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

Agenda

25 February 2021, Thursday, 13.00-14.20

13.00-13.05	**Welcome by chair** 5.1.2e
13:05-13:20	**Session 1:** Vaccination tracker - 5.1.2e, ECDC
13:20-13:50	**Session 2:** Vaccination preparedness and variants - 5.1.2e and 5.1.2e ECDC
13:50-14:05	**Session 3:** Stress tests on vaccine deployment EU/EEA and in the Balkans - 5.1.2e, ECDC
14:05- 14:20	**Discussions**

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Session 1: Vaccination Tracker

5.1.2e, ECDC

The Covid-19 Vaccination tracker that ECDC has developed is the work of a large team of colleagues from ECDC and could not have happened without the daily and ongoing effort of the country teams.

- By mid January 2021 all countries in the EU and EEA had started their vaccination campaigns
- The EC adopted a Communication calling on MSs to speed up the roll out of vaccines with targets: By March 2021 a minimum of 80% of health and social care professionals and people over 80 should be vaccinated, and by the summer of 2021 – a minimum of 70% of the adult population

EU/EEA countries report data to the European Surveillance System (TESSy) twice a week – on Tuesdays and Fridays. On Tuesdays – for the previous week and on Fridays – preliminary data for the current week. This includes weekly number of doses distributed by manufacturers, weekly number of 1st and 2nd doses administered (by total number, vaccine product, target groups) including age groups - for the national level, and if available – also for subnational level. Indicators on population are taken from Eurostat, for long term care residents in facilities countries are also reporting, as well as information on number of persons who refused the first dose.
The first data call was on 15 January, 2021.

Monitoring is conducted and the objective is to provide timely and as complete as possible overview. There are three main outputs:

- The Vaccine tracker, which went live on 1 February with a second version released on 17 February. Data is constantly refreshed.
- Covid-19 weekly review- every Thursday, which presents the status of roll-out as of the previous week.
- ECDC technical reports published to provide an overview of implementation of Covid-19 vaccination strategies and vaccine deployment.

Where can one access the Vaccine tracker?

- ECDC Covid-19 main page
- ECDC Covid-19 Situation update
- ECDC Covid-19 Dashboard

There are different tabs in the Tracker: Vaccine uptake; Target groups (specific ones among them 80+ and health workers); Doses by product received and administered in the countries; National references and Notes on the data.

In order the Vaccine tracker to be as much interactive as possible, there are interactive maps, charts and tables. Indicators of choice can be selected – e.g.: uptake 1st dose, uptake 2nd dose, and by scrolling down and a specific country should be selected. Data on specific indicators can also be obtained and as well as information from the maps, tables and the charts can be extracted.

The First tab is vaccine uptake in adults – 18+ and one can select whether this is 1st or 2nd dose and the MS. When a country is selected, it is highlighted automatically where it is in the chart.

The Second tab is target groups – uptake 1st dose, 2nd doze, there is also a table with disaggregation according to age group. There is information on healthcare workers. Denominators are still missing on national level and work is still going on.

The Third tab is about doses distributed and administered by vaccine product. There is an option to

look at the total number of doses distributed to a country, the proportion by vaccine products, but one can also select a specific vaccine product and it will show the number of doses distributed.

It was considered important to include a Fourth tab - on national references, where links to each country's national strategy and deployment plans can be found, including national trackers and more information, roll out, etc.

The Fifth tab includes disclaimers, and explains the sources of data, interpretation of the data, there is a specific table with notes on specific countries for better interpretation and quality.

Completeness has improved overtime, and so has quality. ECDC is working with the national teams to minimize the errors in reporting and duplicates. It is still work in progress. Currently Version 2 is available, and there are plans to to have a Tracker version for mobile devices, and probably by mid-March – a version 3, with more information about the countries, with country sheets, trend analyses and additional info on the vaccines authorized in the EU.
ECDC welcomes suggestions and recommendations on the tracker.

Q&A
Question: What are the data sources?
Answer: TESSy, data that country teams and MoH report two times a week to ECDC, and the national trackers to make sure the info is consistent.

Question: When will be the next improvement?
Answer: The next improvement is Version 3 which should be launched by mid-March. It will include graphs that present trends, not just snapshots, there will be richer country profiles with different indicators and trends.

Question: What challenges did you experience in the set up?
Answer: Assuring correctness of the reporting, correctness of the templates, avoiding duplicate reporting, cleaning the data base (in communication with the country teams), ensuring quality and consistency of data analysis.

Question: How are data analysed? Are there differences between the countries?
Answer: The aim of the Tracker is to monitor progress in a timely way. The data can be downloaded and analysed, there are multiple purposes: for monitoring, research, and decision making.

Question: As for denominators, Eurostat was mentioned to be the source for the general population. As for the healthcare workers, is it correct that the denominator is reported by the countries?
Answer: Yes, so far this is correct.

Session 2: Vaccination Preparedness and Variants

5.1.2e, **ECDC**

New SARS-Cov-2 variants in the EU/EEA and Options for Response (1)

The presentation builds on the ECDC risk assessment that was published on 15 February, 2021 While most countries are seeing a decline in overall infections, as a result of non-pharmaceutical interventions (NPIs), the introduction and increased spread of new SARS and Cov-2 variants first identified in the UK, South Africa and Brazil have raised concerns

Due to the many new variants of concern that have been identified, the European Parliament and the Council published a Communication (on 17th of February, 2021) with the aim to help to understand the role of the variants. The EC made available additional funding to facilitate:
- The rapid detection of variants;
- The swift adaptation of vaccines (EMA responded this may happen in September 2021);

- Setting up a European Clinical Trial Network - the lead team is based in Germany, but all MS are encouraged to get involved;
- EMA is also working on fast tracking the regulatory approval of updated vaccines;
- Upscaling of production –is difficult as validated factories are needed (e.g. BioNTech/Pfizer bought the old GSK factory in Germany, aiming to have it up and running in April 2021 which is a record fast time for such operation).

The Commission has acted even further. For all EU countries and EEA there are advance purchase agreements signed, and in February 2021 there were additional advance purchase agreements signed with both Moderna and BioNTech/Pfizer - for another 500 million doses.

The vaccines available so far include (by developer): BioNTech/Pfizer; Moderna, Oxford/Astra Zeneca – already authorized. For Johnson and Johnson authorization is expected in mid March 2021. Novavax and Curevac are a bit behind. Another vaccine under development is Sanofi GSK. There is a dialogue with Gamaleya (Russia) and Sinovac (China).

For the risk assessment the key points are vaccine efficacy and effectiveness. We now have data showing high efficacy for vaccines developed by BioNTech/Pfizer and for Moderna – over 90 %; and a bit lower for Oxford/Astra Zeneca, but the trials for these vaccines have several limitations and outcomes. There is new data from Scotland on Astra Zeneca effectiveness, published in February indicating – 94% against hospitalization following dose 1. For the vaccine developed by Johnson and Johnson it has been noted that it will be only a 1-dose programme, at least initially.

There are clinical trials conducted in South Africa, Brazil and the UK and some study efficacy data have been already collected for the different variants and for some of the vaccine products, but more is needed for a comprehensive assessment.

Reinfection and the possibility of breakthrough infection following vaccination
For the **B.1.1.7** variant first identified in the UK **the** reinfection rate is 0.7% - not higher than for previously circulating variants and this is good news. However, although a 2 fold neutralizing antibody reduction in convalescent sera and post vaccination sera compared to the Victoria-1 strain; Despite the neutralizing antibody reduction this reduction up to 60% of convalescent sera retain functional activity above the threshold.

For the **B.1.351** variant initially identified in South Africa there is limited data so far but a 3-10-fold reduction have been observed for some of the convalescent sera and sera obtained from vaccinated individuals. The neutralizing threshold in some studies is down to 10 % of the initial neutralization titres and this is concerning.

Very little is known about the **P.1 variant isolated in Brazil.** Reinfections are noted, but ECDC does not have access to published data. However, with the mutations reported in GISAID it is clear that this variant is of concern and likely will impact on neutralizing antibodies.

Where are we now?
Population immunity: Vaccines are available, as well as much more knowledge about the virus and the diseases compare to one year ago. The population immunity was very different a year ago with no antibodies to SARS-CoV-2 in the global population. .Now the population sero-positive are increasing in all countries however, seropositivity vary between and within countries. Even though we do not know the representativeness of the sample size, there are areas that report very high sero-positivity like India. Further, in Mannaus, Brazil – 76 % sero-positivity was reported, this even before the P.1. outbreak. In 2020 the vaccine strain matched almost perfectly the circulating variants, but now in 2021 there is increasingly suboptimal match, with the new variants of concern emerging.
In 2020 vaccines were not available or licensed. Currently in the EU there are 3 (soon 4) and vaccines are increasingly rolled out.

Vaccine efficacy: Currently, a lot more is known and and it is expected to learn more from the on-going and new clinical trials.
Correlate of Protection: in 2020 absent, in 2021 – emerging evidence pointing to a role of neutralizing antibodies.

Mix & Match
Currently there are not enough vaccines, but ideally it would be good to do Mix&Match of vaccine products from different developers for many reasons: it would be easier to procure vaccines, it would be easier in vaccination offices to take what is in the fridge, and there could be possibilities to improve the immune response. There are trials starting now, for example in Oxford – one vaccine for the first dose and another for the second dose and it is expected some results from this trial already of this process in May 2021. This will make things easier for everyone.

Other points: There are still uncertainties; .e.g. on manufacturing: will manufacturers adapt the current vaccines to the new variants, or will new vaccines be developed; monovalent containing one variant, or multivalent with several variants included? On clinical endpoints, can immunological and safety endpoints be used in the clinical trials for updated vaccines or are full efficacy trials needed?

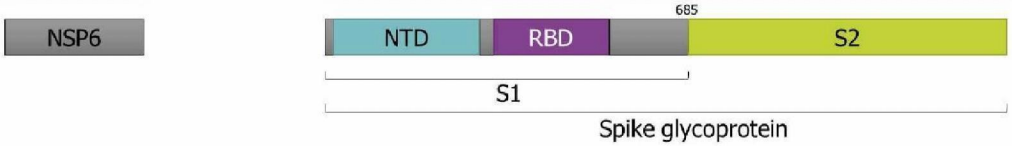
5.1.2e **ECDC**

New SARS-Cov-2 variants in the EU/EEA and options for response (2)

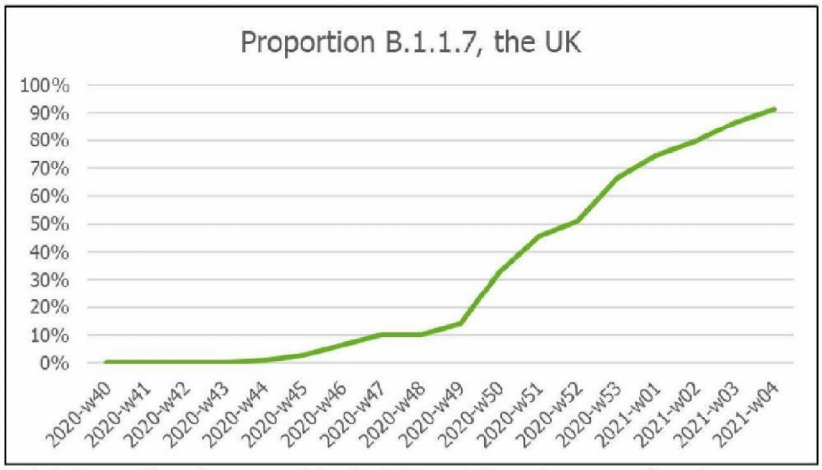
Following existing variants of concern and monitoring emerging variants that need to be examined from the perspective of genomic scientists, the situation is presented as a simplified three with the source of the pandemic and the original virus in the centre, and the new variants of concern around. The variants of concern detected – B.1.1.7, B.1.357 , P.1 are not closely related and have evolved independently, but they have some properties in common due to convergent evolution – properties that allow them to spread more easily among the population. These variants have mutations in common: all have a high number of spike protein; most important epitopes for nAbs seem to be located in the spike NTD and R3D, and they have other mutations in the genome.

Variant	NSP6
B.1.1.7 (+E484K)	**Δ106-108**
B.1.351	**Δ106-108**
P.1	**Δ106-108**

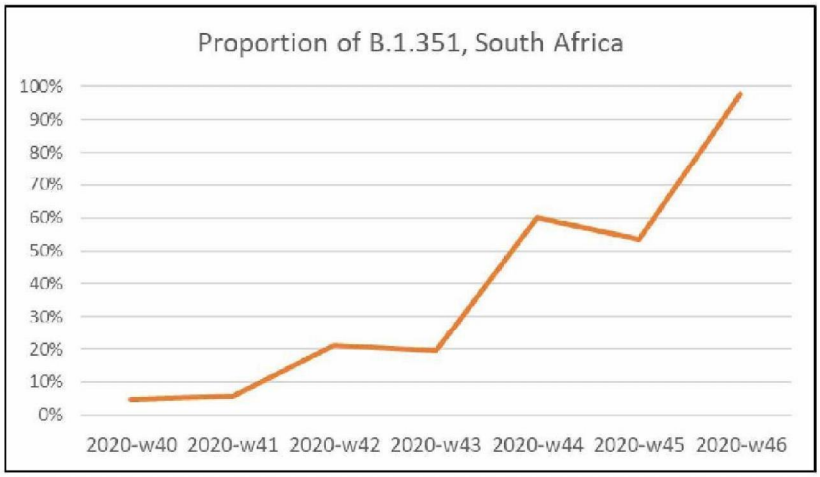
S1: NTD	S1:RBD	S1/S2	S2
Δ69-70 Δ144	**N501Y, (E484K)**	A570D, **D614G,** P681H	T716I, S982A, D1118H
L18F, D80A, D215G, Δ242-244, R246I	**K417N, E484K, N501Y**	**D614G**	A701V
L18F, T20N, P26S, D138Y, R190S	**K417T, E484K, N501Y**	**D614G,** H655Y	T1027I, V1176F



What do they have in common in terms of epidemiology and spread since their emergence?



B.1.1.7 was first discovered in the UK and for quite some time it was spreading only in the UK, then spread rapidly to more and more countries and in a few weeks became dominant, which is a validation of the studies conducted in the UK that this is a more transmissible variant. The UK has good genomic sequencing programme and they have a good detection system.



B.1.351 was first detected in South Africa (SA), started to increase first in SA and it took time before it became detected in other countries increasingly. The genomic programme in SA is less advanced but still OK.

P.1 was first detected in Brazil, the data quality is lower, there is no extensive sequencing programme, and most work is done by individual researchers. The variant spread mostly in Brazil, but subsequently to other countries as well.

It is important to monitor also other variants to see if there is a potential for concern and if investigation of their properties would be needed. It is very challenging to monitor the entire three rather than individual variants. Whole genome sequencing is used to identify variants of interest. Tracking is made in different ways: putting a label on variants, so as to assess if they are associated with change in virological and epidemiological properties; assessing genetic similarities between variants that could imply similar properties; looking for unexpected mutations or combinations of mutations that could warrant further investigations.

In the beginning of the pandemic very little was known about this virus, its properties and mutations. Now we are learning every day. There are for example, some new variants - at least 4 that are found interesting, and mutations related to them. Variant B.1.525 was first reported in the UK, but it is not probably from the UK. It was reported by Denmark and there is a great rise in February. Denmark is the only country where a clear increasing trend can be observed, but there may be a lack of timely data from other countries. A wide geographic distribution indicated that this variant is common in Nigeria. In Nigeria it is the dominating variant with up to 80% for some weeks. This variant is associated with travel, but there is also community transmission. It is not known if this virus is more transmissible and its impact on vaccines.

A works is going on to trying to formalize and structure the assessment of all these new variants. The WHO is developing a variant assessment framework, where experts will be contributing to the different variants. In the UK they are also active in this area and doing a lot internally.

Summary: Variants are already having a significant impact on the pandemic, mostly due to increased transmissibility, as well as changes in infection severity, reported both by Denmark and the UK, which is very concerning. Denmark reported 64% risk of hospitalization with the variant B.1.1.7, which is seen as very concerning, considering that also other European countries might be driven in the third wave with this variant. Another aspect is neutralization by antibodies. Monitoring of these variants will continue to be important.

5.1.2e

Overall Assessment of Risk due to New Variants of Concerns

These include:

- increased transmissibility – round 50% increased severity for at least one of the variants;
- high rate of hospitalization reported from South Africa, which could be an indication of increased severity of other variants as well,
- potential for the existing licensed Covid-19 vaccines to be less effective against Variants of concern
- probability that cases due to B.1.1.7 may increase quite a bit (countries reporting 90% sequence data).

This all will leads to increased risk of spread in EU and EEA. Risk is now assessed as high to very high for the overall population and very high for vulnerable individuals.

Options for response (though countries are different):
Immediate, strong and decisive public health interventions are essential to control transmission and safeguard healthcare capacity. Layered NPIs need to be strengthened and maintained in the coming months in order to reduce SARS-CoV-2 incidence to the lowest levels possible, thereby also minimising the opportunities for new variants to emerge. Optimising the implementation of NPIs is needed, including community use of facemasks and school settings. Test and trace approaches, including strong surveillance and sequencing, remain the cornerstones of the response. The travel should not be undertaken by people who are ill or who have had recent contact with COVID-19 cases; furthermore, ECDC recommends that non-essential travel should be avoided as part of general physical distancing measures in the community. Targeted and robust vaccination programmes will enable the easing of NPIs.

Variants against which current licensed vaccines might have a reduced efficacy, as observed for some vaccines with the B.1.351 variant first identified in South Africa, will probably continue to emerge in the future. This should be mitigated by designing next-generation vaccines with mutated spike sequences and using alternative viral antigens. Consideration should also be given to their use either as booster doses for those vaccines which have already been developed and are being administered, or, if needed, for the primary series.

Pandemic fatigue needs to be properly addressed as a matter of urgency if further waves of infection are to be avoided and population compliance is to be maintained. Public expectations about the likelihood of easing restrictions need to be carefully managed. To facilitate this, authorities should make systematic efforts to ensure they have a good understanding of community perceptions of the pandemic, the NPIs in place and COVID-19 vaccine acceptance based on behavioural research.

Q&A
Question: It was noted that the South Africa variant will not outcompete the UK variant. On what grounds was this concluded?
Answer: The South Africa variant is not increasing in the UK. In some countries in Europe it is circulating. The transmissibility of B.1.351 is not so well characterized. There is big uncertainty.
It will be good to hear from France as the South Africa variant is increasing there with about 20% in Eastern France, as reported in February. Also Netherlands reported first breakthrough infection – a fully vaccinated individual with 2 doses – infected with the variant isolated in South Africa.

Question: What is the most concerning mutation from vaccine perspective? Is it 484K?
Answer: There are multiple mutations, but probably E484K.

Comment: With regard to pandemic fatigue, –ECDC published a *Behavioural Insights* report (https://www.ecdc.europa.eu/sites/default/files/documents/Behavioural-Insights-research-to%20support-the-response-to-COVID-19.pdf). There is work under way to establish a network to share experiences and practices.

Session 3: Stress Tests on Vaccine Deployment EU/EEA and in the Balkans

5.1.2e **ECDC**

Two stress tests were conducted for Member States, in December and in January 2021 and more recently one for the Western Balkans, at the beginning of February 2021.

What is a Stress Test?
This is a simple simulation exercise with the aim to assist countries in assessing their preparedness

for the deployment of vaccines, to reflect what is going to happen with vaccine roll out, identify gaps and follow up actions. The scenario on the Pfizer-BioNTech vaccine roll out was modelled as this was the most likely to be available first and was challenging in its requirement to have an extreme cold chain in place.

The aim of the stress test was to assist countries in assessing their preparedness for the deployment of vaccines. The objectives were: to explore the efficient distribution of vaccines whilst maintaining vaccine-specific cold-chain and storage requirements; to explore the timely distribution and delivery of a COVID-19 vaccine to the identified priority groups according to the country-specific plan; to consider flexibility in planning arrangements and mitigation strategies; to identify key priority areas where there are gaps as well as identifying areas of good practice; and to explore risk communication, which is a very big issue.

What was really stressful about our Stress test exercise?
Normally it takes about 6 months to prepare an exercise like this and engage with member states during that process so they are aware and have chance to prepare. This exercise was delivered at a very short notice and the countries were given a fixed time for response - 8 hours.

In addition to the scenario, a response template with three sections was provided to be completed, The first section was what kind of pre-deployment processes they had in place.
We looked at governance first and noted many Member States had established a specific multiagency task force often involving the military with their great logistics capability; and where federal, all states were represented; there were working groups working below this delivering specific activities. In the Western Balkans the Institutes of Public Health had clear key role, which probably reflects the confidence in their experience in running mass vaccination programmes.

Training has been conducted at all points of distribution (all key points of distribution had training programmes), the training was adapted to specific settings (mass vaccination centres or clinics) and to the different vaccines with their specificities. And all the training was delivered on line, through written guidance, Standard Operating Procedures, leaflets and also supported by e-learning. One good thing about the slow deployment of vaccines - the countries had time for dry runs and rehearsals, exercises and drills to prepare for receiving larger quantities of vaccines later. The opportunity to practice and rehearse and drill turned out very well. In Western Balkan countries they had extensive training packages, and utilised WHO and UNICEF resources to support these.

Distribution: It was very interesting to note that with the Pfizer-BioNTech vaccine there was an opportunity for delivery on a regional level. There was direct engagement with the vaccine manufacturers and hence a clearer idea about the delivery timings and the ability to request delivery at the regional level if required. Large countries were able to take advantage. Most often for this vaccine – the manufacturer delivered to regional sites for storage and onward distribution to local sites and then to mobile teams. In the smaller countries there was one central hub for storage.

Priority groups: The top priority groups included: long term care facility (LTCF) residents and workers, frontline health care workers (HCW), people over 80 years of age, and people with chronic high risk conditions. In Western Balkans priority groups very similar, but with greater emphasis was put on HCW. The invitations to attend vaccination were not a problem for long term care facilities as – vaccine were sent to them, and mobile teams were also used to support the process. Many EU member states had online booking systems. This was observed for Western Balkan countries as well.

Vaccine allocation: Many countries had E-platforms and apps to manage vaccine allocation. Storage capacity locally also drove resupply. Fairness and equitable access were highlighted as being very important – to distribute the vaccine all over the country so that everybody had equal access to it – avoiding a kind of "vaccination lottery", depending on where you live.

The Settings for vaccination included LTCF, hospitals, General Practitioner (GPs) surgeries,

pharmacies, mass vaccination centres, with more flexibility and opportunities to increase the scale of vaccination possible as more vaccines were bought. A real benefit of these programmes was that a lot of money was invested in developing electronic systems. Many of the countries did not have such systems before. Now there is a good legacy with electronic systems in place.

Follow up: some countries introduced a 15 minute wait after vaccination to ensure immediate adverse reactions were captured. More widely there was a use of electronic systems to capture adverse reactions. Moreover, all countries have or will have electronic systems in place. Some systems are still under development. It was not clear in all cases who reported the adverse reactions (individual or HCW). There were some examples of close monitoring of many metrics associated with the vaccination campaign.

Waste reduction: Reserve lists are used and HCW utilise remaining stock. There is a flexibility at local level to use any excess. The vaccine delivery is based on confirmed demand and in some cases there is close monitoring of allocation (larger scale facilities).

Risk communication has been very important in terms of confidence. All countries (including Western Balkans) had plans developed around this. Campaigns were carried out in the media.
Transparency was highlighted as a key word. Opinion leaders were used to promote the message..
The key drive was to maintain public trust. The use of social media was important as a proactive rather than reactive instrument. One Member state worked directly with social media companies to be alerted by them to trends as they emerged. One country in the Western Balkans worked with a PR agency in terms of risk communication.

In terms of promoting vaccine take-up many countries preferred to use ordinary people and put them in front of the camera, rather than celebrities or politicians. Others used recognised community leaders or well-known and respected older people to highlight vaccine rollout.
Public health doctors, GPs, and pharmacists were also used to promote the campaign. In Western Balkan countries it was underlined that engagement of community was crucial for vaccine acceptance and they worked with community leaders to promote the message.

The first stress test was run in December 2020 and as situation has changed since then and it is important to see what we have learned.

Lessons learned from initial rollout: The opportunity to rehearse with the small initial allocation was very useful. It takes different time to vaccinate in different settings (though things may look similar) and one may need to adapt the strategy to the different settings. It was possible to modify the supply chain because of the slow roll out. In Western Balkans and Serbia the biggest challenge remains to have a sufficient number of vaccines. Adaptation of the strategy should be informed by: regular liaison and dialogue with international organisations such as WHO and ECDC and countries, , where the vaccine campaign is a little more advanced. In Western Balkan countries they were able to observe what other countries were doing and adapt strategies accordingly. There were multiple vaccine management, and specific supply chain models and specific SOPs/training. Western Balkan countries made it clear it was very important for them to maintain their normal vaccination programme, not just the vaccination for Covid-19. There was a strong role of WHO and Unicef in these countries.

The first report on the stress tests is available on the ECDC website:
https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-stress-test-logistical-aspects-vaccination-deployment-plans.pdf

Q&A
Question: Do we have plans to follow up on this? The real mass vaccination has not started yet? With the majority of population this will start probably in 1-2 months.
Answer: This was a snapshot in time. Since then things have moved on. The last thing is to start a simulation exercise when people and busy, working hard. The best to do now do is to get countries

to discuss any issues they have and share good practice. That would be worthwhile.

Question: How were countries addressing health Human Resourse requirements?
Answer: The best strategy was to use the people they had in normal vaccination campaigns. There was no "train everybody at the start and this is it". As the vaccination programme developed more and more people were trained. Refresher training was also done.