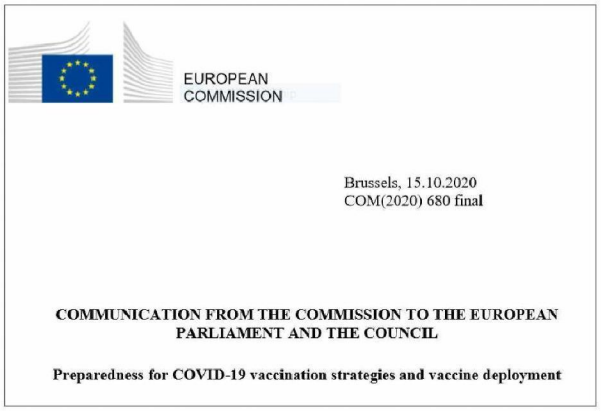
Implementation of COVID-19 VE studies

Expert meeting on COVID-19 VE studies in health care workers, 26 January 2020

European Commission is calling for coordination in MSs to develop COVID-19 vaccination strategies and vaccine deployment plans



EUROPEAN COMMISSION

Brussels, 15.10.2020
COM(2020) 680 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Preparedness for COVID-19 vaccination strategies and vaccine deployment

Nov. 2020: **European Health Union** empowering the two agencies to jointly coordinate independent monitoring studies

ECDC is requested to:

- Closely work with the EU-NITAGs collaboration, as secretariat and in close collaboration with WHO, to support MSs in developing vaccines deployment plans and vaccination strategies;
- Set up a system to collect vaccine coverage data;
- To promote and support the development of electronic immunisation registries;
- To support MS in decision making for planning deployment of COVID-19 vaccines, by developing scenarios for prioritisation strategy based on mathematical models.

ECDC and EMA joint work is:

- To set up a **monitoring framework to estimate vaccination impact, effectiveness and promptly detect and analyse safety signals**

ECDC Vaccine effectiveness monitoring in EU/EEA: 2021 feasibility studies

Initial step (10 month project, 2021)

- lay the ground to set up an infrastructure
- Tendered by ECDC through ECDC procurement procedure

Overview of activities within the project

"Methodological" expert virtual meetings
Coordination ECDC - Epiconcept

Vaccine effectiveness study in health care workers

- EU/EEA study protocol
- study implementation

Vaccine effectiveness study with a hospital based system

- EU/EEA study protocol
- study implementation

Overview of activities within the project

Vaccine effectiveness study in **Long Term Care Facilities**

- study protocol

Vaccine effectiveness study in **outpatients**

- mapping current practices
- study protocol

Vaccine effectiveness study in **another setting**

- study protocol

ECDC team

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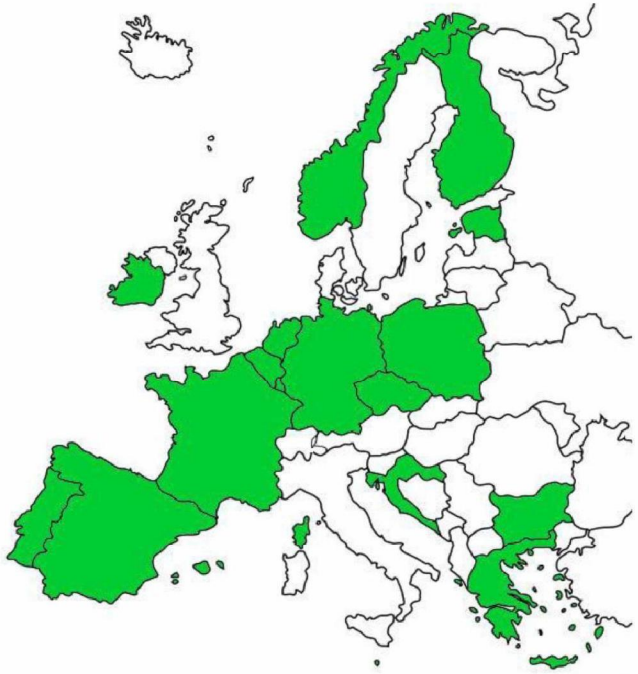
Extra slides

Countries expressing interest in ECDC VE studies

Belgium
Bulgaria
Croatia
Czechia
Estonia
Finland
France
Germany
Greece
Ireland
Luxembourg
Malta
Netherlands
Norway
Poland
Portugal
Spain



Recruitment of sites, main criteria considered

- EU/EEA geographic representation
- High sample size
- Possibility to implement high quality and validated data on vac. Status
- Access to validated laboratory testing
- Previous experience with SARI surveillance (hosp study)
- Previous established cohort of hcw (hcw study)
- Ability to recruit and follow up HCW with regular testing / households members (hcw study)
- Possibility to implement immunogenicity profiles in a subset of the cohort (hcw study)

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SCIENCE MEDICINES HEALTH

Overview of EMA COVID-19 vaccine safety monitoring plan

First ECDC Expert meeting on COVID-19 vaccine effectiveness studies

26 January 2021

5.1.2e

An agency of the European Union

EUROPEAN MEDICINES AGENCY

Joint ECDC/EMA COVID-19 vaccine monitoring programme

- Nov. 2020: EC adopted a proposal to strengthen the EMA and ECDC mandates in response to learnings from the COVID-19 pandemic

  → Creation of a European Health Union, empowering the two agencies to jointly coordinate independent vaccine monitoring activities

- Safety studies to be procured by EMA through its framework contracts (similar to ECDC for effectiveness/impact studies)

- **Jointly managed vaccine monitoring platform with joint Advisory Board** to oversee prioritisation and implementation of vaccine safety and effectiveness studies

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Safety monitoring of COVID-19 vaccines

Preparedness: ACCESS project

EU infrastructure for vaccine monitoring
- Background incidence rates of adverse events of special interest (AESIs)
- Protocol templates for effectiveness studies (cohort/EHRs + hospital-based TND)
- Protocol templates for safety studies (active surveillance, signal strengthening, signal evaluation)
- EU network of secondary data sources for COVID-19 vaccine monitoring, and other tools

Now: Early study

Early safety monitoring to complement spontaneous reporting systems (2021)
- Priority groups, ~10 months duration, in 7 MS (Germany, Croatia, NL, Belgium, Luxembourg, Italy, France) + UK
- Hypothesis-generating
- App-based primary data collection: incidence rates of suspected adverse reactions; observed-to-expected analyses
- Complemented by secondary data collection in healthcare databases (incidence of serious ADRs, rare AESIs)

EC funding 2021-2022

Joint ECDC/EMA vaccine monitoring programme
- Observational safety studies procured by EMA (effectiveness studies: ECDC)

1) Active surveillance of suspected ADRs and AESIs, 2 years, + 10 MS, similar to early study
2) Hypothesis-testing, etiological studies to evaluate and quantify safety signals: assumption for 10 potential safety signals to be investigated over 2 years

Contract with EU PE & PV Research Network (Utrecht University) for both ACCESS project and early safety study

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Thank you for your attention

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Why health care workers

Healthcare workers as priority group for vaccination against COVID-19

WHO SAGE ROADMAP FOR PRIORITIZING USES OF COVID-19 VACCINES IN THE CONTEXT OF LIMITED SUPPLY

An approach to inform planning and subsequent recommendations based upon epidemiologic setting and vaccine supply scenarios

Version 1.1
13 November 2020

World Health Organization

Version 1.1 13 November 2020

Table 1. Epidemiologic setting and vaccine supply scenarios, and recommendations for priority use cases for vaccines against Covid-19 in the context of limited supply[a,b]

(a) Epidemiologic setting scenario: Community Transmission – defined in Legend 2

Overall public health strategy for this epidemiologic setting: Initial focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; also, reciprocity. Expand to reduction in transmission to further reduce disruption of social and economic functions.
(A1) (A2) (A3) (B1) (B2) (C1) (C2) (D1) – labels explained in Legend 1

Vaccine supply scenario	Priority groups
Stage I (very limited vaccine availability, for 1–10% nat. pop.)	Stage Ia (initial launch): • Health workers at *high to very high risk* of acquiring and transmitting infection as defined in Annex 3. **(A1) (A3) (D1)** Stage Ib: • Older adults defined by age-based risk specific to country/region; specific age cut-off to be decided at the country level. **(A1) (C1)**
Stage II (limited vaccine availability, for 11–20%	• Older adults not covered in Stage I. **(A1) (C1)** • Groups with comorbidities or health states determined to be at *significantly higher risk* of severe disease or death. Efforts should be made to ensure that disadvantaged groups where there is underdiagnosis of comorbidities are equitably included in this category. **(A1) (C1) (C2)** • Sociodemographic groups at *significantly higher risk* of severe disease or death (depending on country context, examples may include: disadvantaged or persecuted ethnic, racial, gender, and religious groups and sexual minorities; people living with disabilities; people living in extreme poverty, homeless and those living in informal settlements or urban slums; low-income migrant workers; refugees, internally displaced persons, asylum seekers, populations in conflict settings or those affected by humanitarian emergencies, vulnerable migrants in irregular situations; nomadic populations; and hard-to-reach population groups such as those in rural and remote areas). **(A1) (B1) (B2) (C1) (C2)**

Why assessing vaccine effectiveness in healthcare workers

- Healthcare workers are essential workers professionally exposed to SARS-CoV-2 who can be infected and transmit the virus to vulnerable patients
- Healthcare workers represent a group of individuals of working age with high exposure to SARS-CoV-2 (e.g. higher viral load and repeated exposures)
- Many healthcare workers have been infected with SARS-CoV-2 during the past year, so they represent a heterogeneous group, when it comes to previous infection, with potential diverse vaccine effectiveness

Practical advantages of assessing vaccine effectiveness in healthcare workers

- Most countries have prioritised the vaccination of healthcare workers in stage/tier 1, so they are among the first to receive the vaccine
- Healthcare workers can be followed up and tested rather frequently with different outcomes that can be assessed
- Healthcare workers can be studied as a cohort to assess the effectiveness of COVID-19 vaccines against various outcomes, e.g.:
  - infection and onward transmission,
  - duration of protection,
  - Infection with SARS-CoV-2 variants
- The healthcare infrastructure can be used for e.g. sampling, recruitment, follow-up, and performance of testing