Interim recommendations on COVID-19 vaccination in autumn 2022 for the WHO European Region

Conclusions and recommendations of the European Technical Advisory Group of Experts on Immunization
Ad hoc virtual meeting, 5 July 2022
Abstract

An ad hoc meeting of the European Technical Advisory Group of Experts on Immunization (ETAGE) took place virtually on 5 July 2022 to review COVID-19 vaccination status, current epidemiology and modelling scenarios of SARS-Cov-2 in the WHO European Region and available evidence on COVID-19 vaccine effectiveness against Omicron variant, and co-administration with influenza vaccines in order to provide recommendations to Member States in the European Region on COVID-19 immunization strategies for autumn 2022.
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Abbreviations

ECDC European Centre for Disease Prevention and Control
IC Imperial College London
PHSM public health and social measures
Q1-Q4 quarters 1 to 4 of the calendar year
RSV respiratory syncytial virus
SAGE Strategy Advisory Group of Experts on Immunization
VE vaccine effectiveness
VOC variants of concern
Background

Epidemiology of SARS-CoV-2 in the WHO European Region

- Since the first detections of SARS-CoV-2 in January 2020, the WHO European Region has experienced several waves of SARS-CoV-2 activity. Later waves have been associated with the emergence and spread of new variants of concern (VOCs) – Alpha, Delta and most recently the highly transmissible Omicron VOC.
- The licensure and roll-out of highly effective COVID-19 vaccines have protected many millions of people in the Region, especially those in vulnerable groups, from severe outcomes of SARS-CoV-2 infection. Indeed, a study conducted by the WHO Regional Office for Europe (Regional Office) and the European Centre for Disease Prevention and Control (ECDC) has shown that the rapid introduction, in December 2020, of COVID-19 vaccination for persons aged 60 years and above averted 469,186 deaths in 33 countries in this age group, up to November 2021 (preventing 51% of 911,302 expected deaths in this age group).\(^1\)
- From quarters 1 to 3 of calendar year 2021 (Q1-Q3 2021), countries that achieved high levels of vaccine uptake in priority groups saw reductions in rates of COVID-19-related hospitalization and death. Most countries subsequently relaxed public health and social measures (PHSM). These factors, together with the emergence of new VOCs, led to profound changes in the epidemiology of SARS-CoV-2.\(^2\)
- From week 49/2021, countries have seen the emergence and spread of the more transmissible Omicron variant, which was initially the BA.1 sublineage in many countries, followed by BA.2 and now BA.5.
- The latest Omicron wave was associated with an increase in COVID-19 hospitalizations and deaths throughout the Region. Although the overall hospitalization rates were similar in some countries to the earlier Delta wave, a significant proportion of the cases were hospitalized for other reasons. Still, the large number of symptomatic cases led to disruptions in daily life and high levels of absenteeism from work, including among staff in health care settings, in many countries.
- Middle-income countries have observed higher hospitalization and mortality rates compared to high-income countries for the same period.
- In recent months, age-specific mortality rates continue to be highest with increasing age. The highest rates are in the >80 age group (week 19/2022).

Epidemiology of influenza, week 1/2020 to date in the WHO European Region

- The epidemiology of influenza and other acute respiratory viruses has been impacted by the COVID-19 pandemic. From March 2020 through November 2021, there was a significant reduction in the incidence of reported influenza cases (and many other acute respiratory infections) compared to respective months of previous years. This is thought to have been primarily a result of the almost universal implementation of PHSM and travel restrictions by

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Member States to suppress SARS-CoV-2 transmission as part of the pandemic response before and during the COVID-19 vaccine programme roll-out.

- From week 48/2021, with the relaxation of PSHM in most countries in the WHO European Region, there has been increased and late-season circulation of influenza A(H3N2), which is an atypical picture compared to pre-pandemic seasons.
- In the winter season of 2021, differences by country income level were observed with the highest activity occurring in high-income countries (in the central and western part of the Region).
- The risk of influenza-related severe disease outcomes has been highest in the elderly, children <5 years of age, and groups with underlying clinical risk factors.
- In the southern hemisphere, Australia is now experiencing an unusually early and intense influenza season, dominated by circulation of influenza A(H3N2).

What to anticipate in autumn 2022

- In the upcoming months countries may experience one or more upsurges in SARS-CoV-2 infections, hospitalizations and deaths with or without an increase in influenza cases, and other respiratory viruses, such as respiratory syncytial virus (RSV).
- This will depend upon several key factors:
  - Emergence of new SARS-CoV-2 VOCs or sublineages: the potential emergence of variants with further key phenotypic changes – such as increased transmissibility, infection severity and/or greater immune escape - could result in further waves of infections with related increases of hospitalizations and deaths. The more transmissible Omicron sublineages BA.4/5 were first detected in the Republic of South Africa. In the European Region, BA.5 first became dominant in Portugal followed by a surge in COVID-19 cases and hospitalizations in this country. This was followed by an increase in BA.5 prevalence and rates of infection across many countries in Europe. This emphasizes the key importance of maintaining strong genomic surveillance to rapidly detect emerging VOCs, and strong surveillance systems to detect increasing incidence and severity of cases.
  - Population protection against SARS-CoV-2 infection and severe disease: immunity against SARS-CoV-2 by immunization or previous infection is high in most European populations – which has resulted in a reduced risk of severe outcomes. However, waning immunity (both vaccine-induced and naturally acquired) over time against infection and symptomatic disease is recognized. There may also be waning protection against severe disease but data on vaccine effectiveness of booster vaccination beyond 6 months are very limited. Continuing to monitor SARS-CoV-2 population immunity and vaccine effectiveness against severe disease over time will be key to detecting early signals of significant reductions in population protection.
  - Population mixing patterns: The summer period in temperate countries is typically characterized by decreased indoor population mixing and the school holiday period. In

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In autumn, schools and workplaces will most likely return to normal occupancy with increasing indoor mixing. This will happen in a setting with almost all countries having lifted PHSM. This combination will increase the transmission of respiratory viruses such as SARS-CoV-2 and influenza in populations across the Region.

- Increased international travel: The relaxation of PHSM has been accompanied by the re-establishment of international travel. This will provide the ongoing opportunity for importation and more rapid spread of new SARS-CoV-2 variants, but also influenza types/subtypes, particularly from sub-tropical countries where influenza circulation continues year-round.

- Uptake of both influenza and COVID-19 vaccines: Most countries continue to recommend annual influenza vaccination for older adults, those with underlying clinical risk factors, and health care workers, i.e., the groups at risk of influenza infection and/or of severe disease. It will be important to ensure that these groups are still protected in autumn 2022. All countries offer a primary COVID-19 vaccination series and a booster dose to their target populations. However, in many countries, a substantial proportion of eligible people remain not fully vaccinated with the primary series of COVID-19 vaccines.

In summary, the combination of waning SARS-CoV-2 immunity against infection and to some extent severe disease, changing mixing patterns and the potential emergence of a new SARS-CoV-2 variant may lead to one or more upsurges in SARS-CoV-2 activity in the upcoming months, which may be co-incident with influenza (and indeed other acute respiratory viruses such as RSV) leading to significantly increased pressure on health care systems.

Modelling scenarios

- Several teams in the WHO European Region are undertaking mathematical modelling work to explore a range of scenarios of what the projected incidence of SARS-CoV-2 infection and severe disease may be in the Region and what might be the impact of further immunization of key target groups. However, the modelling work has become increasingly challenging given a more complex current immunological landscape as compared to last year and unknowns about when and which (variant-specific) vaccines will be available by autumn/winter 2022 and their performance, especially with respect to prevention of mild disease and transmission.

  - Imperial College London (IC) has used an individual-based mathematical model of SARS-CoV-2 transmission and vaccination that mirrors a previously published compartmental model. The model has a flexible dose and age-based prioritization strategy with boosters. Individual-level antibody titre and decay are used to capture vaccine- and infection-induced immunity – thereby capturing “hybrid immunity”. The model captures changes in variants through their effect on past immunity (vaccine-induced or acquired through infection), transmissibility and severity. The models assume no seasonality and no further non-pharmaceutical interventions. The model runs were produced for two exemplars – Spain (high-income country) and Bulgaria (upper-middle-income country). IC considered five different longer-term vaccination strategies – age-targeted and 6-monthly versus yearly, with 90% uptake, timed September (yearly) and March (6-monthly). The model found that under Omicron there was a gradual dampening of waves of infection as the infection moved towards endemic level for all five vaccination strategies. The model projected a greater impact of all-age
vaccination on lowering waves of infection and flattening peaks in hospitalizations. The biggest incremental impact was achieved through continued boosting every six months or yearly compared to no booster. All-age vaccination had a wider impact on transmission and thereby a greater impact overall. The efficiency measured by additional events averted per 100 additional vaccine doses (closely related to cost-effectiveness), was higher when targeting the 75+ age group than the 60+ or younger ages, with yearly boosters more efficient than 6-monthly.

Plausible assumptions for the emergence of a new variant, indicate the potential for a severe autumn/winter epidemic. Modelled scenarios include the emergence of a new variant that replaces Omicron in October 2022 with increased severity, additional immune escape, or both. All scenarios indicate the potential for a large future wave at a level that is as bad or worse than the 2020/2021 epidemic waves. Additional immune escape is of concern as this is assumed to reduce direct protection of the highest risk groups. Combined immune escape resulting in higher transmission and return to Delta-like severity levels could be considered “worst-case scenario” for planning purposes.

- Using a model fitted to more than two years of epidemiological data from England, the London School of Hygiene and Tropical Medicine projected potential dynamics of SARS-CoV-2 infections, hospital admissions and deaths to December 2022. They considered key uncertainties including future behavioural change and waning immunity, and assessed the potential effectiveness of booster vaccinations in mitigating SARS-CoV-2 disease burden between October 2021 and December 2022. If no new variants emerge, they anticipate that SARS-CoV-2 transmission is expected to decline, with low levels remaining in the coming months. The extent to which projected SARS-CoV-2 transmission resurges later in 2022 depends largely on assumptions around waning immunity and to some extent, behaviour and seasonality.

- ECDC published a report on the potential role of further additional doses. Mathematical modelling suggests that increasing the proportion of the population that has been provided with immunity through a primary course and first booster has a substantial potential to reduce the COVID-19 death burden by the end of October 2022. This is particularly relevant for countries where gaps in coverage are still large, and efforts to address these gaps remain a public health priority. With regard to the second booster, modelling shows that its roll-out in some vulnerable groups could avert a substantial proportion of COVID-19 deaths between April and mid-autumn 2022. Further indications are set out below. To reduce future COVID-19 burden through a second booster, the effect per dose is highest when targeting vulnerable populations, such as older age groups. The public health benefit of administering a second booster dose is clearest in those aged 80 years and above. Immediate administration of a second booster dose in this population would be optimal in situations of continued high or

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increasing viral circulation. Alternatively, in situations of low viral circulation, administration of a second booster dose should be considered prior to autumn 2022. Mathematical modelling suggests that a second booster roll-out including those aged 60–79 years who are immunocompetent in the European Union/European Economic Area is likely to be beneficial, although the best timing for the roll-out depends on the highly uncertain future of COVID-19 incidence.

COVID-19 vaccine effectiveness against Omicron variant

Primary vaccination series

- Data from available studies showed that vaccine effectiveness (VE) of the complete primary series of COVID-19 vaccination against infection, symptomatic disease and severe disease caused by the Omicron variant is reduced compared to VE against these outcomes caused by other VOCs, and decreases over time. However, little decline in VE against severe disease is observed in contrast to the other outcomes for more than three months after vaccination:
  - 13 of 19 available mRNA VE estimates were ≥70%, while 20 VE estimates were ≥50%.
  - 2 Sinovac-CoronaVac VE estimates were ≥50%.
- In moderately and severely immunocompromised people, current COVID-19 vaccines induce weaker immune responses and less clinical protection against COVID-19 and VE wanes more rapidly over time. Most countries recommend an extended 3-dose primary vaccination series in this group.

First booster dose

- Booster vaccination increases protection against all outcomes and substantially improves VE against severe disease, remaining high among non-immunocompromised individuals 4-6 months after the dose:
  - Most VE estimates for booster vaccination were ≥70% between 14 days and 3 months after receipt of the booster dose (32 out of 33 estimates for mRNA vaccines and 1 of 2 estimates for Janssen-Ad26.COV2.S vaccine).
  - Most VE estimates for mRNA vaccine boosters remained ≥70% between 3 and 6 months post-vaccination (17 of 20 estimates).
- VE of a booster dose against infection and symptomatic disease declines more rapidly over time than against severe disease:
  - Only 2 of 12 available estimates indicate VE of ≥50% at 3 to 6 months following receipt of an mRNA booster dose.
  - Estimates of VE for a booster dose of AstraZeneca-Vaxzevria and Sinovac-CoronaVac 3 to 6 months post-vaccination were <50%.

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• The data on VE of booster vaccination beyond 6 months are not available and further duration of protection is not known.

Additional booster dose

• Data on benefits of an additional (second) booster dose of mRNA vaccine (e.g., fourth vaccine dose of a two-dose primary vaccination series) in health workers and people aged 60 years and above are available from 6 studies conducted in Israel and one study from Canada:
  
  o A fourth mRNA vaccine dose induced IgG antibodies against SARS-CoV-2 receptor-binding domain and increased neutralizing antibody titers in health care workers in Israel. This corresponded to antibody titers slightly higher than those achieved after the third dose.
  
  o An additional mRNA vaccine booster dose administered to health care workers in Israel resulted in reduced infection rates compared to that observed after only a third dose of mRNA: RR was 0.61 (0.54 to 0.71) in the matched analysis; the adjusted HR in the Cox-regression model was 0.56 (0.50 to 0.63).
  
  o Two retrospective cohort studies showed that the relative effectiveness of a fourth dose against severe disease (compared to only 3 doses) in people aged 60 years and older was between 66% and 78% from 7 to 42 days after the fourth dose.
  
  o The study from Israel using test negative design reported relative VE against severe disease of 87% in people aged 60 years and above 49–69 days post fourth dose.
  
  o A target trial in Israel found relative VE of 62% against severe COVID-19, and 74% against COVID-19 related death 7 to 30 days after receipt of the fourth dose in people aged 60 years and above. The difference in risk of severe COVID-19 from 7 to 30 days post fourth dose was 68.8 cases per 100 000 persons.
  
  o The study in Canada using test negative design showed absolute VE against severe disease of the fourth dose of 92% more than 7 days after receipt compared to 82% absolute VE more than 84 days after receipt of the third dose in long-term care facilities residents aged 60 years and above.

• Data on the benefits of additional booster doses in younger people are limited.

Booster dose safety:

• The risk of myocarditis/pericarditis was identified after the first booster dose of COVID-19 vaccine in individuals aged 12 years and older. Among those aged 12–39 years, observed cases

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9 RR=Risk Ratio

10 HR=Hazard ratio

11 Relative VE provides evidence on the value of a fourth dose compared to 3 dose recipients. The relative vaccine effectiveness depends upon the initial VE provided by 3 doses and how much subsequent waning has occurred.

were mostly myocarditis and myopericarditis with onset <7 days after the first booster. However, the risk of myocarditis and myopericarditis was less than that seen after the second dose in the primary series. Among those aged 40 years and older, cases were predominantly pericarditis, and the small, elevated risk was more spread out over the 3 weeks after the first booster.

- Limited data on safety of a fourth dose of mRNA COVID-19 vaccine showed that most adverse events are similar to those following previous doses and are short-lived.\textsuperscript{13,14}
- The data on the risk of myocarditis and pericarditis after second booster doses are not yet available.

**WHO statement on development of new COVID-19 vaccine products\textsuperscript{15,16}**

- Current COVID-19 vaccines continue to exhibit strong protection against severe disease and death across all virus variants seen to date.
- The inclusion of Omicron, as the most antigenically distinct SARS-CoV-2 Variant of Concern, in an updated vaccine composition may be beneficial if administered as a booster dose.
- Given the uncertainties of further evolution, it may be prudent to pursue an additional objective of COVID-19 vaccination of achieving broader immunity against circulating and emerging variants while retaining protection against severe disease and death.

**Co-administration of COVID-19 vaccines**

- For adults, WHO considers co-administration of an inactivated seasonal influenza vaccine and any dose of mRNA COVID-19 vaccine acceptable. Other COVID-19 vaccines with WHO Emergency Use Listing, may be given concomitantly, or any time before or after, other adult vaccines including live-attenuated, inactivated, adjuvanted, or non-adjuvanted vaccines\textsuperscript{17}.

**Overview of COVID-19 vaccination in the WHO European Region**

- Currently, 37 countries of the WHO European Region offer primary COVID-19 vaccination series for people aged 5 years and older. The remaining 16 countries vaccinate people aged 12 years and older, and six of these countries provide the primary vaccination series to children aged 5-11 years with health conditions that put them at higher risk of severe COVID-19. Most countries provide a booster dose to the adult population. Moderately and severely immunocompromised

\textsuperscript{13} Munro APS et al. Safety, immunogenicity, and reactogenicity of BNT162b2 and mRNA-1273 COVID-19 vaccines given as fourth-dose boosters following two doses of ChAdOx1 nCoV-19 or BNT162b2 and a third dose of BNT162b2 (COV-BOOST): a multicentre, blinded, phase 2, randomised trial. The Lancet Infectious Diseases; 2022. Doi: 10.1016/S1473-3099(22)00271-7 (accessed 13 June 2022).


individuals in most countries receive an extended 3-dose primary series and a booster dose. By spring 2022, 20 countries made a decision to introduce the second booster dose to individuals at the highest risk of severe COVID-19 outcomes. Many countries have integrated COVID-19 vaccination into primary health care through national immunization programmes to ensure effectiveness, efficiency and sustainability.

- Significant progress has been achieved in COVID-19 vaccination uptake. By 13 June 2022, more than 1 500 000 doses of COVID-19 vaccines were administered, 63% of the Region’s total population had received the complete primary series of vaccination and 28% of the total population had received a booster dose. However, in 24 countries, a substantial proportion of eligible people, including persons at high risk of severe COVID-19 outcomes remain not fully vaccinated with the primary series, ranging from approximately 60% to 20%18.

- The post-introduction evaluations and behavioural insights studies conducted in middle-income countries in the Region with WHO support reveal that the main barriers in reaching high vaccine uptake in priority populations in these countries vary between context, but the lack of effective vaccine delivery strategies to reach older adults, as well as concerns about vaccine safety among health care workers and the general public are identified as important barriers across settings. The widespread progressively lower perception of risk of severe COVID-19 and decreasing confidence in vaccines due to low protection against mild disease, have contributed to lower demand for COVID-19 vaccines from populations in high- and middle-income countries.

WHO’s Strategic Advisory Group of Experts recommendations on integration of COVID-19 vaccination with primary health care:

- In April 2022, the Strategy Advisory Group of Experts on Immunization (SAGE) recommended that for programme recovery, sustainability, efficiency, and optimal vaccine delivery, the ultimate integration of COVID-19 vaccination with existing primary health care platforms through essential immunization programmes should be facilitated when and where feasible.19

Conclusions

- 37 countries of the WHO European Region offer the primary COVID-19 vaccination series for people aged 5 years and older. The remaining 16 countries vaccinate people aged 12 years and older, and 6 of these countries provide the primary vaccination series to children aged 5–11 years with health conditions that put them at higher risk of severe COVID-19. Most countries provide a booster dose to the adult population.

- By 13 June 2022, 63% of the Region’s total population had received the complete primary series and 28% of the total population had received a booster dose. However, in some countries, a substantial proportion of people who are at high risk of severe disease have not yet received their primary series and first booster dose.

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COVID-19 seasonality is not defined yet and in view of many uncertainties, it is difficult to predict the timing of future waves as well as the likelihood and timing of the potential emergence of new VOCs and their characteristics, including virulence. However, over the last two years, a substantial increase in COVID-19 transmission, hospitalizations and deaths has been observed during the winter season. Therefore, we expect that an increase in SARS-CoV-2 activity may occur this autumn due to a combination of waning SARS-CoV-2 immunity, seasonality and changes in mixing patterns. This may be co-incident with an increase in influenza and RSV circulation and pose a significant threat to individuals and burden to health care systems.

The primary series of vaccination and a booster dose of current COVID-19 vaccines continue to provide high protection against severe disease from Omicron, but VE against infection and symptomatic disease is lower and declines more rapidly over time. COVID-19 vaccine effectiveness in moderately and severely immunocompromised people is lower and wanes more rapidly than in immunocompetent individuals.

Data on VE of booster vaccination against severe disease beyond 6 months are not yet available and further duration of protection is not known.

Evolving evidence suggests that additional benefits in protecting the most vulnerable populations may be achieved through receipt of a second booster dose. Studies conducted in Canada and Israel have demonstrated increased immune responses and relative vaccine effectiveness following the second booster dose. Available evidence shows that the reactogenicity of a second booster dose is similar to the reactogenicity of previous doses and the symptoms are short-lived.

Interim recommendations

- Current COVID-19 vaccines continue to exhibit strong protection against severe disease and death across all virus variants seen to date. Therefore, reaching high coverage with the primary vaccination series and a first booster dose among all eligible people remains a priority.
- ETAGE provided updated recommendations to countries on prioritization of COVID-19 vaccination at its previous meeting, which was held on 14 March 2022.
- All countries should undertake additional efforts to ensure that all eligible people are up-to-date with their COVID-19 vaccinations in line with national COVID-19 vaccination policies. Available evidence shows that individuals who have had SARS-CoV-2 infection still benefit from vaccination because a combination of naturally acquired and vaccine-induced immunity is likely to offer greater protection against re-infection.
- Protection of the most vulnerable people in society will continue to be of primary importance in the upcoming autumn season. To provide additional protection, minimize the risk of severe disease, hospitalization and death from COVID-19 and maximize the resilience of health care provision, countries should:
  - administer a second booster dose to moderately and severely immunocompromised individuals aged 5 years and above and their close contacts (for immunocompromised persons a second booster dose is the fifth dose of COVID-19 vaccine that should be

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administered after the extended 3-dose primary vaccination series and the first booster dose);
  o consider providing a second booster dose as a precautionary measure in a range of possible scenarios, including potential waning long-term immunity against severe disease, to the following individuals:
    ▪ residents and staff of long-term care facilities;
    ▪ older adults (age specific cut-off should be defined by countries based on local COVID-19 epidemiology);
    ▪ health care workers;
    ▪ pregnant women;
    ▪ other patient groups at high risk of severe COVID-19 outcomes defined by countries based on local COVID-19 epidemiology

• The optimal interval between booster doses is yet to be determined. A minimum interval of 3–6 months since the first booster dose could be considered. Heterologous vaccine schedules can be used for the second booster dose.

• ETAGE recommends that countries consider co-administration of COVID-19 vaccines and seasonal influenza vaccines, whenever feasible. This will help to reach higher uptake of both vaccines, increase efficiency and protect stretched health care systems, given that the known risk of serious illness for older adults and other priority groups infected either with influenza virus or SARS-CoV-2 is substantial.

• ETAGE concurs with SAGE recommendations¹³ that countries should consider a broader integration of COVID-19 vaccination into primary health care through national immunization programmes, including common planning, budgeting, joint coordination and integrated vaccine management, service delivery, and programme monitoring.

ETAGE will continue to monitor and review the evolving evidence on COVID-19 epidemiology, forthcoming data on VE over time, and vaccine product developments and will update these interim recommendations, as necessary.
The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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