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COVID vaccine booster doses for omicron variants

On Aug 26, 2022, Pfizer and BioNTech announced that they had applied to the European Medicines Agency to have their omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine authorised as a booster dose. The companies submitted an equivalent application to the US Food and Drug Administration (FDA) on Aug 22. The vaccine combines mRNA coding for the spike protein of the Wuhan strain of SARS-CoV-2, which is the basis of the original Pfizer-BioNTech vaccine, with mRNA coding for the spike protein of the omicron BA.4 and BA.5 subvariants. The US Government has agreed to buy 105 million doses of the updated vaccine, along with 66 million doses of a similarly formulated vaccine from Moderna, for use in the booster campaigns of the autumn and winter. Moderna applied for FDA authorisation of its bivalent vaccine on Aug 23.

Vaccines optimised for BA.4 and BA.5 are unlikely to be available in the UK for the next few months. On Aug 15, 2022, however, a bivalent vaccine from Moderna based on omicron BA.1 was approved for use as a booster dose by the Medicines and Healthcare products Regulatory Agency. Preliminary data indicated that the vaccine generates a strong immune response against the BA.4 and BA.5 subvariants, which are now dominant in the USA and Europe. From Aug 14 to 20, 2022, BA.5 accounted for 89% of all sequenced infections with SARS-CoV-2 in the USA.

Since February, 2022, omicron has been responsible for more than 98% of viral sequences shared with the GISAID initiative, which monitors the distribution of the SARS-CoV-2 variants. “In the earlier stages of the pandemic, we saw a series of very different strains of the virus emerge to dominate”, explained Martin Hibberd, professor of emerging infectious diseases at London School of Hygiene & Tropical Medicine (London, UK). “We are now in a situation where all the outbreaks are being driven by omicron and its subvariants. It makes sense to adjust the vaccine; we might even be able to increase its duration of efficacy.”

The UK Joint Committee on Vaccination and Immunisation (JCVI) has stressed that individuals who are eligible for the booster dose should take whatever is offered, rather than wait for a bivalent vaccine. It noted that, although the Pfizer-BioNTech and Moderna omicron BA.1-adapted vaccines are associated with an increase in neutralising antibodies against omicron, the extent to which this translates into clinical advantage is unclear. The JCVI added that the additional benefit of the bivalent vaccine for patients older than 65 years might be limited to a small decrease in the number of COVID-19-related hospitalisations.

The advent of the bivalent vaccines could mark the beginning of a shift towards an influenza-like situation with the COVID-19 vaccines, in which their composition is regularly altered to match the circulating virus strains. Daniel Salmon is director of Johns Hopkins Institute for Vaccine Safety (Baltimore, MD, USA). “For the influenza vaccines, you have to make an educated guess for the northern hemisphere in February on what the virus is going to look like in the fall, based on what has happened during the previous flu season”, he told The Lancet Respiratory Medicine. The same process occurs in September for the southern hemisphere. “If it is the quadrivalent vaccine, you get four guesses”, said Salmon. “If you get a match, you get a pretty good vaccine. But we know a lot more about predicting flu than we do COVID-19.”

Moreover, COVID-19 does not follow the same kind of seasonal pattern as influenza—the spring and summer months still see plenty of transmission. The efficacy of the available COVID-19 vaccines fades within a few months. “If we are giving the vaccine once a year, that would be much easier; we could simply couple it with the flu vaccine”, said Salmon. “But if we have to give repeated doses over the course of the year, then it becomes a trickier matter.”

The USA recommends annual influenza vaccination for everyone aged 6 months and older. Coverage hovers at around 50% and it is mostly the same sections of the population who present for vaccination every year. Salmon reckons a similar situation is likely to prevail with the COVID-19 boosters.

The current set of COVID-19 vaccines are highly effective in preventing severe disease and mortality, though it is unclear how long this protection lasts. They do not do much to stop transmission or mild infection, especially with omicron, which in turn drives the emergence of new variants. According to WHO, there are 170 vaccines for COVID-19 in clinical development, two of which are intranasal. “Moving the vaccines closer to the circulating strains might offer slightly improved protection against severe disease, but if we can find a way to boost the immunity around the respiratory system, perhaps with an intranasal vaccine, we could in theory reduce the nasal viral load and hence reduce transmission”, said Hibberd. “And if we had a vaccine that generated an immune response that lasted a lifetime, that really would change everything.”

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