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> JCVI statement, September 2021: COVID-19 booster vaccine programme for winter 2021 to 2022



Department of Health & Social Care

Independent report

# JCVI statement regarding a COVID-19 booster vaccine programme for winter 2021 to 2022

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Contents

Introduction

# Introduction Considerations Advice



Print this page

The Joint Committee on Vaccination and Immunisation (JCVI) has been asked by the Secretary of State for Health and Social Care to consider the options for and timing of a booster programme to revaccinate adults in order to reduce mortality, morbidity and hospitalisations from COVID-19 over the 2021 to 2022 winter period and through 2022, as well as to minimise the COVID-19 case infection rate and the chance of new variants emerging.

With increasing levels of social mixing and close social contact, it is expected that during winter 2021 to 2022 SARS-CoV2 will co-circulate alongside other respiratory viruses, including seasonal influenza virus. Seasonal influenza and SARS-CoV-2 viruses have the potential to add substantially to the 'winter pressures' usually faced by the NHS, particularly if infection waves from both viruses coincide. The timing and magnitude of potential influenza and SARS-CoV2 infection waves for winter 2021 to 2022 are currently unknown.

In JCVI's view, the primary objective of a 2021 COVID-19 booster programme is to maintain protection against severe COVID-19 disease, specifically hospitalisation and deaths, over winter 2021 to 2022. This is exceptional advice aimed at maintaining protection in those most vulnerable, and to protect the NHS. This advice is based on evidence from a number of sources, including UK data on the duration of vaccine-induced protection against severe COVID-19. As not enough time has passed to enable a clear understanding of the level of protection 6 months after completion of the primary vaccine course in all persons, extrapolation of some data has been required.

Taking a precautionary position, JCVI considers that on balance, it is preferable to ensure protection is maintained at a high level throughout the winter months in adults who are more vulnerable to severe COVID-19, rather than implement a booster programme too late to prevent large increases of severe COVID-19 in previously double vaccinated individuals.

At present, it is not known whether recurrent boosters will be required in the long term. This advice on booster vaccination therefore only applies to this highly active phase of the pandemic. This programme is timed to maximise the impact of a booster programme on individual protection against severe disease and to protect the NHS during the

winter months.

## **Considerations**

JCVI has reviewed the latest epidemiology of COVID-19 in the UK [footnote 1], mathematical modelling [footnote 2], [footnote 3], data on vaccine safety [footnote 4], [footnote 5] and vaccine effectiveness [footnote 6], [footnote 7], and data from trials undertaken to understand the immunological impact of booster vaccination [footnote 8], [footnote 9]. Operational and vaccine supply constraints have also been taken into consideration.

The COVID-19 vaccination programme has progressed at pace since December 2020. Early in the programme, the decision was taken to offer the second vaccine dose of the primary schedule after an extended interval for both the COVID-19 Pfizer-BioNTech (BNT162b2/ Comirnaty®) vaccine and the AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine. [footnote 10] The extended second dose interval has been demonstrated to generate a better vaccine immune response which may, in turn, contribute towards greater duration of protection [footnote 11], [footnote 12], [footnote 13] Despite this, recent UK data show early signs of a fall in the levels of protection most evident amongst older individuals who completed their primary vaccine course a longer time ago. [footnote 6]

Data from the COV-BOOST trial indicate that booster doses of COVID-19 vaccines are generally well tolerated and provide a substantial increase in vaccine-induced immune responses. [footnote 8]. In particular, mRNA vaccines provide a strong booster effect, regardless of whether the primary course was with the Pfizer-BioNTech (BNT162b2/Comirnaty®) or the AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine. These results are consistent with those from other studies that examined the effect of half dose (50 $\mu$ g) Moderna (mRNA-1273/Spikevax®) vaccine following primary courses of full or half doses of Moderna mRNA-1273 vaccination. [footnote 14] A half dose (50 $\mu$ g) of Moderna (mRNA-1273/Spikevax®) vaccine given as a booster was found to cause a similar level of local and systemic reactions to vaccination (injection site pain and headache) compared to a full dose of Moderna (mRNA-1273/Spikevax®) given as a second dose.

Data from the ComFluCOV trial indicate that coadministration of influenza and COVID-19 vaccines is generally well tolerated with no diminution of vaccine-induced immune responses to either vaccine. [footnote 9]

# **Advice**

JCVI advises that for the 2021 COVID-19 booster vaccine programme individuals who received vaccination in Phase 1 of the COVID-19 vaccination programme (priority groups 1 to 9) should be offered a third dose COVID-19 booster vaccine. This includes:

- those living in residential care homes for older adults
- all adults aged 50 years or over
- frontline health and social care workers
- all those aged 16 to 49 years with underlying health conditions that put them at higher risk of severe COVID-19 (as set out in the green book), and adult carers
- adult household contacts (aged 16 or over) of immunosuppressed individuals

As most younger adults will only have received their second COVID-19 vaccine dose in late summer or early autumn, the benefits of booster vaccination in this group will be considered at a later time when more information is available. In general, younger, healthy individuals may be expected to generate stronger vaccine-induced immune responses from primary course vaccination compared to older individuals. Pending further evidence otherwise, booster doses in this population may not be required in the near term.

JCVI will review data as they emerge and consider further advice at the appropriate time on booster vaccinations in younger adult age groups, children aged 12 to 16 years with underlying health conditions, and women who are pregnant.

### Timing of booster vaccination

JCVI advises that the booster vaccine dose is offered no earlier than 6 months after completion of the primary vaccine course, and that the booster programme should be deployed in the same order as during Phase 1, with operational flexibility exercised where appropriate to maximise delivery. Persons vaccinated early during Phase 1 will have completed their primary course approximately 6 months ago. Therefore, it would be appropriate for the booster vaccine programme to begin in September 2021, as soon as is operationally practicable.

#### Vaccine product for booster vaccination

After reviewing data on booster responses from different combinations of COVID-19 vaccines, JCVI advises a preference for the Pfizer-BioNTech (BNT162b2/ Comirnaty®) vaccine to be offered as the third booster dose irrespective of which product was used in the primary schedule. There is good evidence that the Pfizer-BioNTech (BNT162b2/ Comirnaty®) vaccine is well tolerated as a third dose and will provide a strong booster response. Alternatively, individuals may be offered a half dose (50µg) of the Moderna (mRNA-1273/Spikevax®) vaccine, which should be well tolerated and is also likely to provide a strong booster response. A half dose (50µg) of Moderna (mRNA-1273/Spikevax®) vaccine is advised over a full dose due to the levels of reactogenicity seen following boosting with a full dose within the COV-BOOST trial. Where mRNA vaccines cannot be offered e.g. due to contraindication, vaccination with the AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine may be considered for those who received AstraZeneca (ChAdOx1-S/Vaxzevria®) vaccine in the primary course (please refer to the green book for further details)

#### Other considerations

This advice on booster vaccination is distinct from, and does not supersede, recent

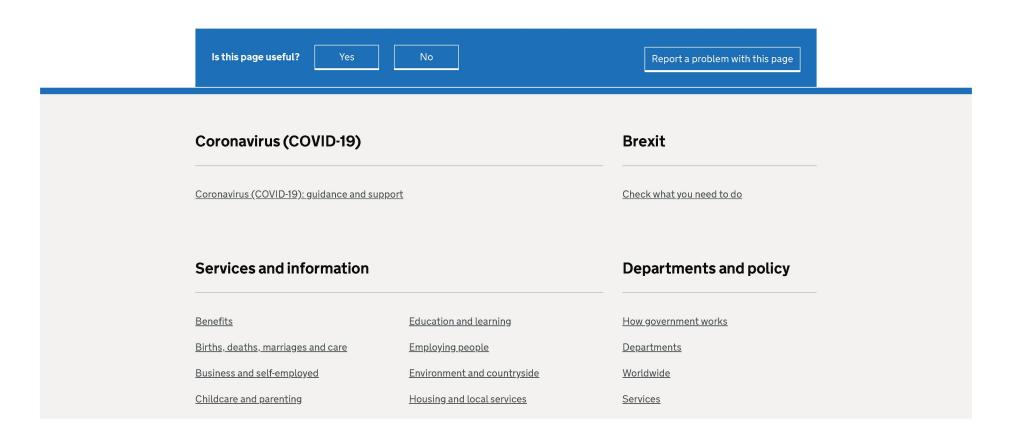
advice from JCVI regarding a third primary vaccine dose for persons who are severely immunosuppressed. JCVI will review at a later date whether such persons require a further booster dose following completion of their 3-dose primary vaccine course.

It is not the intention of JCVI that the 2021 COVID-19 booster vaccine programme should disrupt or delay deployment of the annual influenza vaccination programme. Both of these programmes are important for individual and public health, especially over winter 2021 to 2022. Where operationally expedient, COVID-19 and influenza vaccines may be co-administered.

- 1. GOV.UK, National flu and COVID-19 surveillance reports: 2021 to 2022 season ↔
- 2. Public Health England modelling the impact of third dose boosters [unpublished] ←
- 3. University of Warwick modelling the impact of third dose boosters [unpublished] ↔
- 4. GOV.UK, Coronavirus (COVID-19) vaccine adverse reactions ←
- 5. Flaxman et al. Reactogenicity and immunogenicity after a late second dose or a third dose of ChAdOx1 nCoV-19 in the UK: a substudy of 2 randomised controlled trials (COV001 and COV002). Lancet. 2021;398(10304):981–990. 

  ✓
- 6. Lopez-Bernal et al [unpublished]  $\stackrel{\checkmark}{=}$
- 7. GOV.UK, COVID-19 vaccine surveillance reports ←
- 8. Comparing COVID-19 booster vaccinations (COV-BOOST) [unpublished]  $\underline{\leftarrow} \underline{\leftarrow}^2$
- 9. Combining Influenza and COVID-19 vaccination (ComFluCOV) study [unpublished]  $\stackrel{\ }{\underline{\hookrightarrow}} \stackrel{\ }{\underline{\hookrightarrow}} ^2$
- 10. GOV.UK, Prioritising the first COVID-19 vaccine dose: JCVI statement ←
- 11. Amirthalingam et al. Higher serological responses and increased vaccine effectiveness demonstrate the value of extended vaccine schedules in combatting COVID-19 in England. medRxiv 2021.07.26.21261140 ↔
- 12. Voysey et al. Single-dose administration and the influence of the timing of the booster dose on immunogenicity and efficacy of ChAdOx1 nCoV-19 (AZD1222) vaccine: a

- pooled analysis of 4 randomised trials. Lancet. 2021 Mar 6; 397(10277): 881–891. ←
- 13. Parry et al. Extended interval BNT162b2 vaccination enhances peak antibody generation in older people. medRxiv 2021.05.15.21257017 €
- 14. Moderna Inc., <u>Moderna announces positive initial booster data against SARS-CoV-2</u> variants of concern ↔



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