

**COVID-19  
VACCINE**  
Public Health  
Advice

# National COVID-19 Vaccination Programme: Implementation Plan



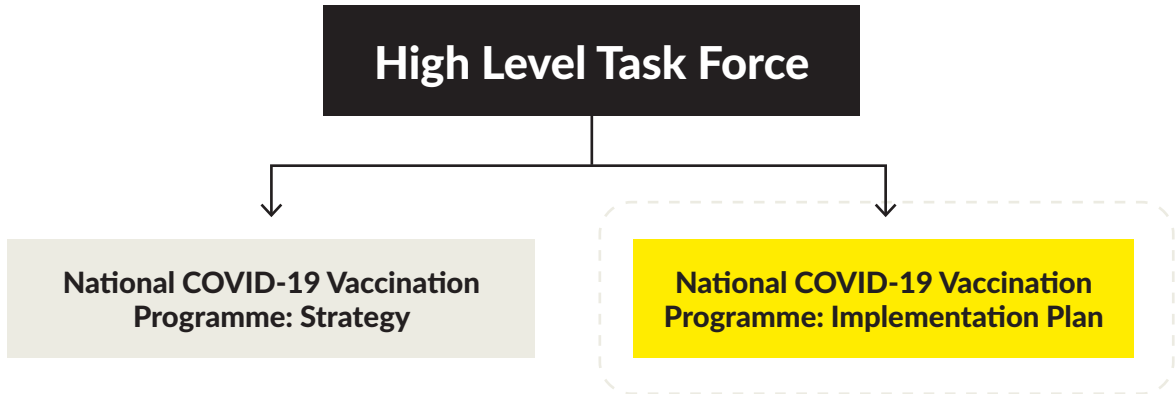


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# 1.

## Background and Context



The Government established the High Level Task Force (HLTF) on COVID-19 Vaccination on November 10th, 2020 to ensure the requisite oversight, agility and specialist input is available to support the HSE and the Department of Health in the effective, efficient and agile delivery of the COVID-19 Vaccination Programme.

**The overall objective of the HLTF is:**

*'To develop a Strategy and Implementation Plan and to monitor the roll-out of a safe, effective, efficient and agile national COVID19 Vaccination Programme that plays a central role in Ireland's exit from the pandemic.'*

**The overarching objective of this Vaccination Programme is:**

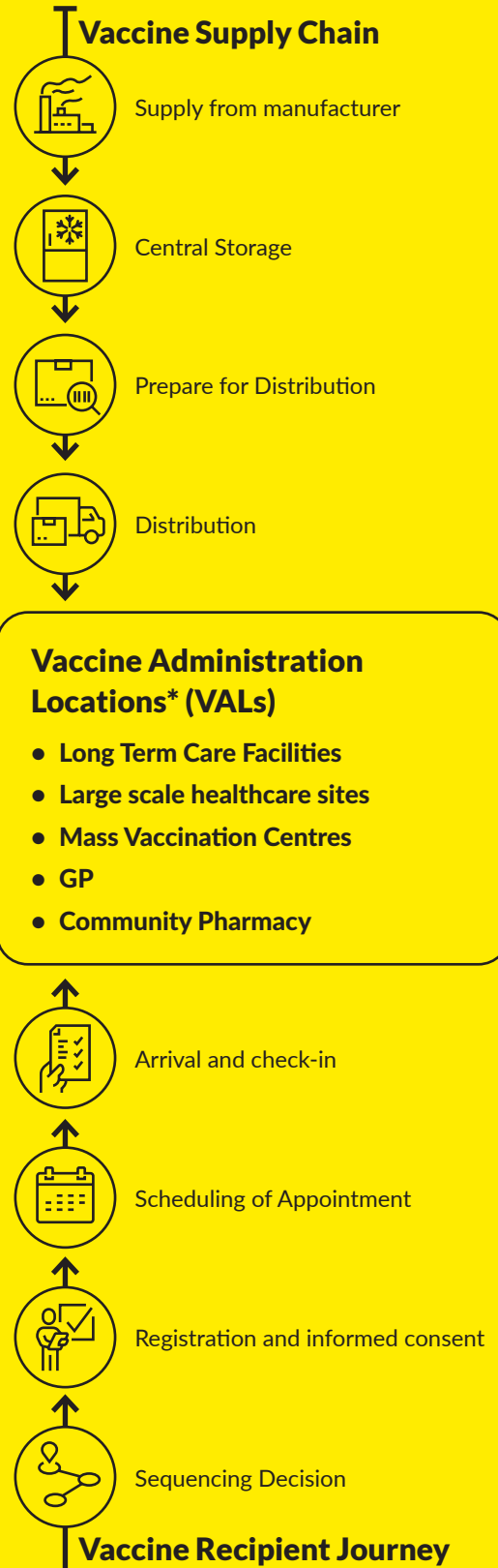
*'To build on the public health response to COVID-19 to date through the efficient provision of safe and effective vaccines to the population and, in doing so, to reduce serious illness and death as a consequence of COVID-19.'*

At the time of writing, there remains a number of unknowns about COVID-19 vaccines and their availability, and, consequently, about the manner in which the overall programme will be implemented. This Implementation Plan is, therefore, designed to be a 'living document' in that it needs to be agile, flexible and to be capable of evolving over time, for example to accommodate vaccines with differing characteristics or to respond to lessons learned in our local experience or internationally.

This plan describes the logistical, operational and human resource requirements for Ireland to begin vaccinations in line with Government guidance in early 2021 assuming the approval of one or more safe and effective COVID-19 vaccines for use.

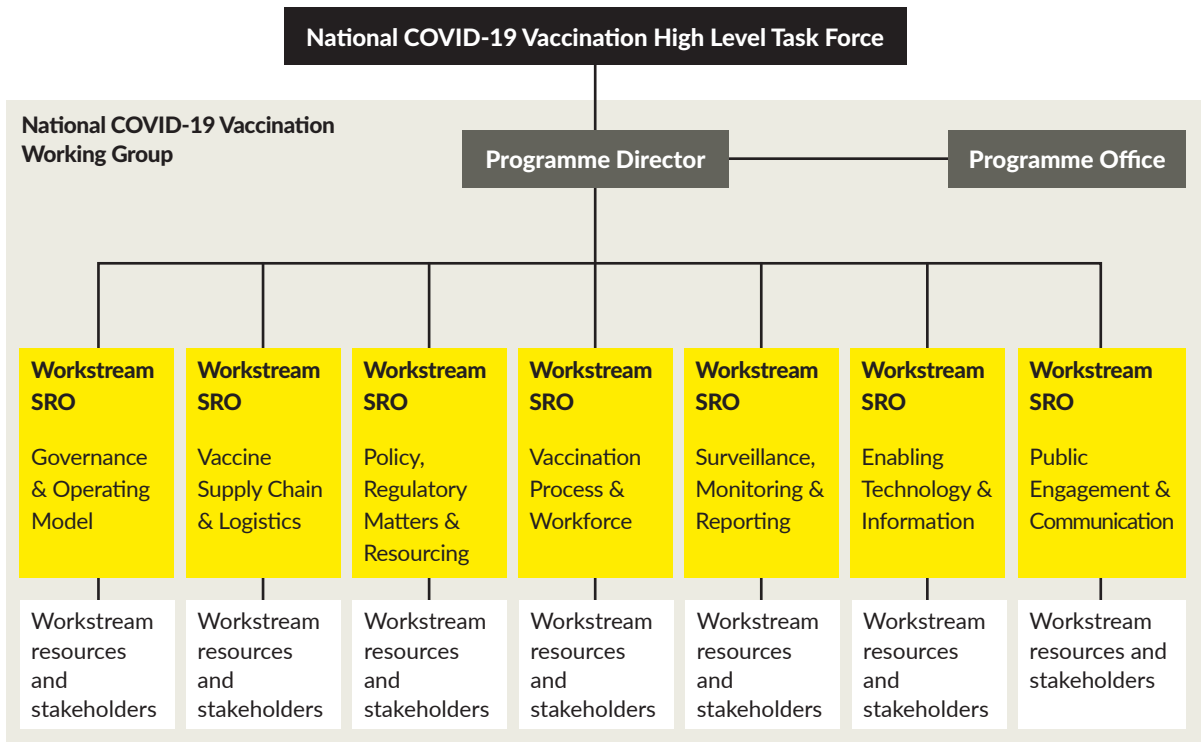
## Overview of key components of the Vaccination Programme

An integrated work programme, comprising seven workstreams (each reflecting a core element of the end-to-end vaccination programme shown in the figure opposite), has been established by the High Level Task Force (HLTF). The programme is using a structured programme and project management approach to manage and deliver all the core elements required in the vaccination process.



\*There will be regular feedback of data from the VALs that will inform the ongoing end-to-end process

# National COVID-19 Vaccination Work Programme Structure



The workstreams (shown above), each led by a Senior Responsible Officer (SRO), were established by the HLTF to create an integrated programme of work that addresses all of the core elements of the end-to-end vaccination process.

## Known Variables and Assumptions

This Implementation Plan is a 'living document', which will be updated on a continuous basis (with regular updates submitted to Government, as appropriate). This version of the Implementation Plan reflects the state of knowledge on December 11, 2020 and provides specific planning details for the early weeks of the Vaccination Programme following a potential granting of Conditional Marketing Authorisation (CMA) for the first vaccine(s). At the time of writing, there are a number of variables, known and unknown, which will impact the planning and rollout of this vaccination programme.

## Known Variables: Candidate Vaccines

The EU has signed six Advance Purchase Agreements (APAs) with pharmaceutical companies, which allow access to a committed quantity of doses, in the event that their respective vaccine is approved for use. At the time of writing, the Irish Government has signed five of these APAs, and signalled its intention to sign up to the sixth when trial data emerges. The EU allocates the APA quantities to Member States based on their population pro-rata share. Based on this approach, Ireland is entitled to receive ca.1.11% of the total quantity, or ca. 14.4 million doses based on APAs signed to date, and assuming that all products are approved for use.

Vaccine	Technology	Doses required per patient	Storage	Approx Irish allocation <sup>1</sup>	Earliest Possible Delivery
AstraZeneca	Non-replicating viral vector	2	Fridge: 2°C to 8°C	3,300,000	January 2021
Sanofi / GSK	Protein subunit	2	Fridge: 2°C to 8°C	3,300,000	July 2021
Janssen Pharmaceutical (J&J)	Non-replicating viral vector	1	Fridge: 2°C to 8°C	2,200,000	TBC
Curevac	mRNA	2	Fridge: 2°C to 8°C	2,475,000	February 2021
Moderna	mRNA	2	Freezer: -20°C	880,000 <sup>2</sup>	January 2021 <sup>2</sup>
BioNTech/Pfizer	mRNA	2	Ultra-low temp freezer : -70°C to -80°C	2,200,000	January 2021
<b>Total</b>				<b>14,355,000</b>	

1 Doses allocated are the agreed amounts under the EU APA, with the exception of Moderna which is under negotiation.

2 Will depend on EU Authorisation, currently under negotiation.

The table above shows that the vaccines use a range of different technologies to protect against the COVID-19 virus and, at this stage, all except one require an individual to have two separate doses of the vaccine, separated in time by a duration dependent on each particular vaccine.

It is also known that these vaccines have different storage and handling requirements. The vaccine already authorised for emergency use in the UK COVID-19 Vaccination Programme is the Pfizer/BioNTech vaccine. There has been significant public interest in this vaccine, and in particular, the requirement to store it at a very low temperature (-70°C to -80°C). Following a controlled temperature adjustment process, this vaccine can be moved and stored at normal fridge temperature (+2 °C to +8 °C), while retaining its effectiveness for a period of 120 hours. This will facilitate it in being distributed around Ireland in the same way as many other vaccines used routinely in the State.

## Known Variables: Vaccine Allocation Strategy

A COVID-19 Vaccine Allocation Strategy has been developed based on the recommendations of the National Immunisation Advisory Committee (NIAC), considered within an ethical framework developed by the DoH. On foot of NIAC advice, the National Public Health Emergency Team (NPHET) made recommendations to Government, which were approved by Cabinet on 8 December. This allocation strategy provides the provisional sequencing for groups to be vaccinated based on clinical priorities and ethical values. Principally, it ensures that the most vulnerable people in our society and those at the highest risk of contracting COVID-19 are prioritised for vaccination.



The sequencing as set out in the table below is one of the key drivers of our planned approach to administering vaccinations and the associated operating model.

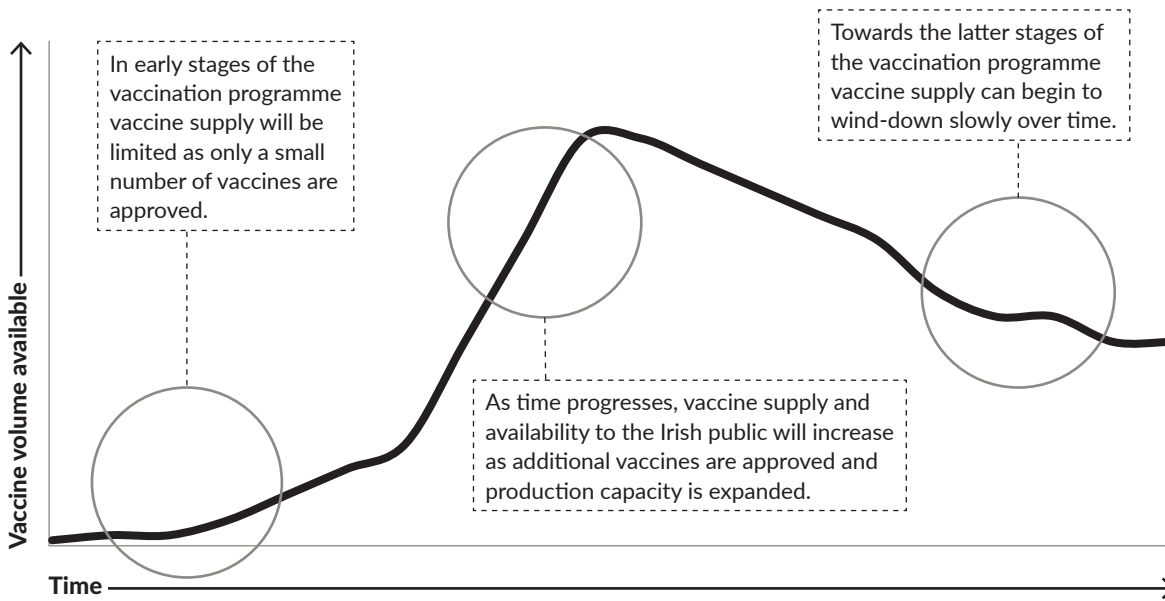
Group	Rationale
Adults aged ≥65 years who are residents of long-term care facilities. Consider offering vaccination to all residents and staff on site.	At greatest risk of severe illness and death. In Ireland, in the first wave of COVID-19, 56% of deaths occurred in this setting.
Frontline healthcare workers (HCWs)* in direct patient contact roles (including vaccinators) or who risk exposure to bodily fluids or aerosols.	At very high or high risk of exposure and/or transmission. In the first wave over 30% cases were in healthcare workers.
Aged 70 and older in the following order: 85 and older; 80-84; 75-79; 70-74.	At higher risk of hospitalisation and death.
Other HCWs not in direct patient contact.	Provide essential health services, protect patients.
Aged 65-69. Prioritise those with medical conditions** which put them at high risk of severe disease.	At higher risk of hospitalisation and death.
Key workers (to be further refined).	Providing services essential to the vaccination programme (e.g. logistical support).
Aged 18-64 years with medical conditions** which put them at high risk of severe disease.	At higher risk of hospitalisation.
Residents of long-term care facilities aged 18-64.	High risk of transmission.
Aged 18-64 years living / working in crowded accommodation where self-isolation and social distancing is difficult to maintain.	Disadvantaged sociodemographic groups more likely to experience a higher burden of infection.
Key workers in essential jobs who cannot avoid a high risk of exposure to COVID-19. They include workers in the food supply system, public and commercial transport and other vital services.	High risk of exposure as unable to work without physical distancing.
Those who are essential to education and who face disease exposure - primary and second level school staff, special needs assistants, childcare workers, maintenance workers, school bus drivers etc.	To maintain the opening of fulltime education of all children who have been disproportionately impacted from the pandemic.
Aged 55-64 years.	Based on risk of hospitalisation.
Those in occupations important to the functioning of society, e.g., third level institutions, entertainment and goods-producing industries who work in settings where protective measures can be followed without much difficulty.	Moderate risk of exposure.
Aged 18-54 years who did not have access to the vaccine in prior phases.	If evidence demonstrates the vaccine(s) prevent transmission, those aged 18-34 should be prioritised due to their increased level of social contact and role in transmission.
Children, adolescents up to 18 years and pregnant women (to be refined).	If evidence demonstrates safety and efficacy.

\*Includes health care workers who work in and out of all healthcare settings

\*\*Chronic heart disease, including hypertension with cardiac involvement; chronic respiratory disease, including asthma requiring continuous or repeated use of systemic steroids or with previous exacerbations requiring hospital admission; Type 1 and 2 diabetes; chronic neurological disease; chronic kidney disease; body mass index >40; immunosuppression due to disease or treatment; chronic liver disease.

The timing of the vaccination of these population groups will depend on a number of factors, including the rate and scale of availability of vaccines. The figure below illustrates a notional profile of vaccine availability over time, starting with limited availability and rising as potentially more candidate vaccines are authorised by the EMA. The various phases shown below are useful in planning the deployment of resources.

### Assumed vaccine availability for distribution over time (illustrative)



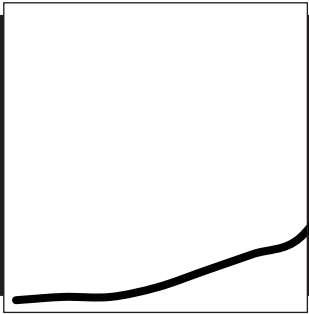
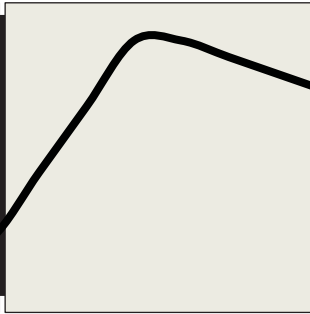
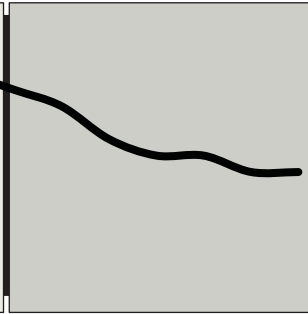
## How the Vaccination Programme Will Work

### A phased approach to roll-out

The safe rollout of the vaccine programme will be delivered in a number of phases depending on the availability of vaccines. As vaccine availability increases and a greater number of cohorts become eligible to access the vaccine, the delivery model (the locations and the workforce) will transition to support a larger volume of vaccinations (as outlined in the table overleaf).

In the initial phase, vaccinations will be delivered to prioritised groups in long term care settings and large scale healthcare sites. As the availability of vaccines increases, additional groups from the vaccine allocation framework will receive their vaccinations. During this mass ramp-up (the second phase), we expect that Mass Vaccination Centres will be introduced for this purpose.

The learnings from the UK roll-out and other international experience will be taken into account. In this context, constructive conversations with counterparts in Northern Ireland have already been initiated.

Plan Stage	Initial Roll-Out	Mass Ramp-Up	Open Access
Vaccine Availability	Limited doses available	Large number of doses available	Large number of doses available
Vaccine Distribution Volume			
Population to be vaccinated	As per Government-approved population sequencing		
Example Vaccination sites used	<ul style="list-style-type: none"> <li>&gt; LTC facilities</li> <li>&gt; Large scale healthcare sites</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Mass Vaccination Centres</li> <li>&gt; GPs and Pharmacies</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Mass Vaccination Centres</li> <li>&gt; GPs and Pharmacies</li> </ul>
Types of vaccine used	<ul style="list-style-type: none"> <li>&gt; First approved vaccine(s)</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Variety of vaccines types as they are approved by the EMA</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Small number of effective and easily stored vaccine types</li> </ul>
Potential Start Date	<ul style="list-style-type: none"> <li>&gt; Early 2021 subject to EMA approval</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Depends on vaccine delivery schedule - to be determined</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Depends on vaccine delivery schedule - to be determined</li> </ul>

## Vaccine Administration Locations (VALs)

The HSE is committed to the implementation of a safe, high quality COVID-19 vaccination programme that provides phased, but timely and efficient access to vaccines to the public. The range of vaccines, their different handling and storage requirements, their availability and the associated clinical guidance mean a range of different delivery options will be employed as part of the Vaccine Deployment Plan.

In the initial roll-out phase when vaccine supply is limited, the approach will be to focus on the highest priority groups identified in the government approved allocation strategy.

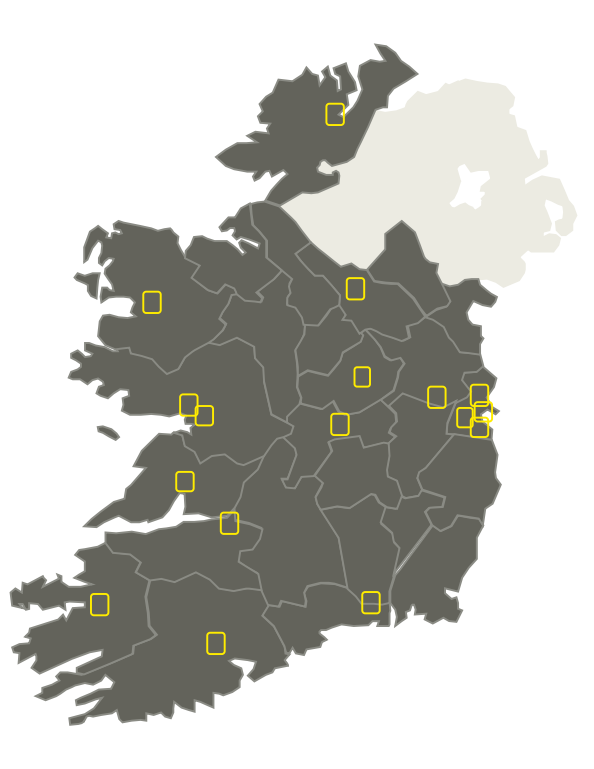
In developing plans for the roll-out of the Vaccination Programme, five types of Vaccination Administration Locations (VALs) have been considered. It is likely that all delivery options will be used at various stages across the implementation of the vaccination programme, subject to necessary agreement. The five types of VAL being considered are:

1. Long-Term Residential Care Facilities
2. Large Scale Healthcare Sites
3. Mass Vaccination Centres (MVC)\*
4. General Practice<sup>1</sup>
5. Community Pharmacy

\*In common with many countries, Ireland will use Mass Vaccination Centres to administer the vaccination programme. These centres will be designed to cater for large numbers of recipients in an efficient and timely manner.

### Example of Vaccination Administration Locations (VALs)

Acute Hospitals
Tallaght University Hospital, Dublin
St. James Hospital, Dublin
Beaumont Hospital, Dublin
Cavan General Hospital
Letterkenny University Hospital, Donegal
Mayo General Hospital
University Hospital Limerick
Cork University Hospital
University Hospital Waterford
University Hospital Galway
Regional Hospital Mullingar, Westmeath
Community Nursing Units
Killarney Community Hospital
Merlin Park University Hospital, Galway
Maynooth Community Care Unit, Kildare
Riada House Community Nursing Unit, Tullamore
Regina House Community Nursing Unit, Clare
Mount Carmel Hospital, Dublin



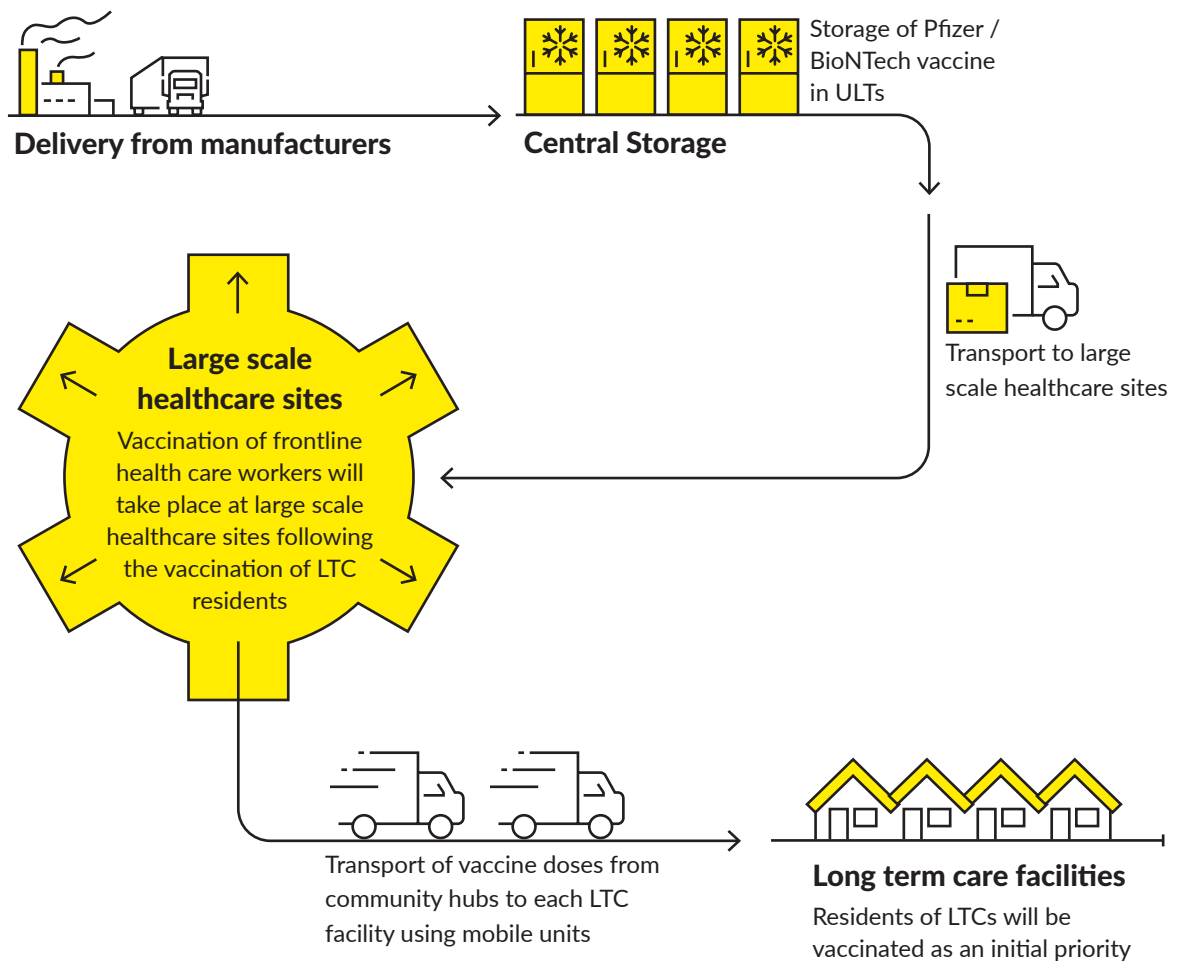
Initially, COVID-19 community vaccination teams will be deployed to administer vaccines to the residents and staff of Long-Term Care Facilities. To date, we have identified a number of large scale healthcare sites that will be used as hubs for mobile vaccination teams to collect vaccines prior to vaccinating in Long-Term Care Facilities. There also has been positive engagement with Nursing Homes Ireland, to identify a number of private nursing homes to be among the locations for the early phase of the vaccination programme.

These large scale health care sites will then also support the vaccination of priority healthcare workers from across the acute hospital and community healthcare settings in a given catchment area.

The model that will be employed to administer vaccinations to the first groups prioritised will rely on a hub-and-spoke model based on large scale health care sites (See Figure on next page).

## Initial Proposed Distribution Model (Hub and Spoke)

Timeline	Early 2021
Population Groups	People aged 65+ in LTC facilities and Frontline HCWs
Vaccine Type	Pfizer / BioNTech (working assumption)
Vaccine Administrators	Members of community vaccination teams and peer vaccinators
Distribution Model	Hub-and-spoke model using large scale healthcare sites as hubs



Following this initial phase, learning from these early sites will be used to stand up a number of MVCs across the country. These centres will be located regionally (see examples below from the Dublin region) and designed to cater for large numbers of recipients in an efficient and timely manner. Discussions are underway with the relevant authorities to ensure that a geographical distribution of such MVCs is provided.

Example Mass Vaccination Centres
Citywest
National Exhibition Centre in Cloghran

All Vaccination Administration Locations will operate to the highest quality standards. The HSE will build on its extensive experience in delivering previous vaccination programmes. In addition, the HSE will harness learning from more recent experience in responding to the COVID-19 pandemic, including the establishment of large-scale COVID-19 Community Testing Centres and the delivery of an end-to-end Test and Trace service for Ireland. Technology has enabled timely delivery and efficient COVID-19 testing services for example from the point of GP referral, through to the laboratory and on to contact tracing.

## Workforce to administer the vaccine

All vaccinators will be qualified and registered healthcare professionals. In addition, they will receive comprehensive and specialist training in the COVID-19 vaccination programme relevant to the types of COVID-19 vaccines they will administer.

For the roll-out of the vaccination programme in Long-Term Care Facilities, the workforce will be drawn from the existing cohort of community-based specialist vaccinators.

**Additional workforce options are being developed to support the scaling up of the programme (further details included in section 3).**

As more vaccines are approved and become available for distribution, and a broader population is targeted for vaccination, General Practice and Community Pharmacy will play an increasing role in vaccine administration, subject to regulatory approval, operational feasibility, and contractual agreement.

## The supply chain and logistics to distribute the vaccine

The supply chain process will begin with the receipt of vaccines in Ireland from a number of manufacturers. Ireland will receive the vaccine supply directly from European manufacturing sites using the air/road distribution channels.

## Storage of vaccines and order management

Given Ireland's geographic size and population, storage of the vaccines will be centralised and managed by a single logistics provider, with substantial relevant experience. As the different types of vaccine require varying temperature storage requirements, (1) Ultra-cold (-70°C to -80°C) (2) Frozen (-15°C to -25°C) and (3) Refrigerated (2°C to 8°C), the logistics partner has prepared substantial storage capacity for each temperature range. For example, specialised Ultra Low Temperature (ULT) freezers have already been installed to store the Pfizer / BioNTech vaccines until they are ready to be distributed to vaccination locations (Note: Qualification and validation remain to be completed at the time of writing).

In order to ensure the correct volume of vaccines are received by each vaccination location at the right time, a robust, accurate, real-time inventory management system is in place to assure availability and maintenance of adequate supplies, minimise potential wastage and accurately forecast demand which can be met.

### Ultra Low Temperature (ULT) Freezers installed in Ireland's central storage facility








## Delivery Logistics

Within Ireland, our existing infrastructure and established vaccination distribution channels will mean vaccines can be delivered efficiently using road distribution channels directly from the central storage facility. Our logistics partner will also manage the delivery fleet and outbound logistics / delivery to the principal vaccination hubs. All deliveries for the initial vaccine will be by chilled (+2 to +8 °C) distribution using the National Cold Chain fleet. One of the vaccines is stored centrally at -70 °C but is thawed to +2 to +8 C for onward distribution and storage. The fleet operates to a very high specification with full GPS monitoring, remote temperature monitoring and redundancy on the cooling systems on the vehicle. The vaccine handling characteristics for other vaccines will be more clearly defined by manufacturers as the regulatory approvals process emerges.

## The vaccine recipient journey

The process of receiving the vaccine will vary slightly depending on the population group and type of vaccination location. However, for a large proportion of the population, the process will be similar to that outlined in the diagram on the following page. The HSE is committed to supporting members of the public through their vaccination journey, ensuring that the process is accessible, safe and easily understood by all. The COVID-19 Vaccination Programme will utilise customised IT infrastructure to assist the public through their vaccination journey. Members of nominated groups for vaccination will be invited to register for, and consent to, vaccination. People will then be offered scheduled appointments to attend a named location for vaccination. Where necessary, support pathways will also be developed to ensure that all groups are enabled to access their vaccination pathway.

# Vaccination Pathway

Registration	Arrival and Check-In	Vaccination	Check-out and discharge	Post-Vaccination
Procedure outside vaccination center	Procedure inside the vaccination center			Procedure outside vaccination center
Vaccination request and preliminary information	Registration	Placement for vaccination, preparation and vaccination	Resting phase, documentation and signout	Return home, observation and reminder for second dose
<p><b>Pre-Vaccination</b></p>  <p><b>Registration:</b></p> <p>Members of nominated groups for vaccination will be invited to register for and consent to vaccination, and people will be offered scheduled appointments to attend a named location for vaccination. The goal is a standard registration process where all key identification data, demographic data, any required medical information and the informed consent is commenced.</p>	<p><b>Registration area</b></p>  <p><b>Arrival &amp; Check In:</b></p> <p>On arrival at whichever site is chosen the pre-registered details are confirmed and the client confirmed.</p>	<p><b>Vaccination area</b></p>  <p><b>Vaccination:</b></p> <p>The vaccination process includes confirmation of patient details, completion of informed consent, recording of the vaccinator details, batch details and time / date stamp. This will also include preparation by the vaccinator of the dose.</p>	<p><b>Rest area</b></p>  <p><b>Check out and discharge:</b></p> <p>The recipient will be asked to wait for fifteen minutes post vaccination to monitor for any immediate adverse reactions. Trained clinical staff will need to be on hand to observe the patients.</p>	<p><b>Post-Vaccination</b></p>  <p><b>Aftercare:</b></p> <p>Follow up reminders to ensure that the client returns for their second dose.</p> <p>While the clinical setting will vary the goal is to provide a consistent process with a common data and technology platform. This will ensure a consistent process, accurate data capture and timely reporting.</p> <p>The recipient will be able to report any suspected side effects experienced post the vaccine on a portal on the HPRA website.</p>



Each stage of the recipients journey will be enabled and assisted by ICT systems

Greater detail about the IT infrastructure being developed for the Vaccination Programme is detailed in Section 3.



# 2.

## Programme Structure

A programme plan has been developed which incorporates all activities necessary to commence vaccine distribution and administration in Ireland in early 2021. The programme plan is organised into seven workstreams, each of which has an appointed Senior Responsible Officer (SRO):

	<p><b>Governance &amp; Operating Model Workstream</b></p> <p>Ensure appropriate governance for the implementation of the integrated COVID-19 Vaccination Programme.</p>
	<p><b>Vaccine Supply Chain &amp; Logistics Workstream</b></p> <p>Ensure all necessary products and services are procured on time to facilitate the rollout of the COVID-19 Vaccination Programme.</p>
	<p><b>Policy, Regulatory Matters &amp; Resourcing Workstream</b></p> <p>Develop a population model to support the delivery of the sequencing strategy for the COVID-19 Vaccination Programme. Ensure that the required policy, regulatory and resourcing steps required to deliver the programme are implemented on a timely basis.</p>
	<p><b>Vaccine Process &amp; Workforce Workstream</b></p> <p>Design the end-to-end COVID-19 vaccination process, identify the workforce required to deliver it and the sites to be used for the vaccination clinics. Operationalise and deliver the capacity to achieve a national vaccination programme.</p>
	<p><b>Surveillance, Monitoring, &amp; Reporting Workstream</b></p> <p>Design and deliver the surveillance, monitoring, and reporting for the implementation of the COVID-19 vaccination programme.</p>
	<p><b>Technology &amp; Information infrastructure Workstream</b></p> <p>Select, deploy and maintain a vaccine information solution to deliver key functionality and enable scheduling, registration, vaccine administration and reporting.</p>
	<p><b>Public Engagement &amp; Communication Workstream</b></p> <p>Design, develop, and implement a communications strategy that encourages universal vaccination. Public engagement on the vaccination programme should complement existing public health education on the virus and the other tools in use to suppress the virus e.g. face coverings, social distancing, etc.</p>

## High Level Implementation Plan

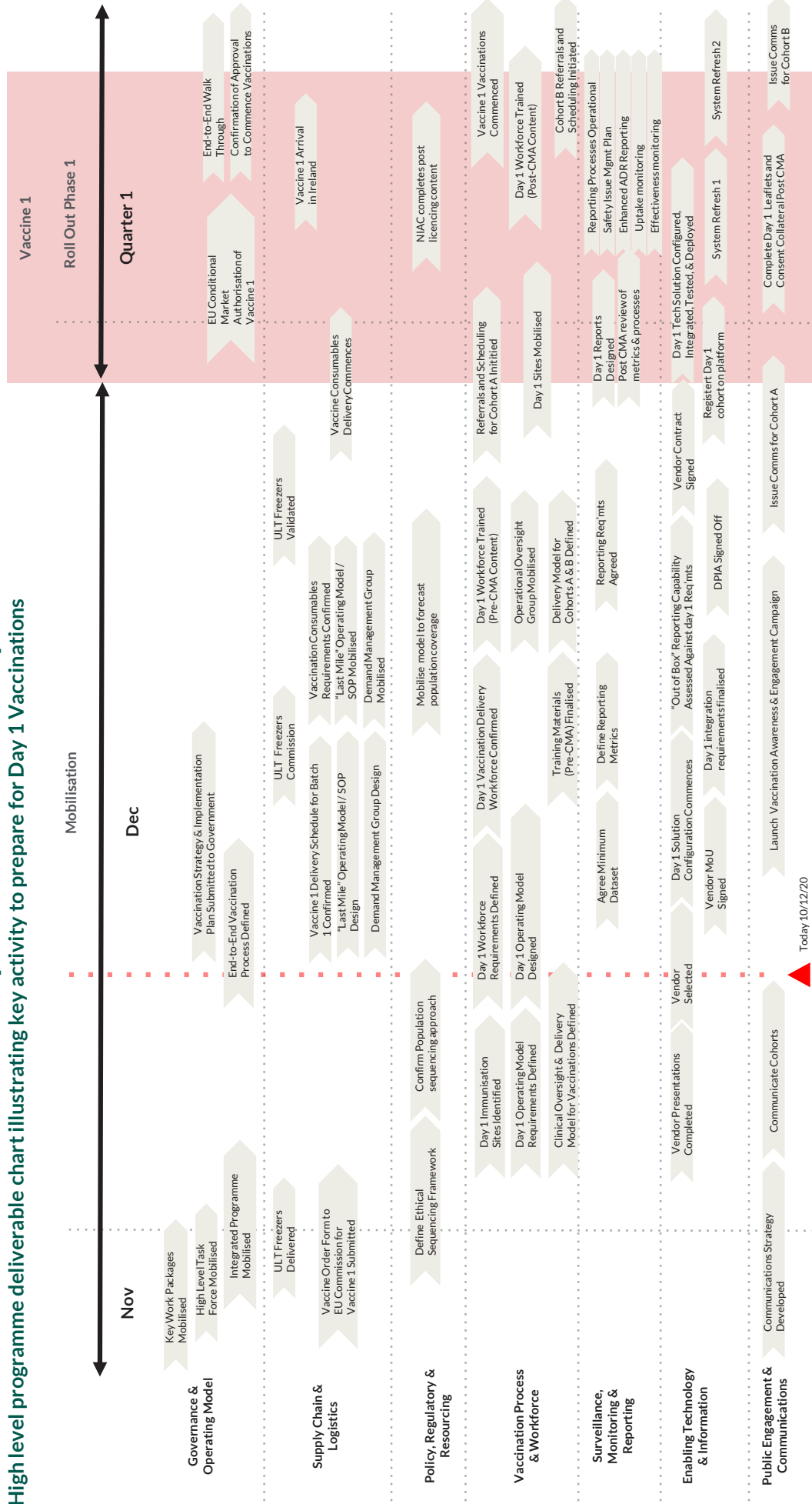
A summary of the key deliverables in the Implementation Plan related to mobilising for the commencement of vaccination delivery is set out in the diagram overleaf.

At the time of writing, due to the number of unknown variables it is not possible to be exact about the date of commencement of COVID-19 vaccinations. Key external factors that have specific impact on planning include the likely dates for regulatory approvals of vaccines by EMA, and the delivery dates of vaccines in Ireland. The programme is making assumptions regarding these, and is progressing all work it controls directly in advance to be ready for the commencement of vaccine delivery as quickly as possible.

# National COVID-19 Vaccination Implementation Delivery Plan

## High level programme deliverable chart illustrating key activity to prepare for Day 1 Vaccinations

v3.0 as of 10 December 2020



## Current Areas of Special Focus

Three key areas have been given particular emphasis to date in the programme:

### 1. IT Infrastructure

### 2. Workforce

### 3. Communications

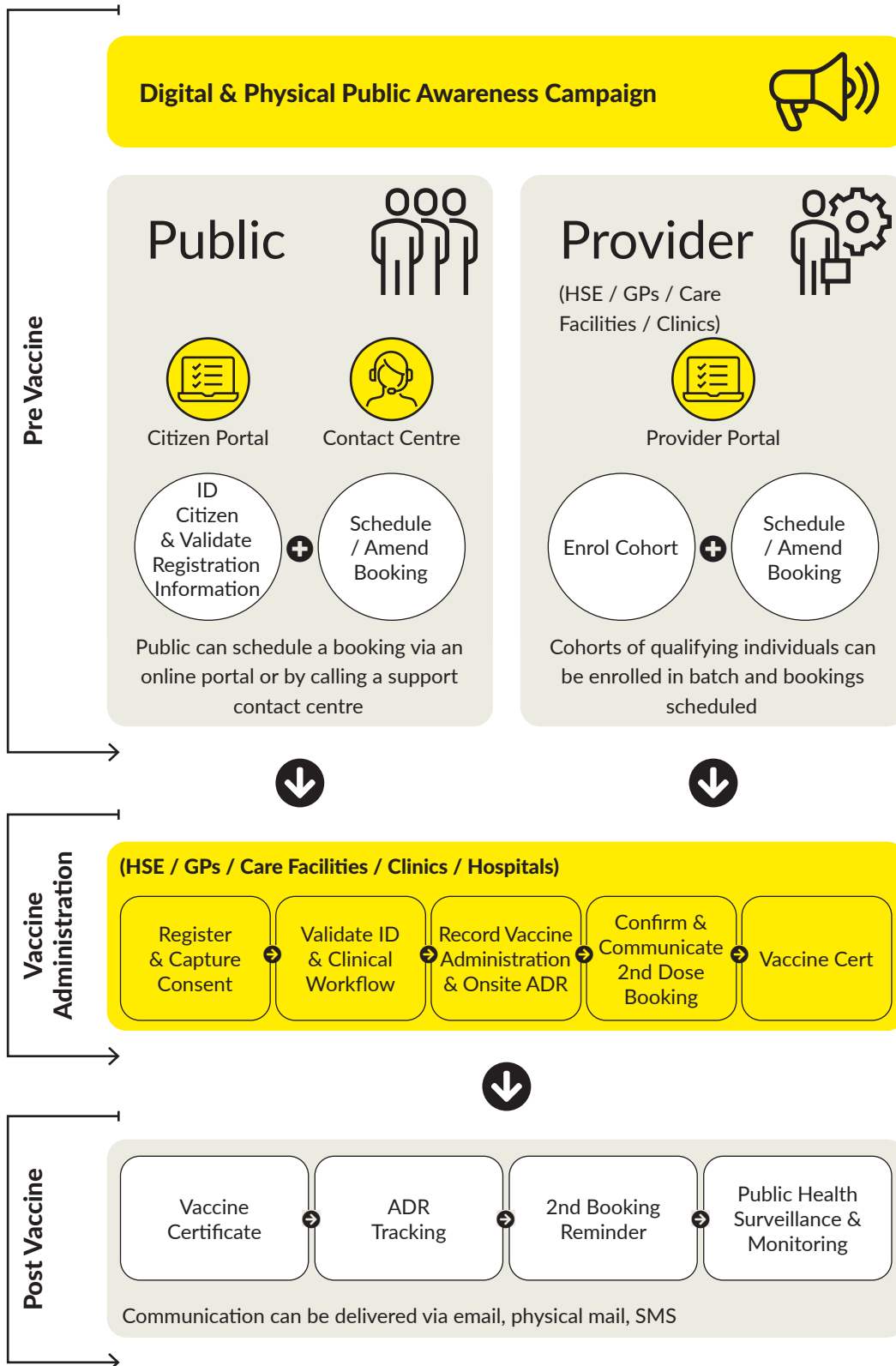
### 1. IT Infrastructure

For efficiency at scale, safety and accurate record keeping and reporting, it is critical that the end-to-end process is systematically enabled and key data elements are captured at the time of execution of each phase within a comprehensive IT system.

A key challenge with the enablement of the process is that Ireland does not have a national vaccination ICT system with the required level of functionality to support the COVID-19 vaccine rollout. Therefore, a functionally rich and proven solution for the proposed vaccination programme must be sourced, purchased, implemented and integrated into the HSE ICT infrastructure before the end of the year. To date, a detailed specification has been developed (see below), comprehensive vendor presentations have been held, a number of which demonstrated live systems.

The table overleaf sets out the core functionality for the IT system that will be required to support the COVID-19 vaccination programme.

## Outline Workflow - Core Functionality



## Pre-Vaccination

The solution must be able to support the key data requirements and workflows of the key clinical and operational stakeholders. The first step is to enable public registration and to facilitate the booking of an appointment to receive the vaccination. Utilisation of the Individual Health Identifier is critically important as it will ensure that each person is uniquely identified for full traceability of the individual. The appointment booking element of the solution will allow the public to pick an appointment time and location that best suits their needs.

The requirements for GP and Pharmacy solutions have yet to be fully defined and the national solution will have to facilitate the integration of these systems.

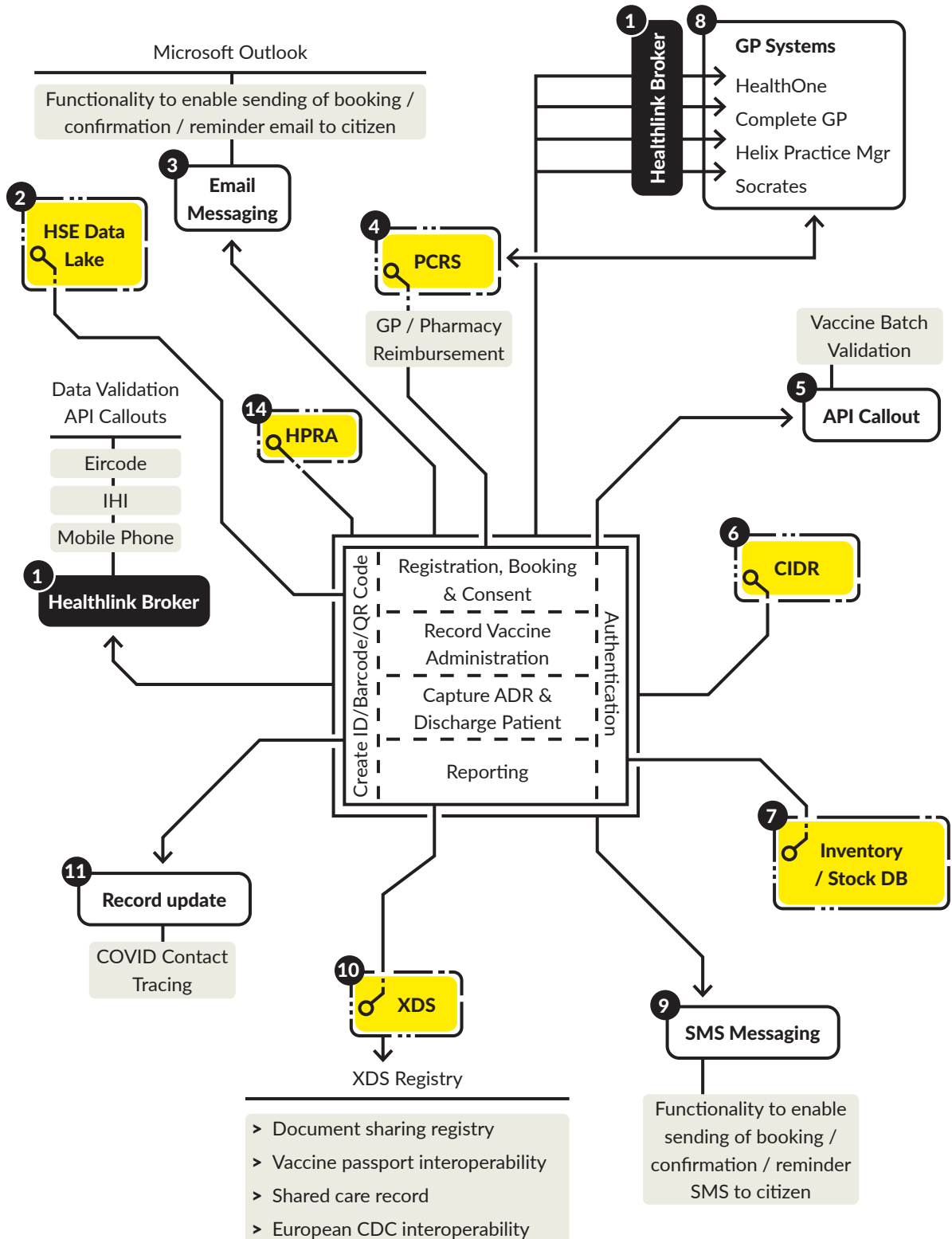
## Vaccine Administration

The vaccine administration process must ensure that the vaccine delivery to the public is efficient and that all the required information to record the vaccine dosage is accurately recorded at the time of the vaccination. The capture of an individual's consent to receive the vaccine is critical as is the validation of the person's identification and confirmation that they are within the allocated cohort. Any adverse reactions must be captured in a codified manner on the solution.

The solution must also potentially cater for the production of a vaccine certificate. The design of this certificate and the scope of how it will be delivered (e.g. physically, digitally or both) is currently being progressed with a number of stakeholders, including the EU.

The core IT system will also need to be able to integrate with a number of existing systems and databases across the state infrastructure. The schematic below sets out the potential complexity of these requirements. The ICT solution is being developed using a staged approach to ensure that the priority needs of the vaccination process will be supported as they develop.

## Outline Application & Integration Architecture



## Data Processing

It is important that a Vaccine Information System can guarantee the security and privacy of personal health information. The system will be hosted in accordance with the appropriate standards for protected personal health information, i.e. security/encryption, disaster recovery, confidentiality and privacy practices, and policies based on pertinent laws or regulations that protect subjects whose data are recorded in the system.

The capturing and processing of personal health data on the Vaccine Information System is required for the purpose of rolling out the COVID-19 vaccine to protect the health of individual citizens. The impact of the operation of administering the vaccine on the protection of personal data and how the rights to privacy and confidentiality of users are protected will be formally assessed as part of a Data Protection Impact Assessment (DPIA). **As part of that process, engagement with the Data Protection Commissioner is underway.**

## 2. Workforce

Under current regulations, medical, nursing and dental professionals are able to administer vaccinations. Furthermore, the HSE has a pool of trained and skilled vaccinators in the health system, including specialist vaccinators and peer vaccinators, available to deliver vaccinations.

The trained vaccination workforce currently identified includes:

- > Up to 180 dedicated community-based specialist vaccinators, and
- > Approximately 1,500 healthcare workers who were trained as peer vaccinators, in the recent flu vaccination campaign.

As more doses of vaccines become available during 2021, there will be a need to expand the pool of skilled workforce to administer vaccines and to deliver the programme. General Practice and Pharmacists have successfully delivered very significant numbers of flu vaccines and can offer enhanced capacity for this programme subject to agreement.

Currently a number of options are being progressed to support the scaling up of workforce for the programme. This includes the following:

- > Backfill of nurses in acute settings (agency or recruitment)
- > Rehiring of recently retired medical and nursing staff
- > Asking staff to work additional hours (either overtime or bringing part time workers back fulltime)
- > Ambulance service paramedics
- > Leveraging of other State and voluntary service providers
- > Contracted private vaccination services
- > Additional skilled ICT and support staff (agency or recruitment)
- > Authorising and training other appropriate professions.

In order to develop these options, consultations with relevant parties will be advanced as a matter of priority.

This vaccination programme will also require significant increases in the number of administrative and support staff, in this regard there may be opportunities to leverage the broader public service to achieve this.

An important consideration will be to ensure that the deployment of staff, particularly from within the Health sector, is planned and designed to ensure non-COVID health and social services can continue to operate and that there is no major disruption to services many of which have not returned to full operations. This will be kept under close review.



### 3. Communications

A comprehensive communications strategy and plan has been developed to support the COVID-19 Vaccination Programme.

Communication around the programme will be informed by the following principles:

1. Ongoing understanding of public sentiment regarding vaccine
2. Open and transparent communication led by public health and immunisation experts
3. Clear and consistent communication to encourage vaccine uptake
4. Cross Government collaboration reinforcing the public health advice

The communications and engagement strategy will have two main phases.

1. The first is preparing for the vaccine, talking to the safety and regulatory processes that are taking place in Ireland, Europe and across the world, engaging with people who have genuine hesitations around the vaccine, communicating the Government Plan from acquisition to prioritisation to distribution and talking to the results of the clinical trials when they are available.
2. The second phase will focus on the execution of the vaccine – national and local communication from medics encouraging the public to get the vaccine, informing who will administer it and where, identifying people of trust to act as ambassadors for the vaccine.

**As part of the approach to building confidence, public health doctors will address misinformation which appears on social media and across the dark web, pointing people to trusted sources of information including gov.ie and hse.ie.**

The vaccine communications and narrative has already begun. The first messages are already being communicated and these include:

1. The State will only use a vaccine if it meets the required standards of safety and effectiveness. All the recommended vaccines used in Ireland are licensed by the EMA (European Medicines Agency) and will be subject to ongoing monitoring in Ireland by the HPRA (Health Product Regulatory Authority). They are licensed for use only when they have been shown to be both safe and effective.
2. Due to the urgency posed by the pandemic, exceptional efforts are ongoing to develop COVID-19 vaccines and make them available as soon as possible. Unprecedented levels of scientific research and collaboration, investment and early and proactive engagement between vaccine developers and regulators has helped speed up development and ensured that quality, safety and effectiveness are not compromised.
3. Vaccines are a proven, cost-effective intervention to protect public health; second only to the provision of clean water. Worldwide, they save at least 2-3 million lives each year – and many more from crippling and lifelong illnesses.
4. Certain priority groups will be vaccinated first. For example, people aged 65 or older living in long-term residential care, frontline healthcare workers and older people living in the community. Once these priority groups have been vaccinated, the vaccine will be available to the rest of the population.
5. The vaccines will be delivered in stages so it will take time to vaccinate everyone. This means we will need to continue to be careful about our individual actions to stop the spread of COVID-19. For example, social distancing, wearing a face covering and regular hand washing. We cannot afford to drop our guard now.

## Key Communications Activities in December

What	When
COVID-19 Vaccine briefing to DOH Vaccine Alliance	4 Dec
Government announcement of vaccine prioritisation	8 Dec
COVID-19 Vaccine briefing to ICGP Webinar	9 Dec
Launch of HSE COVID Vaccine webpage	10 Dec
Launch of national PR campaign to run through Dec featuring senior vaccination and public health experts	10 Dec
Launch of gov.ie/COVID-19 Vaccine and explainer videos	11 Dec
CMO letter to parents of schoolchildren	14 Dec
Launch of The National COVID-19 Vaccination Strategy	15 Dec
COVID-19 Vaccine briefing to Vaccine Advocacy Group (200+ organisations)	16 Dec
COVID-19 Vaccine briefing to Medicines Group (Wholesalers, community pharmacies, Hospital pharmacies, unions)	17 Dec
Launch of local PR campaign with HSE public health doctors	18 Dec

## Delivery Planning Approach

The programme, including all of its workstreams, must develop its plan across two periods which will be implemented in parallel as follows:

1. Identification and implementation of all necessary processes required to safely commence vaccinations in early 2021;
2. Preparation to scale the Vaccination Programme as both the number and supply of vaccines increases.

Planning for these two phases needs to take into consideration the requirements for the safe commencement of the vaccination programme in addition to the longer term requirements for a number of areas, including:

- > The logistics and distribution models for all vaccines; in particular the differing supply chain / cold chain requirements of each of the vaccines
- > Mobilising a variety of vaccination sites across the country to best meet demographic needs and distribute the vaccines as safely and quickly as possible (based on the available delivery allocation to Ireland)
- > Implementing a technology solution that will allow for consistent management of the process from commencement of the Vaccination Programme
- > Establishing comprehensive reporting that will scale effectively as cohorts, vaccination site types, and vaccines are added
- > Identifying and mobilising the workforce required to deliver the vaccination programme
- > The definition and implementation of a communication strategy that is consistent with a national message to inspire public confidence in both the vaccine and the integrated vaccination programme but also is nuanced to the needs of individual population cohorts; engaging with each group in turn to encourage vaccine uptake, and provide practical information on topics such as scheduling and consent

Ongoing detailed programme planning will continue across the programme workstreams to further clarify requirements and drive implementation. Identification and mapping of dependencies and planning assumptions at all levels will be essential to understanding the risk carried by the programme and to clearly define the critical path.

The plan focuses on the delivery requirements to safely start COVID-19 vaccinations as soon as possible after EU Conditional Market Authorisation (CMA) is granted. The majority of activities in the plan between now and the forecast CMA are owned and will be delivered by the HSE and DOH.

Due to the scale of interdependent work, and current planning assumptions, there are a number of parallel work items on the critical path. To mitigate the risk to the critical path, from now to the date of CMA approval, and beyond, the Programme Office will continue to engage with the workstreams to drive implementation of these activities and support the resolution of any challenges.

During this initial phase, a number of deliverables are dependent on the activity outside of the control of the integrated programme, most notably the CMA approval and licensing, as well as the delivery of vaccines to Ireland from the pharmaceutical suppliers. These two deliverables drive a number of other key activities that sit on the critical path. As more information, in particular the expected timelines, becomes clear, it will be possible to identify the proposed date for vaccination commencement.

The focus of the Programme Working Group is to mobilise a safe and efficient delivery model (including the required level of trained staff) to administer vaccinations to the prioritised cohorts (in line with the Vaccination Allocation Strategy approved by Government), and manage the risk and complexity of the vaccine requirements of supply chain and cold chain, as well as delivering on the conditional market authorisation.

## Critical Deliverables Pre-CMA

As we wait for the EMA to grant the first CMA, and the subsequent approvals from the HPRA, a number of key activities are being advanced. Detailed planning is currently underway with the workstreams to define and validate the timescale, dependencies, and risks associated with this work. There is a significant number of deliverables to be completed across the next four week period, with complex dependencies and interdependencies including:

**Population cohorts & sequencing** - A COVID-19 Vaccine(s) Allocation Strategy has been developed based on the recommendations of the National Immunisation Advisory Committee (NIAC), considered within an ethical framework developed by the Department of Health. The strategy identifies a sequencing of cohorts for groups to be vaccinated.

**Last Mile Operating Model and Key SOPs** - A critical deliverable currently being progressed is the Operating Model and key Standard Operating Procedures (SOPs) for the management of the vaccine from the cold chain environment to where it will be administered. This will be critical to enabling safe, effective, and efficient management of the vaccine in various healthcare and vaccine delivery environments.

**Vaccination locations mobilised** - Identification of locations, recruitment and deployment of workforce, and a clear operating model are all required to establish and mobilise vaccination sites. Five vaccination delivery locations are being developed leveraging our existing models for other vaccination programmes. In the early phase of the programme we plan to focus on delivery through large scale health care sites and a hub and spoke model out to LTCF.

**Workforce and training** - A significant workforce will need to be deployed to appropriately staff the vaccination programme; this will include clinical staff, administration, and logistics staff. A broad range of training, from the technicalities of vaccine administration through to how to operate the supporting technology system, will need to be developed and delivered to enable effective management of the vaccination administration sites. This training is being developed and will build on previous vaccination programme training and international best practice.

**Surveillance enabled** - Monitoring and reporting of vaccine uptake and additional metrics to monitor adverse reactions and other safety concerns will need to be enabled prior to the commencement of the vaccination campaign. Key to delivering this will be the definition of the minimum data set required, the development of reporting requirements and the implementation of required processes and systems.

**Supporting technology solution selected and implemented** - In order to ensure consistent management of the vaccination programme, the technology solution will need to be identified and implemented prior to the first vaccinations; it will then continue to evolve and scale with the programme over the coming months.

## Critical Deliverables Post-CMA of Vaccine 1

Once conditional market authorisation is granted, there are a number of critical deliverables that will need to be implemented in quick succession prior to the commencement of vaccinations. These include:

**Delivery of the Vaccine** - The earliest delivery time from the vaccine production site to Ireland is within days following approval from the CMA. The Vaccine Supply Chain & Logistics workstream continues to engage with the manufacturer regarding the expected delivery schedule and timing of the first batch of deliveries.

**NIAC creating key content post CMA** - Within Ireland, NIAC has responsibility to provide specific recommendations and advice for the use of approved vaccines in Ireland. Once the EMA has approved the vaccine, NIAC will finalise a chapter of guidance on the use of the vaccine. This will be used to finalise the training for the vaccinators. This guidance will also be used to finalise the communications collateral for population cohorts as well as key communications related to consent information. Work is currently ongoing in this area to ensure that the above can be finalised promptly once the CMA and HPRA approval has been received.

**Information leaflets and consent collateral for Day 1** - Once approval has been granted, final changes specific to the content of the CMA can be made to communications materials and consent collateral.

**End-to-end walk through prior to the commencement of vaccinations** - A readiness assessment will be undertaken, supported by the end-to-end walk through for all site models prior to operation. Specifically, the end-to-end will comprise a detailed validation that all processes are ready; that design is fit for purpose; all training on the relevant protocols and processes has been appropriately delivered; and to demonstrate that the infrastructure is in place to enable a smooth start to vaccinations in Ireland.

# 3.

## **Oversight and Governance**

## Introduction

The delivery of this Implementation Plan will rely on the governance structures and statutory responsibilities of a range of existing bodies. Notwithstanding these existing institutional arrangements, good governance is a system and process, not a single activity and therefore successful implementation of a good governance requires a systematic approach that incorporates strategic planning, risk management and performance management across the integrated programme. There is a need to augment and support existing arrangements given the programme interdependencies between them as well as the level of responsiveness and decision making that will be required as the programme rolls out.

Notwithstanding the complexity and uncertainty referenced in this document, the process to begin to estimate the potential range of costs for the four HSE work streams is underway. Financial sanction for these costs is a technical and formal matter primarily between the DOH and DPER, albeit one which the HSE will engage with and support to the greatest extent practical, as information around likely costs becomes available. However, it is essential that there is coherence and full alignment between the pace at which the HSE is requested / expected by the Task Force to act in relation to this vaccination programme and the pace or information / certainty threshold at which DPER and DOH are mandated to act in relation to provision of financial sanction (by DPER), or at least formal approval to permit HSE to proceed (by DOH).

## High-Level Task Force on COVID-19 Vaccination

The High-Level Task Force on COVID-19 Vaccination was established to support the Department of Health and the Health Service Executive to deliver a COVID-19 Vaccination Programme that meets best practice and good governance.

Working with the DOH and the HSE, the Task Force has developed a national COVID-19 Vaccination Strategy as well as this Implementation Plan for the safe, effective and efficient procurement, distribution, administration and recording of COVID-19 vaccines.

## Implementation: Programme Management

Given the complexity involved and the flexibility required in the rollout of our national COVID-19 Vaccination Programme, a Programme and Project Management (PPM) approach based on international standards and recent guidance developed for the Irish civil and public service is being adopted and that draws on principles, practices and activities that are applicable to the effective management of vaccination programmes of this nature.

To turn our COVID-19 Strategy into action, this programme has established an agreed, appropriate and proportionate decision-making structure through which the outcomes are set out, implementation approach is agreed and performance is monitored. This robust and flexible governance structure and operational model is based on close collaboration between partners at all levels and also incorporates the flexibility to detect and respond to emerging issues.

**It supports but does not displace or replace existing institutional responsibilities or governance arrangements.**

It also recognises the accountability and governance requirements of the various entities involved that have come together to deliver and roll-out this Programme. Lines of communication are established so that key stakeholders ranging from Government, key Departments, HSE, the HLTF advisory and regulatory partners can make or escalate decisions as appropriate and are briefed on progress.

A programme management office (PMO) has been established to support the Task Force in its ongoing monitoring role.

## Objectives of the Programme Management Approach

In the context of the Vaccination Programme, our programme management approach is focused on three key objectives:

1. Preserving and strengthening public confidence that the programme is safe, effective, fair and efficient.
2. To ensure the constituent organisations perform as well as possible and achieve the goals and continue on a sustainable track to success in delivering this programme over the entire period of the roll out.
3. To ensure the programme and the activities of the constituent organisations are well placed to respond to a changing environment.

## Programme Management Principles

Key Programme Management Principles have already guided the development of the Strategy and Implementation Plan and these will continue to inform the Programme Office approach to oversight and reporting.

- > **Pace of Roll-out:** A programme roadmap and underlying Implementation Plan is being developed on a rolling basis that considers all project activities, the dependencies between them, the resources and time required to achieve them, key deliverables, the critical path and assurance and review activities and will be updated on an ongoing basis.
- > **Management of Uncertainty:** The world is experiencing an unprecedented global pandemic of COVID-19 caused by a novel coronavirus. This national strategy associated with this Implementation Plan, highlights the challenges presented by uncertainty across a number of headings including complexity, novelty, technology and pace and the forces that these inevitably exert on a programme of this scale. Continuous monitoring for situational awareness will be crucial for a successful outcome. This requires a well-defined systematic approach to the identification, evaluation and control of issues that may result in change and with sufficient agility to respond and adapt plans as appropriate.
- > **Stakeholder & Public Engagement:** Effective, clear, transparent, fact-based and concise communication will be critical for stakeholder and public engagement. A Communication plan, underpinned by key principles, has been developed to support the roll-out of the national vaccination strategy.
- > **Roles and Responsibilities:** Precise roles and responsibilities are well defined and assigned to appropriately skilled and experienced people, with lines of authority, responsibility and accountability clearly identified and defined in the programme structure to avoid gaps in ownership and risk to delivery.
- > **Risk Management:** A structured process is established in understanding the risks inherent in this programme, their likely impact and mitigating actions. This serves to support good governance as it assists in analysing uncertainties, in clarifying accountabilities and in demonstrating how the public interest is best served.
- > **Resource Management:** The financial and other resources required of each organisation to deliver this strategy is being identified to meet objectives and ensure they are managed, monitored and utilised to their fullest extent. Underlying work-streams are being resourced with sufficient people having a suitable mix of subject matter expertise, and project management skills, to enable the vaccination programme to be delivered (See Section 3 Introduction).

- > **Improvement Planning:** As with any vaccination programme roll-out, this Programme has drawn on lessons learned from planning and workshop exercises and real-world outbreaks that have affected Ireland in the past such as the 2009 H1N1 Pandemic.
- > **PPM Closure:** Once confidence is met that operational delivery of the vaccination programme is appropriately scaled, efficient and effective to deliver the intent of the national COVID 19 vaccination strategy, arrangements will be put in place by the HLTF to support the transition and handover to business as usual. At an appropriate time, the HLTF will stand down and the PPM approach will be closed and that information required to support the business as usual environment is documented and readily available.

## Agile Decision-Making and Communications

A Programme and Project Management approach is being used across seven Work-Streams. Each Work-Stream is led by a Senior Responsible Officer (SRO) supported by programme and project professionals and subject matter experts.

Taken together, the SROs and the Programme Director form a Programme Working Group established to coordinate, integrate and to report progress on work. The Programme Director reports to the HLTF and the institutional members on the Task Force, COVID Oversight arrangements and ultimately to Government. Activity is well advanced across these work-streams through already-established work programmes that were ongoing in both the HSE and DoH to prepare for the roll-out of the vaccination programme.

The PMO is putting in place a decision-making framework across the Work-Streams, on behalf of the HLTF, to ensure that decisions are identified and taken to achieve the successful outcome of the COVID 19 vaccination programme. This is to ensure that necessary decisions identified at a work stream level are taken or escalated through normal institutional governance arrangements within the relevant organisation.

Decisions affecting programme integration will also be identified for decision at an institutional level. Decisions, including those spanning across institutional governance arrangements, that cannot be resolved will be escalated through the Programme Director for discussion at the HLTF, existing COVID Oversight arrangements and or consideration by Government as appropriate.

## Reporting

The PMO is putting in place procedures for monitoring and reporting across various critical programme planning and agile implementation elements, including performance targets, resources, staffing, and a range of activities being progressed by subject matter experts.

SROs will provide regular updates to the PMO in order to allow the Programme Director report overall progress to the HLTF in accordance with its terms of reference.



## Unknown Variables and Assumptions

There remain a number of unknowns that could materially impact our approach to the safe deployment of the COVID-19 vaccines. These unknowns are summarised in the table below. We expect that clarity will be received in each of these areas over the coming weeks and we will refine our Implementation Plan and approach as appropriate in light of this new information.

Unknown variable on December 11 2020
> The exact approval dates, if any, for all candidate vaccines by the EMA are still unknown
> The finalised delivery schedule for each potential vaccine has yet to be confirmed by the respective manufacturers
> The specific characteristics of a number of the vaccine candidates are still unknown (this includes the details in relation to any specific preparation, logistics or storage requirements beyond initial details of refrigerated storage and reconstitution requirements).
> Additional recipient monitoring that may be required as part of CMA approval, the details of which are not yet known.

We have therefore had to make a number of assumptions in developing our Implementation Plan over recent weeks. These high-level assumptions include the following:

High level assumptions
> It is expected that at least one, and likely multiple vaccines, will be granted CMA by the EMA in early 2021
> Ireland will have access to its allocation of these vaccines as per the APA agreement applying to all EU Member States
> Provisional delivery schedules outlined by major manufacturers will be largely adhered to and thus there will be availability of vaccines in early 2021
> The vaccines will mostly be configured in two-dose regimens and some will require refrigerated storage temperature indicated at this time by manufactures.

As information becomes available the Implementation Plan based on these assumptions will be adjusted accordingly.

## Risk Management Framework

In a programme of this scale, there are essentially three types of risk; risks that affect single projects/ programmes within the overall programme and managed by the SROs, aggregated risks which are similar risks that affect more than one project within the programme and are best managed at a programme level and, finally, programme risks that concern the uncertainty of the programme and affect the whole programme.

The PMO has established a structured process in understanding these three types of risks inherent in this programme at work-stream and program

level, their likely impact and consideration to the development of mitigation and contingency plans, including associated triggers. As discussed earlier, this plan highlights the challenges of managing uncertainty across a number of related headings including complexity, novelty, technology and pace and this means that continuous monitoring for situational awareness by the wider programme teams, Working Group and HLTF will be crucial for a successful outcome.

A detailed risk log will be managed at workstream and programme level throughout the programme. At the time of writing this document, we have set out below the key high level risks and the approach to managing these during the vaccination programme (see table below).

Risk area	Description	Risk Management activity
<b>Approval / delivery delay</b>	There is potential for EMA consideration of licensing or the manufacturing delivery schedules for one or more of the potential vaccines to take longer than anticipated	<ul style="list-style-type: none"> <li>&gt; Ireland is proactively working with the manufacturers to gain clarity on the final delivery schedules to enable clarity regarding vaccine delivery schedules</li> <li>&gt; We are working closely with the HPRa to ensure all preparatory steps can be met in a timely manner once EMA approval is given</li> <li>&gt; A number of APAs have been agreed, meaning Ireland has an excess allocation of potential vaccine volume, reducing risks of delay and providing contingency</li> </ul>
<b>Vendor IT infrastructure is not configured and deployed on Day 1</b>	The Vaccine Information System may not be available for Day 1	<ul style="list-style-type: none"> <li>&gt; Vendors have been clearly briefed on the day 1 requirements and have made commitments around their capabilities to deliver to these timelines</li> <li>&gt; A contingency IT solution is being developed in parallel (use of the existing SwiftQ platform for scheduling and bookings and the development of a bespoke, cloud-based solution that enables core vaccine administration data to be captured at the point of vaccination - this is being developed by OGCI0)</li> <li>&gt; Physical forms will be required as a mitigant where a catastrophic systems / power failure at a site location prevents access to the vaccine administration solution</li> </ul>

Risk area	Description	Risk Management activity
<b>Adequate capacity of trained workforce is not available</b>	Given the complexity and scale of the programme there is a risk that required levels of workforce may not be available to support the roll out and slow the speed of the vaccination programme	<ul style="list-style-type: none"> <li>➤ Existing vaccination and healthcare workforce will be augmented by a range of additional professionals to ensure continuity of non-COVID services in so far as is possible</li> <li>➤ The speed of the vaccination programme rollout will take account of the workforce constraints and the practicalities of large scale vaccination</li> </ul>
<b>A third peak in the spread of COVID-19 may impact the speed of which the vaccine can be rolled out</b>	A third peak of the virus could impact the level of workforce available to administer the vaccine and the ability of the targeted cohorts to access the vaccine	<ul style="list-style-type: none"> <li>➤ A targeted roll out will be implemented in the early phase and then scaled to manage the risk around workforce</li> <li>➤ Guidance from Public Health clinicians will be sought around protocols to be adhered to if a third peak occurs</li> </ul>
<b>Low adoption</b>	Adoption rates in certain cohorts may be lower in some cohorts than envisaged and there is a risk that this is further exacerbated by misinformation in the public domain	<ul style="list-style-type: none"> <li>➤ An ongoing communications campaign will consistently reinforce public health messaging about trust in the vaccine programme and providing factual information about the vaccine process and its role as part of wider public health measures</li> </ul>
<b>Communications</b>	There is a risk that the communications campaign is not effective in a) delivering the key messages to support the required uptake and b) in meeting the requirements of communicating clearly information in relation to the rapidly changing vaccine related data.	<ul style="list-style-type: none"> <li>➤ The communications team will continue to engage with the public to measure public sentiment and with the behavioural experts to understand the evolving communication needs</li> <li>➤ A rigorous but agile process will be put in place to ensure all the latest and appropriate PILs (Patient Information leaflets) information for informed consent is available for people as required</li> </ul>
<b>Logistics and consumables</b>	Logistical challenges such as transportation, storage or consumables may delay the roll-out	<ul style="list-style-type: none"> <li>➤ Where possible, existing trusted and reliable delivery mechanisms of vaccination have been employed</li> <li>➤ Where additional requirements have augmented existing structures these have been thoroughly tested and reviewed, with resilience and contingency measures developed</li> </ul>
<b>Information reporting</b>	There is a risk that the daily reporting of data is not available on day 1	<ul style="list-style-type: none"> <li>➤ A minimum reporting data set is being developed to ensure basic reporting can be administered from day 1.</li> </ul>
<b>A serious adverse event or quality defect occurs in Ireland or elsewhere post deployment</b>	The emergence of a very serious unforeseen event	<ul style="list-style-type: none"> <li>➤ Rapid and timely reporting</li> <li>➤ Rapid and timely action by national experts in the case of a local event</li> <li>➤ Ongoing monitoring and surveillance</li> <li>➤ Integration with EU and international monitoring systems</li> </ul>

