



Ad-hoc meeting of the
European Technical Advisory Group of Experts on
Immunization (ETAGE)

Virtual meeting, hosted in Copenhagen, Denmark
28 April 2021

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Abbreviations

AEFI	Adverse events following immunization
ETAGE	European Technical Advisory Group of Experts on Immunization
GACVS	Global Advisory Committee on Vaccine Safety
IVB	Immunization, Vaccines and Biologicals Programme
SAGE	Strategic Advisory Group of Experts on Immunization
TTS	Thrombosis with Thrombocytopenia Syndrome
VPI	Vaccine-preventable Disease and Immunization Programme
WHE	WHO Health Emergencies programme
WHO	World Health Organization

Opening remarks

The meeting was opened by Professor Adam Finn. Meeting participants were welcomed on behalf of the WHO Regional Office by Dr Nino Berdzuli, Director, Division of Country Health Programmes. Guidance is needed by the Member States on decision making on the use of COVID-19 vaccines. The ETAGE recommendations and conclusions will help instill trust in the population, which is needed at this time. The strength of the ETAGE is the diversity of its members and the many countries represented. ETAGE should ensure that decisions are both evidence-based and regionally driven. Dr. Alejandro Cravioto, SAGE Chair, provided comments on recent SAGE recommendations.

Objectives

The objectives of the meeting were to request advice and guidance from ETAGE members on the following topics:

- guidance on the use of ChAdOx1-S [recombinant] COVID-19 vaccine in the context of reported cases of thrombosis and thrombocytopenia;
- guidance for countries in the Region on setting vaccination coverage targets for COVID-19 vaccination as part of planning for and setting national vaccination strategies.

Session 1: Programmatic considerations on the use of ChAdOx1-S [recombinant] vaccine against COVID-19 in the context of reported cases of thrombosis and thrombocytopenia

Overview

Dr Joachim Hombach, Immunization, Vaccines and Biologicals, WHO headquarters, provided an overview of the updated interim SAGE recommendations for ChAdOx1-S [recombinant] COVID-19 vaccine. Dr Richard Pebody, WHO Health Emergencies programme (WHE), WHO Regional Office for Europe, and Dr Liudmila Mosina, Vaccine-preventable diseases and immunization programme (VPI), WHO Regional Office for Europe, reviewed programmatic considerations on the use of ChAdOx1-S [recombinant] COVID-19 vaccine in the context of reported cases of thrombosis and thrombocytopenia.

Background

- The ChAdOx1-S [recombinant] vaccine against COVID-19: AZD1222 (SII Covishield and SK Bioscience) received WHO's Emergency Use Listing (EUL) following reviews of quality, safety and efficacy data from the clinical trials:
 - Data from clinical studies demonstrated a high safety profile (most adverse reactions were mild to moderate in severity) and high efficacy against symptomatic COVID-19 disease (VE* 63 % (95% CI 51.81 to 71.73)) and

hospitalization and severe disease (no vaccinated persons were hospitalized in the observed time frame)¹.

- High vaccine effectiveness against hospitalizations and death was confirmed after one dose of AZD1222 COVID-19 vaccine^{2,3}.
- WHO's Global Advisory Committee on Vaccine Safety (GACVS)⁴ reviewed all available safety events data and concluded the following:
 - A very rare new type of adverse event called Thrombosis with Thrombocytopenia Syndrome (TTS), involving unusual and severe blood clotting events associated with low platelet counts, has been reported after vaccination with COVID-19 vaccines Vaxzevria** and Covishield***.
 - Based on the latest available data, the risk of TTS following vaccination appears to be very low. Data from the United Kingdom suggest the risk is approximately four cases per million adults (1 case per 250 000) who receive the vaccine, while the rate is estimated to be approximately 1 per 100 000 in the European Union.
- Based on the GACVS assessment, the WHO Strategic Advisory Group of Experts on Immunization (SAGE)⁵ concluded the following:
 - A very rare syndrome of blood clotting combined with low platelet counts, described as TTS has been reported following vaccination with the ChAdOx1-S [recombinant] COVID-19 vaccine. A causal relationship between the vaccine and TTS is considered plausible although the biological mechanism for this syndrome is still being investigated.
 - In countries with ongoing SARS-CoV-2 transmission, the benefit of vaccination in protecting against COVID-19 far outweighs the risks. The benefit–risk ratio is

* VE = Vaccine Efficacy (determined in clinical trials)

¹ WHO Strategic Advisory Group of Experts on Immunization. Background document on the AZD1222 vaccine against COVID-19 developed by Oxford University and AstraZeneca. 5 March 2021 (<https://www.who.int/publications/i/item/background-document-on-the-azd1222-vaccine-against-covid-19-developed-by-oxford-university-and-astrazeneca>) (Accessed 22 April 2021)

² Vasileiou E et al. Covid-19: First doses of vaccines in Scotland led to a substantial fall in hospital admissions. BMJ 2021; 372 doi: <https://doi.org/10.1136/bmj.n523> (Published 22 February 2021)

³ Public Health England, Impact of COVID-19 vaccines on mortality in England. December 2020 to February 2021. (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/972592/COVID-19_vaccine_impact_on_mortality_240321.pdf) (Accessed 22 April 2021)

⁴ WHO Global Advisory Committee on Vaccine Safety. review of latest evidence of rare adverse blood coagulation events with AstraZeneca COVID-19 Vaccine (Vaxzevria and Covishield). 16 April 2021 ([https://www.who.int/news/item/16-04-2021-global-advisory-committee-on-vaccine-safety-\(gacvs\)-review-of-latest-evidence-of-rare-adverse-blood-coagulation-events-with-astrazeneca-covid-19-vaccine-\(vaxzevria-and-covishield\)](https://www.who.int/news/item/16-04-2021-global-advisory-committee-on-vaccine-safety-(gacvs)-review-of-latest-evidence-of-rare-adverse-blood-coagulation-events-with-astrazeneca-covid-19-vaccine-(vaxzevria-and-covishield))) (Accessed 22 April 2021)

** AZD1222 COVID-19 vaccine

*** SII Covishield COVID-19 vaccine

⁵ World Health Organization. Interim recommendations for use of the ChAdOx1-S [recombinant] vaccine against COVID-19 (AstraZeneca COVID-19 vaccine AZD1222, SII Covishield, SK Bioscience). Interim guidance. Updated 21 April 2021. (https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1) (Accessed 22 April 2021)

greatest in older age groups as the risk of severe COVID-19 disease outcomes including COVID-19 related thromboembolic events increases with age.

- Benefit–risk assessments may differ from country to country, and countries should consider their epidemiological situation, individual and population-level risks, availability of other vaccines, and alternate options for risk mitigation.
- It is currently unknown whether there is a risk of TTS following the second dose.

ETAGE notes

- The COVID-19 pandemic situation in the WHO European Region is serious. In April 2021, the Region surpassed 1 million confirmed COVID-19 deaths, with 85.5% of reported deaths occurring among persons aged >65 years; 1.6 million new cases are reported every week⁶. Hospitalization remains at high levels (13/100 000 population as of 11 April), with continued reports of intensive care usage having exceeded capacities in some countries of the Region.
- The ChAdOx1-S [recombinant] COVID-19 vaccine was shown in clinical trials to be highly efficacious in preventing severe diseases and deaths due to COVID-19 and demonstrated a good safety profile.
- More than 25 million doses of these vaccines have been administered in the WHO European Region and around 200 million doses have been administered around the world. High effectiveness of AZD1222 COVID-19 vaccine in preventing hospitalization and deaths among the general population has been demonstrated in the United Kingdom.
- A causal relationship between Vaxzevria** and Covishield*** vaccines and TTS is considered plausible although the biological mechanism for this syndrome is still being investigated.
- A specific case definition for TTS is being developed by the Brighton Collaboration⁷. This will assist countries in identifying and evaluating reported TTS, and aid in supporting causality assessments.
- Currently, the global production capacity of COVID-19 vaccines is insufficient, and limited vaccine supply is likely to continue.
- The ChAdOx1-S [recombinant] COVID-19 vaccines comprise a substantial proportion of available COVID-19 vaccines to be delivered through COVAX. Restrictions, especially in countries with limited COVID-19 vaccines supply, may cause delays or interrupt

⁶ WHO Regional Office for Europe. COVID-19 situation Dashboard.

(<https://worldhealthorg.sharepoint.com/sites/WHERegionalOfficeforEurope>) (Accessed 22 April 2021)

⁷ Brighton Collaboration. Interim Case Definition of Thrombosis with Thrombocytopenia Syndrome (TTS). 21 April 2021 (<https://brightoncollaboration.us/thrombosis-with-thrombocytopenia-syndrome-case-finding-definition/>) (Accessed 22 April 2021)

vaccination campaigns resulting in cases of severe disease and deaths that could be prevented with vaccination.

- Several countries in the WHO European Region do not report adverse events following immunization (AEFIs) to the WHO global database, which is needed to support evidence-informed recommendations.

Conclusions

- In light of the available evidence, ETAGE concurs with the SAGE conclusion that the overall benefits of the ChAdOx1-S [recombinant] COVID-19 vaccines in protecting against COVID-19 outweigh potential risks.
- In line with the updated interim SGE recommendations⁵ ETAGE acknowledges that the two dose schedule and the interval between the doses of ChAdOx1-S [recombinant] COVID-19 vaccines remain unchanged.
- ETAGE also concurs with the SAGE conclusion that it is currently unknown whether there is a risk of TTS following the second dose of ChAdOx1-S [recombinant] COVID-19 vaccines. As data from additional studies become available, recommendations on vaccination will be updated, as appropriate.

Recommendations

(Recommendations are interim and may be revised as new evidence become available)

- In light of the plausible link between the ChAdOx1-S [recombinant] COVID-19 vaccine and very rare TTS, ETAGE recommends that countries develop guidance for medical professionals on diagnosis and management of TTS to facilitate early diagnosis and treatment. Countries should also provide information to vaccine recipients on the potential risk of TTS as well as suggestive signs and symptoms of TTS so that they can seek urgent medical care in the event of suspected TTS.
- The national immunization programmes should enhance surveillance for AEFIs to ensure timely detection, reporting and causality assessment of all AEFIs, including TTS, following all COVID-19 vaccination. Countries should also ensure timely reporting of AEFIs to the WHO global database.
- ETAGE notes that some countries of the WHO European Region have made varied decisions on the use of ChAdOx1-S [recombinant] COVID-19 vaccine, including in some cases limiting the use to certain age groups. ETAGE urges that any decision-making on the use of ChAdOx1-S [recombinant] COVID-19 vaccines should be evidence based using the following information.
 - COVID-19 epidemiology with focus on and not limited to:
 - hospitalizations and deaths, including trends in different age groups.

Consider - quality of local data on disease epidemiology, public health measures.

- COVID-19 vaccination status:

- proportion of priority population groups vaccinated against COVID-19 (uptake by risk groups and number of doses).
 - Assessed balance between reported TTS following the ChAdOx1-S [recombinant] COVID-19 vaccines and the current and future risk of deaths from COVID-19 disease and, the potential of these vaccines to reduce hospitalizations and deaths due to COVID-19 disease in different age groups.
 - Consider – availability & quality of local data on TTS or use available estimates*
 - Availability of and timely access to alternative COVID-19 vaccines to ensure an uninterrupted COVID-19 vaccination campaign with special focus on number of unimmunized persons in priority target groups, current and projected COVID-19 vaccine supply and vaccination campaign schedule.
 - Programmatic feasibility to use alternative COVID-19 vaccines, including vaccine logistics and management systems, the need for additional training for health workers, perceptions and acceptance among health care providers and stakeholders.
- Considering the potential impact that the ChAdOx1-S [recombinant] COVID-19 vaccine safety signal can have on public trust, not only in this vaccine but also in COVID-19 vaccines in general, ETAGE recommends that countries:
 - activate and implement risk communication plans and, establish/activate the response (coordination) group related to AEFIs;
 - communicate to the public the steps established and taken in the regulatory process to assess and ensure vaccine safety;
 - communicate what is known about the risks and benefits of vaccination against COVID-19, including with the ChAdOx1-S [recombinant] COVID-19 vaccines;
 - communicate the country's policy with regard to immunization with the ChAdOx1-S [recombinant] COVID-19 vaccines, and the evidence upon which this policy is based;
 - communicate what is anticipated as next steps/what to expect;
 - monitor vaccine safety concerns and other barriers to acceptance in different segments of the population and develop evidence-based communication strategies tailored to respond to these concerns and barriers;
 - provide information to the vaccine recipients on expected effects following vaccination, as well as the signs and symptoms of TTS and when to seek medical care.

Session 2: COVID-19 vaccination coverage target for the WHO European Region in planning for and setting national vaccination strategies

Overview

Dr Roberta Pastore and Dr Richard Pebody reviewed evidence to support the discussion on vaccination strategies in the context of increased vaccine supply and considerations to set coverage targets for COVID-19 vaccination in the Region.

Summary of deployment of COVID-19 vaccine and vaccination status⁸

- As of April 2021, all (54) countries and territories⁹ of the WHO European Region have started COVID-19 vaccination campaigns.
 - Regional uptake for the first dose is around 16% of national population (ranges from <1% to 62%)¹⁰ and for complete vaccine series is 6.7% (ranges from <1% to 57%).²
 - 11 countries have achieved >20% vaccination uptake of national population with at least one dose (any vaccines).
- Vaccination strategies implemented by the countries adhere to ETAGE recommendations on population group prioritization:
 - 81% of health workers have received at least 1 vaccine dose (reports available from 28 countries).
 - 40% of ≥60-year-old population have received at least 1 vaccine dose (reports available from 36 countries).
 - Overall, one-dose vaccination uptake in various age groups (reports available from 31 countries) is as follows:
 - ≥80 years old: 72%
 - 15 countries have achieved >70% uptake and 22 countries have achieved >50% uptake
 - 60-79 years old: 40%
 - 50-59 years old: 17%
 - 25-59 years old: 11%
 - 18-24 years old: 10%
- Most countries have established vaccination coverage targets in their national COVID-19 vaccine deployment plan, which vary from 10% to 80%. Most of them do not outline a rationale.
- Capacity for vaccine deployment is deemed high:

⁸ Figures of vaccination uptake and vaccine utilization are all reported as of epidemiological week 15 of 2021

⁹ COVID-19 vaccine introduction and uptake are being monitored for all 53 countries of WHO/Europe and 1 territory, Kosovo (UNSCR 1244) that is a COVAX AMC.

¹⁰ Uptake data refer to data reported as of week 15/2021; [WHO/Europe Covid-19 vaccine programme monitor \(shinyapps.io\)](https://shinyapps.io)

- considering the last four weeks, on average, weekly utilization of received vaccine doses in the Region was 83% (ranging from 42% to 87%, among the 40 reporting countries), with lower utilization in countries that have only recently started to vaccinate.
- Programmatic challenges linked to use of vaccine as per national strategy with specific reference to prioritization and expected uptake have been reported by some countries. WHO/Europe has provided operational guidance to address identified programmatic challenges.
- Currently, the global production capacity of COVID-19 vaccines is insufficient; it is expected to increase substantially during 2021 and in 2022¹¹, with substantial increase in estimated volume of vaccines available for distribution through the COVAX Facility.
 - Estimated production capacity should increase 2-fold by December 2021.
 - COVAX is expected to distribute 100 million doses of vaccines by December 2021 to Advance Marketing Commitment and self-financing countries in the Region.

Summary of available evidence and modelling data

- **Mathematical modelling** of the vaccination scenarios aligned to the SAGE roadmap and ETAGE recommendations show the following:
 - With 50% vaccination uptake of the overall population by mid-September 2021, substantial infections, hospitalizations and deaths can be averted, with the majority of averted deaths and hospitalization being among the ≥60 years old population and the majority of averted infections being among the younger age groups.
 - By increasing uptake from 50% to 80%, an additional 11% of deaths could be averted by the end of 2022.
 - Beyond 20% vaccination uptake of the overall population, for population groups <60 years of age, targeting population groups in order of descending age (starting from the higher) seems slightly more effective than targeting simultaneously the entire population of 18-60 years old in most countries.
 - However, if rapid rollout of vaccination can only be achieved by making vaccines available across the population, it would be even more impactful than a slower age-wise approach.
- **Impact assessment** studies from countries in the WHO European Region reaching high vaccination uptake suggest that vaccination uptake of 50% and above among priority population groups correlates to decreased morbidity and mortality.
 - Note: This result is based on only a few countries and the vaccination impact would be difficult to infer widely for the Region as countries have varied COVID-19 epidemiology, and adherence to and stringency of public health and social measures.

¹¹ COVID-19 Vaccine Market Dashboard, Supply Division, UNICEF; [COVID-19 Vaccine Market Dashboard | UNICEF Supply Division](#)

- **Disease surveillance** data from 21 countries suggest a correlation between increasing vaccination uptake and decreasing mortality in specific age groups.
 - As vaccination uptake increases in the oldest age groups, age-specific mortality rate in this group tends to decrease faster than in other age groups, suggesting that targeting vaccination to the highest risk group is effective in reducing the disproportionate severe disease burden.
 - In some countries, despite relatively high uptake among ≥80-year-olds and 60-79-year-olds (about 70% with one dose), no significant decline in mortality rates has been observed, suggesting that other factors (i.e. increasing transmission levels, relaxation of public health and social measures, saturated case management capacity) could have an impact.
 - High uptake among older age groups is not generally associated with reduced rates of infection among younger age groups, which bare the highest risk of infection but significantly lower risk of death. Some countries are experiencing reductions in infection in all age groups, likely linked to strengthening of public health and social measures.
- **Evidence on effectiveness of COVID-19** vaccines against transmission is still limited, although some degree of impact of vaccination on transmission is likely to be expected, in particular as evidence accrues on effectiveness against infection, reduction of viral load and indirect protective effect from vaccination.

ETAGE notes

- Vaccination uptake in priority groups is rapidly increasing in the WHO European Region although large variability exists between countries. A fourth of countries have already achieved or exceeded 20% uptake with at least 1 vaccine dose, although the current vaccination uptake with complete dose series is much lower (only 3 countries achieving ≥20%).
 - While uptake with at least 1 dose is a suitable measure to monitor progress towards access and initial deployment of the vaccine, uptake with a complete vaccine series should be monitored as a key indicator for effective implementation of COVID-19 vaccination campaigns.
- Vaccination strategies and prioritization of population groups are currently focused around limited vaccine availability sufficient to cover 20% of population.
- In order for the national governments to plan for and allocate adequate financial and other resources for COVID-19 vaccination and other health priorities in 2022 and beyond, countries should define a target (proportion of their population) to be vaccinated.

Conclusions

- Based on observational studies and modelling, rapidly reaching high vaccination uptake among older age groups (≥60 years of age) optimizes the impact of vaccination on reducing severe disease, including deaths. Subsequent vaccination of younger age groups

leads to incremental impact on overall reduction of morbidity and mortality. Preliminary evidence supports impact of vaccination on reducing transmission, and reduction is likely to occur especially among younger populations.

- Despite the available evidence, it is not yet feasible to establish a coverage target linked to disease control outcomes, because:
 - correlation between vaccination uptake and severe morbidity and mortality will be affected by local epidemiology, variants of concern and changes in public health and social measures;
 - limited evidence is available on vaccine effectiveness against transmission and emerging variants of concern;
 - there has been insufficient time to observe any waning of immunity following vaccination.
- Most countries in the Region have capacity to utilize vaccine doses as per their national strategies and have set national targets for immunization not necessarily linked to any specific disease control outcome.

Recommendations

Note: Vaccination uptake targets here should be read as “complete vaccine series”

- In the context of limited vaccine supply (stage I and II of SAGE roadmap)¹², countries:
 - should continue to follow ETAGE recommendations on prioritization of target groups¹³ to optimize the impact of COVID-19 vaccination in protecting health workers and averting severe disease and deaths;
 - should rapidly identify and correct any programmatic challenges in achieving high uptake (seeking to achieve at least 80% and as high as possible) among health workers and priority population groups among which most severe disease and deaths occur;
 - may consider vaccinating other population groups simultaneously, if need be, to avoid wastage of available vaccine doses and to accelerate overall population uptake.
- In the context of increased vaccine supply (for >20% of population), countries should:
 - vaccinate population groups <60 years of age in groups of descending order with highest age group first and then other lower-risk population groups to incrementally increase impact of vaccination in averting severe disease and deaths; or, if not programmatically feasible
 - consider prioritizing vaccination of population groups at elevated risk of acquiring and transmitting infection, such as social/employment groups not

¹² [WHO SAGE Roadmap For Prioritizing Uses Of COVID-19 Vaccines In The Context Of Limited Supply](#)

¹³ Priority groups for COVID-19 vaccination include individuals \geq 60 years of age, health workers, and individuals < 60 years of age with underlying health conditions

covered in earlier stages of limited vaccine supply to accelerate the overall vaccination uptake.

- While evidence is premature to establish a target for disease control¹⁴, countries should seek to achieve at least 80% coverage of their adult population (18 years and above) as soon as feasible, in light of:
 - an expected increase in availability of COVID-19 vaccines through 2021 and in 2022;
 - recent evidence and modelling indicating that substantial infections (30-40%), hospitalizations and deaths (60-70%) can be averted starting from 50% vaccination uptake and estimating that by increasing uptake to 80% of the population, an additional 11% of deaths¹⁵ could be averted;
 - the rapid progress that has been already demonstrated in vaccination uptake in many countries in the Region and considerable adaptation of the immunization programme to improve uptake.
- Countries should assess barriers and drivers of vaccination in targeted population groups and implement evidence-based tailored strategies to enhance acceptance and uptake¹⁶.

¹⁴ Refers to population target (X%) linked to a well-defined level of reduction in morbidity, mortality or infection

¹⁵ Based on modelling data and assuming that countries have followed the ETAGE recommendations to prioritize their at-risk population (stage I and II) and are achieving high vaccination uptake amongst these population groups

¹⁶ [WHO/Europe | Vaccines and immunization - TIP Tailoring Immunization Programmes \(2019\)](#)

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