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ECDC and EMA issue advice on fourth doses of mRNA COVID-19 vaccines

ECDC and EMA's COVID-19 task force (ETF) have concluded that it is too early to consider using a fourth dose of mRNA COVID-19 vaccines (Pfizer's [Comirnaty](#) and Moderna's [Spikevax](#)) in the general population.

However both agencies agreed that a fourth dose (or second booster) can be given to adults 80 years of age and above after reviewing data on the higher risk of severe COVID-19 in this age group and the protection provided by a fourth dose.

ECDC and EMA also noted that there is currently no clear evidence in the EU that vaccine protection against severe disease is waning substantially in adults with normal immune systems aged 60 to 79 years and thus no clear evidence to support the immediate use of a fourth dose. Authorities will continue to monitor data to determine if there is an increasing risk of severe illness among those who are vaccinated. If the current epidemiological situation changes and new signals emerge, it may become necessary to consider a fourth dose in this age group. In the meantime, national authorities will also consider local data in deciding whether to use a fourth dose in those people at higher risk.

For adults below 60 years of age with normal immune systems, there is currently no conclusive evidence that vaccine protection against severe disease is waning or that there is an added value of a fourth dose.

As re-vaccination campaigns could start in the autumn, authorities will consider the best timing for additional doses, possibly taking advantage of updated vaccines.

So far, no safety concerns have emerged from the studies on additional boosters.

Vaccination against COVID-19 remains the most effective way to prevent severe illness during the current pandemic, including severe illness caused by the Omicron variant.

ECDC and EMA urge EU citizens to complete their schedules for both initial and booster vaccinations in line with national recommendations. As of the end of March 2022, 83% of adults had received full initial vaccinations and only 64% had received a booster dose.

What the evidence says about second booster doses

Evidence on the effects of a fourth dose comes largely from Israel, where data indicate that a second booster given at least 4 months after first booster restores antibody levels without raising any new safety concerns. Data also suggest that a second booster provides additional protection against severe disease, although the duration of the benefits is not yet known and the evidence is still limited.

Details of the evidence assessed by both agencies is available in the [joint ECDC-EMA statement on second boosters](#).

Other factors to be considered in vaccination campaigns

National authorities in the EU make final decisions on the roll-out of vaccines, including booster doses, taking into account factors such as the spread of infection, the effects of COVID-19 in different populations and the emergence of new variants.

ECDC and EMA will continue to review available evidence on the effectiveness of COVID-19 vaccines and update their recommendations accordingly. EMA will also consider all emerging data on the safety and effectiveness of booster doses with a view to updating the product information for COVID-19 vaccines where applicable.