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Covid-19: UK will roll out Moderna's omicron BA.1 vaccine as part of autumn booster programme

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Moderna's bivalent covid-19 vaccine—which targets both the original version of SARS-CoV-2 and the omicron BA.1 variant—will be rolled out alongside the original Moderna, Pfizer, and Novavax covid-19 vaccines, the Joint Committee on Vaccination and Immunisation (JCVI) has said.

NHS England has yet to confirm how and when eligible people will be able to access the booster vaccine, but the UK Health Security Agency has said that it will be offered to those at higher risk of severe illness.

Vaccines being rolled out in the autumn booster programme

The JCVI has advised that adults aged 18 and over should be offered a single dose of one of the following:

- Moderna mRNA bivalent omicron BA.1/original "wild-type" vaccine
- Moderna mRNA original "wild-type" vaccine
- Pfizer-BioNTech mRNA (Comirnaty) original "wild-type" vaccine
- Novavax Matrix-M adjuvanted wild-type vaccine (Nuvaxovid)—which may be used when no alternative clinically suitable UK approved covid-19 vaccine is available

For people aged 12 to 17:

- Pfizer-BioNTech mRNA (Comirnaty) original "wild-type" vaccine

For children aged 5 to 11 years:

- Pfizer-BioNTech mRNA (Comirnaty) original "wild-type" vaccine paediatric formulation

The announcement on 15 August came the same day that the regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA), approved Moderna's bivalent vaccine for use in adults. The vaccine has been given conditional marketing authorisation for adult booster doses in Great Britain, while emergency use authorisation has been granted in Northern Ireland.

Half of each bivalent booster dose (25 micrograms) is made up of Moderna's original covid-19 vaccine, while the other half (25 micrograms) is made up of the updated version.

Evidence base

The MHRA said that its approval was based on study data showing that the bivalent vaccine triggered a "strong immune response" against both BA.1 and the original virus, as well as a "good immune response" against BA.4 and BA.5.

A preprint published in June reported that, as part of the ongoing phase 2/3 open label study, 437 participants (who had previously had three doses of the original Moderna vaccine) received a booster dose of the bivalent omicron vaccine, while 377 received a second booster dose of the original vaccine.[1] These data appear to be the same as those included in the summary of product characteristics for the vaccine, which was highlighted by the MHRA when *The BMJ* requested the evidence underlying its approval.[2]

In participants with no history of covid-19, the estimated neutralising antibody geometric mean titres (GMTs) against the original virus—after adjusting for age groups and pre-booster titres—were 6422.3 (95% confidence interval 5990.1 to 6885.7) 28 days after the bivalent vaccine and 5286.6 (4887.1 to 5718.9) after the original Moderna vaccine.

Meanwhile, the estimated GMTs against BA.1 were 2479.9 (2264.5 to 2715.8) 28 days after the bivalent booster and 1421.2 (1283.0 to 1574.4) after the original vaccine booster.

The bivalent vaccine "elicited a superior neutralising antibody response against omicron" when compared with the original vaccine, and it showed a "non-inferior neutralising antibody response" against the original SARS-CoV-2 virus, the preprint said.

The researchers also assessed the neutralising antibody response 28 days after the bivalent vaccine against the BA.4 and BA.5 subvariants. Looking at all participants regardless of prior SARS-CoV-2 infection, GMTs were 172.7 (147.5 to 202.3) before the booster and rose to 940.6 (826.3 to 1070.6) after it, with a fold rise of 5.4 (5.0 to 5.9), the preprint reported.

Safety and reactogenicity profiles were reported as being similar and well tolerated in both the bivalent group and the original vaccine group.

Emerging variants

Commenting on the approval, Jonathan Ball, professor of molecular virology at the University of Nottingham, said, "The early data certainly suggests that the new Moderna vaccine, targeting two different flavours of SARS-2 coronavirus spike protein, works better against the newly emerged omicron variants.

"These variants have been the most able to escape the antibodies raised through infection or vaccination by previous variants. This should provide people with better protection against the omicron variants."

However, Ball, who himself receives funding to develop next generation covid-19 vaccines, added that the virus was "unlikely to stand still, and omicron targeted immunity might push the virus down other evolutionary paths." "That said, unless there is a major shift in the virus, immunity will

continue to protect the vast majority from serious disease caused by emerging variants."

Beate Kampmann, professor of paediatric infection and immunity and director of the Vaccine Centre at the London School of Hygiene and Tropical Medicine, said that the availability of a bivalent vaccine was "good news" but added, "The bivalent vaccines have not yet been widely tested in large heterogeneous population groups.

"In essence, I think it is wise not to recommend a 'personalised vaccination approach' but to go with the wider entirely pragmatic public health message that boosters are an important intervention for the winter period and should be taken up across age groups, as recommended, with the most vulnerable to be first in line."

1 Chalkias S, Harper C, Vrbicky K, et al. A bivalent omicron-containing booster vaccine against covid-19. *medRxiv* [preprint] 2022 (published online Jun 25). doi: 10.1101/2022.06.24.22276703. https://www.medrxiv.org/content/10.1101/2022.06.24.22276703v1.full.pdf

2 Summary of product characteristics: Spikevax bivalent Original/Omicron. Gov.uk. 2022. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097996/Spikexax_bivalent_Original_Omicron_SmPC.pdf