccination will be administered
- To ensure that their residents are aware that they will require a follow up vaccination

- To be aware of the need to support residents with special needs/cognitive impairment/communication difficulties as necessary

b. National Support Team

The role of the National Support Team is:

- To be a point of contact for the Covid-19 Vaccination leads re issues arising that need to be addressed nationally, e.g. ICT issues / Procurement issues / cold chain
- Support risk management and issue resolution
- Monitoring of activity and performance
- Supporting a standardised approach and facilitate sharing of knowledge and learnings across areas
- Ensuring communication in a standardised manner with key stakeholders including CHO Leads and representative bodies as applicable
- Advising local teams with regard to protocol changes in a timely manner

c) Community Healthcare Organisation Lead for Covid-19 Vaccination

The role of the CHO lead for Covid-19 Vaccinations will be

- A single point of contact within their respective CHO
- A single point of contact for the National structure

The role will involve

- Providing information from National Groups to their local management structure and vaccination teams.
- Provide feedback from the local management structures and local teams to the National Groups
- Organise engagement with Residential Care Facility's e.g. Briefings, communication etc.

The role will have oversight for;

- Quality assurance
 - ✓ Ensuring adherence Policies, Procedures, Protocols and Guidelines (PPPG) and training
 - ✓ Audit
 - ✓ Risk Assessment
- Work with existing CHO management structures to ensure readiness for the delivery of the Covid-19 Vaccine at CHO and LHO level. This will include reviewing;
 - ✓ Training of staff
 - ✓ Communications and information
 - ✓ IT support and preparedness
 - ✓ Workflow processes

- The delivery of the Covid-19 Vaccine in their perspective Community Healthcare Organisation within the timeframes specified including overall responsibility to deliver the schedule for administration of the vaccine in Residential Care Facility's
- Ensure the local coordination of any 'mop up' vaccination for persons (Residential Care Facility staff and residents) who are unable to be vaccinated at appointment date within the Residential Care Facility.
- The role will involve working with the CHO Administration team in the roll out of the vaccines within their Community Healthcare Organisation. This will involve working collaboratively with key partners across the health and social care system including;
 - ✓ Members of the multiple CHO care groups and partner contacts in Residential Care Facilities.
 - ✓ Members of the hospital group work stream
 - ✓ Members of the IT management system
 - ✓ Members of the logistics group
- Developing excellent relationships with stakeholders supporting teams and local management structures to roll out the vaccination programme
- The Community Healthcare Organisation Lead will feed back information from National Groups to the vaccination teams, ensuring compliance with National Policy and Standards

d. CHO Covid-19 Vaccination Off-site Administration Team

The CHO Covid-19 vaccination off-site administration team will be responsible for the following;

- Ensure coordinated and planned approach to the administration of the vaccine within Residential Care Facilities
- Engaging with Residential Care Facilities in relation to registration of residents and staff and scheduling of vaccinations
- Engage with cold chain in relation to vaccine supplies, and procurement in relation to consumables
- Provide point of contact for logistical support for Residential Care Facilities and vaccination teams
- Rostering the CHO Covid-19 vaccination teams
- Will communicate local and national policies in relation to the administration of the Covid-19 vaccine administration
- Prepare reports on activity as required

e. Role of Vaccination Team

Roles and responsibilities may be assigned to team members at CHO level according to the professional qualifications and expertise of team members and available resources.

It is the responsibility of each member of the vaccination team to ensure the smooth through flow and safety of all residents and staff at all times.

It is the responsibility of all members of the vaccination team to ensure they are up to date with the appropriate training required to carry out vaccinations.

It is the responsibility of each member of the vaccination team to ensure they work within their scope of practice. Should they feel that they are in a position that requests them to work outside their scope they should consult with the team lead.

It is the responsibility of each member of the vaccination team to ensure they are familiar with the following documents;

- Operational Guidance for covid-19 vaccination in Residential Care Facilities
- National Immunisation Guidelines for Ireland. Chapter 5a Covid-19
<https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf>
- HSE Clinical Guidance for COVID-19 Vaccination
<https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf>
- Data Protection Policy <https://www.hse.ie/eng/gdpr/hse-data-protection-policy/hse-data-protection-policy.pdf>
- National Consent Policy <https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/national-consent-policy-hse-v1-3-june-2019.pdf>
- IPC guidelines <https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectionpreventionandcontrolguidanceandframework/Interim%20HSE%20Guidance%20on%20IPC.pdf>
- "Anaphylactic Reactions: Treatment in the Community" protocol, in the Immunisation Guidelines for Ireland available at <http://bit.ly/NIACGuideline>
- HSE Communicating Clearly with Patients and Service Users guidelines
<http://bit.ly/CommClear>

f. Lead Vaccinator ADPHN/PHN/CNM/ RGN/Community Medical Doctor/Medical Officer

Key liaison with CHO project team to ensure logistics and equipment supplies are arranged and delivered to Residential Care Facility site prior to vaccination commencement.

Communication with Residential Care Facility Person In Charge (Person In Charge) and Residential Care Facility staff to ensure completion of site visit prior to vaccination commencement.

- Identify and agree actions with Person In Charge to be undertaken at Residential Care Facility to ensure facilitation of the vaccination conduct Team lead on day ensuring;
 - ✓ All team members are clear of roles and IPC considerations for site
 - ✓ Cold chain vaccine management and reporting of any breaks and any unused vaccine.
 - ✓ Consent protocols are adhered to and vaccine evidence and aftercare provided
 - ✓ Session Reporting is completed (online) with each vaccinators PIN
 - ✓ Verification of Vaccines and equipment with other vaccinators
 - ✓ Reporting of adverse effects
 - ✓ Complete session report form (see Clinical Guidance Document <https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf>) including inventory to account for all doses of COVID-19 vaccine delivered to site
 - ✓ Ensure anaphylaxis kits are brought to each session and cool boxes where required.

- Administer vaccine
- Manage team using 'time out' protocols.
- Work with Residential Care Facility Person In Charge and CHO Administration Team to arrange 'mop up' clinics residents and staff not able to participate on the day

The lead Vaccinator will be the key liaison with the CHO project team their responsibilities will include;

- Responsible for ensuring the number of residents and staff registered to receive the vaccine has been communicated to the vaccine suppliers
- Responsibility for ensuring equipment supplies are arranged and delivered to Residential Care Facility site prior to vaccination commencement.
- Will arrange communication with residential care facility person in charge and project team to ensure completion of site visit prior to vaccination commencement.
- Will ensure all team members are clear of their roles and responsibilities and IPC considerations for the site
- Will ensure cold chain vaccine management and report any breaches that may occur
- Will ensure the adherence to processes for returning any unused vaccine under cold chain conditions.
- Will ensure consent protocols are adhered to and vaccine evidence and aftercare are provided
- Will ensure the session report is completed at the end of the vaccination session and must contain each vaccinators PIN/MRN
- Ensure compliance of medication protocols and medication management standards
- Responsible for reporting any adverse events to the Health Products Regulatory Authority that may occur while the vaccination team are on site
- Ensures staff report incidents on the NIMS System
- May be required to administer the vaccine as per Immunisation Guidelines for Ireland
- Will be responsible for calling 'time out' at the beginning of the vaccination session, and at any stage there may be a change to the flow/routine to the vaccination session
- Works with Residential Care Facilities Person in Charge and CHO Project team to arrange mop-up clinics of any residents and staff not able to participate on day.
- Delegates the team responsibilities and ensures each team member is aware of their role and responsibilities during the vaccination session
- The team lead will ensure that all vaccines are used within the recommended time frame following reconstitution
- Ensure all members of the vaccination team are familiar with the location of the;
 - ✓ Fire exits
 - ✓ Toilets
 - ✓ Rest areas
 - ✓ Exit and entrance

g. Vaccinator; RGN/PHN/RGN/Community Medical Doctor/Medical Officer/Paramedic

- Administers vaccines to Residential Care Facility staff and residents ensuring verification of consent prior to administration.
- Responsible for;
 - ✓ Set up of vaccination area and inventory check
 - ✓ Verification of vaccine and equipment with one other vaccinator/lead
 - ✓ Clinical waste management
 - ✓ Completion of reports/online records
 - ✓ Safe transition to recovery area
 - ✓ End of day packing away and inventory update.
- Work with Residential Care Facility Person in Charge and CHO Administration team to arrange mop-up clinics of any residents and staff not able to participate on the day.
- All vaccinators are responsible for administering vaccines as per Immunisation Guidelines of Ireland.
- All vaccinators are responsible for ensuring they have received the appropriate training required to administer vaccinations.
- All vaccinators are responsible for;
 - set up of the vaccination area and inventory check
 - verification of vaccine and equipment with one other vaccinator/lead
 - clinical waste management
 - completion of reports/online records
 - safe transition to recovery area
 - end of day packing away and inventory update

h. Onsite Administrative Support

- Ensures documentation and information materials are available
- Provides IT system support
- Checking in of resident and staff
- Supports vaccinators and recovery nurse/medic as required
- Links with Residential Care Facility to ensure smooth through-flow of residents and staff
- Collates records including required mop-up of residents and staff

Recovery Observation Nurse/Paramedic/Health and Social Care Professional/Community Medical Doctor/Medical Officer (requires anaphylaxis training)

- Provides safe space for individuals to be observed for 15 or 30 min post vaccination
- Ensures individual/carer is provided with evidence of vaccination and aftercare information
- Observes recover in partnership with Residential Care Facility team
- Observes recovery in partnership with Residential Care Facility team
- Identifies signs and symptoms of adverse reactions and follows adverse events protocols. Anaphylaxis protocol as per NIAC guidelines in the event of anaphylaxis.
- Links with emergency services and local hospital regarding transfers to hospital

i. Other roles

i. National Supporting Services e.g. Order of Malta, National Ambulance Service

- Responsible for assisting the HSE Covid-19 vaccination teams as required
- Responsible for clinical governance for staff
- Responsible for ensuring that any staff assisting with the vaccination teams are fully trained and work within their scope of practice.
- Responsible for liaising with HSE CHO Covid-19 project team re schedules and assist with workforce planning.

ii. Logistics

- Logistics team responsible for liaising with CHO Covid-19 project team and Residential Care Facility's to discuss scheduling delivery of vaccine and consumables
- Logistics team to clarify what the process will be for returning any unused vaccine and collection of cool boxes/sharps boxes

iii. Hospital

- Responsible for provision of mop up vaccination appointment for staff working in Residential Care Facilities

5) Briefings/Training

a. Residential Care Facilities

Residential Care Facilities will be supported by CHO Vaccination leads.

Initial briefings for Residential Care Facility staff will cover the information in this guidance including roles and responsibilities of;

- Consent including assisted decision making
- Registration using the online system
- Vaccination day preparation including site visit and logistics
- Typical Day scenarios for vaccination
- Adverse events and incident protocols

b) Vaccination Teams

To ensure that training can be delivered in a timely manner, initial launch of the training programme will be delivered by webinar. The training will then be hosted on HSEland. All members of the vaccination team will complete this training as appropriate.

Vaccinators and recovery observation roles should ensure Basic Life Support (BLS) and anaphylaxis training is up to date. Update training be undertaken now if it has not.

- Consent and assisted decision making capacity: This training is available on HSEland
- COVID vaccination IT system training to be made available from IBM Salesforce

Upon completion of training vaccinators and recovery observation staff will be required to complete a self-assessment of competency and/or submit evidence of training to include evidence of BLS, anaphylaxis and COVID-19 vaccination training, to their clinical line manager.

Vaccination Teams will receive IT training to enable consent to be confirmed and vaccination details recorded. The system will also enable reporting of adverse events.

c) CHO Vaccination Off-site Administration Staff & Vaccination Team Leads

CHO vaccination leads and off-site administration team will receive regular email updates from the National support team.

6. Initial Preparation

A schedule of vaccinations will be agreed and the CHO team will confirm date for vaccination. The Residential Care Facility Person in Charge will inform residents, staff, and families in advance, place posters to keep everyone informed. The assigned lead person from the residential service will be identified to communicate with the CHO team and answer questions and provide support to residents and families.

Vaccination should be deferred until clinical recovery from COVID-19 infection 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 those with persisting symptoms post COVID-19 infection unless there is evidence of recent clinical deterioration.

The CHO team will contact the Residential Care Facility to arrange site visit where practical and complete the following checklist. Both CHO teams and Residential Care Facility need to familiarise themselves with the infection prevention and control (IPC) guidance below.

a. Site Checklist

Facility Details		
Please return to the HSE Covid-19 vaccination team at your earliest convenience		
Name of Facility		
Facility Registration no		
Type of facility (Nursing Home, Community Unit etc)		
Address		
Eircode		
Date of Site Visit (if completed)		
Date of Vaccination team visit		
Expected date of vaccine delivery		
Date of vaccine delivery		
Access to Broadband/Wifi	Yes	No
Wifi login details		
Access to power supply/extension lead requirements		

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Meal times considerations applicable? (if yes, detail below)	
Shift times considerations applicable? (if yes, detail below)	
Residential Care Facility Staff details	
Person in Charge on date of vaccination team visit	
Mobile no for person in charge	
Person responsible for receiving team on vaccination day	
Phone no of person responsible	
Name of person responsible for accepting delivery of vaccine onsite	
Phone no of person responsible for accepting delivery of vaccine onsite	
Name of person responsible for maintenance of cold chain until the arrival of vaccination team	
Phone no of person responsible for maintenance of cold chain until arrival of vaccination team	
Number of staff	
Number of staff registered to be vaccinated	
Number of staff not consenting to vaccination (note this may not be known finally at this stage)	
Number of staff pending registration	
If possible please provide a list of staff to be vaccinated and order of same (Staff on night duty should be vaccinated first in the morning)	
Resident details	
Number of residents	
Number of residents registered to be vaccinated	
Number of residents not consenting to be vaccinated (note this may not be known finally at this stage)	
Number of residents pending registration	
Number of residents who have special needs/cognitive impairment or any communication difficulties	
Number of residents who have mobility issues	
If possible please provide a list of residents to be vaccinated and order (the vaccination team may assist with this at the site visit)	
Vaccination Facility requirements	
Access to hand washing facilities with hot water, paper towels and bin	
Access to toilet facilities as close to vaccination area	
Access to tea/coffee making facilities	
Check in/reception area	
Washable table and chair	
Accessibility to hand sanitising for residents and accompanying staff/family member at entrance to vaccination area	
Vaccination area	
Area should be suitable to complete clinical assessments and vaccine delivery	
Room should enable residents confidentiality and privacy	
1 washable table and chair per vaccinator 1m apart	
1 washable chair for resident 1m from table	

Area is well ventilated	
One way access preferable	
Post vaccination/Observation area	
To be immediately adjacent to vaccination area	
Chairs for residence to wait for 15 minutes (30 mins in some circumstances)	
If possible access to bed or bedroom nearby for management of any potential effects	

Meal Times		
Breakfast	Lunch	Afternoon tea/Dinner

The vaccination team will schedule the vaccinations around meal times

Shift Times			
Day shift	Morning shift	Afternoon shift	Night shift

The CHO vaccination team will discuss with the Residential Care Facility regarding arrival times to facilitate staff working the attached shifts

Operational Requirement Checklist	
Week prior to vaccination team visit	
Liaise with Vaccination teams and facilitate a site visit/virtual visit to discuss site readiness/preparation	
Accommodate site visit/ virtual visit by member of the vaccination team	
Work with vaccination team in planning the order residence will receive their vaccinations	
Share site map with vaccination team if available	
Provide list of residents and staff to IBM Salesforce system	
Disseminate Patient Information Leaflet to residents and staff	
Supports are put in place to ensure informed consent from all residents including those requiring additional supports to consent. This is clearly documented. (See consent information attached)	
Complete Electronic consent for residents who require additional support	
Liaise with vaccination team regarding schedule of vaccinations on the day and follow up visits	
Ensure adequate staff are available on the day of vaccination team visit to facilitate flow of residents to and from vaccination area	
Days prior to vaccination team visit	
Ensure all excess furniture is removed from the rooms identified for use by the vaccination team	
Where possible ensure there is sufficient fridge capacity for vaccines with data logger	
Ensure there is sufficient storage space for the vaccine consumables and waste generated by the local vaccination teams.	

Liase with Vaccination teams regarding site readiness	
Ensure there is an area suitable for vaccine preparation this must be a clean area with a large washable table	
Ensure all Residential Care Facility staff are aware of the arrival of the vaccination team	
Ensure all Residential Care Facility staff are aware residents to be dressed in a manner that provides ease of access to upper arm on the morning of vaccination	
Ensure all staff residents family members are aware of time and date of vaccination team visit	
Ensure vaccination team are aware of any resident that has a history of fainting	
Ensure vaccination team are aware of any residents who have a history of medical conditions/medications/allergic reactions etc	
Ensure the safe storage of consumables delivered by the HSE	
Ensure the safe storage of vaccine delivered by HSE - maintenance of the cold chain	
Morning of vaccination team visit	
Ensure residents are dressed appropriately to facilitate easy access to the upper arm	
Ensure all residents have a meal before receiving vaccine	
Ensure all residents are reminded of vaccination team visit	
Ensure a familiar person is present with residents to confirm identity, create calm environment and to discuss medical history with vaccinator	
Ensure person responsible for meeting with the vaccination team is available	
Post vaccination/Observation area	
Ensure there is adequate staff to assist with any resident that may have difficulty waiting in the observation area for 15 minutes (30 mins in some circumstances)	
Ensure calm activity, refreshment is available for any resident who might require this following vaccination	
Ensure adequate experienced staff available to monitor residents in the hours following vaccination	
Ensure all staff are familiar with the procedure following vaccination in the event they experience any issues/concerns (see HSE guidance given)	
Ensure residents are aware there will be a repeat visit required	
Confirm with the vaccination team the scheduled date of 2nd dose/mop up visit	

**b. Infection Prevention and Control; General infection prevention and control
Guidance for Long term care facilities in relation to vaccine administration**

Each unit need to identify a designated vaccination and observation area for the purpose of administering COVID -19 vaccinations. The area should have a separate entry and exit point to allow for smooth access and egress. A separate space for clinical observation post vaccine is recommended. Extraneous items and equipment should be removed from the area identified for vaccination. Therefore residential services need a clear plan in place to manage resident and staff flow on the day of vaccinations.

The area chosen must have enough space to safely maintain minimum distancing between residents and must be capable of accommodating staff working in the vaccination areas. Maintaining a minimum distance of 1m between all patients/service users at all times in so far as practical to do so reduces risk of contact and droplet transmission from people with unrecognised colonisation or

infection. Note however that a recommendation for mask use within a distance of 2m of a patient or other healthcare worker currently applies in the context a specific recommendation to this effect by the National Public Health Emergency Team (NPHE) convened in the context of the COVID-19 pandemic.

The chosen areas for vaccination and observation post immunisation must have sufficient space to safely maintain minimum distancing between residents and must be capable of accommodating staff working in the area. It is the responsibility of each individual service to ensure that an appropriate management plan is in place to identify potential risks and ensure safe capacity levels of the chosen vaccination areas so that residents and healthcare workers can maintain minimum distancing. It is recommended that residents attend the vaccination area in their designated social pods allocated to them within each LTCF of 4-6 residents if capacity of chosen area allows for safe social distancing. It is advised that all residents continue to be monitored twice daily and only asymptomatic residents attend group vaccination sessions within their pre-planned social pods in the designated vaccination areas. If a resident is unable to attend this area it is recommended that they receive their vaccine at the end of the clinic in their room to reduce cross contamination and disruption to the entry and exit flow.

What equipment will I need to be compliant with IPC standards?

- Alcohol hand gel
- Tissues
- Alcohol wipes
- Approved detergent wipe or combined Disinfectant /detergent wipes or solution
- General waste bin
- Healthcare risk waste bin
- Sharps container
- Clean tray/ kidney dish
- Spillage kit
- PPE: Surgical mask and access to plastic apron and gloves

Arrival at Vaccination Site

When the vaccination team arrive on site they are required to go through the same procedure as all other essential workers who visit the facility; including compliance with all IPC measures that are currently in place. The vaccination team will then proceed to setup their work flow area inclusive of hand hygiene station, PPE and the waste stream including sharps management.

An outbreak should be notified to the vaccination team for risk assessment in relation to progressing with the vaccination session.

All members of the vaccination team and residential setting must adhere to standard precautions. Standard Precautions are a group of routine infection prevention and control practices and measures that should be used for **all** clients at **all** times regardless of suspected, confirmed or presumed infectious status, in **any** setting in which healthcare is delivered. When Standard Precautions are consistently implemented, the risk of spread of infection to HCWs and clients is minimised. Standard Precautions are based on the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin and mucous membranes may contain transmissible infectious agents.

Client Placement

Standard precautions must be applied to all patients at all times, further risk assessment needs to be undertaken on an individual basis if there is a risk of cross contamination. To reduce risk maintaining a minimum distance of 1m between all patients/service users at all times in so far as practical is recommended

PPE

In addition to standard precautions the recommended PPE use for the vaccination team is a surgical mask. The requirement for additional PPE such as apron and gloves is based on a risk of blood and/or body fluid exposure.

The use of gloves, apron, and eye protection by vaccinators should be solely based on risk of exposure to bodily fluid. Gloves should not be used as an alternative to good hand hygiene practice and must only be used in conjunction with WHO5 moments of hand hygiene. Further guidance regarding PPE is available at <https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/ppe/>

Residents should be encouraged to wear a mask during the vaccination or observation process if tolerated.

Where an RCF is experiencing an outbreak additional PPE may be required as per HPSC Guidance.

Hand Hygiene

Healthcare workers should clean their hands as per the WHO 5 moments of hand hygiene (see Appendix ii: Poster - Your Moments for Hand Hygiene, Vaccination Campaign). Effective hand hygiene relies on appropriate technique as much as on selection of the correct product. Inappropriate technique can lead to failure of hand hygiene measures to appropriately remove or kill microorganisms on hands despite the superficial appearance of having complied with hand hygiene requirements.

Hand sanitizers should be placed at the entry and exit points of the vaccination and observation areas. They should also be placed in close proximity (point of care) of the individual vaccinators in the administration zone of the resident to achieve the recommend WHO 5 moments of hand hygiene.

Residents should be encouraged and assisted to participate in Hand Hygiene as this can reduce risk of cross contamination by enhancing all key opportunities to the safety of the residents.

Maintain a Clean Environment and Work Area

To the greatest extent possible, the facility should be such as to allow all surfaces, particularly all contact surfaces to be readily cleaned and disinfected. There should be minimum equipment in the vaccination room to allow for all horizontal surfaces to be cleaned/disinfected easily between each patient. The facility should be free of any unnecessary objects. Areas/zones need to be clearly demarcated as clean or contaminated.

Decontamination

Clean frequently touched surfaces with detergent solution at least daily, when visibly soiled and after every known contamination. Clean general surfaces and fittings when visibly soiled and immediately after spillage. A detergent solution (diluted as per manufacturer's instructions) is

adequate for cleaning general surfaces. The area used for both vaccination and observation should be decontaminated at the end of the vaccination clinic.

The level of cleaning required depends on the objects involved and the risk of contamination. It is good practice to clean frequently touched surfaces routinely such as table top, chair, door handles etc. Frequently touched areas in the vaccination and observation areas should be cleaned between residents and staff. In general a neutral detergent can be used to clean surfaces. Detergent impregnated wipes may be used for a single piece of equipment or a small area but should not be used routinely as a replacement for the mechanical cleaning process. For further information on cleaning methods and product choice go to <https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectionpreventionandcontrolguidanceandframework/Interim%20HSE%20Guidance%20on%20IPC.pdf>

Multiple users can record information on the same laptop provided hand hygiene is performed and all high touched surfaces of the laptop are cleaned in-between each user.

Waste Management

Waste should be contained in the appropriate receptacle, identified by colour and label, and disposed of according to the facility waste management plan. Segregation should occur at the point of generation. The facility must also comply with any other legislation that controls the management of clinical and related waste (including sharps) and workplace health and safety.

The majority of dry non sharp waste generated as part of a vaccination clinic may be disposed of as healthcare non-risk waste/ domestic waste.

Non sharp items which are blood stained or deemed infectious should be disposed of as healthcare risk waste. For further information on waste see <https://www.hse.ie/eng/about/who/healthbusinessservices/national-health-sustainability-office/files/hse-waste-management-handbook.pdf>

Sharps Disposal

Where possible healthcare workers should choose needle free/ needle safe products to minimise the risk of a sharps injury. Sharps bins must be used for the disposal of sharps in a vaccination clinic in a residential setting. The following practice applies:

- Sharps bins should be assembled correctly before use
- Sharps bins should be securely stored at working height out of reach of clients, visitors and children
- Sharps should be discarded into a designated sharps bin at the point of use. Sharps trays with integral sharps bins are available and these can be taken to the point of care
- Syringes and needles should be disposed of as a single unit
- Needles must never be re-capped, bent, broken or disassembled
- Sharps bins should only be filled to the fill line ($\frac{3}{4}$ full) and then securely sealed
- Sharps bins should be disposed of as healthcare risk waste

- All clinical waste must be tagged to enable traceability

Injection Safety

Injection safety, or safe injection practices, is a set of measures taken to perform injections in an optimally safe manner for patients, healthcare personnel, and others. All healthcare workers who administer injections must understand the importance of safe injection practices. A safe injection does not harm the recipient, does not expose the provider to any avoidable risks, and does not result in waste that is dangerous for the community (e.g., through inappropriate disposal of injection equipment). Injection safety includes practices intended to prevent transmission of infectious diseases between one patient and another, or between a patient and healthcare provider, and also to prevent harms such as needle stick injuries. Safe injection practice includes practices relating to single and multi-dose injection vials and incorporates aseptic technique.

Standard Aseptic technique

In this context, standard aseptic technique refers to the manner of handling, preparing, and storing of medications and injection equipment/supplies (e.g., syringes, needles) to prevent microbial contamination.

Standard aseptic technique should be used in procedures that breach the body's natural defences and vaccination staff should be trained and competent in standard aseptic technique. The underlying principles of Standard aseptic technique are,

- Always wash hands effectively.
- Never contaminate Key-Parts/Key-Sites
- Touch non Key-Parts with confidence
- Take appropriate infection prevention and control measures

Needle Safety

It is good practice to dispose of single-use sharps immediately into an approved sharps container at the point-of-use. The healthcare worker who has administered the vaccine is responsible for the sharps immediate and safe disposal. Sharps containers must not be filled above the mark that indicates the maximum fill level.

The container should be located at the point of use or, must be appropriately placed so that they're at an accessible height for the healthcare worker but out of reach of others to prevent hands and fingers entering the disposal unit.

In the event of a sharps injury:

There are numerous safety devices available that assist with safe removal and disposal of sharps (for example scalpel blade removers). Local protocol and procedures need to be developed to outline their appropriate use. Reducing risks if a sharps injury is sustained: Please see Guideline for the

Emergency Management of Injuries and Post-exposure Prophylaxis (PEP) at
<https://www.hpsc.ie/a-z/EMIToolkit/>

Respiratory Hygiene and Cough Etiquette

Respiratory hygiene is vital to prevent the spread of respiratory infections. Respiratory hygiene and cough etiquette must be applied as a standard infection control precautions at all times. Covering sneezes and coughs prevents infected persons from dispersing respiratory secretions into the air. Hands must be cleaned after coughing, sneezing, using tissues, after contact with respiratory secretions or objects contaminated by these secretions. Wearing of a surgical mask (if tolerated) assists in reducing dissemination of respiratory virus however this does not replace minimum distancing between residents. Ensure there is an adequate supply of tissues, bins and hand gel in the vaccination and observation area in order to adhere to respiratory hygiene and cough etiquette.

Considerations when Responding to Adverse Events

PPE requirements when responding to adverse events as the same as listed above; standard precautions, surgical mask and, if there is a risk of body fluid exposure, apron and gloves.

Extract from lay rescuers guidance: <https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/layrescuersguidance/>

Although CPR is regarded as an Aerosol Generating Procedure (AGP) this is related to airway management as part of CPR. Use of an Automated External Defibrillator (AED) and performance of chest compression in the absence of airway management are not considered as AGPs associated with an increased risk of transmission of infection. If an ambu bag is being used a viral filter needs to be considered.

Considerations when Providing Vaccination at the Bed-Side

For bedside vaccination PPE is the same as listed above. Vaccinators need to adhere to standard precautions and wear a surgical mask within 2m of a resident. Particular attention needs to be given to hand hygiene when administering a vaccination. Sharps need to be disposed of at the point of care.

7) Workforce Planning/Preparation

a. Team definition (size of site)

Residential Care Facilities will be notified of the vaccination schedule at least 14 days prior to vaccination date wherever possible. This will enable time for the setting to consider staff rosters as additional staff may be required to support residents during vaccination and to free-up staff to access vaccination themselves.

The on-site vaccination teams are led by a lead vaccinator and this person will work closely with the Person in Charge in the Residential Care Facility to deliver the vaccine effectively and efficiently.

CHO Vaccination Team size and number of teams is dependent on the size and number of Residential Care Facilities in each CHO. The following modelling is based upon HIQA registered older adult nursing home settings.

Number of open nursing homes:	583
Number of registered beds:	32,212
Number of residents (includes registered beds where occupancy wasn't available)	29,456
Staff to resident ratio:	1.3
Staff Headcount (includes registered beds multiplied by ratio where staff headcount wasn't available):	41,856
Total to be vaccinated:	71,312
Average amount of time to administer 1 vaccine (minutes):	12
Number of vaccines administered per vaccinator per day:	35

The size of each residential setting is based upon either upon the number of staff and residents submitted by CHOs or in the absence of this data, the number of registered beds and staff at a ratio of 1.3 staff headcount per registered bed. The modelling allows for an initial vaccine allocation for every individual, thus assuming a 100% uptake. In reality each CHO team will engage with each Residential Care Facility directly to accurately define vaccine requirements to reduce vaccine wastage. The model is based both upon the mobilisation of vaccination teams from the CHO, and utilisation of existing peer vaccinators within Residential Care Facilities; this may include but not be limited to HSE Community Units, Psychiatry of Older Age and Nursing Home settings. Note that the **model and assumptions herein are still undergoing validation.**

Each RCF has been categorised into a size category ranging from A (1-70 people being vaccinated) to G (316 + people being vaccinated). The make-up of a team and the number of days vaccination will take is dependent on the size category.

There is a requirement for three different sizes of vaccinator teams:

- Team X (4.0WTE): 1 vaccinator lead, 1 vaccinator, 1 observation clinician, 1 administrator
- Team Y (5.0WTE): 1 vaccinator lead, 2 vaccinators, 1 observation clinician, 1 administrator
- Team Z (6.0WTE): 1 vaccinator lead, 3 vaccinators, 1 observation clinician, 1 administrator

Smaller sites of 70 or less people being vaccinated will require one team of four individuals over one day, and in comparison, a site with 106 -140 people being vaccinated will require a team of six individuals over one day. The larger sites will require more days to complete vaccination; with sites of over 281 people being vaccinated requiring three days. Teams with over 4 vaccinators (1 team lead, 3 vaccinators) have not been modelled due to the space limitations for vaccination and observation space in most residential care facilities.

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Number of Staff required on each team

Vaccination Team	Number of Vaccinations	Observation	Vaccinator	Admin	Days
A	1-70	1	2	1	1
B	71-105	1	3	1	1
C	106-140	1	4	1	1
D	141-210	1	3	1	2
E	211-280	1	4	1	2
F	281-315	1	3	1	3
G	316+	1	4	1	3

Note: One vaccinator per team will act as a vaccinator team lead

The following outlines the planned approach for delivery of the vaccine for RCFs for Older Persons. The planned approach for other RCFs, including those for Mental Health Services and Disabilities, will be defined at a later stage.

The distribution of RCFs per size category in each CHO is detailed in the table below. This enables us to consider the differing needs in each CHO.

Count of Nursing Homes

Number of Vaccinations Required:	1-70	71-105	106-140	141-210	211-280	281-315	316+	
CHO	A	B	C	D	E	F	G	Total
CHO 1	9	21	12	10	2	1	-	55
CHO 2	26	30	18	5	3	-	-	82
CHO 3	17	16	9	6	6	-	-	54
CHO 4	24	31	16	9	7	2	2	91
CHO 5	25	15	22	10	5	2	-	79
CHO 6	6	15	11	9	5	1	2	49
CHO 7	5	11	17	7	5	3	5	53
CHO 8	15	19	14	10	6	1	-	65
CHO 9	4	13	10	11	7	3	7	55
Total	131	171	129	77	46	13	16	583

Based upon this distribution of Residential Care Facilities the number of and size of vaccination teams per CHO can be calculated.

Staff Numbers Required for all first dose to be administered 21 days apart

Requirement if teams can move between counties within the CHO

CHO	Observation	Vaccinator	Admin	Total Staff
CHO 1	5	16	5	26
CHO 2	6	18	6	30
CHO 3	5	16	5	26
CHO 4	8	25	8	41
CHO 5	7	22	7	36
CHO 6	5	17	5	27
CHO 7	6	21	6	33
CHO 8	6	19	6	31
CHO 9	7	25	7	39
Total	55	179	55	289

Based on teams working 5 days a week over a 3-week period for vaccine 1; 6 weeks in total for administration of two vaccines.

The CHO Covid Vaccination Lead will communicate with Residential Care Facility sites that directly employ experienced vaccinators to ensure that these staff can be facilitated to access COVID vaccination training so they can support vaccination in their place of work. This may include but not be limited to HSE Community Units, Psychiatry of Older Age and Nursing Home settings. Wherever possible vaccinators that are familiar to residents and peers will be facilitated to support vaccine uptake in their setting.

b. Vaccination Scheduling and Rostering

The National Vaccine Schedule for Residential Care Facilities will be approved by the National Programme Team and disseminated to the Residential Care Facilities by the CHO Project Team.

The CHO Administration Team will be responsible for rostering of vaccination teams following the publication of the National Vaccine Schedule for Residential Care Facilities.

The table below outlines a typical day for vaccinator team members, based on an assumed 39-hour week.

Start time	End time	Activity	Duration
08:40	09:00	Set up	20 minutes
09:00	11:00	Vaccinations	2 hours
11:00	11:15	Break	15 minutes
11:15	13:00	Vaccinations	1 hour 45 minutes
13:00	13:30	Lunch	30 minutes
13:30	16.30	Vaccinations	3 hours
16:30	17:00	Final activities/finish	30 minutes

8) Informed Consent and Registration

Purpose

The purpose of this document is to clarify the issues relating to consent for vaccination against Sars-CoV-2. This document will lay out the principles and processes of consent generally and will then describe the consent process to be adopted in relation to the delivery of the vaccination for Sars-CoV-2.

Principles of Consent

Consent is the giving of permission or agreement for an intervention such as a vaccination following a process of communication about the proposed intervention. This requirement is consistent with fundamental ethical principles, with good practice in communication and decision-making and with national health and social care policy. The need for consent is also recognised in Irish and International law.

Informed consent involves a process of communication between a healthcare professional and an individual that enables that individual to have a clear understanding of the nature of the intervention, and likely risks and benefits of receiving it, thus enabling the individual to make an informed choice about whether or not to proceed. Individuals may withdraw their consent from a procedure at any time prior to the start of that procedure/intervention.

For informed consent to be valid, the individual must:

- Have received sufficient information in a comprehensible manner about the nature, potential risks and benefits of the proposed intervention, of any alternative intervention and of not receiving the intervention,
- Not be acting under duress; and,
- Have the decision-making capacity to make the decision (even if requiring support to do so).

There is no maximum duration for consent. Consent remains valid for an indefinite period unless:

- It is withdrawn
- There has been a change in the individual's capacity to give consent
- There has been a change to the proposed intervention to which the individual has previously given consent.

Consent and Vaccination for Sars-Cov-2

In order to give valid, informed consent, an individual should be provided with written information in advance. Information should be provided in an accessible format and translation/interpretation support should be made available as required. In the context of vaccination for Sars-CoV-2, the HSE Vaccination Leaflet should specify the vaccine being given. As a general principle, all material risks and benefits of the vaccine must be disclosed. Additionally, in relation to Covid-19 vaccination such information should include individual as well as societal benefits that may be conferred by 'herd immunity'.

For informed consent to be valid, the person must:

- Have received sufficient information in a comprehensible manner about the nature, potential risks and benefits of the proposed intervention, of any alternative intervention and of not receiving the intervention
- Not be acting under duress; and

- Have the decision-making capacity to make the decision (even if requiring support to do so).

For the purposes of vaccination for Covid-19, Statutory Instrument 698 of 2020 outlines those healthcare professionals who can supply, administer and consent for vaccination and include:

1. A registered nurse (including a registered midwife),
2. A registered pharmacist,
3. An advanced paramedic,
4. A paramedic,
5. An emergency medical technician, or
6. A person registered in the register of the Physiotherapists Registration Board established under section 36(1)(a) of the Health and Social Care Professionals Act 2005 (No. 27 of 2005),

Very specifically, it is important to note consent requirements in the following situations and that the general principles of consent apply:

1. Wards of Court: the Registrar of the Wards of Court has confirmed that there is no requirement to seek a Court Order or Court Consent for the administration of the vaccine. Individuals who indicate verbally or otherwise that they do not wish to be vaccinated should not be vaccinated. In the case of a dispute between the individual and their committee that cannot be resolved locally, the matter should be referred to the Registrar of the Wards of Court.
2. For individuals detained under the MHA 2001, the same principles of seeking consent also apply and detention does not preclude the need to obtain consent.

Situation/Condition-Specific Consent

While there is a general presumption that individuals have capacity to consent, there are situations when individuals may need additional supports to make decisions. Consent is always specific to the proposed intervention.

Impaired Capacity

If there are concerns about an individual's capacity to consent, the following considerations apply:

- Is the decision urgent or could it be deferred until the individual regains capacity to make their own decision?
- Where the individual has communication difficulties, every practicable effort should be made to support them through the use of communication aides or to support them with the assistance of others who may have an insight into how the person communicates.
- If the individual is unable with support to express fully their own will and preferences, any view that they can express will be central to the decision. This can be supported by discussions between Health Care Worker and trusted people close to the individual about the individual's will and preferences.
- The person should be given information in a manner and language that they understand in relation to the vaccination.
- The person should have access to an independent advocate and/or a someone nominated by the individual to support them in their decision-making e.g. a friend or family member.

Bearing in mind that all individuals are presumed to have capacity to give consent, an assessment of capacity should take place when there are concerns about an individual's capacity. There **are four key considerations in determining if a person has capacity to consent:**

1. Does the individual understand the information relevant to the decision, including the risks of refusing vaccination?
2. Is the individual able to retain the information long enough to make a decision?
3. Can the individual use and weigh the information to make a decision? This may involve enabling another person to help the individual.
4. Can the individual communicate the decision? Communication can be verbal, using sign language or any other means of communication.

An individual must fulfil all of these criteria in order to be determined to have capacity to make a decision. Individuals should be provided access to a private space to maintain confidentiality during the consent process, as far as is practicable. An individual's decision to refuse should be respected.

It is important to note that no other person such as a family member, 'next of kin', friend or carer and no organisation can give or refuse consent to vaccination on behalf of an adult person who lacks capacity to consent unless they have specific legal authority to do so. An attorney under the current Enduring Power of Attorney Act currently does not have authority to make a healthcare decision such as vaccination. The views of anyone the person has nominated to be consulted and of people who have a close, ongoing, personal relationship with the individual should be considered in ascertaining the individual's will and preferences, values, beliefs and values. Such persons do not have authority to give or refuse consent on behalf of the individual.

In the case of an individual for 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. in the presence of incapacity, the expressed views of the person 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."*

This procedure should be followed when considering vaccination for an individual who has been assessed as lacking decision-making capacity, noting that that the benefit of most people will be best served by vaccination. This is particularly the case for individuals in a higher-risk group. If the individual cannot express a preference, those with a close ongoing relationship to them should be informed about vaccination and asked to indicate what they think the individual's wishes would be. The outcome of this discussion should be documented in the healthcare record. **People who do not wish to have the vaccine should not be given it.**

Pregnant Women

In Ireland, to date, the incidence of Covid-19 amongst pregnant women has remained very low and there have been no Covid-related deaths in this group, unlike many other European countries. Although the available 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. Pregnant women who meet the priority criteria for vaccination and their obstetric caregivers should engage in shared decision-making in advance of vaccination. Counselling should balance available data on vaccine safety, risks to pregnant women from SARS-CoV-2 infection, and a woman's individual risk for infection and severe disease. Where the risk/benefit is favourable, the two doses should be given at least 21 days apart. The two-dose schedule should not commence before 14 weeks gestation and should be completed by 33 weeks gestation.

Digital Registration and Consent

A national registration system is now being constructed under the auspices of information technology within the HSE. Thus, individuals will be able to register and consent on-line. Others will also be able to register individuals who are either unable to register themselves or lack the capacity to consent to vaccination. Such a person could be a trusted friend or family member, the Person in Charge (PIC) of an RCF or the proprietor of a registered Mental Health Facility.

Impaired Capacity to Consent

There will be three options for those using the registration system in relation to consent:

1. I consent **OR**
2. I confirm this person has given me consent their consent for this (if an administrator/trusted other is entering the data on behalf of another person prior to or at the time of vaccination) **OR**
3. This person cannot give consent and is being vaccinated in accordance with an assessment of their best will and preferences.

Vaccinators will have access to this information at the time of vaccination. In the case of those for whom others register who have been deemed to lack capacity to consent, this is a registration, not a consent process, and the process of consent/determination of benefit/will and preferences should be recorded in the individual's healthcare record.

Pregnant Women

For these women, the following questions will pertain on the digital registration process:

- 1) Are you pregnant? (if YES, then...)
- 2) I am 14 weeks pregnant or more, but 33 weeks pregnant or less **AND**
- 3) I confirm I have discussed the risks and benefits of receiving the COVID-19 vaccine with my obstetric care provider, they have confirmed I am at the correct stage of pregnancy to receive the vaccine and complete the course of two doses before 33 weeks of pregnancy and I consent to receive the vaccine .

Summary

It is generally presumed that individuals have capacity to consent and informed consent involves providing sufficient and appropriate material to enable informed decision-making. A three-tiered approach to the provision of this information is recommended:

1. The essential information required for informed consent-the HSE Vaccine Information Leaflet.
2. Provide the product information leaflet which will be available on line and in hard copy.

3. More detailed information for those who would like it. There will be links on HSE website and accessible and available in other formats.

Information must be made available in other formats to those who lack digital access or may have issues with digital literacy.

The absence of complete access to a digital system should not prevent proceeding with vaccination, provided that the information required, e.g. for those with impaired capacity or pregnant women, is outlined in the patient record.

For those with impaired capacity, every reasonable effort should be made to enable a person to make an informed decision about receiving the vaccination. In situations where this is not possible, the final decision on whether or to vaccinate an individual lies with the healthcare professional, having assessed decision-making capacity specifically with reference to the four key questions set out above. The basis on which the individual has been assessed as lacking decision-making capacity to make this decision and the basis on which the benefit of the vaccine to the individual has been determined should be documented in the healthcare record.

Pregnant women should only be vaccinated, pending a shared decision-making process between themselves and their healthcare provider, between weeks 14 and 33 of gestation.

Documents Referenced/Considered

1. Assisted Decision Making Act 2015.
2. HSE Policy on Consent <http://bit.ly/ConsentQID>
3. Mental Health Act 2001
4. Advices of the Attorney General to the HSE regarding the Covid Vaccine 2020.
5. STATUTORY INSTRUMENTS. **S.I. No. 698 of 2020** MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 7) REGULATIONS 2020

9) Equipment and supplies

a. Residential Care Facility provided resources

As part of the preparation process the CHO team will liaise with the Residential Care Facility with regards to on-site resources. This may include;

- Tables and chairs
- Hand sanitizer and PPE for residents and staff
- Access to power supply (extension leads)
- Waste bin

b) Consumables and equipment

Please see table below

Pack Requirements per initial RCF vaccination:			
Item no	Item	Description	Comments
Consumable Items specific for Pfizer vaccine administration			
1	Needles for administration	23G x 25mm Needle	1 needle per administration/ injection of vaccine
2	Needles for Reconstitution	21G x 40mm Needle	1 needle per 6 dose vial of Pfizer vaccine
3	Syringes for administration	1ml Syringe marked 0.1ml graduations	1 syringe per administration/ vaccine dose
4	Syringes for Reconstitution	3ml Syringe marked 0.1ml graduations	1 syringe per 6 dose vial of Pfizer vaccine
5	Saline for reconstitution of Pfizer vaccine	Saline 0.9% NaCl 10ml ampoule	1 ampoule per 6 dose vial of Pfizer vaccine
6	Disinfectants	Alcohol Swabs (to wipe vial)	8 swabs per 6 dose vial
Ancillary consumables pack			Ancillary Consumables Pack (per 2 vaccinators)

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7	Sharps Containers	Sharps 5 litre bins	20,000 initially ordered in cases of 24	3 (On basis of 2 vaccinators: 1 bin per vaccinator + 1 reconstitution bin required)
8	Cotton Wool	Cotton Wool	200 cotton balls per box, 24 boxes per case	1 box
9	Tape	Tape	Box of 12	2 rolls
10	Surface Wipes	Surface Wipes	Tub of 240 wipes (cases of 10 x 240 wipes)	1 tub
11	Kidney Dishes (disposable)	Kidney Dishes		10
12	PPE	Hand disinfectants	From PPE supply chain available in 100ml, 250 ml or 500ml	2 x 250ml
13	PPE	Masks	Via PPE supply chain	Minimum pack quantity - 10 or 50 (depending on pack size)
14	PPE	Medium Gloves		1 box medium gloves
16	Tissues		Aftercare	1 box
17	Anti emetic bags			5
18	Lrg Black Sacks			

10) Vaccination Process

An example patient journey from the perspective of a care facility resident can be found in Appendix iii.

a) Details of Vaccination Process

Registration for vaccination

- HSE informs RCF regarding the process for registering residents and staff for a Covid-19 vaccine
- This process is completed electronically via the web-based IBM Salesforce IT system
- Within the IT system a work list of residents and staff registered to receive a vaccine are recorded
- The HSE CHO Covid-19 vaccination team liaise with the RCF to discuss the scheduling of a site visit to prepare for the upcoming vaccination team visit
- The HSE CHO Covid-19 vaccination team liaise with the RCF to discuss the scheduling of the vaccination teams visit
- The residents and staff are advised of the vaccination team visit in advance
- Each CHO vaccination team will have a list of the residents and staff who have consented to receiving the vaccination in advance of arriving to the Residential Care Facilities

Operational aspects prior to the arrival of the vaccination team

- Prior to the vaccination date all queries should be dealt with. A system should be available locally to deal with immunisation queries or concerns.
- It is recommended that each CHO has a central email/telephone number for the RCF's to contact
- The schedule of RCF site visit by the CHO Covid-19 vaccination team should ideally be decided with the RCF's in advance of the scheduled vaccination date.
- RCF's should receive information regarding the vaccine and vaccination process in advance of the planned vaccination session.
- The composition of immunisation teams should be agreed locally in advance and will depend on the number of residents in the relevant facility.
- The RCF and vaccination team will review the resident list and discuss any concerns in relation to residents expected to attend for vaccination. This may include any communication, mobility issues, or cognitive impairment residents may have, as well as information of allergies and anticoagulants. A specific care plan should be in place for individuals identified as having additional care needs/requirements.

Operational aspects on the day of the RCF vaccination session

- The team should be at the RCF in advance of the vaccination session to ensure that it commences promptly at the appointed time.
- Before the vaccination session begins the staff at the session must agree who is to take the "lead role" for the vaccination session and have an overall oversight for the operation of the vaccination session. This oversight role will not diminish the roles and responsibilities of all team members.

- Each member of the team has a responsibility to ensure the smooth through-flow and safety of patients and staff at all times, ensuring both CHO Vaccination Team and RCF are clear on timings; enabling residents and staff to be available in a waiting area, where feasible, in advance of their allotted time.
- At the beginning of each vaccination session two vaccinators from the team should verify the identity, expiry dates and batch numbers of the vaccine for use on the day, and record it on the vaccination session report form.
- The current temperature of the probe in the cool boxes at the beginning and end of the vaccination session should be recorded on the vaccination session report form.
- The team lead will designate a person to take responsibility for ensuring that all necessary documentation, information materials and consumables are available for the vaccination session.
- The team lead will designate a person to take responsibility for ensuring that all the equipment necessary for the administration of the vaccines is in compliance with best practice.
- The team lead will designate a person to take responsibility for ensuring that the correct and appropriate vaccines for residents have been brought to the vaccination session.
- The team lead will designate a person to ensure that the correct vaccine and appropriate quantity is available at the vaccination session and that vaccines are in date, stored and maintained within cold chain.
- The team lead will designate a person to take responsibility for bringing the resuscitation kit to the RCF and for ensuring that all the necessary resuscitation equipment and drugs are available and in date. These should be checked by two clinical members of the team and recorded on the vaccination session report form at the start of each vaccination session.
- The team lead should designate a person to check that all IT equipment is set up and working correctly
- In the event of IT failure the team lead should ensure there is a back up plan (paper consent forms available onsite) to minimise the disruption caused to the schedule caused by IT issues
- The team lead should ensure that all staff are ready to proceed
- The team lead should call a “Time Out” to check all is in order before vaccinations begin to ensure
- The team should be aware of fire exits and also be aware of appropriate safety procedures and evacuation plans in the event of an emergency.

- Each vaccinator’s station should be set up with the correct equipment
 - ✓ Sharps box
 - ✓ Hand sanitiser
 - ✓ Cotton wool balls
 - ✓ Tape
 - ✓ Laptop/tablet and phone

Operational aspects at the time of the vaccination

The schedule of the setting should be considered regarding night-shift staff, shift changes and meal times wherever possible.

- RCF staff will be asked to bring residents to the vaccination area in advance of the vaccination time.
- On arrival the patient will be greeted by the administration staff.
- The administration staff will advise the resident and companion where relevant, to use the hand gel available to clean their hands and request they put on a mask, if not contra indicated.
- The admin will “Check-In” the resident and confirm the residents identity by checking the name and date of birth concur
- The resident will then be lead to the next available vaccinator
- The team lead and the RCF staff will ensure the smooth through-flow and safety of patients and staff at all times and ensure that all staff are maintaining a 1m distance
- The resident will sit in a chair or wheelchair 1m from the table
- The vaccinator will introduce themselves to the resident; confirm the resident’s identity, explain the procedure and confirm consent to carry out the vaccination.
- The vaccinator will sanitise their hands and administer the vaccination into the less dominant arm of the resident.
- The vaccinator will dispose of the needle and syringe in the sharps box and sanitise their hands
- The vaccinator will record the details onto the IT system and provide the resident or accompanying person with some after care advice.
- The vaccinator will clean the chair and any exposed surfaces in preparation for the next resident.
- Each vaccinator is responsible for the secure disposal of sharps and clinical waste in a sharps container and for ensuring that the sharps container is secured at the end of each vaccination session as per HSE guidelines “Healthcare risk waste management segregation packaging and storage guidelines for healthcare risk waste” 4th edition 2010, available at <http://bit.ly/HCRiskW>
- The team lead will designate a person to complete the vaccination session report form at the end of the vaccination session.
- All members of the team should be responsible for cleaning/tidying up after the vaccination session so as to ensure that the vaccination venue is left as it was found.
- A minimum of two clinical team members must remain at the vaccination venue for at least 30 minutes following the last vaccination.
- Details of residents who did not register for the vaccine, refused vaccination on the day or whose vaccination was deferred should be entered on SIS and scheduled to receive their first dose vaccine when the vaccination team return to the RCF in 21 days.
- Lists of residents for mop-up clinics should be compiled

Mop-up/rescheduled vaccination process

- Each Residential Care Facility will be allocated a day 1 (first vaccination) and day 21 (second vaccination). All residents and staff will be invited to consent in advance and then receive vaccination on these dates wherever possible.
- The Residential Care Facility Person in Charge is responsible for providing records of residents and staff requiring vaccination in advance of the scheduled vaccination dates to enable adequate vaccine to be ordered. Changes to the numbers requiring vaccination will be checked by the PIC and reported to the CHO administration team.

Residents from Residential Care Facilities

- Residents who require vaccination outside of the proposed vaccination schedule for whatever reason will be accommodated by the CHO mop-up/rescheduled vaccination team. This team will endeavour to facilitate vaccination as soon as possible for those residents, considering all appointments required CHO-wide.
- Residents from RCFs that do not participate in vaccination on day 1 will be invited to receive their 1st vaccination on day 21 and will be re-visited by the CHO vaccination team to ensure they receive their second dose once at least 21 days has passed.
- Residents that receive their 1st vaccination on day 1 and cannot receive their 2nd vaccination on day 21 will be re-visited as early as possible by the CHO vaccination team.
- Residents that cannot receive their vaccination on any of the planned dates will be scheduled by the CHO administration team.
- The RCF PIC is required to work closely with the CHO administration team to ensure timely access to the vaccine for all residents by accurate sharing of resident details and notification of new residents.

Staff from Residential Care Facilities

- Staff who require vaccination outside of the proposed vaccination schedule will be asked to re-book their vaccination at a hospital hub as appointments become available on the system.
- It should be noted that the medicines protocol outlines that two doses are required, a minimum of 21 days apart.
- As vaccination is rolled out CHO-wide patterns and predictors of mop-up requirements will emerge and CHOs should consider this information to enable planning staffing beyond the initial six week schedule.

Operational aspects after vaccination session

A designated member of the team is responsible for ensuring the correct processes are followed for returning unused vaccine to the cold chain.

Vaccines that are not used on a particular day and are in their original packaging and have been maintained under cold chain conditions should be returned to the cold chain. They should be clearly marked so that they are used first at the next vaccination session

Any suspected adverse events that occur during the RCF vaccination session or are subsequently notified by the RCF should be reported to the HPRA as appropriate.

Please see Clinical Guidance

<https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf>

Reporting

- All vaccination team members will have a debriefing/safety pause with the team lead at the end of the shift to discuss any concerns and to utilise this time for learning for the vaccination session.
- The team lead is responsible for providing daily/weekly updates to the CHO Covid Vaccination Lead, including vaccine session report
- The team lead is responsible for assisting any staff member with completion of a National Incident Report Form as per the HSE Incident Management Framework Updated NIRF 01 V11 Person and NIRF 04 V07 Dangerous Occurrence, including the Interactive NIRF's, can be obtained at <https://www.hse.ie/eng/about/qavd/incident-management/>
- All incidents must be reported to the CHO Covid Vaccination Lead as soon as possible following the incident

Incident reporting

In the event of an incident occurring during a vaccination session, an incident report form must be completed by the professional primarily involved in the incident and forwarded to the relevant manager for review and sign off. Managers must ensure the following:

- All immediate safety issues are dealt with to mitigate risk of reoccurrence
- Service user and staff care and support is in place, as necessary
- Open disclosure takes place
- The incident is inputted and recorded on the National Incident Management System (NIMs)
- Review incident in accordance with the HSE Incident Management Framework
- Learning is implemented and shared, as appropriate

If there is a vaccine administration error, e.g. an incorrect vaccine is administered to one or more individuals, the National Immunisation Office must also be informed. Such an error must be reported to the relevant line manager.

The incident and all actions taken must be recorded and the relevant National Incident Report Form completed (National Incident Report Form - NIRF-- 01-V 11 March 2020) and administrative support is in place to input all incidents on the NIMs. <https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf>

In the course of work Vaccinator Team members may encounter and/or witness practice/systems that are not in keeping with best practice and are cause of concern in terms of safeguarding.

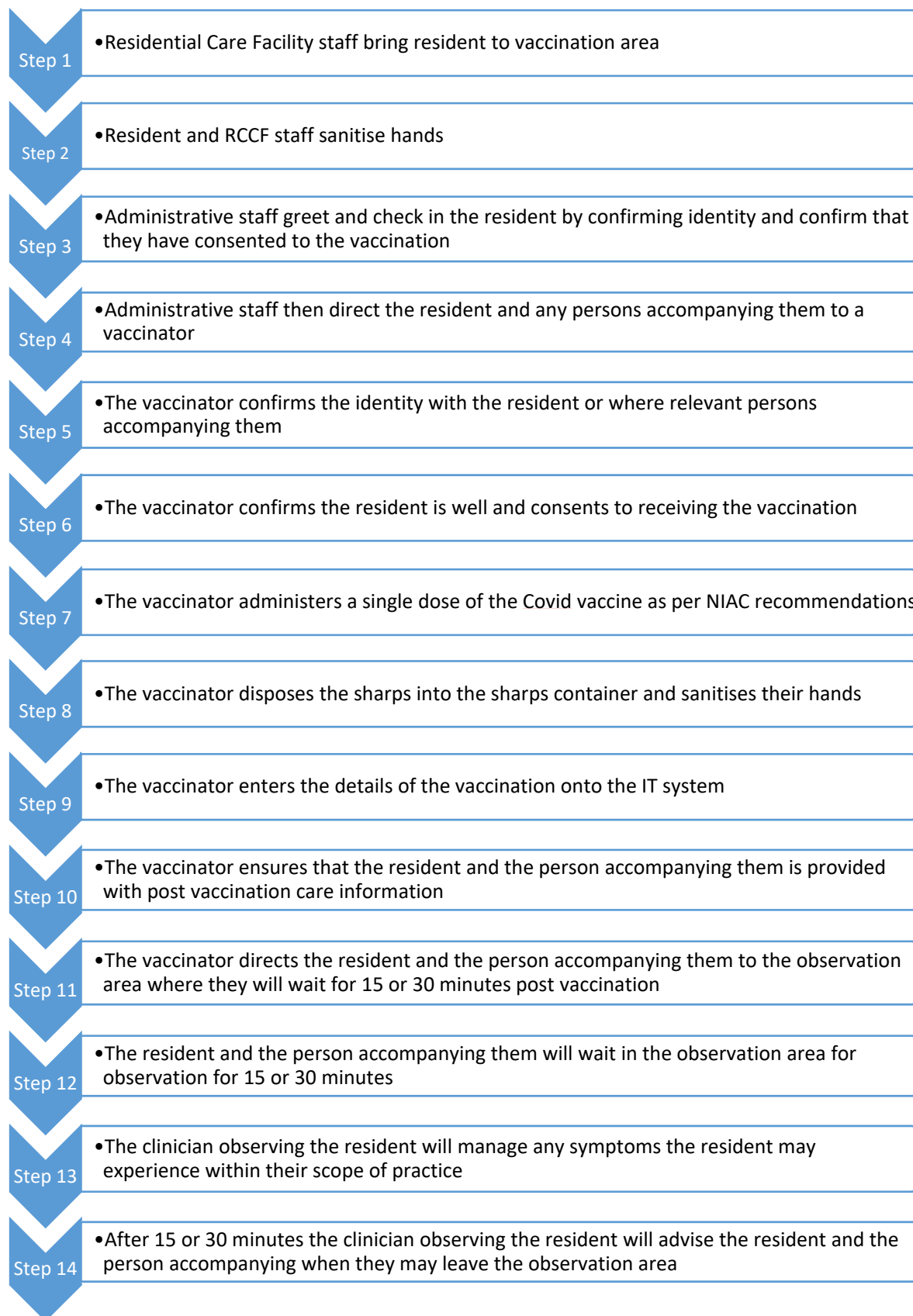
The following steps should be taken:

1. Before leaving the clinical area, report the incident/observations to the Person In Charge and identify what steps will be taken by the facility
2. Report the incident/observations to your line manager
3. Seek additional support from peers/EAP etc.
4. If you are not happy with the resolution put forward report the incident/observations to HIQA
5. If the incident/observation warrants, contact an Garda Siochana

Immunisation guidelines of Ireland

- Immunisation Guidelines for Ireland are available at <http://bit.ly/NIACGuideline>
- Immunisation training slides for Health Professionals 2020, available at <http://bit.ly/NIPConf>
- Vaccines may be given by medical officers and nurses. Nurses may administer vaccine under doctor or Registered Nurse Practitioner prescription or under a medicine protocol within their scope of practice. Immunisation Guidelines for Ireland are available at <http://bit.ly/NIACGuideline>
- Immunisation training slides for Health Professionals 2020, available at <http://bit.ly/NIPConf>

b) Process flow chart



11) Appendices

Appendix i: Poster - Your Moments for Hand Hygiene, Vaccination Campaign

Your Moments for Hand Hygiene

Vaccination Campaign



1	BEFORE TOUCHING A PATIENT	WHEN?	Clean your hands before touching a patient.
		WHY?	To protect the patient against harmful germs carried on your hands.
2	BEFORE CLEAN/ASEPTIC PROCEDURE	WHEN?	Clean your hands immediately before performing a clean/aseptic procedure.
		WHY?	To protect the patient against harmful germs, including the patient's own, from entering his/her body.
3	AFTER BODY FLUID EXPOSURE RISK	WHEN?	Clean your hands immediately after a procedure involving exposure risk to body fluids (and after glove removal).
		WHY?	To protect yourself and the environment from harmful patient germs.
4	AFTER TOUCHING A PATIENT	WHEN?	Clean your hands after touching the patient at the end of the encounter or when the encounter is interrupted.
		WHY?	To protect yourself and the environment from harmful patient germs.



World Health Organization

SAVE LIVES
Clean Your Hands

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Appendix ii: Outline of the processes to be undertaken, by role, from the preparation stage through provision of vaccination within Residential Care Facilities, and aftercare.

Stage	National Support Team	CHO RCF Vaccination Administration Team	Vaccinator Team	Residential Care Facility (management and staff)	Resident
Pre-Registration	<p>Issue initial briefing material and communications information to CHO RCF Vaccination Project Teams (including expectations and resourcing requirements)</p> <p>Provide briefing (online and webinars) including use of IT system, consent in RCF setting, and addressing vaccine hesitancy</p>	<p>Issue initial communications and materials to RCFs</p> <p>Issue communications to clinicians</p> <p>Provide first line helpdesk support to RCFs with dedicated single phone number and email by CHO (or by County)</p>	<p>Undertake site visit (discussing vaccine, site layout, connectivity, etc) and run through Preparation checklist – identify actions for RCF PIC to ensure facilitation of vaccination day activities</p> <p>Attend briefing (including use of IT system, consent in RCF setting)</p>	<p>Receive initial communications and distribute messages/materials to residents and members of staff as appropriate</p> <p>Support site visit / follow checklist by Vaccination Team member</p> <p>Attend/undertake briefing(s)</p> <p>Prepare teams and facilities within RCF for Day 1, following guidance provided, checklist and discussions during site visit</p> <p>Assess numbers and needs of residents that need bedside vaccination, require physical help to attend vaccination, or have cognitive impairment</p>	<p>Receive initial materials relating to the vaccine and the vaccination process</p>
Registration	<p>Monitor registration and uptake nationally and engage with Communications</p>	<p>Provide first line helpdesk support to RCFs with dedicated single phone number and email by CHO</p>		<p>Facilitate and manage the process for collection of appropriate consent from residents to be vaccinated</p>	<p>Register for vaccination and provide consent</p> <p>Confirm health status</p>

OPERATIONAL GUIDANCE FOR COVID-19 VACCINATION IN RESIDENTIAL CARE FACILITIES
Version 10.0

Stage	National Support Team	CHO RCF Vaccination Administration Team	Vaccinator Team	Residential Care Facility (management and staff)	Resident
	team/Logistics etc. as required	(or by County) Provide support for registration and consent process Monitor registration levels at each RCF and follow up as required		Follow assisted decision-making processes where required for consent Record “opt outs”, feed back to Vaccination Admin. Team	including COVID status
Vaccination ordering and scheduling	As above	Once IT system is closed for registration (Day -7), collate registration data Order vaccines from cold chain supplier Work with RCF to schedule session in detail		Work with Vaccination Admin. Team to schedule session in detail Ensure that facilities are prepared and that staff and residents are informed	
Day -1	As above		Engage RCF representative to confirm key session details and carry out final run-through of checklist	Work through checklist with Teams and put any final arrangements in place, including site layout	
Move to Vacc. Site; Vaccination; Monitoring; Aftercare	<i>See Operational Guidance for Covid-19 Vaccination in Residential Care Facilities and Clinical Guidance documents</i>				

Appendix iii Patient Journey Example

Long Term Residential Care Facility (LTRCF): Resident Journey

John

- Resident of a Long Term Residential Care Facility (LTRCF) in Laois
- Requires support to make decision / provide consent
- Requires extensive help along the entire process

