ECDC Meeting Report

Joint Meeting for National Focal Points for Preparedness and Response & National Focal Points for Threat Detection, EWRS and IHR

Agenda

17 Sept 2020, Thursday, 13.00-14.00

13:00-13.05 **Welcome by** 5.1.2e

Chaired by 5.1.2e

13.05-13.30 **Session 1**

- COVID-19 vaccines, 5.1.2e, 5.1.2e 5.1.2e

13.30-13.45 **Session 2**

- COVID-19 clusters and outbreaks in occupational settings in the EU/EEA and the UK, 5.1.2e 5.1.2e

13.45-14.00 **Discussion**

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Acronyms

APAs – Advance Purchase Agreements

CEPI - Coalition for Epidemic Preparedness Innovations

ECDC – European Centre for Disease Prevention and Control

EU – European Union

HCWs – Health care workers

MoH – Ministry of Health

NITAG – National advisory committees on immunization

NRA - National Regulatory Authorities

PPE – Personal protective equipment

SAGE - Strategic Advisory Group of Experts on Immunization

WHO – World Health Organization

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Session 1: COVID-19 vaccine availability and monitoring needs upon the introduction to the EU/EEA

5.1.2e, 5.1.2e ECDC

The EU vaccine strategy has been created to accelerate the development, manufacturing and deployment of vaccines in the EU/EEA. In return for the right to buy specified number of vaccines in a given timeframe, the European Commission will finance part of the upfront costs through the Emergency Support Instrument in the form of Advance Purchase Agreements (APAs). The aim of the vaccine strategy is to create a portfolio of potential vaccines with different profiles and produced by different companies. The EU funding provided is to be considered as a down payment on the vaccines that will then actually be purchased by the Member States.

The European Commission has negotiations with eleven vaccine producers, but as of now, only one APA has been signed with AstraZeneca for 300 million doses and with the option to procure additional 100 million doses of a vaccine candidate developed by Oxford University. Although only one APA has been signed, we are preparing for the possibility of having as many as eleven vaccines authorized in the EU market. In addition to active immunisation, several companies are working on passive immunisation alternatives (monoclonal antibodies and hyperimmunoglobulins). Before formal vaccine authorization in the EU, there is also a possibility to provide compassionate use. Bilateral agreements between some European countries and vaccine manufacturers are also in place. Globally, the COVAX Facility is available to ensure that all countries in the world will have access to vaccines.

The eleven COVID-19 vaccines currently under development have new technology platforms behind them, which will have implications for the vaccination strategies and monitoring. This will require new monitoring techniques.

There are three conditionally authorised vaccines available from China and Russia, which have been approved for limited use. The question is whether we should also expect compassionate use approvals in the EU/EEA countries. It is still unknown when the first COVID-19 vaccines will become available. On 18 September, the European Commission is offering a public webinar where more information on the timeline for vaccine availability might be shared.

Scientific evidence is key, but the different stakeholders – public health (MoH, NITAGs) and regulators (NRA, EMA) - will have different information needs. Studies and monitoring are needed to obtain information on exposure, vaccine immunogenicity (short and long-term), vaccine safety, vaccine effectiveness, and vaccine acceptance. Vaccine safety will be an important topic, as the COVID-19 vaccine is expected to receive much scrutiny from both health care workers (HCWs) and general public. Therefore, enhanced and active surveillance will be needed to support the already strong routine monitoring system in Europe.

Should several vaccines reach authorization in the EU/EEA, it will be important to conduct product-specific studies and product-comparative studies. However, it is unlikely that the vaccine manufacturers will conduct comparative studies. Another important question is whether mixed vaccination will be needed and what the implications will be for vaccine studies. Through stakeholder mapping, the EMA, NRA, ECDC, NPHI/NITAGs, vaccine producers (obliged by law to conduct studies) and some academic groups have been identified as potentially being able to carry out such studies.

COVID-19 vaccine supply is expected to be limited and prioritization will be needed. So far, we know that HCWs, other front line workers, individuals over 70 and other risk groups for severe disease will be prioritized. A values framework for vaccine allocation and prioritization was published by the WHO SAGE on 14 September. More specific recommendations from WHO SAGE will become available in early October and other recommendations have also been published by NITAGs. Monitoring activities have started in a few countries and work has been done on electronic immunisation registries. Approximately half of the EU/EEA countries already use electronic immunisation registries for parts of or the whole population, but these will need to be expanded for COVID-19 to cover the whole population and include information on target groups, e.g. being a HCW.

Conclusion and remaining questions

The question of vaccine allocation, prioritization and equity will be a key area for discussion along with vaccine safety. In addition, we have to consider if COVID-19 vaccine monitoring preparedness plans are needed. This question is particularly important if there is a safety signal, such as during the 2009 influenza pandemic. For COVID-19, AstraZeneca recently halted their Phase 3 trial due to a safety signal (one case with a severe

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neurological disorder). It is important to prepare for safety signals, but there is a need to discuss what vaccine monitoring preparedness plans should include.

Discussion

How do you view the different vaccine candidates in terms of their potential strength of immune response and is this something that we are able to monitor?

Both B and T cell immunity is monitored by vaccine manufacturers during the clinical trials. B cell immunity assays are quite standardised, there is an entity in the UK (NIBSC), which has developed standard sera. With T cells, there is until now no standardised technology and there are less than ten laboratories in the world doing excellent work on T cell immunity. CEPI has just signed agreements with reference laboratories across the world to support vaccine developers. These will provide standardised T-cell immunity assays. However, we need to understand much more about COVID-19 and immunity, and standardisation for public health studies on the T cell side would be very helpful, for developers and public health. The different vaccine candidates will trigger different aspects of immunity, for example, some of the newer technologies trigger T cell immunity. Therefore, it is crucial to know how well the vaccines perform in the population and in the real world, not only in clinical trial participants.

What advice is there for people working in preparedness and response and what realistic levels of supplies can be expected? There are APAs and bilateral agreements underway, but are there further reflections on this topic?

To be able to stop the COVID-19 pandemic, we need the world to be immune. This is a tricky exercise and we have to try and support it as much as possible. The COVAX Facility led by GAVI is one way and has many supporters including the EU. Large sums (100 million €) have been contributed to the COVAX Facility from the EU and some Member States are participating in the COVAX Facility with the aim to receive some vaccine. The goal for the COVAX facility is to be a large group of high-income, middle-income and low-income countries with enough procurement power to support vaccine production and availability for all countries. Pricing will be tiered so that low-income countries will pay less for vaccines than high-income countries.

For the mixed use of vaccines, do you prefer monitoring to be conducted by manufacturers or the public health sector and should the mixed use of these vaccines have evidence of safety?

This is a very difficult question. The preference is to have formal clinical trials, with people randomized in different schedules. Last year there were studies from Quebec, Canada on the mixed use of HPV vaccines but this took place 15 years after approval in North America and the EU. It would be good to have safety data by both the manufacturers and the public health sector. Until we know more about the vaccines, the preference is not to mix them. However, we may be forced, should the outbreak become very severe.

The AstraZeneca COVID-19 Oxford vaccine seems to be one of the closest candidates. Will it be two doses? This will be important to know in terms of coverage and acceptance.

It seems that two doses will be needed, but they are testing both one dose and two doses. Two doses were also needed for the Ebola vaccine with similar technology. We will likely have to anticipate that many vaccines will need two doses. Another difficulty is the cold chain, they can only be out of the cold chains for a day.

Session 2: COVID-19 clusters and outbreaks in occupational settings in the EU/EEA and the UK.

5.1.2e 5.1.2e **ECDC**

There was a lot of media attention around May and June on different clusters and outbreaks in occupational settings, including slaughterhouse-related outbreaks in Germany, Netherlands, US, UK, as well as outbreaks in mines, warehouses, etc. In response to this issue, ECDC has published a Technical Report in early August.

Method

- Country based data collection from EU/EEA countries and UK – different variables including occupational setting, date of identification of cluster, number of cases, number of deaths, identified risk factors and other variables.

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- Epidemic intelligence activities at ECDC
- Rapid literature search

Results

ECDC received 17 responses, 13 of which reported data on specific clusters in occupational settings, three countries provided aggregated data only, and one country provided the number of cases in different occupational groups.

A total of 1376 clusters were reported with ~18200 cases. The vast majority of clusters, cases and deaths have been reported from health and social care. Most occupational clusters were reported from long-term care facilities (LTCF), followed by hospitals and food packaging and processing (including slaughtherhouses). Most deaths were reported from hospitals. The vast majority of clusters have been linked to indoor settings (over 95%). The size of the clusters ranged from two to a several hundreds.

Factors contributing to clusters in occupational settings

- Lack of physical distance
- Lack of facilities to wash hands
- Language challenges among migrant workers
- Staff socialising together in the community
- Close/direct contact with cases
- Insufficient or incorrect use of PPE

The lack of physical distance was a risk factor mentioned for all occupational settings included in the report.

Conclusion

Clusters have been reported in various occupational settings, even from settings, which may have not been expected prior to this report. The majority of cases have been reported in the health and social care settings but it is important to consider that routine testing is conducted in those settings; therefore there might be testing bias. The vast majority of clusters were predominantly in indoor settings. Consideration should also be given to overcrowded living conditions of migrant and seasonal workers. The health and safety of staff is important not only for the protection of the workers but also to prevent further spread.

An increased focus on testing in workplaces, combined with robust and strictly enforced policies for physical distancing, hygiene and cleaning, appropriate use of PPE, and hand hygiene could help prevent outbreaks in those settings.

There are several limitations to the report – it is not a complete overview of all countries and occupational settings, no information on age/sex and underlying conditions was collected. There is no consistent definition of how occupational outbreaks are classified, investigated or reported by MS in the EU/EEA and UK. In case-based surveillance of COVID-19, occupation is not a routinely collected variable, which makes it difficult to get an overview and comparison between countries. Results of investigations on outbreaks in occupational settings are not always made public; therefore, there is very limited and mostly anecdotal evidence.

Discussion

Have you collected and analysed information on ventilation / fresh air supply?

Not in this study. The aim was to make data collection as simple as possible, also due to time constraints. However, there was an option to provide more information, but this was not brought up by the survey respondents.

Was there information on mask wearing within the workplace?

No, this information was not available.

Do you know if any specific country has been more affected by occupational outbreaks than others?

Most countries have reported outbreaks from food packaging and processing. It would be possible to obtain this information from the data. However, reporting occupational outbreaks per country would be very biased, because only 17/30 countries answered the ECDC survey. Some countries only reported clusters in certain regions as they were not able to provide information for the entire country.

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Concluding remarks (ECDC)

The next webinar is planned for 8 October 2020 on the topic of Health Economics and Data, with presentations by invited speakers from the Organisation for Economic Co-operation and Development (OECD).

ECDC Announcement – [redacted]

In-Action Review online workshop – reminder to the NFPs

- 4 h interactive online workshop based on **ECDC guidance on AAR/IAR**
- Dates: 6 October am or 7 October pm (4.5 h)
- By invitation only – NFPs have been asked to nominate participants
- Will cover planning and delivery and dissemination in an informative and interactive way
- Developed in conjunction with ISS, Italy and PHE

Competency based training – 20 and 22 October

- NFPs have received a request to nominate a participant
- Target audience: PH experts working in the area of preparedness and response
- Two modules: Detection and Assessment and Health Services – more details in the nomination request
- 4.5h per module
- Interactive online workshop delivered by PHE supported by ECDC
- COVID-19 focus

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