COVID-19
VACCINE
Public Health
Advice

National COVID-19 Vaccination Programme: Strategy

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

Rialtas na hÉireann
Government of Ireland

An Roinn Sláinte
Department of Health

Preface

The aims of any vaccination programme are to reduce morbidity and mortality in the population. Vaccines are critical public health interventions as they mitigate disease at the population level by offering protection to individuals and, depending on the mode of action of the vaccine, curbing community transmission.

The key function of a COVID-19 vaccination programme is to offer the vaccine to the whole of the population for whom it is indicated. The Irish COVID-19 Vaccination Programme is designed to ensure the safe, effective and efficient administration of a COVID-19 vaccine to all residents of Ireland who are indicated and wish to receive it. The vaccination will be free at the point of delivery.

This document describes Ireland's national COVID-19 vaccination strategy. It lays out the process to date and outlines the basis of the key recommendations underpinning the associated implementation plan. It is likely that, subject to a favourable outcome from assessment processes, a number of vaccines may be approved by the European Medicines Agency (EMA) in the coming weeks. On this basis, planning assumptions are based on commencement of vaccinations in early 2021, in line with the Government-approved sequencing, and to implement this key public health measure to create a sustainable long-term response to the challenges posed by COVID-19.

The scale of the COVID-19 vaccination programme will be much larger and more complex than previous vaccination programmes. This strategy draws on significant Irish experience in mass vaccination programmes and international best practice.

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 Health Service Executive (HSE) and the Department of Health (DoH) 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 COVID-19 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.'

The Strategy has been developed by drawing primarily on the advice and expertise of a broad range of groups and individuals, including members of the HLTF. It has also built upon already-established work that was ongoing in both the HSE and the DoH to prepare for the vaccination programme.

The Strategy also draws on relevant input from the World Health Organisation (WHO) and the European Centre for Disease Control (ECDC) as well as learnings from other jurisdictions. In line with the latest guidance from the ECDC [1], our strategy lays out the plans to ensure that the following key elements are in place:

- An ethical and equitable access to vaccination (section 5)
- A transparent communication plan (section 10)
- A vaccine delivery infrastructure and supply chain (section 4)
- The appropriate legal and regulatory frameworks for vaccine deployment (sections 3 & 8)
- A technology solution to underpin the vaccination programme (section 9)
- A means of capturing vaccination data in timely fashion (section 9)
- Monitoring of suspected adverse reactions (sections 3 & 9)
- Post-marketing studies on effectiveness and impact (section 3)
- An evidence-based approach to decision making (section 11)

At the time of writing, there remains a number of unknowns about the vaccines and their availability, and, consequently, about the manner in which the overall programme will be implemented. This Strategy is designed to be a comprehensive framework establishing clear objectives and principles and to identify the pathways for managing a programme of this scale.

It will be accompanied by an Implementation Plan that is 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. The HLTF is committed to the ongoing oversight and monitoring of the vaccination programme and will update and revise the Implementation Plan as required, to serve the overall goals of the programme.

Chair of the High-Level Task Force, Prof Brian MacCraith, thanks all members and their teams for their efforts in the development of this Strategy and the associated Implementation Plan.

December 11th, 2020.

1 www.ecdc.europa.eu/en/publications-data/overview-current-eu-eea-uk-plans-COVID-19-vaccines

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Executive Summary

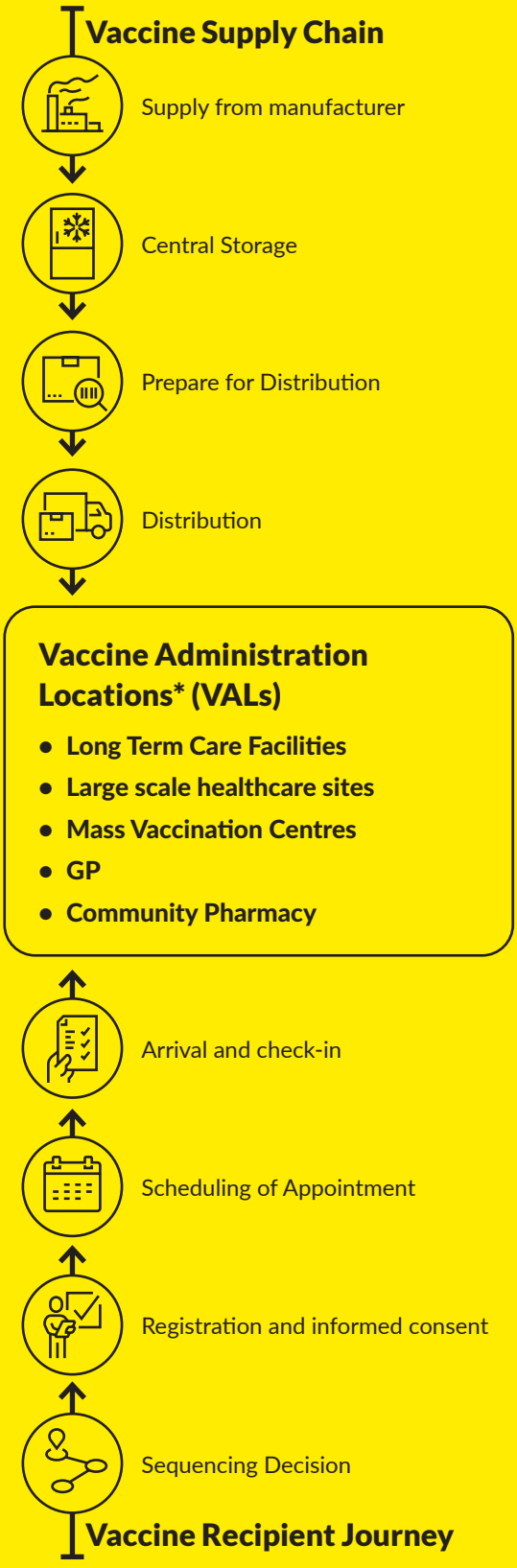
The ongoing COVID-19 pandemic has had a profound effect on the lives of all Irish people over the course of 2020. The Irish public has risen to the exceptional challenges posed by the disease with repeated sacrifices to ensure that important public health measures such as social distancing, hand hygiene, wearing of face-coverings, and restriction of movement have contributed greatly to suppressing infection levels and protecting the most vulnerable in our community.

A programme of effective vaccination against COVID-19 represents the next step to be deployed along with existing public health measures to limit the impact of the disease. The objective of the vaccination programme is, in the first instance, to reduce mortality and morbidity as a consequence of COVID-19. In addition, successful deployment of safe and effective COVID-19 vaccine(s) will be a more sustainable long-term public health measure, over time allowing society to re-open more fully, our communities to reconnect in the ways we used to take for granted and for our economy to resume a positive growth trajectory.

Through its membership of the EU, Ireland has secured access to six prospective vaccine candidates at volumes that are sufficient to vaccinate our total population, assuming all of the vaccines are authorised. The vaccines are currently undergoing rigorous safety and efficacy trials and evaluation, and, if approved by the European Medicines Agency (EMA), are expected to be available for distribution from early 2021. Other candidate vaccines may come on stream in the future.

This document describes Ireland's high-level Strategy for the administration of the COVID-19 Vaccination Programme, while maximising continuation of service delivery in the rest of our healthcare system. The Strategy, and associated Implementation Plan, will coordinate a range of complex requirements to ensure that vaccinations can be administered safely, efficiently and effectively.

Figure 1. End-to-end Vaccination Process



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

Our response to this challenge is underpinned by a range of proven capabilities already in place in the HSE, the DoH, and across the wider public sector, in implementing safe vaccination programmes for the public. These include:

- Highly experienced teams in the HSE's National Immunisation Office (NIO) and Health Protection Surveillance Centre (HPSC) as well as in at the Health Products Regulatory Authority (HPRA)
- A reliable and trusted National Cold Chain solution, which has distributed all vaccines on behalf of the HSE as part of the National Immunisation Programme over the last fifteen years
- Qualified and trained healthcare workers who will administer the vaccine, including hospital doctors, community medical officers, nurses, GPs and pharmacists
- Experience in mobilising significant operations and processes for previous mass immunisation campaigns, and for swabbing, testing and tracing as part of our COVID-19 response.

These tried and trusted delivery mechanisms will be augmented by enhanced structures and processes to ensure the safe and efficient administration of vaccinations at a large scale. These include:

- New settings such as Mass Vaccination Centres, developed following learnings from the early stages of the management of the pandemic
- ICT systems to enable the planning and scheduling of vaccinations, and also to support the monitoring and evaluation of the success and effectiveness of the vaccination programme

Production of vaccines is ongoing and availability will grow if an increasing number of vaccines achieve marketing approval and manufacturing capacity is enhanced. In the early stages of the vaccination programme, when there will be limitations on the numbers of vaccine doses available, access to the vaccine will be sequenced according to equitable, ethically-informed and clinically-driven principles to ensure the most vulnerable in our society are protected. This sequencing (shown in Figure 2 overleaf), which the Government has approved, is based on recommendations from NPHET, on foot of advice from the National Immunisation Advisory Committee (NIAC). As Ireland moves from this initial phase to a larger scale mass vaccination programme, the settings and pathways for vaccine recipients will continue to adapt to meet the requirements to allow a greater level of access.

Figure 2. Vaccination Allocation Sequencing

The vaccination allocation sequencing approved by Government is set out below

Group
Adults aged ≥65 years who are residents of long-term care facilities. Consider offering vaccination to all residents and staff on site.
Frontline healthcare workers (HCWs)* in direct patient contact roles (including vaccinators) or who risk exposure to bodily fluids or aerosols.
Aged 70 and older in the following order: 85 and older 80-84 75-79 70-74.
Other HCWs not in direct patient contact.
Aged 65-69. Prioritise those with medical conditions** which put them at high risk of severe disease.
Key workers (to be further refined) including those 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.
Residents of long-term care facilities aged 18-64.
Aged 18-64 years living working in crowded accommodation where self-isolation and social distancing is difficult to maintain.
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.
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.
Aged 55-64 years.
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.
Aged 18-54 years who did not have access to the vaccine in prior phases.
Children, adolescents up to 18 years and pregnant women (to be refined).

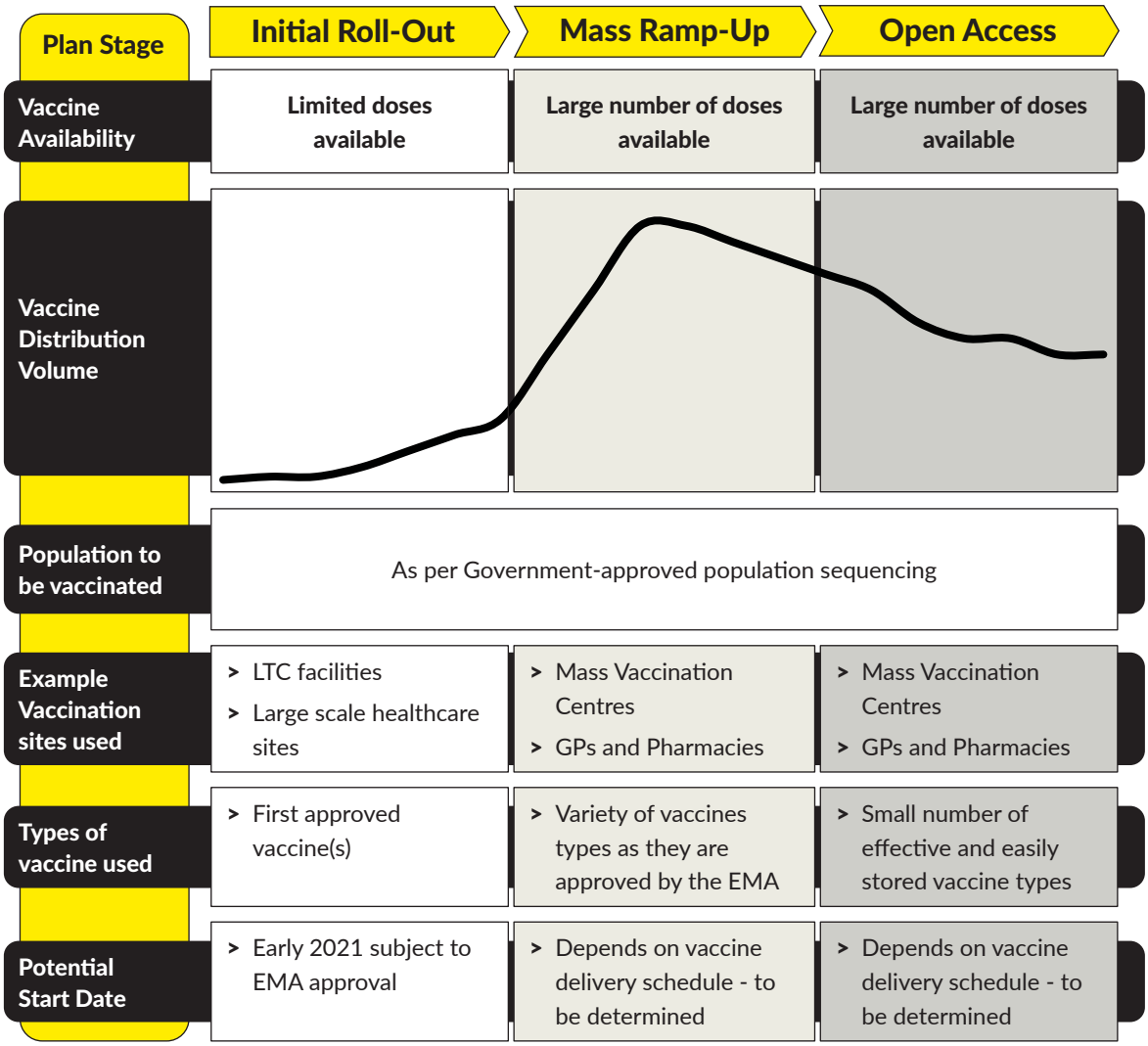
*Includes health care workers who work in and out of all healthcare settings
**Chronic heart disease, including hypertension with cardiac involvement; chronic respiratory disease, including asthma requiring continuous or repeated use of systemic steroids or with previous exacerbations requiring hospital 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 HLTF is confident that, in early 2021, Ireland can begin vaccinations in line with the Government-approved population sequencing. The recommendations above are being provided at a time when there has been very encouraging news in relation to vaccine trials and there is now widespread optimism that vaccines will become available in 2021. However, until there is certainty regarding their safety and efficacy and until there has been a significant proportion of the population vaccinated, there will be a continued need for vigilance and the application of non-pharmaceutical public health interventions. But these developments should strengthen our resolve and give us new momentum to sustain and build on the progress we have made over recent weeks.

It is understood that the sequencing of population groups may need to be adapted as more evidence on vaccine effectiveness, safety and suitability becomes available for specific population groups.

Much is still unknown about the specific supply chain and of some vaccine candidates that may ultimately be approved for use. Consequently, this Strategy provides for the health service approach to be highly agile and iterative to adapt to the circumstances and phases of vaccination roll-out as it progresses.

Figure 3. Overview of three phases of the roll-out



As set out above (Figure 3) 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 prioritisation. These people will receive their vaccines at specified settings, for example in a large scale hospital or through a hub-and-spoke model involving the provision of vaccinations in long-term residential care settings.

As the availability of vaccines increases, additional groups from the vaccine allocation sequencing will receive their vaccinations. During this mass ramp-up, we expect that Mass Vaccination Centres (MVCs) will be introduced to augment other traditional delivery systems and to provide for acceleration of the programme where vaccine supply allows.

1.

Developing Ireland's COVID-19 Vaccination Programme

1.1 Context

The COVID-19 pandemic is an ongoing global crisis, continuing to affect people around the world. In Ireland, the pandemic has been keenly felt, having a profound effect on the lives of everyone. It has transformed the way we live our lives and how we interact with each other. Many families have lost loved ones, people have experienced loneliness and isolation and many people have lost their jobs. The impact of the pandemic on society and on the economy has been extremely challenging.

To date, the virus has infected over 70,000 people in the Republic of Ireland and claimed the lives of over 2,000 people. In order to suppress transmission of the virus, stringent public health measures have been implemented. The public has been asked to socially distance, significantly restrict their movements, regularly wash their hands and wear a face covering. Public compliance with these measures has been critical to the success we have achieved in suppressing this highly transmissible disease and in protecting our health service. Government has supported implementation of these measures on a substantial scale to mitigate or ameliorate the social and economic impacts of necessary public health measures. Yet, the virus continues to impact negatively on the health and wellbeing of the country and the measures necessary to reduce its transmission have had their own impact on health, wellbeing, broader society and our economy.

The overarching objective of the national response to COVID-19 to date has been to protect public health in the first instance, particularly in relation to those most vulnerable to the severe outcomes of COVID-19; to ensure the safe delivery of health services for health needs unrelated to COVID-19; to enable safe provision of childcare services and to ensure that schools and colleges could remain open.

Through widespread commitment and adherence to the public health measures put in place by Government, much of the potential impact of COVID-19 has been averted, the objectives advised by the NPHET have been met, and transmission of the disease has reduced significantly. This is particularly evident by reference to the experience of almost all other countries in Europe in Autumn 2020. In early October, Ireland was mid-table in Europe in terms of disease incidence. The measures in place since then have seen a sharp reduction in incidence, hospitalisation, critical care admissions and mortality. In that time period, most of Europe continued on a path of increasing incidence which led to levels of hospitalisation, ICU admission and mortality which have been largely averted in Ireland by the Government's pre-emptive action.

The overarching objective of this Vaccination Programme will be 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.

COVID-19 vaccines help our bodies develop immunity to the virus that causes COVID-19 without us having to get the illness. Different types of vaccines work in different ways to offer protection, but with all types of vaccines, the body is left with a supply of "memory" cells that will remember how to fight the virus if we are exposed to it in the future.

A number of vaccines for COVID-19 are currently at late stage development. Assuming that these candidate vaccines are approved by the European Medicines Agency (EMA), and continue to show benefit through completion of specific obligations by Marketing Authorisation Holders and on-going post-market surveillance, they will provide a simple, safe and effective way of protecting people against the severe impact of COVID-19 infection. The candidate vaccines use a variety of methods to support the body's natural defences to build resistance to the virus. Over time, as knowledge accumulates, we will learn more about the ability of vaccine candidates to halt transmission, their continuing safety and the duration of immune response following vaccination.

Approval by the EMA will mean that the vaccine, based on the evidence provided for the authorisation, is safe to use and that it is efficacious in preventing illness for someone who contracts the virus. The availability of safe, effective vaccines is an important step in reducing the impact of the disease. Of course, stopping a pandemic requires using all the tools available to us. Vaccines work with one's immune system so that the body will be ready to fight the virus if one is exposed. Other steps, like face masks, social distancing, and washing one's hands help reduce one's chance of being exposed to the virus or spreading it to others. All of these measures will continue to be extremely important over the coming months as we seek to navigate our way through the next phase of this pandemic.

1.2 Guiding Principles

The aim of the COVID-19 vaccination programme is to protect those who are at most risk from serious illness or death from COVID-19. This COVID-19 Vaccination Strategy is based on seven guiding principles.

Figure 4. Guiding Principles	
	**Safety** First and foremost, our priority is safety. The European Medicines Agency (EMA), an independent authority, will carry out a thorough assessment of clinical data to reach a scientific opinion on whether each vaccine is safe and efficacious. The Health Products Regulatory Authority (HPRA) will ensure locally that all standards and conditions of the approval and post-market surveillance are met.
	**Ethical, equitable & clinically driven distribution** Ireland's approach to COVID-19 vaccine distribution will be based on a transparent, ethical framework incorporating clinical and equitable standards which combines ethical principles for stewardship of scarce resources as well as equitable access with prioritisation for those most in need[2].
	**Transparency** Throughout the COVID-19 crisis to date, the State's presentation of facts, and its reliance on scientific and medical expertise, helped build public trust and confidence in Government action. In the same way, the Government will continue to be transparent regarding all aspects of the COVID-19 vaccination programme.
	**Building on existing public health measures** Vaccination does not negate the importance of other public health measures that have served us well to date in the containment of COVID-19. The Government will continue to urge compliance in 2021 with social distancing, mask wearing, hand washing and other measures.
	**Public Outreach** Effective communication will be a critical element of Ireland's vaccination programme. The approach will build on the successful communication and engagement programme delivered throughout the COVID-19 pandemic to date. All communication efforts will have a particular focus on maximising the public's understanding of the vaccines, including oversight in real world use, and on connecting with underserved, hard to reach, vulnerable, and vaccine hesitant populations, as well as focused outreach approaches to communities at highest risk of COVID-19.
	**Balanced with other health services** The design and implementation of the programme recognises the need for balance; in so far as is possible, the continued provision of regular health services; the continued delivery of an extensive COVID-19 test, track and trace capability; and the implementation of a comprehensive vaccination programme.
	**Agile and iterative** Currently there are substantial information gaps in terms of which vaccines will be available, their specific and complex characteristics, their suitability for particular population cohorts, the timing of their approval by the EMA, and experience from on-going monitoring and real-world use. As a result, the plan and its implementation will need to be agile and iterative in order to adapt to new knowledge regarding the ability of vaccines to reduce illness and infection, and circumstances as they arise.

2 See Chapter 5 for the Ethical Foundations for Priority Decisions

2.

Governance and Decision-Making

2.1 Introduction

The challenge presented in devising and implementing a Vaccination Programme of this scale, complexity and desire for speed is unparalleled here and around the world. The successful roll-out of the national COVID-19 vaccination programme requires precise coordination across Government, several State Agencies, HSE and a wide range of advisory, regulatory and delivery partners across the health sector and private sector providers. Close cooperation on each of these fronts has already begun, as detailed throughout this Strategy, to ensure the safe, effective and efficient administration of a COVID-19 vaccine to all residents of Ireland who wish to receive it.

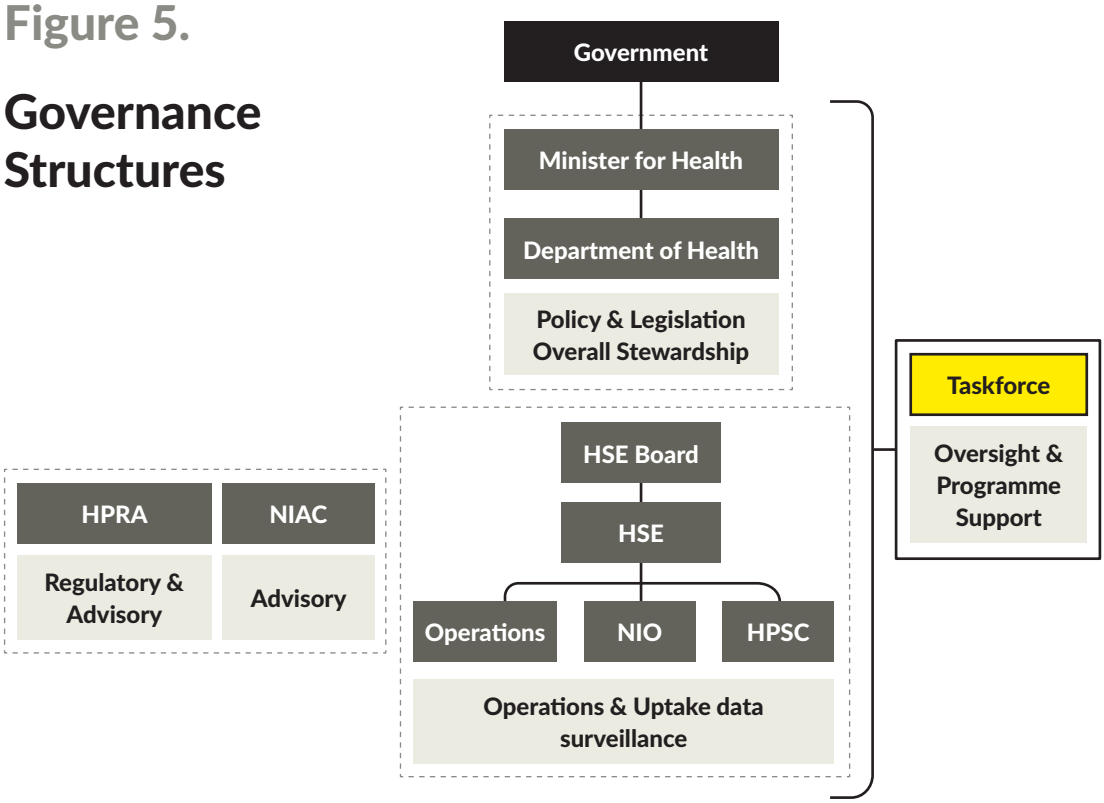
As set out in this strategy, there are number of variables, known and unknown at the time of writing, which will impact the planning and rollout of this vaccination program. These include timing of vaccine authorisations and approvals by the EMA, further definition of priority groups, delivery by providers, distribution and storage requirements, dosage requirements and other variables. This will require a flexible strategy that can accommodate a range of scenarios.

Ireland has a very strong set of institutional arrangements to support good governance, in particular, and most importantly, in respect of the safety of any vaccine.

The implementation of the Strategy will rely in the normal way on the governance structures and statutory responsibilities of a range of existing bodies. However, there will be a need to augment and support existing arrangements given the range of responsibilities, actors and the responsiveness that will be demanded as the programme rolls out. Figure 5 shows the existing roles and responsibilities which are not replaced or displaced, but which will be supported by the oversight role and programme management support of the High Level Task Force.

Figure 5.

Governance Structures



2.2 Existing Institutional Responsibilities & Governance

Department of Health

The **Department of Health**'s role includes formulating policy and providing direction on national health priorities; protecting the interests of patients and consumers; supporting practitioners and professionals to practice to the highest standards by providing a prudent and appropriate regulatory framework and providing effective stewardship of health resources.

In respect of immunisation programmes and policy, the Department makes policy decisions based on advice from the National Immunisation Advisory Committee and these are then implemented by the HSE through the National Immunisation Office.

Vaccine Roll-Out Remit/Lead: *Overall public health policy; legislative and regulatory arrangements, Communications (lead); EU co-operation arrangements in respect of co-ordination of response to disease threats (lead).*

Health Service Executive

The **Health Service Executive** has statutory responsibility for the delivery of health and personal social services including the prevention of illness and infectious disease through immunisation and vaccinations services.

The **HSE COVID-19 Immunisation Programme Team** will lead on operational matters related to the roll-out of the vaccination programme.

Vaccine Roll-Out Remit/Lead: *Overall lead on operational matters relating to HSE roll-out of the vaccination programme, resource and facilities management.*

The **National Immunisation Office (NIO)** is the HSE office responsible for managing vaccine procurement and distribution and developing training and communication materials for the public and health professionals. NIO develops immunisation training and has a role in communications to the public; manages logistic considerations for vaccine storage, distribution under validated cold chain conditions.

Vaccine Roll-Out Remit/Lead: *Vaccine procurement and distribution; immunisation training; communications to the public; logistic considerations for vaccine storage, distribution and return if appropriate under validated cold chain conditions.*

The HSE's **Health Protection Surveillance Centre (HPSC)** collects immunisation data and is responsible for compiling and publishing uptake (coverage) statistics during the rollout of vaccine programmes in Ireland, liaising closely with the European Centre for Disease Control (ECDC). Data presented by the HPSC ultimately feedback to immunisation implementation planning and policy development.

Vaccine Roll-Out Remit/Lead: *Data collection in respect of uptake and coverage (lead).*

Health Agencies

The **Health Products Regulatory Authority (HPRA)** is the national body which grants licences for medicines (other than those licensed centrally on the basis of an EMA opinion), in Ireland, following a review of their safety, quality and efficacy. The HPRA is also responsible for monitoring vaccine safety, quality and effectiveness post-authorisation, and, where medicines are licensed centrally for all EU member states, works closely with the European Medicines Agency (EMA) at the European level.

Vaccine Roll-Out Remit/Lead: *The HPRA participates in EMA assessment process, including those leading to authorisation opinion, as well as post-marketing benefit/risk monitoring and variation applications. The HPRA operates the national safety monitoring and risk management system and has oversight of quality defect reports.*

The HPRA oversees quality defect reports on vaccines and other medicines and in addition licenses the facilities that carry out related manufacturing and distribution activities.

Existing Cross Agency Structures & Processes:

The **National Public Health Emergency Team**[3] oversees and provides national direction, guidance, support and expert advice on the development and implementation of a strategy to contain COVID-19 in Ireland. It advises Government on the public health aspects of what is a cross-Government response to COVID-19.

Vaccine Roll-Out Remit: *Cross-agency advice on vaccine programme including in particular relating to prioritisation in the context of pandemic management.*

Both the **HPSC and the Department of Health** work closely with the European Centre for Disease Control (ECDC), which is the European body responsible for risk assessment of infectious disease. The DOH is represented on the Health Security Committee (HSC) of the EU Commission, which coordinates the response of EU member states to infectious disease threats.

Vaccine Roll-Out Remit: *Ongoing advice on the role of vaccine programme and impact in terms of pandemic management; sequencing of roll-out; response to emerging issues.*

The **High-Level Task Force on COVID-19 Vaccination** was established to support the Department of Health (DoH) and the Health Service Executive (HSE) to deliver a COVID-19 vaccination programme that meets best practice and good governance.

Working with the DOH and the HSE, the Taskforce has developed this national COVID-19 Vaccination Strategy and an associated Implementation Plan for the safe, effective and efficient procurement, distribution, administration and recording of COVID-19 vaccines.

Notwithstanding the existing institutional arrangements, good governance is a system and process, not a single activity and therefore successful implementation of a good governance strategy requires a systematic approach that incorporates strategic planning, risk management and performance management across of these actors. Therefore, the High Level Taskforce will have an ongoing role in the oversight and monitoring of programme implementation.

Vaccine Roll-Out Remit /Lead: *Monitoring the progress of implementation of the National COVID-19 Vaccination Strategy and reporting to the Government (lead).*

3 The NPHET's membership is multi-disciplinary and multi-sectoral in line with best international practice. Membership comprises representatives from across the health and social care service including the DOH, HSE, HPSC, Health Information and Quality Authority (HIQA), Health Products Regulatory Authority (HPRA), NIAC and others with relevant expertise in health and/or other related matters.

3.

Vaccine Overview

3.1 Vaccine Development and Marketing Authorisation

Vaccines represent one of the most successful public health interventions in human history. According to the World Health Organisation (WHO), global vaccination programmes save up to 3 million lives per year[4].

The eradication of Smallpox and the virtual elimination of Polio; protection against cervical cancer; protection of the vulnerable against influenza — all arose from vaccination. Indeed, the immense suffering that today's vaccine preventable diseases caused to children, families and societies just 50 years ago should act as a constant reminder that we need to keep promoting and investing in vaccination.

There are over 200 COVID-19 vaccine candidates worldwide in various stages of development. The EMA is currently assessing detailed information regarding two of these. In addition, the EMA has been reviewing or will review data on other vaccines.

In order to ensure their safety and efficacy, COVID-19 vaccines are developed according to a rigorous and highly regulated process:

1. Discovery - understanding the genetic structure of the virus, confirming suitability for an immunisation approach and the subsequent identification of vaccine candidates.
2. Preclinical testing - the identification of safe vaccine candidates.
3. Three-stage clinical trial process - the testing of vaccine candidate safety, dose optimisation and general safety and efficacy in accordance with Good Clinical Practice.
4. Regulatory review and approval, which includes all the details relating to the candidates' safety, efficacy and quality.
5. Manufacturing, testing and distributing in accordance with EU Good Manufacturing and Distribution practice.
6. Post-marketing surveillance through active and passive monitoring as outlined in Section 3.2 and 3.3

Every vaccine that is approved for use in Ireland must go through these stages of testing and approval. Although the development and authorisation of COVID-19 vaccines are being carried out under an accelerated timeline (achieved primarily due to unparalleled levels of collaboration, a global scientific concerted effort, and the significant resources invested in this process), the standards for normal vaccine quality, safety and efficacy still apply.

In order to gain approval for a vaccine in Ireland, each vaccine developer must make a formal application to the European Medicines Agency (EMA). This submission, in line with European Guidelines and standards, includes data covering aspects of candidate safety, quality and efficacy. These reviews are completed by expert scientists and clinicians and conclude with a formal, documented and publicly available decision and rationale on each candidate being delivered via standard process within the EMA and European Commission.

It is expected that any vaccine candidates deemed to have a positive risk-benefit profile following review the EMA will be subject to a Conditional Marketing Authorisation (CMA)[5]. However, all vaccines are subject to rigorous and ongoing monitoring before, during and after authorisation has been granted.

The mechanism chosen at EU level to accelerate the assessment and authorisation of COVID-19 Vaccines is that of a Conditional Marketing Authorisation.

The conditional marketing authorisation (CMA) procedure, when used in emergency situations, is specifically designed to enable marketing authorisations at the earliest time point, as soon as sufficient data becomes available to demonstrate that the benefits outweigh the risks.

4 www.who.int/health-topics/vaccines-and-immunization#tab=tab_1
5 www.ema.europa.eu/en/glossary/conditional-marketing-authorisation

A CMA is a fast and pragmatic regulatory tool that offers multiple controls, valid for one year and renewable. It is an EU marketing authorisation with corresponding rights, obligations, liabilities and provides an agreed plan, with specific and enforceable obligations on the applicant, to ensure that comprehensive data is still generated after approval[6].

The CMA also provides full product information, laying out the medicine's conditions for use in all EU languages, as for all authorised medicines by the time EC issues its decision. Lastly, it provides an investigation plan[7] for future use of the medicine in children.

All this ensures a high level of protection for EU citizens when the vaccines will be used across all EU Member States in mass vaccination campaigns.

As information and advice from vaccine authorisation-holders changes or is updated, it should be recognised that this will be included and implemented in our vaccine handling and administration process. This will require an agile and rapid approach to our communication, education campaigns and consenting process.

3.2 Monitoring Vaccine Safety

At the time of approval, the main body of evidence for vaccine safety and efficacy comes from large controlled, randomised clinical trials. Selected volunteers are randomly allocated to receive the vaccine being tested and followed up under controlled conditions in line with strict protocols. By necessity, clinical trials are limited in duration and in the number of people involved. As such, monitoring of benefit and risk must continue post-approval, so that any changes are detected, including any new safety information emerging from use in more diverse and larger populations, in particular of rare or very rare reactions.

The EU has a comprehensive safety monitoring and risk management (pharmacovigilance) system. The HPRA, as a National Competent Authority, participates in EU safety monitoring activities, together other member state agencies, which are coordinated overall by the EMA.

Using well-established systems of safety surveillance, available safety and effectiveness data, collected through each national monitoring system, as well as that submitted by vaccine marketing authorisation holders, will be continuously monitored to detect any changes in benefit-risk balance. The EMA's safety committee will make any further recommendations on use of the vaccines, as and if needed.

In view of the public health urgency and the extensive vaccination campaigns foreseen worldwide, an additional safety monitoring plan specific for COVID-19 vaccines has been agreed. The plan builds on the well-established surveillance system, with aspects intensified to take account of the anticipated high and rapid uptake, and to enable the necessary monitoring of use in the real-word setting, across larger and more heterogeneous populations, including special groups who may, by necessity, have had limited representation in pre-licensing clinical trials. All vaccines recommended for authorisation by the EMA will be monitored according to this plan, in addition to existing requirements.

In Ireland, the HPRA is responsible for operating the national pharmacovigilance system and for participating in EU-wide safety monitoring coordinated by the EMA. In this regard, the HPRA will undertake the following key activities:

- Overseeing enhanced passive reporting from health-care professionals and members of the public, as well as the HSE, of suspected adverse reactions, with onward reporting of anonymised individual case safety reports to the EMAs Eudravigilance database, for inclusion in further analysis to detect and evaluate any potential signals.

6 The applicant commits through specific legally binding obligations to provide the additional data according to set pre-defined deadlines. When all the specific obligations, have been fulfilled, a CMA can be turned into a standard marketing authorisation, also renewable and valid for 5 years.

7 www.ema.europa.eu/en/human-regulatory/research-development/paediatric-medicines/paediatric-investigation-plans#accelerated-procedure-for-covid-19-treatments-and-vaccines-section

- Onward provision of anonymised vaccine coverage data, to enable scientific analysis of observed rates of adverse events of special interest.
- Aligning with EMA plans to communicate regular and periodic public updates on safety experience.
- Involvement in EU-wide safety reviews, including of periodic data provided by the marketing authorisation holders, as well as any emerging data from other sources, such as independent studies.
- Escalation of emerging safety issues, if any, as appropriate.

The safety monitoring plan will be adapted, as needed, to include any additional elements considered necessary following the evaluation of vaccine quality, safety and efficacy data, and the risk management plans for individual vaccines by the EMA during the marketing authorisation evaluation process.

3.3 Monitoring Vaccine Effectiveness

Pre-licensure clinical trials undertaken by the vaccine developers have been reported to demonstrate convincing vaccine efficacy. These data will be considered independently by the EMA, prior to a recommendation being given to authorise a vaccine. Clinical trials are a highly controlled environment, designed to determine how well the vaccine works across several outcomes in a defined population. It is necessary to gather further information post-authorisation, regarding effectiveness in real world use, to address any uncertainties on aspects of vaccine efficacy.

In the case of SARS-CoV-2, an efficacious vaccine might prevent infection, disease, or transmission. The emerging data on the most promising COVID-19 vaccine candidates suggests that, while they may be effective in preventing disease symptoms and reducing the severity of disease, it remains unclear whether vaccinated people could still develop asymptomatic infections — and thus still be able to spread the virus to others. Until more information is available on transmission, and in any event until a large proportion of the population have been vaccinated, it will be of vital importance that we continue with the other protective measures to reduce the risk of transmission, including physical distancing, hand-washing and using facemasks.

Further research and monitoring will be essential throughout a programme of vaccination.

During and following the implementation of the vaccination programme, it is necessary to monitor the impact and vaccine effectiveness on the population. The HSE will monitor the vaccine effectiveness nationally following the implementation of the programme. Such ongoing assessments are necessary to determine how well these vaccines are protecting people from contracting COVID-19 in the wider population under normal conditions. Factors that can affect a vaccine's effectiveness include vaccine transport and cold chain management, how clients are vaccinated, timing of vaccination (interval between doses), but may also be affected by underlying characteristics of the individuals vaccinated (age, medical conditions of those receiving the vaccine). These assessments are also invaluable to determine the duration of protection from COVID-19 and whether booster doses may be needed and at what interval after the primary vaccination. Vaccine effectiveness studies can also be used to understand how well a vaccine is working in groups of people not included or not well represented in clinical trials.

The HPRA and the HSE's HPSC have an established arrangement in place for the exchange of information on cases of vaccine failure, collected through the national pharmacovigilance system or through national vaccine impact and effectiveness monitoring, respectively. Any cases reported to the HPRA, will be reported onward to the EMAs Eudravigilance database, for cumulative signal detection purposes. Further, the EMA will make recommendations on any additional approaches, including studies, required by vaccine marketing authorisation holders to monitor for vaccine effectiveness, as part of the authorisation process and consideration of the risk management plan. Any long-term data from clinical trials on vaccine efficacy will also be considered through post-authorisation submissions. Any regulatory recommendations and decisions arising from these data will be made by the EMA, and the HPRA will engage with national public health partners, as appropriate, in relation to any such updates.

3.4 Ireland's COVID-19 Vaccine Allocation

The EU has signed up to six Advance Purchase Agreements (APAs) with pharmaceutical companies, which allow access to a committed quantity of doses, in the event that their vaccine is approved for use. At the time of writing, the Irish Government has signed up to five of these six APAs, and signalled its intention to sign up to the sixth when trial data emerge. 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.14.3m doses based on APAs signed to date and assuming that all products are approved for use.

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.

Some of the COVID-19 vaccines are likely to be manufactured and supplied in multi-dose vials, may require reconstitution and have a limited shelf life outside of refrigerated storage (typically a number of hours once reconstituted).

As more information on vaccine characteristics and availability becomes known, vaccine storage, transport and cold chain requirements will need to be carefully assessed in the context of logistical plans for delivery.

All the currently known requirements related to the current vaccine candidates have been factored into the logistics and detailed implementation planning in terms of cold-chain, transport and delivery mechanisms and this will be kept under constant review.

4.

Programme Logistics

4.1 Vaccine Distribution

Managing the supply, storage and distribution of potentially multiple COVID-19 vaccines will involve complex logistical operations. In line with other countries across Europe, Ireland will leverage and build on existing vaccination delivery services and structures for the rollout of COVID-19 vaccination plans. The process will be managed using the expertise of the HSE, its National Immunisation Office (NIO), and the national cold-chain logistics partner. All these parties have extensive experience in managing the logistics of previous mass national vaccination programmes in Ireland. While the specific logistics associated with each potential vaccine are not yet fully known, each vaccine will broadly follow a similar supply chain to reach the vaccination locations as outlined in the process below. Additional supply chain and logistics expertise across the wider public sector and the private sector will be leveraged where necessary.

End-to-end supply chain

The supply chain process will involve the receipt of vaccines in Ireland from a number of manufacturers, the storage of these vaccines in a temperature-controlled central storage facility, preparation of vaccines for distribution to vaccination locations and the delivery logistics to vaccination locations.

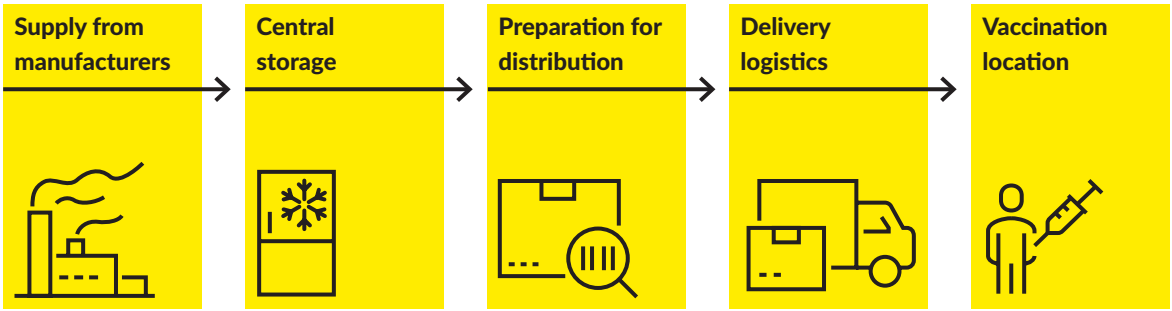
Supply from manufacturers

The arrangements for supply of potentially approved vaccines from pharmaceutical companies and the timing of delivery to Ireland are currently under discussion. It is expected that the volume of vaccines delivered will ramp-up through 2021 as production capacity increases. Shipping methods from manufacturing sites will include both air and road/sea and these will be agreed with manufacturers. Supply Chain risks associated with Brexit are being included in contingency planning.

Storage of vaccines

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 HSE's logistics partner has prepared substantial storage capacity for each temperature range.

Figure 6.



Order Management and Preparation for Distribution

In order to ensure the correct volume of vaccines are received by each Vaccination Administration Location (VAL) at the right time, a robust, accurate, real-time inventory management system will be in place to assure availability and maintenance of adequate supplies, minimise potential wastage and accurately forecast demand which can be met. The varying storage temperatures and shelf-lives out of storage of each vaccine type will mean certain vaccine types may be more suited to certain vaccination location types (e.g. Large Scale Health Care Facilities), depending on the volume of vaccinations carried out at the setting and the storage facilities on site. Ensuring adequate availability of the vaccine for the second dose will also be considered when managing stock levels.

Delivery Logistics

Within Ireland, existing infrastructure and established vaccination distribution channels will mean vaccines can be delivered efficiently using road distribution channels directly from the central storage facility. The HSE's logistics partner will also manage the delivery fleet and outbound logistics / delivery to the principal vaccination locations. All deliveries will be by chilled (+2 to +8 °C) distribution using the National Cold Chain fleet. One of the potential vaccines must be 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.

Vaccination Administration Location (VAL)

All Vaccination locations will require appropriate resourcing, consumables and equipment. The handling and storage of vaccines at vaccination locations will require Standard Operating Procedures (SOPs) and specialist training for on-site staff. For certain vaccine types, there are also additional steps in preparing the vaccine for use that will need to be carried out by trained individuals or vaccinators on-site before administering.

5.

Accessing the Vaccine

5.1 Ensuring Equitable Allocation of the Vaccine

It is likely that when vaccines are approved there will be more demand than there will be vaccine doses available. For a range of practical reasons and in order to ensure that the maximum benefit at a population level is achieved, a prioritisation is necessary – so as to allocate vaccines in a fair and appropriate way and reduce morbidity and mortality across the population.

Vaccine supply levels may vary during the COVID-19 Vaccination Programme. Planning will be flexible by design to respond to a variety of scenarios. As vaccine supplies are likely to be limited at the start of the programme, the allocation of doses must be targeted first at those population cohorts prioritised by Government. The vaccine supply is then anticipated to increase in the following months, allowing for vaccination to be expanded to additional population groups. Prioritisation of groups may also be modified as more evidence becomes available about the COVID-19 disease epidemiology and vaccine characteristics, including information on vaccine safety and efficacy by age and target group. This information will be essential to modelling different scenarios and refining the prioritisation process.

5.2 Ethical Foundations for Priority Decisions

Decisions about how to prioritise limited supplies of COVID-19 vaccine(s) should not be based on public health considerations alone. The priority-setting process has tangible consequences for people's health and quality of life, and this requires that the values and principles which underpin choices regarding prioritisation should be made explicit. Using ethical principles to guide decision-making can enhance trust and solidarity and can strengthen the legitimacy and acceptability of the decisions reached.

The Allocation Framework developed by the DoH combines ethical principles for the stewardship of scarce resources as well as equitable access, with prioritisation for those most in need. Four core ethical principles provide a guide for group prioritisation for vaccination: the moral equality of all persons, minimisation of harm, fairness, and reciprocity:

- **The principle of moral equality** recognises that human beings have equal worth and an equal right to respect and dignity, and as such no one person is more valuable or worthy of consideration for priority than another.
- **The principle of minimisation of harm** recognises the obligation to protect the public from serious harm. Harm is a broad concept and includes physical, psychological, social and economic harm. Harm is most obviously observed as COVID-related mortality and morbidity.
- **The principle of fairness** requires that those with relevantly similar interests are treated similarly, and that no individual or group should shoulder a disproportionate burden or benefit relative to others. This implies that equal weight is given to equal claims of people to resources.
- **The principle of reciprocity** requires that special consideration be given to those groups who play an essential role in responding to the pandemic and, in doing so, place themselves at greater risk of being infected than the general population.

The framework also points to the importance of the procedural values of transparency, inclusiveness, responsiveness, reasonableness and accountability in reaching decisions regarding the allocation of a COVID-19 vaccine.

5.3 Population Sequencing

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 (NPHET). It provides the provisional sequencing for groups to be vaccinated based on clinical priorities and ethical values.

While the goal is to offer the vaccine to those for whom it is indicated, given the global demand, it is likely that supply of any authorised COVID-19 vaccine will be limited initially, and will not be sufficient to vaccinate the entire population. Likewise, any vaccine will take time to distribute and administer. Determining who should be given priority for vaccination during this period of scarcity will require careful deliberation and informed planning. Identifying priority groups for COVID-19 vaccination is an essential element of planning a successful population-wide vaccination programme.

Provisional sequencing, as set out below, is based on the epidemiology of COVID-19 and preliminary information on vaccines in development. It assumes that candidate vaccine(s) are safe and effective in all groups. Another underlying assumption informing the prioritisation process is that the majority of the population remains susceptible to COVID-19 and that prior infection is not necessarily proof of immunity.

This is an initial allocation strategy; it will be capable of adaptation based on further expert advice and in accordance with the data and status of evidence that emerges over time. Scientists and clinicians will continue to play a key role in determining the ongoing evolution of vaccine sequencing to ensure the optimum approach from a public health perspective. Thus, the vaccine allocation strategy should be considered a “living document” which will be constantly updated and adapted where necessary in light of any new findings.

Importantly, those in our society at highest risk of suffering, and most vulnerable to the worst effects of COVID-19, are prioritised as part of this listing.

Figure 7. Vaccination Allocation Sequencing

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.

6.

Vaccine Deployment Plan

6.1 Vaccine Administration Location (VALs)

The range of vaccines, their different handling and storage requirements, their availability and the associated clinical guidance will mean a range of different options must be employed as part of the Vaccine Deployment Plan. In addition, the Government's COVID-19 Vaccine Allocation Strategy will influence the sequence in which those locations are used. Five types of Vaccination Administration Locations (VALs) are envisaged to reflect this fact and it is likely that all five will be used at various stages across the lifecycle of the vaccination programme, subject to necessary agreement. The five types of VAL being considered are:

- **Health Care Facilities** – e.g hospital
- **Long-Term Residential Care Facilities** - e.g. residential facilities for older persons; other congregated settings.
- **Mass Vaccination Centres** (MVCs)
- **General Practice**
- **Community Pharmacy**

In developing its plans to establish VALs, the HSE is undertaking modelling exercises to consider the number of sites required to distribute the vaccines in line with the sequencing framework approved by Government, the required workforce to deliver the vaccines, and the necessary vaccine and consumable supplies required.

In the early phases of the vaccination programme, we are expecting that at least one large acute hospital / community hub in each of the 9 Community Healthcare Organisations (CHO)* within the HSE will be used as the initial vaccination locations. These sites can also be used as the hubs for mobile distribution of vaccines to long-term residential care facilities. Following this phase, learning from these early VALs will be used to stand up a number of MVCs across the country. 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.

A rigorous approach to managing a VAL has been developed using the learnings from the development of COVID-19 swabbing sites and the delivery of the 2009 H1N1 vaccine programme. The successful and efficient execution of any vaccination point will require:

- **Vaccines** available in the appropriate quantities with sufficient time before expiry
- **Supplies** including needles, syringes, emergency medicines, PPE, services, IT and other consumables
- **Vaccinator staff** qualified and trained for the particular vaccine in use
- **Other staff** to cover administration, reception, security and other tasks
- **Clients** scheduled, time-separated and aligned to the available staffing and vaccine. Adherence to ongoing public health guidelines should be ensured.

A significant portion of the country's population may be vaccinated at MVCs. The selected MVCs will have suitable space to enable full compliance with all public health guidelines and will comply with rigorous Infection Prevention and COVID-19 Control measures. In order to achieve this, the HSE has identified existing spaces that can act as national, regional and local VALs. VALs must be of a sufficient scale to be efficient and optimise vaccine throughput. In addition, they need to be in, or near to, areas of population density and have sufficient internet connectivity to enable access to the digital solution.

Community Healthcare Organisations are the organisational structures for the HSE services outside of the Acute Hospital System.

7.

Vaccination Workforce

7.1 Vaccinators

All vaccinators will be qualified and registered healthcare professionals. In addition, they will receive comprehensive training in the COVID-19 vaccination programme in respect of the attributes of the particular vaccine that they are administering. Vaccinators may include:

- Medical and nursing staff in the acute hospital system
- Medical and nursing staff in the community healthcare system
- Medical and nursing staff in private hospitals and healthcare facilities
- General Practitioners
- Other regulated healthcare professionals approved to vaccinate[8]

Existing plans will need to be expanded to train additional vaccinators in 2021, as required. As part of this, we are considering the actions being taken by other jurisdictions, e.g. the licensing of recently retired health professionals or maintaining registration in the case of others.

In addition to the vaccinators themselves, the implementation of the development of the VALs, and the workforce that support it, will require significant coordination between a series of Government, voluntary organisations and private businesses.

Nursing and Midwifery are the largest workforce with many trained vaccinators across the acute and community system. Involvement in all vaccination programmes to date as part of the multidisciplinary team in roles such as coordination and vaccine administration provides experience with a broad reach to support efficiency and optimisation across the range VALs outlined.

The wider role of nursing and midwifery including patient assessment, risk management, observation, monitoring, mobility and management of adverse events will be key for management of vulnerable populations and societal groups and an important consideration for workforce planning.

7.2 Training

The COVID-19 Vaccination Programme will be delivered by skilled and trained staff working in a variety of delivery locations. All staff working in the programme will receive training relevant to their role in the team and service. Training programmes will be delivered on-line, and where required, in person. In addition to the specialist clinical training required for vaccinator staff, induction and orientation training will be provided for all staff working in Vaccination Centres and as part of COVID-19 community Vaccination Teams. This will include, but is not limited to, training in Infection Prevention Control and in relation to the technology solutions which support the vaccination process.

Standard operating procedures, including an overarching vaccination protocol, will be developed for the vaccination centres and teams which will outline all required processes to support the vaccination pathway.

7.3 Scaling the Workforce

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. Currently a number of options are being explored to support the scaling up on workforce for the programme and discussions will be taking place with respective staff groups and bodies over the coming weeks.

In particular, General Practice and Pharmacists can and have successfully delivered very significant numbers of flu vaccines and can offer enhanced capacity for this programme subject to agreement.

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.

8 Pharmacists may need to be specifically licensed for COVID-19 vaccines (Subject to any necessary amendment of Medicinal Products (Prescription and Control of Supply) Regulations 2003 to 2015)

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.

8.

Supporting Informed Decisions by Citizens Participating in the Vaccination Programme

8.1 Informed Consent

Obtaining informed consent for immunisation is both an ethical and legal requirement in any vaccination programme. Consent derives from the principle of autonomy and forms an important part of medical and public-health ethics, as well as international law. The importance of consent is that it facilitates the freedom to make choices that reflect the individual's own values, beliefs and life experiences.

The primary principle for informed consent is described in the Irish Medical Council's Guide to Professional Conduct, which states: [11.1] "You must give the patients enough information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care. Consent is not valid if the patient has not been given enough information to make a decision."

While the context of a public health immunisation programme differs from both primary and secondary care prescribing, similar principles apply. For consent to be valid, it must be informed, understood and voluntary, and the person consenting must have the capacity to make the decision. Special consideration must be given to consent arrangements for those individuals who may lack capacity to give consent. Informed consent must be preceded by disclosure of accurate, adequate and relevant information in a manner that is comprehensible to the person about the nature, purpose, benefits and risks of vaccination.

The benefits of vaccination should address both benefit to the individual and to society such as the potential for individual and herd immunity. Risks, both in terms of known risks e.g. adverse side effects as well as the potential for unknown risks attaching to the vaccine, should be communicated to the vaccine recipient.

In the current context, it will be important to make clear to potential recipients of a COVID-19 vaccine that the duration of immunity conferred is currently unknown and may not be equally effective across all age-groups. The benefits and risks that are disclosed will depend on what is known about them at the time consent is given. This should include information on the product and the Patient Information Leaflet (PIL). Knowledge about the vaccines will continue to advance and it is important that the benefit/risk ratio be continually reviewed and updated in all information and consent material provided to potential recipients will often change.

8.2 Building Confidence

It must be also recognised that people will have questions about a COVID-19 vaccine. Potential recipients should be given an opportunity to ask questions and to discuss any fears they may have around immunisation. This is particularly pertinent in the context of promoting vaccine confidence.

Ireland is no different to other countries when it comes COVID-19 vaccination planning and the myriad of challenges this presents. As our public health clinicians and their teams get ready for the national effort to vaccinate against COVID-19, public health and healthcare and clinical experts, policy makers, and the public will benefit from lessons learned from planning and workshop exercises and examining the experience of previous public health mass vaccination programmes.

This Strategy and associated Implementation Plan have considered both the expertise developed and the experience gained by Expert Groups, organisations and agencies across the State from pandemics and outbreaks that have affected Ireland in the past, including the 2009 H1N1 Pandemic, and have proactively applied these lessons learned to COVID-19 vaccination planning.

Communications to the public and all the participants involved in supporting and delivering the vaccination programme is a critically important and discrete workstream in this Strategy and detail on the wider population approach is set out in Section 10.

8.3 Provision of Concise and Clear Information

The HSE, in consultation with the Irish Medical Council and the National Adult Literacy Agency, will generate information for patients, consistent with the available authorised product information. For each vaccine, this will be written in plain English and will be displayed prominently and be freely available at all VALs. It will also be available on request from the HSE and online. A copy of the regulatory, approved patient information leaflet will also be made available (paper or electronic means).

This will help to ensure that each person receiving a vaccine is giving informed consent to receive a COVID-19 vaccination, and that they (or their parents or guardians) will be provided with consent forms and sufficient information to allow an informed choice to be made. This information will be provided in a way that is fully comprehensible, and will describe the nature, purpose, benefits and risks of the vaccination and any measures to alleviate the symptoms arising from after effects (e.g. paracetamol to relieve high temperature).

All information surrounding the vaccine development, testing limitations (if any), and administration held by the manufacturer and regulatory authorities must be fairly represented in a balanced and summarised manner. In order to provide valid consent, potential recipients, who might have a range of literacy and numeracy skills, should understand the core message of the vaccine's purpose, benefits and risks. This includes disclosing that suspected adverse reactions might not be caused by the vaccine and that rare side effects may not have been detected in clinical trials.

8.4 Providing Up to Date information

The HSE information leaflets and the authorised Patient Information Leaflet (PIL) will be subject to change as new data emerges, and will include all significant facts about the vaccine, such as:

- Approval process related to the vaccine's market authorisation, including testing and limitations of testing
- Licensing
- Any new component or technology that has not been licensed or used previously
- Post-marketing analysis by the relevant regulatory agencies
- Potential and known side effects and adverse reactions including that described in the regulated package leaflet (issued by EMA)
- How and where to report side effects – a phone number will be included
- How to alleviate possible symptoms arising

The HPRA website will include links for the up to date authorised product information.

Additional and updated information such as a Patient Information Leaflet (PIL) should be provided and easy to find, with access to a central information source such as a designated website and telephone service. While all information provided will represent the state of knowledge at that time, new information and emerging facts will be documented and promulgated where appropriate and in a timely manner. It is strongly recommended that no comparison or recommendation is made between vaccine variants currently available or yet to be approved.

8.5 Continuous Engagement with the Regulatory Authority

The HSE and the Department of Health will continually monitor data from the regulatory authority (HPRA nationally and EMA at EU level) in relation to vaccine safety signals, as well as any data arising from public health monitoring and surveillance activities. As stated elsewhere within this Strategy, the relevant authorities will be carrying out formal post-monitoring surveillance on the use of the COVID 19 vaccines to identify any emerging issues including significant adverse, purported or coincidental events. The HSE and the Department of Health will ensure that any necessary information arising from this monitoring of the vaccines will be adequately and promptly communicated. All information in relation to licensed vaccines for COVID-19 will be available from the HSE website, which will be kept up to date with all relevant and appropriate information.

The EMA will further issue public statements in relation to the benefit risk of vaccines, including any updated recommendations. The HPRA will publish safety summaries, outlining national reporting experience. The HPRA may further approve Marketing Authorisation Holders to issue Direct Healthcare Professional Communications. Any emerging safety issues will be communicated to public health partners, or escalated to NIO and NIAC, as appropriate.

9.

Digital Infrastructure

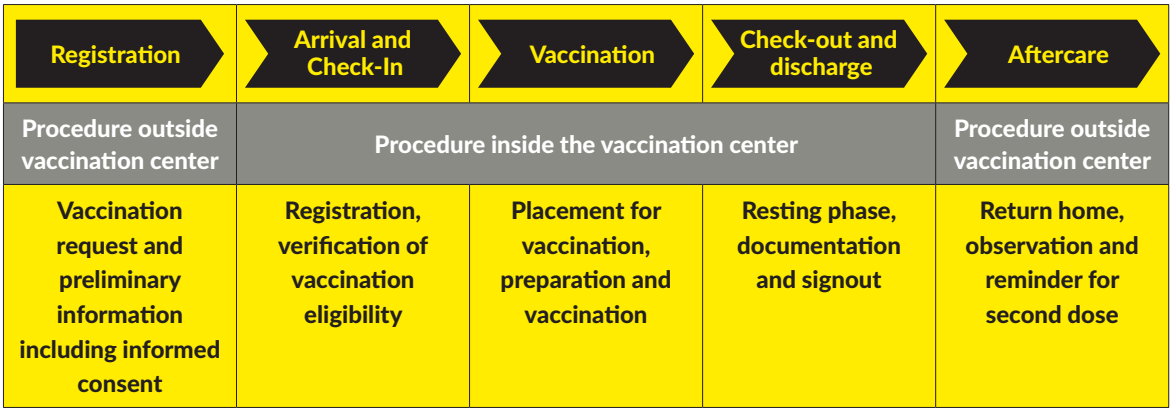
9.1 System Specification & Requirements

Regardless of where people receive the vaccine, the approach and process will be similar. The HSE is developing an end-to-end, comprehensive digital solution to underpin this process and support the delivery of the vaccination programme. The diagram below sets out the process that everyone being vaccinated will go through.

It is critical for efficiency at scale and accurate record keeping and reporting that this process is systematically enabled, and key data elements are captured at the time of execution of each phase.

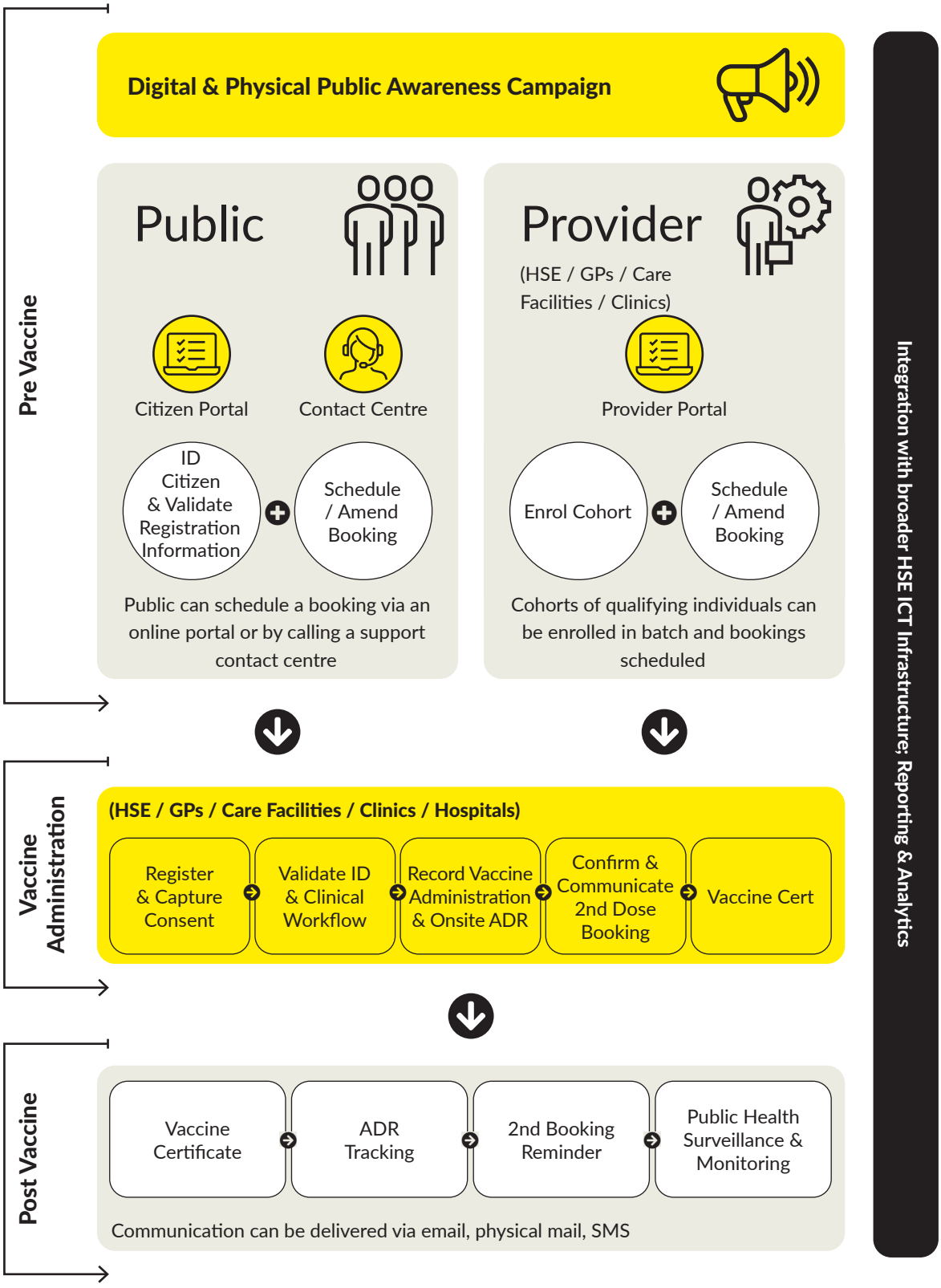
A key challenge with the enablement of the process is that Ireland does not have a national vaccination ICT system with the required level of functionality to support the COVID-19 vaccine rollout. Therefore, a functionally rich and proven solution for the proposed vaccination programme must be sourced, purchased, implemented and integrated into the HSE ICT infrastructure before the end of the year.

Figure 8. Vaccination process



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

Figure 9. Outline Workflow - Core Functionality



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 several existing systems and databases across the state infrastructure. 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.

9.2 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.

Under the GDPR, processing of personal health data is generally prohibited, unless it falls into one of the expressly foreseen scenarios in Articles 6 and 9 of the GDPR (i.e. there is a 'legal basis'). 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.

9.3 Vaccination Uptake Monitoring

As noted by the ECDC, monitoring uptake of COVID-19 vaccines will provide information about the performance and efficiency of the vaccination programme and its capability of reaching most of the population. In addition, it will provide information on how equitable (in terms of access to vaccines) and how acceptable the programme is to target populations. Data collected at the most detailed geographical level and in specific subgroups will allow for the identification of areas with low coverage and pockets of susceptible individuals (or specific groups that may pose a risk for the wider community, e.g. healthcare workers).

The NPHET will review and report vaccination data at regular intervals and, in line with its commitment to transparency, will communicate the data publicly. Transparency is vital for ensuring that all aspects of the vaccination programme are worthy of trust and can promote the necessary solidarity and mutual responsibility needed for a successful strategy.

Vaccination uptake will be assessed in an ongoing manner to track the implementation of the programme and acceptance of the vaccination in the populations targeted in line with the prioritisation framework. Monitoring of the uptake by population group may be done where it is possible to obtain denominator data (e.g. census data for different age groups). Where denominators are not readily available, estimates will be made based on estimates of populations at risk. Analysis will be carried out on uptake by demographic characteristics, such as gender, age, area of residence, HSE region (LHO and CHO), workplace settings for HCWs (University hospital groups, hospitals, long-term care facilities, primary care sites), occupational or clinical risk group.

Data obtained on vaccination will also be monitored at individual, target group, and population level, including specific vaccines administered, number of 1st doses and 2nd doses received, and calculation of completed vaccinations (1st and 2nd dose, if appropriate, and 'DNAs', who do not attend for scheduled appointments or who do not complete the required vaccination schedule (dual dose).

The ability to link COVID notification data with vaccination data will be a key feature of disease surveillance once the vaccination programme begins.

9.4 Supporting Post-Vaccine Evaluation

This section should be read in conjunction with section 3.2 which relates to post-marketing monitoring of the vaccine, including for safety & effectiveness.

The HPRA, as part of the EU regulatory network of medicines agencies, together coordinated by the EMA, will closely monitor the safety profile of COVID-19 vaccines by reviewing the totality of available data, including reports of 'suspected adverse reactions'. Through the HPRA's suspected adverse reaction reporting system, members of the public, carers and healthcare professionals can report side effects by using the HPRA's online reporting facility, by email or by phone. Should details of suspected adverse reactions be captured at the time of vaccination, this information will be provided to the HPRA electronically from the vaccination IT system, in order to facilitate enhanced reporting by avoiding duplication of records at the point of care. All reports received by the HPRA are processed and collated within the national pharmacovigilance database, according to established EU rules, with anonymised cases in turn reported to the European database Eudravigilance, with frequent analysis on cumulative data performed to detect potential signals.

The HPRA also closely monitor national cases and will publish safety summary reports. The EMAs safety committee, in which the HPRA participates through an Irish delegate, will make safety recommendations, if necessary, following evaluation of the totality of post-marketing safety and effectiveness data, including that from passive and active surveillance.

10.

Communications and public engagement

10.1 Overview

As guided by WHO, in a pandemic, public communications, solidarity and civic participation are a central part of any nation's response. In this regard, consistent communication of the public health advice to protect from COVID-19 has played a central role in Government's response to the pandemic, earning wide public co-operation.

Clear and transparent communication on all aspects of COVID-19 vaccines, led by subject matter experts, to build public trust in vaccine safety and efficacy will be a critical element to the success of Ireland's vaccination programme. The approach will build on the successful communication and engagement programme delivered throughout the COVID-19 pandemic to date, ensuring the communications response to the vaccine programme is integrated into existing COVID-19 communications.

The arrival of vaccines will not mean zero COVID-19. Instead, the COVID-19 vaccine will be added to the existing public health toolkit. Aligned to this, Government public health advice will expand to include the availability of a vaccine. As the vaccines roll out across the country, it will remain important that we continue to work with the public health advice which asks us to wash our hands, cough into our elbows, maintain 2m social distance and wear face coverings where appropriate.

It is important to note that the health system in Ireland has a strong track record on vaccination. The HSE, and a range of healthcare professionals, provide all of Ireland's public immunisation programmes for children and adults, safely protecting millions of people in Ireland with vaccines each year.

Ireland has a very high existing rate of vaccine uptake, and, unlike many other countries, we have a positive experience of restoring confidence in the HPV vaccine nationally, after it was challenged in the past by a misinformation campaign.

10.2 Communications Strategy

This Strategy aims to position COVID-19 vaccines as an additional tool in the public health advice to protect against COVID-19 and encourage universal vaccination. 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

Communication on COVID-19 public health advice, including the COVID-19 vaccination programme, will need to be agile as with our response to the pandemic to date this will involve regular communications and updates via the Minister, Department of Health and HSE.

Once the vaccination programme has commenced, data on the vaccine uptake will be incorporated into the daily COVID-19 press release, COVID-19 data hub, and current communication channels.

10.3 An Evidence Informed Approach

Since the early days of the COVID-19 pandemic, both the Department of Health and the HSE have actively listened to the public, understanding, reacting and responding to public sentiment had been a core element of the COVID-19 campaign. As progress has been made in vaccine development, that work has continued, and has informed every element of this Strategy.

Key insights from work to date with the public:

- Many people who doubt the vaccine are in a dilemma: they want the vaccine but are cautious. People are concerned as to the speed of the development of the vaccines and want to be reassured as to their safety and effectiveness.
- Overall, we must own the idea that science is never 100%; no guarantees; no cast iron certitudes.
- We should be forthright and proportionate in what we say. People of different ages have different understanding and expectations about what vaccines will bring in the short to medium term.
- Communication on the vaccine must be led by medics coming from a perspective of expertise, science and health advice.
- Whatever the unknowns are, they need to be stated and owned; only communicate when we have the facts.
- We need language that anyone will understand - so that everyone feels welcomed into the communication.

10.4 Key Elements

A Phased Approach

The communications and engagement strategy will have two main phases.

1. The first is preparing for the vaccine, speaking about the safety and regulatory processes that are in place in Ireland, Europe and across the world; engaging with people who have genuine hesitancies around the vaccine; communicating the Government Plan from acquisition to prioritisation to distribution; and communicating about 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.

Active expert participants in the campaign will come from the Dept of Health, the HSE and the HPRA, ensuring clear and consistent communications from a trusted source.

Trusted Voices and Peer to Peer support

Healthcare workers are an important at-risk population group. They are also a recognised and trusted source of information and influence. GPs, in particular, are trusted sources of information for the public. The HSE and DoH will prepare targeted messaging and briefings for this important stakeholder group.

One of the most effective means of increasing uptake of the flu vaccine among healthcare workers (HCW) continues to be peer-to-peer communication and support. The HSE will identify and inform local champions on the importance of all HCWs receiving the COVID-19 vaccine when it is available to them.

This approach will also be taken with the general public. Local public health experts in each HSE area will be supported to work with local print and broadcast media, as well as local stakeholders to inform their communities and support uptake of vaccine in their community.

It is recognised that uptake will be influenced by a wide range of influencers, depending on demographics. The role of community leaders, religious leaders and other influencers, will be important in conveying the message and will part of the plan.

Audiences and Stakeholders

The COVID-19 vaccine programme will touch every person, every healthcare worker, every household, every family in Ireland. This is a challenge in terms of scale and timing, and it also offers us an enormous open door to build trust and confidence in this vaccination programme, because, like COVID-19 itself, the vaccine is something that everyone cares about and has been affected by.

There are challenges in the scale of the programme, the need for sequencing in how we offer the vaccine to people in priority groups, and in providing assurance about safety and effectiveness.

Pressures may grow in the coming months on those areas of challenge, but most people in Ireland have a good experience of existing vaccination programmes, and regularly share their good experiences with the people around them and their social networks. This plan will work from this very strong base.

10.5 Initial Key Messages

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

- 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.
- 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.
- 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.
- Certain priority groups will be vaccinated first. For example, frontline healthcare workers and people who are most at risk from serious infection if they catch COVID-19. Once these priority groups have been vaccinated, the vaccine will be available to the rest of the population.
- 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.

10.6 Promoting Vaccine Confidence

The majority of individuals do not have an inherent bias for or against a vaccine. The vaccine confidence continuum includes a small minority who refuse all vaccines with conviction, and those who have valid concerns and need more information before deciding to take a vaccine as well as those who have a positive predispostion to vaccination programmes.

Recent data from Amárach shows that while 5% of the population say they definitely won't take the COVID-19 vaccine, 45% say the definitely will take the COVID-19 vaccine, with 50% of the population unsure. Those unsure are looking to understand how COVID-19 vaccines have been developed at speed and to be reassured by Regulators that the vaccines are safe for themselves and their families.

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.

There is precedence for the introduction of novel vaccines in response to significant health risks associated with certain diseases, for example, polio, meningitis and haemophillus influenza B (HiB) vaccines as part of the childhood vaccination programme, and pertussis vaccine in pregnancy.

After the Ebola outbreak of 2014-2016, researchers in Oxford University began preparing plans to create a vaccine for any new emerging diseases that might afflict the world in the shortest possible time. This body of work formed the basis of the Oxford-AstraZeneca vaccine development process.

The Pfizer/BioNTech Phase 3 Clinical trials involved over 43,000 participants. Normally, clinical trials can be held back due to low volunteer numbers and low disease prevalence – neither of which have been an issue in the case of COVID-19.

While we await EMA reports from the vaccine trials, Government communication will prioritise that proportion of the population that are unsure, addressing their questions and concerns through clear and transparent evidence-based communication via a multitude of channels.

11.

Programme Implementation

11.1 High-Level Task Force Programme Management

The Government established the High-Level Task Force on COVID-19 Vaccination to ensure oversight, agility and specialist input is available to support the delivery of the COVID-19 Vaccination Programme.

Given the complexity involved and the flexibility required in the rollout of our national COVID-19 vaccination strategy, 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 and that are applicable to the effective management of vaccination programs of this nature.

To turn this 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 strategy. Lines of communication are established so that key stakeholders ranging from Government, the HLTF, key Departments, HSE, advisory and regulatory partners can make or escalate decisions as appropriate and are briefed on progress.

A programme management office (PMO) has also established to support the Taskforce in its monitoring role.

11.2 Objectives & Principles

In the context of the Vaccination Programme, clarity of governance 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 organisation 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.

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 has been prepared that considers all project activities, the dependencies between them, the resources and time required to achieve them, key milestones dates, the critical path and assurance and review activities and updated on an ongoing basis.
- **Management of Uncertainty:** The world is experiencing an unprecedented global pandemic of coronavirus disease caused by a novel coronavirus. This national strategy 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 as set out above have been assigned to appropriately skilled and experienced people, with lines of authority, responsibility and accountability clearly identified and defined in the programme organisational 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 and their likely impact, consideration to the development of mitigation and contingency plans, including associated triggers. 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 required to deliver this strategy has been identified to meet objectives and ensure they are managed, monitored and utilised to their fullest extent. Underlying workstreams 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.
- **Improvement Planning:** As with any vaccination programme roll-out, this strategy and underlying 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.
- **Programme Closure:** Once confidence is met that that 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.

11.3 Agile Decision-Making and Communications

A Programme and Project Management approach is being used across seven Work-Streams established by the HLTF to manage and deliver all the core elements required of the 'end-to-end' vaccination process.

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 through the Chair of the HLTF and the institutional members on the taskforce, COVID Oversight arrangements and ultimately to Government. Activity is well advanced across these workstreams 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.

11.4 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 Chair and HLTF in accordance with its terms of reference.

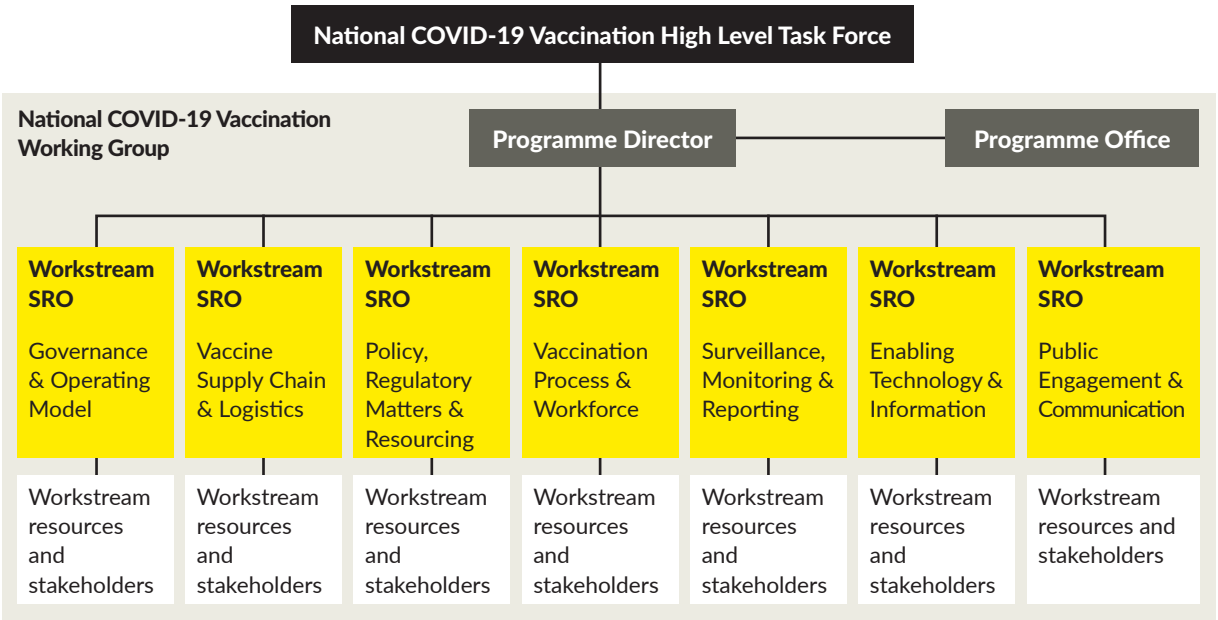
Membership of the Programme Working Group (including & Senior Responsible Officers*) is set out in Appendix 1.

Risk management

In a programme of this scale there are essentially three types of risk; risks that affect single projects/ programmes within the overall programme and are 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 is establishing a structured process in understanding these three types of risks inherent in this programme at workstream and program level, their likely impact and consideration to the development of mitigation and contingency plans, including associated triggers. As discussed earlier, this Strategy 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.

Figure 10. National COVID-19 Vaccination Work Programme Structure



Appendices

A.1 Membership of HLTF and Working Group

Membership of the HLTF

- Prof Brian MacCraith - Chair, High Level Task Force on COVID-19 vaccination
- Elizabeth Canavan - Chair, Senior Officials Group on COVID-19
- Fergal Goodman - Assistant Secretary, Department of Health
- Dr Colm Henry - Chief Clinical Officer, Health Service Executive
- Dr Tony Holohan - Chief Medical Officer, Department of Health
- Rachel Kenna, Chief Nursing Officer, Department of Health
- Barry Lowry - CIO, Office of the Government Chief Information Officer
- Derek McCormack - Expert on Cold Chain Logistics
- Dermot Mulligan - Assistant Secretary, Innovation and Investment Division, Department of Enterprise, Trade and Employment
- Dr Lorraine Nolan, CEO, Health Products Regulatory Authority
- Dalton Philips - CEO, DAA PLC
- Paul Quinn - CEO, Office of Government Procurement
- Paul Reid - CEO, Health Service Executive
- Martin Shanahan - CEO, IDA Ireland
- Derek Tierney*, Office of the Taoiseach (Programme Director)

Participants at Task Force Meetings

- Sean Bresnan - National Director of Procurement, HSE
- Dr Lorraine Doherty - National Clinical Director, Health Protection, HSE
- Dr Ronan Glynn - Deputy Chief Medical Officer
- Gerry O'Brien - Acting Director, Health Protection Division, Department of Health
- Kate Waterhouse - Secretariat, High Level Task Force on COVID-19 Vaccination
- Deirdre Watters - Head of Communications, Department of Health

Membership of the Programme Working Group (including Senior Responsible Officers*)

- Sean Bresnan*, National Director of Procurement, HSE
- Dr John Cuddihy*, Director, Health Protection Surveillance Centre (HPSC)
- Dr. Lucy Jessop, Director, National Immunisation Office, HSE
- Siobhán McArdle, Assistant National Director, Primary Care Operations, HSE
- Gerry O'Brien*, Director, Health Protection Division, DoH
- Fran Thompson*, CIO, HSE
- Derek Tierney*, Office of the Taoiseach (Programme Director)
- David Walsh*, National Director, COVID, HSE
- Deirdre Watters*, Head of Communications, DoH

A.2 List of Acronyms

APA	Advance Purchase Agreements
CHMP	The Committee for Medicinal Products for Human Use (a committee of the EMA)
CHO	Community Healthcare Organisation
CMA	Conditional Marketing Authorization
DAA	Dublin Airport Authority
EMA	European Medicines Agency
EU	European Union
ECDC	European Centre for Disease Prevention and Control
GP	General Practice
H1N1	Swine Flu
HCW	Healthcare Worker
HLTF	National Vaccination High Level Task Force
HPRA	Health Products Regulatory Authority
HSE	Health Service Executive
IDA	Industrial Development Agency
NIAC	National Immunisation Advisory Committee
NPHET	National Public Health Emergency Team
PIL	Patient Information Leaflet
PMO	Programme Management Office
SAGE	WHO Strategic Advisory Group of Experts on Immunization
SRO	Senior Responsible Officer
ULT	Ultra Low Temperature
VAL	Vaccine Administration Location
WHO	World Health Organisation

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