

#### **TECHNICAL REPORT**

## **Overview of COVID-19 vaccination strategies and vaccine deployment plans in the EU/EEA and the UK**

#### 2 December 2020

## **Key findings**

This report provides an initial overview of the national COVID-19 vaccination strategies and vaccine deployment plans in the countries of the European Union and European Economic Area (EU/EEA) and the United Kingdom (UK).

This overview is based on results from an ECDC survey and meeting among members of the EU/EEA National Immunisation Technical Advisory Groups (NITAG) Collaboration in October 2020 and a survey undertaken by the Health Security and Vaccination unit of the European Commission's Directorate-General for Health and Food Safety with members of the EU Health Security Committee (HSC) in November 2020.

This report provides insights into the main aspects of national deployment plans currently under development in countries. The information presented will continue to evolve in the coming weeks and months as countries further develop their vaccine deployment plans and more information becomes available on the different characteristics of various COVID-19 vaccines.

#### Initial considerations for priority groups and underlying evidence

- All 31 EU/EEA countries and the UK responding to the ECDC survey have started evaluating available information with the goal of establishing interim recommendations for first priority groups for vaccination. As of 30 November 2020, nine countries had already published interim recommendations for priority groups (Austria, Belgium, Czechia, France, Luxembourg, the Netherlands, Spain, Sweden and the UK).
- Countries responding to the ECDC and the HSC surveys and those that have already published recommendations have primarily prioritised elderly people (with various lower age cut-off across countries), healthcare workers and those persons with certain comorbidities. Some countries have started to prioritise further among the priority groups selected for first vaccination, as it is probable that vaccine doses will be in limited supply in the initial phase of the vaccination campaigns.
- Prioritisation groups may also be modified as more evidence becomes available about the COVID-19 disease epidemiology and characteristics of vaccines, including information on vaccine safety and efficacy by age and target group.
- Modelling different options for vaccine efficacy for different outcomes (including severe disease, mild disease, infection and infectivity, and death) and vaccine uptake in EU populations, as well as different scenarios for prioritisation, is an important step that will inform decisions on vaccination strategies and estimate their possible impact.

Suggested citation: European Centre for Disease Prevention and Control. Overview of COVID-19 vaccination strategies and vaccine deployment plans in the EU/EEA and the UK – 2 December 2020. ECDC: Stockholm; 2020.

#### **Logistical considerations**

- For the roll-out of future COVID-19 vaccines, many countries will make use of existing vaccination structures and delivery services as much as possible. Responses from the HSC survey showed that some countries were planning to train more people to carry out the vaccinations.
- Several countries indicated that there is a need to procure additional equipment for the cold-chain requirements due to the ultra-low temperature required for some of the COVID-19 vaccines.
- Most countries reported that COVID-19 vaccines will be provided free of charge for their citizens.

## Monitoring systems for vaccine coverage, safety, effectiveness, and acceptance

Electronic immunisation registries for the monitoring of individual and population-level vaccine uptake are available at the national or subnational level in 14 countries, and developments towards such national systems are ongoing in 10 further countries. Two countries have an insurance-based system that will be used for the monitoring of vaccine uptake. Documentation regarding which vaccine product has been administered and when is key to the success of vaccination programmes. Such documentation is also important for monitoring any safety signals, such as an adverse event following immunisation (AEFI) that may arise for any of the vaccine products. Information in these registries could serve as the basis for immunisation cards.

#### Limitation of the information collected

The information collected in this report is not intended to be exhaustive. Most of the countries are currently in the development phase of their deployment plans, and the questions in the surveys were also mostly open-ended in nature, so some information may not have been captured. ECDC is planning to issue a new interim report in January.

## **Scope of this document**

This document outlines the initial developments in EU/EEA member states and the UK regarding vaccine deployment plans and national vaccination strategies for COVID-19 vaccines, including interim considerations for priority groups, evidence to be considered for the prioritisation of target groups, logistical considerations and monitoring systems for post-marketing surveillance (e.g. vaccine coverage, safety, effectiveness and acceptance).

Target audiences for this document are the European Commission, the Health Security Committee (HSC), the EU/EEA NITAG Collaboration and national public health institutes and ministries of health in the EU/EEA and the UK, as well as public health experts at subnational level in charge of developing vaccine deployment plans.

### Background

Since December 2019 and as of November 2020 there have been over 62 000 000 cases of COVID-19 globally, including over 1 400 000 deaths [1]. One or several effective vaccines for protection against COVID-19 are needed in order to contain the pandemic (along with non-pharmaceutical interventions and antivirals). This has led to a large global effort to develop vaccines, with several different established and new vaccine production technologies being used in the development of vaccine candidates. To date, there are no EU-authorised COVID-19 vaccines available, but there are several vaccines currently in phase 3 trials and the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use has initiated the rolling review procedure for four vaccines (AstraZeneca/Oxford, Janssen-Cilag International NV, Pfizer/BioNTech and Moderna). Two of these vaccine developers (Pfizer/BioNTech and Moderna) have now applied for Conditional Marketing Authorisation to the EMA. On 2 December 2020, the UK's Medicines and Healthcare Products Regulatory Agency approved the Pfizer/BioNTech vaccine for use in the UK.

Successful national and EU-level COVID-19 vaccine deployment will require several key components to be in place, including [2]:

- a robust COVID-19 disease surveillance system;
- post-marketing studies on effectiveness and impact;
- active and passive monitoring of adverse events following immunisation;
- robust and timely vaccination coverage data;

- evidence-based decision-making;
- legal and regulatory frameworks for vaccine deployment;
- vaccine delivery infrastructure and supply chain management;
- monitoring of vaccine acceptability and behavioural research;
- communication plans;
- ethical and equitable access to vaccination.

To enable these building blocks to be successfully adopted and integrated into national vaccination schedules when a new vaccine is available relies on strong and coordinated deployment and vaccination plans. To prepare for this on 17 June 2020 the European Commission (EC) published a Communication on EU Strategy for COVID-19 vaccines to accelerate the development, manufacturing, and deployment of vaccines against COVID-19 in Member States [3].

Building on this, the EC further published on 15 October 2020 a Communication on Preparedness for COVID-19 vaccination strategies and vaccine deployment and on the 28 October a Communication on additional COVID-19 response measures [5-6]. Considerations on the introduction and prioritisation of COVID-19 vaccination in EU/EEA and the UK have also been documented in a recent ECDC publication [2] in addition to a WHO publication on strategic considerations in preparing for deployment of COVID-19 vaccines and vaccination in the WHO European Region [7,8].

The EC's Communication of 15 October presented the key elements for Member States to take into consideration for their COVID-19 vaccine deployment and vaccination strategy plans, in order to prepare the EU and its citizens for when one or more safe and effective vaccines are available. These key elements include the selection of priority groups to consider vaccinating first at the start of the vaccination roll-out, when there will most likely be limited doses available, evidence to consider, ensuring that there is sufficient capacity of vaccination services, how to ensure easy access to vaccines, infrastructure and logistical considerations, monitoring of vaccination data and communication plans on how to communicate on the benefits, risks and importance of COVID-19 vaccines. In order to capture this information, share knowledge and encourage a coordinated response to vaccine deployment in the EU/EEA and the UK, the EC requested ECDC provide an initial overview of the national COVID-19 vaccination strategies and vaccine deployment plans in these countries.

### **Methods**

The information provided in this report was collected from the following sources:

#### **ECDC survey**

On 20 October 2020, ECDC sent a survey by email to the EU/EEA National Immunisation Technical Advisory Groups (NITAG) collaboration members (representing 27 EU member states, three EEA countries and the UK) [9]. Countries were asked to provide information on their vaccine deployment plans (final or in development) and a link to the document if available, information on interim priority groups for vaccination if selected, evidence to be considered upon selection, logistical considerations, and any product-specific monitoring information. The six questions were open-ended (Annex 1).

Bilateral follow-up contacts were organised either through e-mails or telephone calls with those countries who had not responded to the initial deadline to responding to the ECDC survey. On 24 November 2020 a preliminary survey report that included a summary of results and analysis from the ECDC survey was sent to each of the survey responders for validation.

#### **EU/EEA NITAG collaboration dialogue meeting**

As a follow-up to the survey, ECDC organised a dialogue meeting on 23 October 2020 with the EU/EEA NITAG collaboration (hereafter named NITAG collaboration) with invited observers from public health, regulatory agencies, ministries, and the Joint Action on Vaccination (https://eu-jav.com) to enable countries to further share details of their vaccination plans.

#### Health Security Committee (HSC) Members survey

On 16 November 2020, the Health Security and Vaccination unit of the EC's Directorate-General for Health and Food Safety sent a survey using the EU Survey online tool to Members of the HSC for an update on EU Member States' implementation of the Commission Communication on Preparedness for COVID-19 Vaccination Strategies and Vaccine Deployment. The survey included a total of 18 closed and open-ended questions on technical and logistical aspects of country vaccine deployment plans (Appendix 2). The EEA countries (Liechtenstein, Iceland and Norway), and the UK did not receive this survey. Information collected from this HSC survey on different topics was incorporated into this report to provide a more comprehensive picture of the current state of play of vaccine deployment plans in the EU/EEA and the UK.

### Results

There were 31/31 responses from the EU/EEA and the UK to the ECDC survey. All had initiated deployment and vaccination plans for COVID-19 vaccines.

Twenty six of 27 EU Member States responded to the HSC survey (Austria, Belgium, Bulgaria, Czechia, Croatia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Ireland, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden).

#### **Availability of deployment plans**

As of 30 November 2020, nine countries had published interim recommendations for priority groups to be considered for vaccination: Austria [10], Belgium [11], Czechia [12], France [13,14], Luxembourg [15], the Netherlands [16], Spain [17], Sweden [18] and the UK [19]. The other countries were in the process of developing such recommendations through NITAG meetings/expert group meetings (see Table 1).

#### **Priority groups defined for vaccination**

Preliminary information identifies that older age groups, healthcare workers and persons with underlying conditions are the most common target groups being considered by countries as priority groups for vaccination. Among the elderly, countries provided different age ranges for vaccine priority. Healthcare workers and residents in long-term care facilities (LTCF) were often listed as one of the first groups to be prioritised for vaccination.

As of 30 November, Austria, France and Spain had further prioritised target groups within the priority groups to receive the first doses of the vaccines once they become available.

## Table 1. Overview of priority groups (in no specific order) of COVID-19 vaccination interimrecommendations in EU/EEA Member States and the UK as of 30 November 2020 (informationgathered from the ECDC survey n=31 and the HSC survey n=26)

Countries	Priority groups identified				
	Elderly (in years)	Adults with co- morbidities	Healthcare workers	Other risk groups (i.e. workers of essential public services other than health; social care workers; others)	Comments
Austria [10]	65+	Yes	Yes Those working in long term care facilities And the others	Yes	As of 25 November 2020 First phase: Prioritisation of: - Elderly aged 65+ living in long term care facilities - Adult with comorbidities - Prioritisation of healthcare workers.
Belgium [11]	65+	People aged 45-65 years with comorbidities	Yes	Yes	As of July 2020, the NITAG recommendations are to prioritise: - All healthcare workers - All people 65+ - People aged 45-65 with comorbidities
Bulgaria	Recommendations	s under developm	ient		
Croatia	Yes	Yes	Yes	Workers of essential public services other than health; social care workers	
Cyprus	65+	Yes	Yes	Essential workers (e.g. armed forces, police, security forces, Social services, firemen, ambulance services, staff working in elderly people homes)	This may be modified as new data and information becomes available
Czechia [12]	65+	Yes	Yes	Staff in social services and part of critical infrastructure	As of September 2020 [11], chronically ill people and those aged 65 years and older, healthcare workers, public heath staff, and social workers will be the very first prioritised.
Denmark	65+	Yes	Yes	Social workers and part of critical infrastructure	The precise recommendations are still under development.
Estonia	70+	Yes	Yes	Social care workers and receivers of these services,	In a longer perspective, we consider making vaccination available for the whole population (depending on

Countries			Priority grou	ps identified	
				essential workers, other workers working in healthcare institutions	the final quantities of the vaccine delivered).
Finland	Yes	Yes	Yes		
France [13,14]	65+	Yes	Yes	Health and social care workers, risk groups for severe COVID-19 disease	As of November 30, an initial vaccine plan will target those in LTCFs, including residents and healthcare workers with associated risks.
Germany [15]	Recommendations	s for priority grou	ps still under de	velopment	·
Greece	Yes	Yes	Yes	Workers of essential public services other than health; social care workers	
Hungary	60+	Yes	Yes	Critical infrastructures; social care workers	
Iceland	Recommendations under development				
Ireland Italy	Recommendations Those in long term care facilities Age based recommendation	s under developm Yes	ent (Iterative p Yes	ogramme) Social care workers	
Latvia	60+	Yes	Yes (Healthcare professionals and long- term care facilities (both residents and staff)	Social care workers	
Liechtenstein	Recommendations	s under developm	ient		
Lithuania	Yes Age range to be specified	Yes	Yes		
Luxembourg [16]	65+		Yes	Vulnerable individuals (according to national definition for COVID-19 vulnerability)	
Malta	Yes	Yes	Yes	Workers of essential public services other than health; social care workers	On 4 November 2020, the ACIP (NITAG) recommended that residents in long-term facilities should be specified as a priority group, as well as health/social Care workers in the same facilities.

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Countries	Priority groups identified				
The Netherlands [17]	60+	Yes	Yes		
Norway	Recommendations	s under developm	nent		
Poland	65+	Yes	Yes	Social care workers, essential workers (e.g. armed forces, police, security forces)	This may be modified as regulators data and more information becomes available.
Portugal	Yes, but age- cut-off not specified yet	yes	yes	Social care workers	These groups are being considered, but their prioritisation is not decided yet
Romania	65+	Yes	Yes	Social care workers and staff of critical infrastructure	These groups are being considered. Vaccination strategy is now in the final step of approval at the government level
Slovakia	Yes	Yes	Yes	Workers of essential public services other than health; social care workers	
Slovenia	Yes, but age cut-off not specified yet		Yes	Other risk groups (especially residents in long- term care facilities and elderly)	
Spain [18]	Elderly: nursing homes will be first to be vaccinated. Different groups depending on the stage of quantity of vaccines available	Yes	Yes, first- line workers in the first stage, second priority group	Other risk groups: staff of nursing homes in first stage	First stage: 1. Residents and health and social care personnel in care homes for the elderly and the disabled 2. Front-line health personnel 3. Other health and social health personnel 4. Dependent people with disabilities who require intensive support measures (non-institutionalised highly dependents)
Sweden [19]	70+	Risk groups for severe COVID-19 disease	Yes		
The UK [20]	80+ as first priority, then 75+, then 70+ etc.	Yes (High-risk adults under 65 years of age)	Yes	Workers in older persons' care homes	Prioritisation by age group

Note: some information for countries may not have been captured due to open-ended questions

#### Evidence to be considered for prioritisation of target groups

The ECDC survey collected information about the evidence that will be or has been considered to date in order to prioritise different target groups for vaccination, such as the role of impact modelling of different vaccination strategies, enhanced epidemiological surveillance or reported vaccine safety and efficacy by age and population group from phase 3 trials (see Table 2).

Major considerations that countries mentioned to be taken into account included epidemiological surveillance data, analysis of country specific data (e.g. on hospitalisation and mortality) and information from the literature

on groups at higher risk of severe disease and death due to COVID-19 disease and its complications. Eleven countries responded that they used or will use mathematical modelling as a tool for prioritisation of target groups, but no further description of the scenario was provided. Some countries responded that they will consider guidelines from ECDC, WHO and US CDC. Ethical considerations were mentioned by ten countries and included the involvement of ethics expertise, ethical committees and using ethical frameworks.

Many countries highlighted that information on the specific vaccine products from the phase 3 studies will be taken into consideration once available (which may impact the final modelling exercise).

## Table 2. Overview of evidence that has been or will be considered for the prioritisation exercise oftarget groups to be vaccinated by country as of November 2020 (information gathered from the ECDCsurvey n=31)

Evidence considered for prioritisation of target groups	Countries
Modelling	Austria, Finland, Germany, Luxembourg, Malta, the Netherlands, Norway, Slovenia, Spain, Sweden, the UK
Epidemiological data	Austria, Belgium, Croatia, Denmark, Estonia, France, Germany, Greece, Ireland, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Spain, Sweden, and the UK <sup>*</sup>
Literature reviews	Belgium, Denmark, Estonia, France, Germany, Greece, Ireland, Malta, Norway, Poland, Portugal, Spain
Transmission data	Estonia, Finland, France, Portugal, the UK
Ethics	Austria, Belgium, Denmark, Estonia, France, Germany, Greece, Ireland, Norway, Spain
Vaccine characteristics data	Austria, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Slovenia, Spain
Vaccine acceptance data	Denmark, Estonia, Germany, Spain
Guidelines from EU, WHO etc	Austria, Belgium, Denmark, Estonia, Greece, Malta, Norway, Poland, Portugal, Spain

\*including serological data

Note: some information for countries may not have been captured due to open-ended questions

#### Use of mathematical modelling exercises e.g. for demand planning and vaccine intervention exercises and plans to regularly review critical factors

Based on responses from the HSC survey, 11 countries reported having no plans to carry out modelling exercises for demand planning and vaccine intervention exercises and eleven countries reported that they do plan to carry out modelling exercises. Spain reported that their modellers are currently in contact with the European Centre for Disease Prevention and Control (ECDC), Malta mentioned they will use the modelling experience from their seasonal flu vaccine deployment for the COVID-19 vaccine. Austria, Germany, Slovakia, Finland and France reported that they will carry out modelling studies (e.g. on how to stop transmission, to facilitate fast and evidence-based decisions, evaluate different aspects of the deployment).

Based on responses from the HSC survey, 25 countries reported that they are planning on regularly reviewing critical factors and consequently redefining, reassessing and adapting COVID-19 vaccination objectives, targets, priorities and strategies accordingly. Most countries reported they will have close and continuous monitoring and review of critical factors (Table 3). Two countries (Estonia, Slovenia) reported having either a steering group or working group set up to carry out this evaluation. Malta indicated that they will be using current systems in place to regularly review critical factors. Two countries (Greece and the Netherlands) reported that their National Immunisation Technical Advisory Group (NITAG) will hold regular meetings and provide advice on the incoming evidence. Lastly, Romania mentioned that vaccination coverage will be monitored through their immunisation information system.

## Table 3. Overview of national plans to carry out modelling exercises e.g. for demand planning and vaccine intervention exercises and plans to regularly review critical factors (information gathered from HSC survey n=26)

Plans to carry out modelling exercises and to review critical factors	Countries
No plans to carry out modelling exercises	Belgium, Bulgaria, Czechia, Croatia, Estonia, Greece, Hungary, Latvia, Lithuania, Slovakia, Slovenia,
Plans to carry out modelling exercises	Austria, Denmark, Finland, France, Germany, Italy, Luxembourg, Malta, the Netherlands, Portugal, Romania, Spain, Sweden
Plans to regularly review critical factors	Austria, Belgium, Bulgaria, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Ireland, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden
Plans to regularly review critical factors based on:	
Epidemiological situation at national and subnational levels	Austria, Bulgaria, Denmark, Estonia, Latvia, Luxembourg, Malta, Greece, Lithuania, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden
New evidence about the virus and its impact on human health	Austria, Bulgaria, Czechia, Denmark, Estonia, France, Greece, Hungary, Latvia, Lithuania, Luxembourg, Malta, Portugal, Romania, Slovenia, Spain, Sweden
Actual vaccine uptake and by whom	Austria, Czechia, Bulgaria, Denmark, Estonia, France, Germany, Hungary, Greece, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovenia, Spain, Sweden
Vaccine storage and supply chain capacities	Austria, Belgium, Bulgaria, Czechia, Denmark, Estonia, France, Greece, Hungary, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Romania, Slovenia, Sweden
(Human) resources required for vaccination of the population	Austria, Belgium, Bulgaria, Denmark, Estonia, France, Greece, Spain, Lithuania, Latvia, Luxembourg, Malta, Portugal, Romania, Slovakia, Slovenia,
New information regarding COVID-19 vaccine characteristics	Austria, Bulgaria, Czechia, Denmark, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden

Note: some information for countries may not have been captured due to open-ended questions

#### Logistical considerations

#### Delivery settings

The ECDC survey collected information on how vaccines will be delivered (e.g. dedicated vaccination centres, routine GP practices, pharmacists, etc), how the identified target groups will be invited to be vaccinated (invitation letter sent, etc) and any further details on the organisation of vaccination campaigns that could be helpful to others.

Most countries specified that they were planning to use and build on existing vaccination delivery services and structures for the roll-out of COVID-19 vaccination plans. In particular, many countries indicated that the structures currently used for the delivery of seasonal influenza vaccines would be leveraged. Some countries said that in the initial phases, delivery of vaccines would be through general practitioners and primary health centres, while other countries responded that vaccines would be delivered through designated vaccination centres (see Table 4).

#### Table 4. Overview of planned COVID-19 vaccine delivery settings in the EU/EEA Member States and the UK as of November 2020 (information gathered from the ECDC survey and the HSC survey n=31)

Planned COVID-19 vaccine delivery settings	Countries
Existing vaccination structures/ influenza vaccine structures	Austria, Croatia, Czechia, Estonia, Finland, France, Greece, Hungary, Italy, Ireland, Lithuania, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain
Dedicated vaccination centres	Austria, Croatia, Czechia, Denmark, Estonia, Germany, Ireland, Lithuania, Luxembourg, Malta, Romania, Sweden
GP practices	Austria, Croatia, Czechia, Estonia, France, Germany~, Ireland, Lithuania, Luxembourg <sup>#</sup>
Healthcare centres	Austria, Denmark, Estonia, France, Greece*, Iceland, Lithuania, Luxembourg, Malta, Poland, Slovenia, Spain, Sweden
Mobile vaccination teams/sites	Austria, Denmark, Estonia, Germany, Latvia, Luxembourg, Spain
Other delivery settings	Austria (company, medical offices), Czechia (hospitals, workplace), Estonia (workplaces, nursing care homes), Malta (long-term healthcare facilities), France (nursing care homes, hospitals)

Note: some information for countries may not have been captured due to open-ended questions

\*Dedicated vaccination teams placed in Health Centres and other primary healthcare units/services.

~Later stage

#If feasible

#### Sufficient workforce, adequate personal protective equipment (PPE), payment for vaccines and coordination of health authorities and civil authorities in deployment of vaccines

Based on responses from the HSC survey, some countries mentioned the need for a bigger pool of skilled workforce to administer the vaccines as more doses will become available. Twelve countries reported on planning to mobilise and train other medical staff (e.g. nurses, midwives, medical students, general practitioners, other medical staff) in order to ensure sufficient capacity of vaccination services to deliver COVID-19 vaccines. Romania specifically mentioned mobilising skilled workforce from other medical services under less pressure. Germany mentioned the involvement of non-governmental organisations such as humanitarian aid and civil protection as well as the armed forces and volunteers to help coordinate the vaccination strategies. Germany and France were planning to reactivate retired doctors to help with vaccination plans. Latvia and Italy reported that they are currently working on a strategy to deploy COVID-19 vaccines.

Most countries reported that COVID-19 vaccines will be provided free of charge for their citizens. Regarding adequate PPE for those workforces administering the vaccines, some countries plan to stockpile through joint EU or national procurement, others plan to use their own national reserves of PPE, and some plan to use both. Nearly half of the countries (n=13/26) who responded to the HSC survey said that they plan for health authorities and civil authorities to coordinate in the deployment of the vaccines, while others (Estonia, Latvia, Malta, Portugal, Slovenia and Spain) were still determining whether there will be coordination (see Table 5).

## Table 5. Overview of plans for trained workforce for administering the vaccines, payment for vaccines, adequate PPE and coordination of health authorities and civil authorities in deployment of vaccines (information gathered from the HSC survey n=26)

Ensuring sufficient capacity for deployment of vaccines and vaccine cost	Countries
Use same workforce currently in place to administer vaccines	Bulgaria, Croatia, Czechia, Estonia, Finland, Greece, Luxembourg, Malta, Poland, Spain, Sweden
Mobilise and train other medical staff to administer vaccines	Austria, Belgium, Denmark, France, Germany, Hungary, Ireland, Lithuania, the Netherlands, Poland, Portugal, Romania, Slovakia
Working on a strategy for sufficient work force	Finland, Italy, Latvia
Provide the vaccine for free	Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Ireland, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovenia, Spain, Sweden
Stockpile PPE through joint EU or national procurement	Austria, Belgium, Bulgaria, Germany, Italy, Ireland, Malta, the Netherlands, Portugal, Romania, Slovakia, Slovenia, Spain
Use their own reserves of PPE	Croatia, Czechia, Estonia, Finland, France, Greece, Hungary, Lithuania, Malta, Poland, Portugal, Sweden
Health authorities and civil authorities to coordinate in vaccine deployment	Austria, Croatia, Denmark, France, Germany, Greece, Italy, Ireland, Luxembourg, the Netherlands, Poland, Romania, Slovakia

Note: some information for countries may not have been captured due to open-ended questions

#### Infrastructure

Based on responses from the HSC survey (Table 6), 13 countries of 26 reported that they were currently reviewing their vaccination deployment infrastructure to procure additional necessary equipment for the cold chain. Four countries reported that their current infrastructures will be sufficient for the deployment of vaccines across their countries. Five countries reported that they will be using the same infrastructure but are currently reviewing it to ensure it will be sufficient for COVID-19 vaccines. Twelve countries are currently reviewing their vaccination deployment infrastructure to procure additional necessary equipment for the cold chain. Germany reported that the pharmaceutical companies will be responsible for delivering the vaccines to the main distribution centres at federal level.

Based on responses from the HSC survey, regarding national plans for purchasing supplies and materials required for carrying out COVID-19 vaccinations, 17 of the 26 countries reported that they will make use of joint procurement to purchase items.

### **Table 6.** Overview of national plans on infrastructure and use of joint procurement of items to carry out vaccinations (information gathered from the HSC survey n=26)

Infrastructure and use of joint procurement of items to carry out vaccinations	Countries
Use infrastructures already in place (deemed sufficient for deployment of vaccines)	Bulgaria, Hungary, Malta, the Netherlands, Sweden
Reviewing current infrastructure to ensure it is sufficient	Croatia, Denmark, France, Italy, Luxembourg, Portugal
Reviewing infrastructure to procure additional equipment for the cold chain	Austria, Belgium, Czechia, Denmark, Estonia, Finland, France, Greece, Ireland, Latvia, Lithuania, Slovakia, Spain
Will use the joint procurement to purchase items required to carry out vaccinations	Austria, Belgium, Croatia, Czechia, Estonia, Finland, France, Germany, Latvia, Lithuania Malta, the Netherlands, Portugal, Romania, Spain, Slovakia, Slovenia
Will not use the joint procurement	Bulgaria, Hungary
Currently discussing use of the joint procurement	Denmark, Greece, Italy, Luxembourg, Sweden

Note: some information for countries may not have been captured due to open-ended questions

## Monitoring systems vaccine coverage, safety, effectiveness, and acceptance

Countries were asked to provide information on how product-specific vaccine monitoring systems will be organised to document vaccine status/coverage, safety, effectiveness and acceptance.

Fifteen countries have electronic immunisation registry systems currently in place and/or that were improving their electronic system in place and/or are developing their own system. In Denmark, Finland, Norway and Sweden, the electronic immunisation registry can be linked to health outcomes and can also provide data on safety and effectiveness. Many countries, including Belgium and Finland, reported that they may be able to report monitoring information by vaccine brand. Spain is planning to expand its regional registry. Malta is currently developing an effective product-specific monitoring system. Austria, Estonia, Germany, Greece, Hungary, Ireland, Lithuania, Luxembourg, Poland and the UK are currently developing ad hoc or new electronic systems.

Countries that will use other systems already in place include Czechia (insurance) and Germany (insurance). Estonia will improve the implementation of the e-immunisation passport at national level (individual record of vaccination in the central health information system) and plans to develop additional supportive solutions for a mass vaccination campaign.

Countries not giving any specific information or who are currently working on this (without any other information disclosed) include Bulgaria, Cyprus, Hungary, Liechtenstein and Slovakia.

### **Table 7.** Overview of system in place for documentation of individual COVID-19 vaccine status in the EU/EEA Member States and the UK (information gathered from the ECDC survey, n=31)

System in place for the monitoring of COVID-19 vaccination status	Countries
Countries with electronic immunisation registry system currently in place and/or improving and/or developing their own system	Belgium, Croatia, Demark, Finland, France, Iceland, Italy, the Netherlands (in progress), Malta, Norway, Portugal, Romania, Slovenia, Spain, Sweden
Any other electronic system currently in place or being developed	Austria, Estonia, Germany, Greece, Hungary, Ireland, Lithuania, Luxembourg, Poland (being implemented), the UK
Countries who will use other systems already in place (e.g. insurance claim database, etc)	Latvia, Czechia, Germany
Electronic card	Estonia
Other (e.g. paper registry, etc)	Bulgaria, Cyprus, France, Hungary, Liechtenstein, Slovakia

Safety is usually in the mandate of national regulatory agencies, but in some countries it is a shared responsibility between public health authorities and regulators (in Norway, for example). However, if a safety signal occurs, this will likely impact the vaccination campaigns and public health will need to become involved in all countries to facilitate investigations.

Eight countries responded that existing reporting systems in place for vaccine safety will also be used for COVID-19 vaccines (Belgium, Croatia, Czechia, Denmark, Finland, Lithuania, Luxembourg and Spain).

Finland and Norway will use their electronic registry that is linked to health outcomes for safety monitoring purposes. An expert group will review safety events in Belgium. Poland and Italy are strengthening their current existing system for COVID-19 safety monitoring purpose. The Netherlands and Spain reported that they will use their routine safety monitoring system without further details provided. In Germany, the pregnancy register was also cited as a tool to be used for safety monitoring purposes.

Belgium, Finland, Germany, Latvia and the Netherlands are planning for either case-control or cohort studies to assess vaccine effectiveness or safety. For more detailed information about national plans for monitoring vaccine coverage, safety, effectiveness and acceptance see Annex 3.

#### Acceptance of COVID-19 vaccines

Belgium and Luxembourg have undertaken COVID-19 vaccine acceptance surveys in the general population. Luxembourg is also planning a survey among general practitioners. France, Germany, Lithuania and Spain reported that acceptance of COVID-19 vaccines will be monitored using surveys. No other information was provided on how acceptance of the vaccines will be monitored.

## **Communication on the benefits, risks and importance of COVID-19 vaccines**

Based on responses from the HSC survey, 14 countries of 26 (Austria, Belgium, Bulgaria, Croatia, Denmark, Greece, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Portugal, Romania, Spain) were in the process of developing their communication plans. Seven countries (Belgium, Czechia, Finland, Germany, Malta, Slovakia, Slovenia) mentioned that their ministry of health, in some cases with close cooperation of other associations and institutes, would be responsible for the communication of the COVID-19 vaccines. Two countries (Estonia and Hungary) mentioned having plans to centrally coordinate their communication with the help of experts and healthcare workers. Poland indicated it has started to develop a specific plan to centrally coordinate communication to the public with the help of experts and healthcare workers, and that this is an ongoing process. Sweden reported having a group of different agencies be responsible for the communication. Ireland has had a very clear communication system since the start of the pandemic.

### **Conclusions**

This report provides some insight into aspects of the national deployment plans currently under development in the EU/EEA and the UK, such as initial considerations for priority groups, evidence to be considered for prioritisation of target groups, logistical and infrastructure considerations and monitoring systems for vaccine coverage, safety, effectiveness, and acceptance.

All countries were in the process of developing recommendations for priority groups to be vaccinated at the time of the ECDC survey. Healthcare workers and elderly people (with various age limits across countries) were mostly considered for prioritisation, but also individuals with chronic conditions resulting in a higher risk of developing severe COVID-19 disease. In light of the probable limited supply of vaccine doses in the initial phase of vaccine deployment, it is expected that most countries will refine their priority groups as Austria, France and Spain have done. In addition, it is likely that product-specific recommendations may be made as detailed information about vaccine efficacy and the main features of specific vaccines become available. This information will be essential to modelling different scenarios, an important tool used by many countries in their prioritisation process.

As more information on vaccines' 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 in the EU/EEA and the UK. Countries are currently looking into existing vaccination structures and delivery services to ensure adequate capacity for carrying out vaccinations and ensuring that adequately trained healthcare professionals are available. As more vaccines become available, it is expected that additional skilled workforce will be involved in the campaigns.

Monitoring of vaccination status as well as the collection of data for post-authorisation surveillance and formal studies are key elements of a vaccination programme. The development of electronic immunisation registries or any electronic health systems for COVID-19 vaccine monitoring purposes is ongoing in some countries that currently have no existing electronic registry. Further description of these systems is required to understand what type of information can be provided at point of clinical care, at population level and in those priority groups receiving the vaccine first. Linking these electronic systems with health outcome databases will be valuable for post-authorisation studies on safety and effectiveness. In settings in which no electronic system is planned to be deployed, a comprehensive overview of methods to be used for monitoring purposes should be carried out.

Several activities will be undertaken by ECDC to support EU/EEA countries in their efforts to prepare vaccination plans and implement monitoring systems in order to document safety, effectiveness and vaccination coverage/acceptance. These activities include: a periodical mapping of deployment plans for COVID-19 vaccines; mathematical models on different vaccination strategies for various target groups and vaccines with different characteristics; close collaboration with the WHO Regional Office for Europe in order to align principles and actions through the development of the COVID-19 vaccine framework in the European Region; the formation of a working group to support countries developing new immunisation registries (a webinar on the topic of documentation of vaccination was held on 17 November 2020); close collaboration with the EMA for post-authorisation surveillance activities; and finally a close collaboration with the EU/EEA NITAG collaboration network, of which ECDC acts as secretariat.

# **Contributing ECDC experts (in alphabetical order)**

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## Acknowledgements

The European Commission Directorate-General for Health and Food Safety C3 staff Rita Figueira, Martine Ingvorsen, Ingrid Keller and Katherine Poole Lehnhoff who developed, ran and analysed the survey that was provided to the Health Security Committee Members.

The EU/EEA NITAG Members and the Members of the Health Security Committee for their responses to the surveys.

## Disclaimer

All data published in this report are correct to the best of our knowledge at the time of publication.

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#### Annex 1. ECDC Survey given to EU/EEA NITAG Collaboration members

Please respond by ticking relevant box and respond shortly to the open questions. I represent the following Member State: \_\_\_\_\_

- 1. Is a vaccine deployment plan for COVID-19 vaccines currently under development or already available?
  - □ Yes
  - 🗆 No
  - 🗆 Unknown
- 2. If yes, would you be able to share the document with ECDC? If in the public domain, please share the link:
- 3. Have you developed recommendations for priority groups to be vaccinated in the initial phases of the campaigns when vaccines are in short supply?
  - $\hfill\square$  Yes, please provide further information:
  - 🗆 No
  - □ Not yet, but currently under development
  - 🗆 Unknown
- 4. What evidence will be/have been considered and by whom in order to prioritise the target groups for vaccination (e.g. role of impact modelling of different vaccination strategies, enhanced epidemiological surveillance, reported vaccine safety and efficacy by age and target group from phase 3 trials ...)? Please provide further information:
- 5. Please provide information on how vaccines will be delivered (e.g. dedicated vaccination centres, routine GP practices, pharmacists etc), how the identified target groups will be invited to be vaccinated (invitation letter sent, etc). Please provide further details on the organisation of vaccination campaigns that can be helpful to others.
- 6. Please provide information on how product-specific monitoring systems will be organised to document vaccine coverage, safety, effectiveness and acceptance.

#### Annex 2. European Commission DG SANTE C3 survey given to Health Security Committee Members

- How does your country plan to ensure sufficient capacity of vaccination services to deliver COVID-19 vaccines in terms of a) skilled workforce?
   and b) medical and personal protective equipment?
- In relation to this, please specify whether your country plans to make use of the joint procurement to purchase items required for COVID-19 vaccination.
- How does your country plan to ensure easy access to vaccines for target populations in terms of a) affordability? and b) physical proximity?
- How does your country prepare for deployment of vaccines with different characteristics and storage and transport needs, and has your country reviewed the required vaccination infrastructure, in particular in terms of cold chain, cooled transport and storage capacities?
- Does your country have an Immunisation Information System or another type of vaccination registry?
- Is this system updated and ready to process COVID-19 vaccination data?
- How does your country ensure clear communication on the benefits, risks and importance of COVID-19 vaccines?
- Are health authorities and civil protection authorities coordinating in your country to deploy COVID-19 vaccines?
- Has your country defined a priority target groups for COVID-19 vaccination? If yes, please specify:

Older persons	Healthcare workers	Workers of essential public services other than health (e.g. education, police)
Persons with chronic diseases	Social care workers	C Other

Please specify age:

Others (please specify):

 Does your country plan to carry out modelling exercises, e.g. for demand planning and vaccine intervention exercises?

If yes, please also specify if your modelling exercises will allow for cross-European learning and exchange of experiences

- Is your country planning to regularly reviewing critical factors and defining, reassessing and adapting COVID-19 vaccination objectives, targets, priorities and strategies accordingly? If yes, please specify the factor(s):
  - Epidemiological situation at national and subnational levels
  - New evidence about the virus and its impact on human health
  - Actual vaccine uptake and by whom
  - Vaccine storage and supply chain capacities
  - (Human) resources required for vaccination of the population

Please specify how this is being done.

#### Annex 3. Table with further details on monitoring for vaccine coverage, safety, effectiveness and safety, by country

Country	Information on how product-specific monitoring systems will be organised to document vaccine coverage, safety, effectiveness and acceptance
Austria	<ul> <li>Use of electronic documentation system:</li> <li>System is being piloted with influenza-vaccines in some parts of Austria starting in November</li> <li>Vaccine safety: mandatory reporting of adverse events by health professionals already in place</li> </ul>
Belgium	<ul> <li>Monitoring strategy is currently under-development. Current draft project includes the following elements (changes and adaptations are possible):</li> <li>Vaccine uptake and coverage based on electronic national vaccine registry</li> <li>Vaccine safety: <ul> <li>Spontaneous reporting system of adverse events accessible to vaccine recipients and healthcare professionals (Non-COVID-19-vaccines specific)</li> <li>Specific system for reporting adverse events following COVID-19 vaccination integrated in the registry system; accessible to healthcare professionals</li> <li>Safety monitoring of a cohort of vaccines through a web application (ACCESS project task 3): solicited reporting of adverse events of special interest</li> </ul> </li> </ul>
	<ul> <li>Severe breakthrough cases will be identified through the national COVID-19 hospital surveillance survey.</li> <li>In exploration: possibility of linking the electronic national vaccine registry to the national registry of COVID-19 laboratory test results, to identify frequency of breakthrough cases</li> <li>Vaccine effectiveness:         <ul> <li>ILI (sentinel general practitioners) and SARI (sentinel hospitals) surveillance adapted to COVID-19; test-negative case-control design</li> <li>ILI surveillance in nursing homes adapted to COVID-19; test negative case-control design</li> <li>In exploration: possibility of linking the electronic national vaccine registry to the national registry of COVID-19 laboratory test results, and applying a test-negative case-control design</li> </ul> </li> </ul>
Bulgaria	Under development
Croatia	Same as for other vaccines:       -       Through the routine immunisation coverage system (immunisation registry),         -       Adverse event following immunisation reporting system         -       Study on vaccine safety.         If the immunisation registry is fully operational at the time vaccination begins, effectiveness could be estimated through a data linkage system.
Cyprus	Under development
Czechia	<ul> <li>Vaccine specific product monitoring: <ul> <li>Not fully specified yet</li> <li>Standard systems as used for other vaccinations are expected, e.g.</li> <li>GPs documentation = patient personal record (vaccination date, vaccine type and batch)</li> <li>reporting to the health insurance information systems</li> </ul> </li> <li>Safety, effectiveness: <ul> <li>The State Institute for Drug Control (SÚKL - http://www.sukl.cz/) will oversee everything for COVID-19 vaccines, as with other vaccines and drugs.</li> <li>The State Institute for Drug Control is a Czech government agency responsible for regulation of the safe production of pharmaceuticals in the country, clinical evaluation of</li> </ul> </li> </ul>
	medicines and for monitoring the advertising and marketing of both medicines and medical devices. Its powers stem from the Act on Public Health Insurance.
Denmark	<ul> <li>Vaccine coverage, effectiveness:</li> <li>Electronic immunisation registry (DDV).</li> <li>Linked to other registries to monitor product-specific uptake, coverage and effectiveness.</li> </ul>

Country	Information on how product-specific monitoring systems will be organised to document
	vaccine coverage, safety, effectiveness and acceptance
	Varcine safety:
	Similarly, vaccine safety is planned to be monitored by linking suspected adverse reactions and selected adverse event of special interest from the hospital discharge register, with information about vaccination-product and batch numbers from DDV.
Estonia	Vaccination coverage, acceptance and effectiveness are under the health board administration.
	Safety is under State Agency of Medicines. The pharmacovigilance is currently carried out in a separate system. The central health information system data will be enriched to trace also product-specific information.
Finland	<ul> <li>Currently being planned.</li> <li>Nationwide post licensure impact monitoring including coverage, effectiveness and safety:         <ul> <li>Link between vaccine, outcomes and adverse event possible through national vaccine register, population registry and nationwide personal number</li> <li>Vaccine register allow the recording of trade name and Lot number</li> </ul> </li> </ul>
	<ul> <li>Insurance data on usage of drugs which can be used to amplify understanding on morbidity</li> <li>Cohort design preferred rather that test negative design for the monitoring of effectiveness</li> <li>Use of sentinel surveillance not excluded</li> <li>Preparatory work currently undergoing, including discussion with clinicians on which ICD to</li> </ul>
	code health outcomes
France	Not yet established. Monitoring systems will depend on the deployment plan for COVID-19 Acceptance studies are and will be regularly conducted by the National Public Health Agency.
	France possesses different system information (SI) to monitoring storage, shipping and pharmacovigilance. At that stage, France is working on one SI to aggregate all those systems in order to have an overall view.
Germany	<ul> <li>Vaccine coverage:         <ul> <li>A stand-alone central electronic database currently under development</li> <li>Telephone surveys (subsequent surveys), surveys among hospital staff, and analyses of insurance claims data will also be implemented</li> </ul> </li> </ul>
	Vaccine effectiveness: - Targeted studies (hospital-based case-control study)
	Vaccine safety: <ul> <li>Cohort study (using an app)</li> <li>Pregnancy register</li> <li>Routine observed-vs-expected analyses based on country background incidences</li> </ul>
	Vaccine acceptance:
Crooco	- Subsequent surveys
Greece	vaccination for COVID-19 (and hopefully will be the basis for a vaccination registry for all vaccines in the future) and will be linked to the existing system of "electronic prescription of medicines" and the systems of "therapeutic protocols" (electronic registries of patients under treatment regimens) which exist for selected diseases.
Hungary	No further information provided
Iceland	National Vaccination Registry.
Ireland	Currently under development.
Italy	The electronic platform for registering vaccination activities will be used.
	<ul> <li>Effectiveness and safety:         <ul> <li>A specific surveillance system for adverse events and effectiveness under development by the Italian medicine Agency.</li> </ul> </li> </ul>
Latvia	No individual record on vaccine status.
	Number of distributed does available.
Liechtenstein	Under development
Lithuania	Vaccination coverage will be monitored by e-health system as all vaccination records have to be
	provided to e-health.

Country	Information on how product-specific monitoring systems will be organised to document vaccine coverage, safety, effectiveness and acceptance
	Safety monitoring will be done by adverse event following immunisation monitoring system. Surveillance data and vaccination coverage data will be used for evaluation of the effectiveness. The acceptance of any vaccine should be evaluated by surveys of the population's attitude to it.
Luxembourg	<ul> <li>Vaccination registration e-tool (ad hoc system for COVID-19 vaccine) under development:</li> <li>Use by vaccine provider</li> <li>Send appointment invitation and reminder (e-appointment system)</li> <li>Deliver vaccination certificate</li> <li>Vaccine registration tool</li> </ul>
	Efficacy: - Linkage Vaccination registration e-tool with COVID-19 cases database (efficacy)
	Separate Existing Pharmacovigilance surveillance system
	<ul> <li>Acceptance: <ul> <li>Intention to vaccinate (population survey) undertaken in September</li> <li>Survey to be repeated to see the trend and tailor campaigns</li> <li>Large media campaign on large scale testing, conveying the concept of herd immunity and cocooning</li> </ul> </li> </ul>
Malta	Implementation of an effective product-specific monitoring system under development.
	Safety: - Mandate of the Maltese national medicine agency
The Netherlands	National register currently under discussion.
	Effectiveness: - Through existing platform
	Safety:
Norway	<ul> <li>The Norwegian Institute of Public Health is responsible for establishing a plan for follow-up of vaccine efficacy/effectiveness, safety and vaccination coverage.</li> <li>Surveillance of COVID-19:         <ul> <li>Norwegian Surveillance System for Communicable Diseases (MSIS) and the laboratory database (MSIS Lab database)</li> </ul> </li> </ul>
	Norwegian medicine agency electronically (Norwegian injury registration system): - Surveillance and monitoring of vaccination - national health registries - Surveillance of COVID-19 vaccination
	<ul> <li>Norwegian Immunisation Registry (SYSVAK)</li> <li>Suspected adverse events after immunisation will be reported by healthcare professionals to BIVAK registry at NIPH</li> </ul>
	<ul> <li>Patient reported adverse events are reported to the Norwegian Medicines Agency</li> </ul>
	Other national health registries: - Emergency register for COVID-19 (Beredt-19), Norwegian patient register (NPR) and a possible link with the Norwegian Registry for Primary Health Care (NRPHC) and the Norwegian Cause of Death Registry (DÅR)
Poland	Details on the documentation system for vaccination are being determined. An electronic system linked to COVID-19 data is being considered. A strengthened surveillance of the vaccine safety system (beyond routine pharmacovigilance) is under development
Portugal	Dedicated Information Systems that are in place will include these new vaccines (Monitoring of vaccine coverage and vaccine safety). Vaccine coverage will be monitored through the National online platform for registry and management of vaccines and vaccination (VACINAS), coordinated by the Directorate-General of Health (DGS). Safety will be monitored by the online pharmacovigilance system, coordinated by the National Medicines Authority (INFARMED).
Romania	No further information provided
Slovakia	No further information provided

Country	Information on how product-specific monitoring systems will be organised to document vaccine coverage, safety, effectiveness and acceptance
Slovenia	Use of Immunisation information registry (eRCO) and national database on confirmed COVID-19 cases.
	In accordance with the regulations, the distribution and administration of COVID-19 vaccines will be closely monitored, as well as monitoring of possible side effects.
Spain	<ul> <li>Vaccine coverage         <ul> <li>Specific COVID-19 vaccination registry under development.</li> <li>Data can be used for the monitoring of effectiveness.</li> </ul> </li> <li>Safety         <ul> <li>current pharmacovigilance system in place</li> </ul> </li> </ul>
	- Surveys
Sweden	The national vaccination register will be adapted for registration of all vaccinations against COVID-19. The work is ongoing now. It includes legal as well as IT adaptations.
The UK	No further information provided.