ROYAL COLLEGE OF PHYSICIANS OF IRELAND

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17 August 2023

cc Dr Colette Bonner DCMO
Ms Richael Duffy Principal Officer
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Re: NIAC review of Autumn 2023 COVID-19 booster recommendations

Dear Breda,

As requested in your correspondence of 2 June 2023, NIAC has reviewed its recommendations issued in March this year (updated to version 1.1 submitted on 11 April) concerning the COVID-19 vaccination strategy for 2023. The Committee has conducted a comprehensive review of recent COVID-19 epidemiology, newly published data regarding effectiveness and durability of bivalent vaccines against severe disease and hospitalisation, optimal dose intervals and emerging evidence regarding co-administration of COVID-19 and flu vaccination. An examination of the limited evidence available in respect of newly adapted monovalent COVID-19 vaccines targeting XBB variants has also been undertaken. Details of these assessments are contained in Appendix 1 to this letter.

Having considered the available evidence, NIAC has determined that the March 2023 recommendations pertaining to the Autumn/Winter vaccination campaign remain substantially unchanged. In light of the developments in respect of adapted vaccines, NIAC have made an additional recommendation regarding the preferential use of the newly adapted XBB.1.5 monovalent vaccines for booster doses in place of currently recommended bivalent vaccines when they become available. See Appendix 2 for the details of the revised recommendation. The recommendations regarding eligible cohorts and the timing of booster vaccination remain unchanged.

While rates of COVID-19 related hospitalisations and deaths remain relatively low this year, SARS-CoV-2 is still prevalent in our community. For certain vulnerable groups, especially the elderly, immunocompromised individuals, those with underlying health conditions and those who are pregnant, further protection from severe COVID-19 is necessary through administration of booster doses of COVID-19 vaccine to ensure optimal protection in the face of waning of vaccine effectiveness. Optimising protection of healthcare workers recognises their increased exposure to COVID-19 and

should contribute to maintaining healthcare system resilience. Younger healthy individuals who have natural, vaccine induced, or hybrid immunity have higher levels of durable protection against severe disease compared to older individuals.

Co-administration with influenza vaccine is likely to maximise uptake of both vaccines. While there is some evidence suggesting a reduction in the antibody response elicited by COVID-19 vaccines when co-administered with influenza vaccines, the clinical significance of these findings remain unclear. The Committee concurs with the emerging international consensus that the population health benefits of co-administration continue to outweigh any potential risks.

The emergence of the XBB recombinant sublineages as the dominant strain has raised concerns about its increased immune evasiveness, which has likely resulted in the reduced effectiveness of current bivalent vaccines. Early data suggest that newly adapted monovalent XBB containing vaccines are expected to enhance the immune response against XBB sublineages in recipients. Thus, NIAC recommends the preferential use of new XBB adapted monovalent vaccines for booster doses when they become available in Ireland. In the interim, bivalent mRNA COVID-19 vaccines should continue to be used. It is important to note that currently approved COVID-19 vaccines continue to provide protection against severe disease and death. In the event of supply constraints of newly adapted monovalent XBB vaccines, the highest-risk groups, particularly those of advanced age, should be prioritised for receipt of these vaccines.

While the WHO predicts that XBB is likely to be the source of future SARS-CoV-2 variants in the near term, the exact timing, specific mutations, antigenic characteristics, and potential public health risks of these variants remain unknown. As always, NIAC will continue to regularly review COVID-19 epidemiology and scientific data and recommendations may be updated as more information becomes available.

Yours Sincerely,

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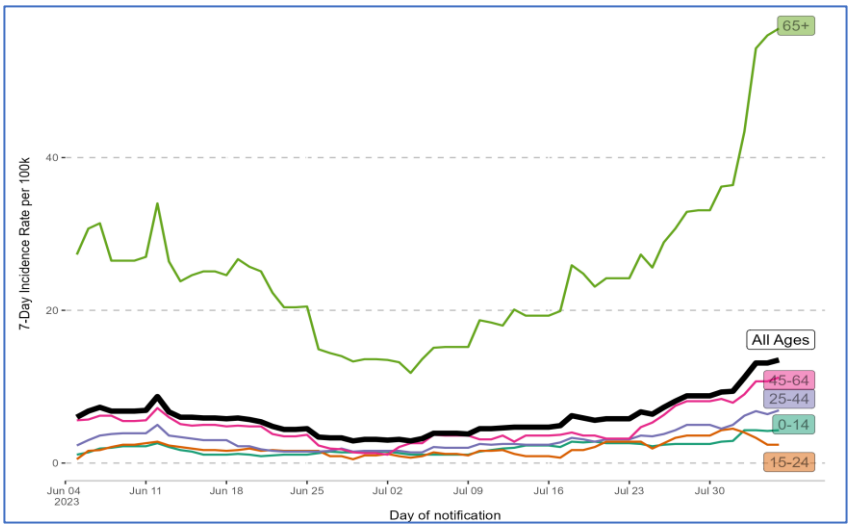
APPENDIX 1: NIAC EVIDENCE SYNTHESIS REGARDING AUTUMN/WINTER 2023 COVID-19 VACCINATION STRATEGY

Epidemiology

From 1 January to 31 July 2023, compared to the corresponding period in 2022, there have been considerably less COVID-19 cases notified in Ireland. Following a peak over the winter months, there was an overall downward trend in cases from February to July 2023.[1] This aligns with epidemiological patterns observed throughout Europe.[2] However, since week 27, beginning July 2 there has been an increase in reported cases in Ireland, particularly among individuals aged 65 years and above. (Figure 1)[3] In younger age groups a slight increase in cases has also been observed, although the overall numbers remain relatively low. This needs to be interpreted in the context of reduced community testing, which is now only conducted following healthcare provider referral. Furthermore, the detection of SARS-CoV-2 in 100% of samples tested by the National Wastewater Surveillance Programme in July indicates that high levels of the virus are still circulating in the community.[4]

Figure 1. COVID-19 moving 7-day incidence rate per 100,000 population from 4 June to 5 Aug 2023. Source: HPSC.[3]



An increase in the number of hospitalised cases since week 27 has been reported, with a 70% increase in cases in week 31 compared to week 30 2023. Nonetheless, indicators of severity such as ICU admissions and deaths remain low and stable. (Figure 2)[3]

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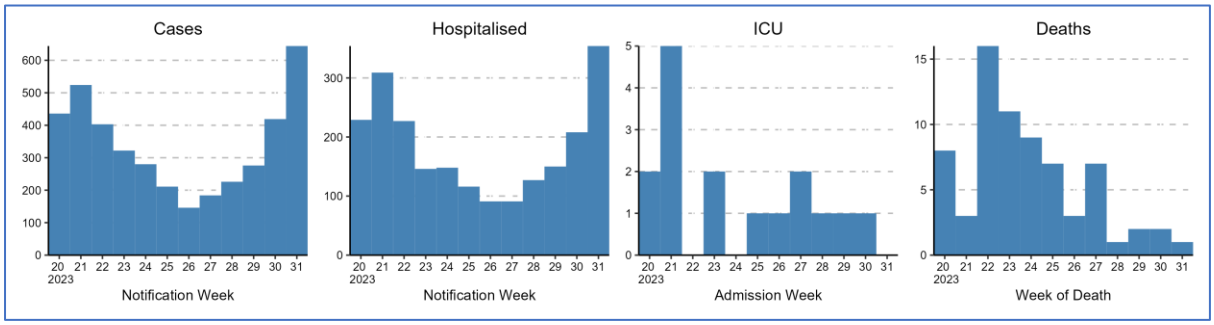
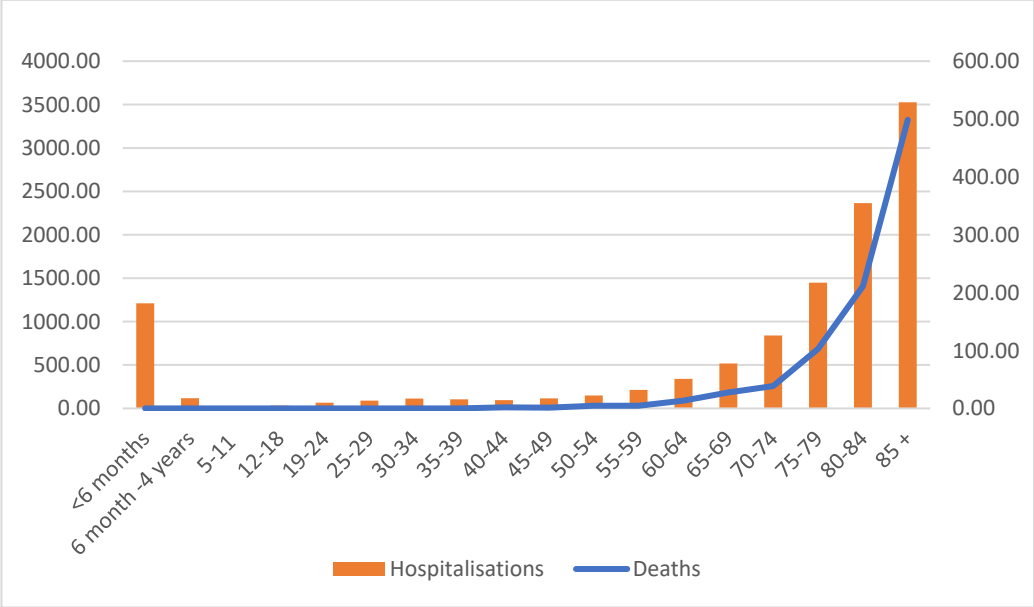
Figure 2. The number of COVID-19 cases, hospitalisations, ICU admissions and deaths from 14 May to 5 Aug 2023. Source: HPSC.[3]



Severe COVID-19 related outcomes continue to disproportionately affect older adults. The rate of hospitalisation for those aged 50 years and older from September 2022 to June 2023 increased incrementally with advancing age. Mortality rates began to rise from age 60 years. Both hospitalisation and mortality rates are especially high for those aged over 80 years. (Figure 3)[5] It should also be noted that the rate of hospitalisation was substantially higher in those aged less than six months, compared to older children and young adults.

Figure 3. Hospitalisations and deaths among confirmed COVID-19 cases per 100,000 population from 1 Sept 2022 to 12 June 2023. Source: HPSC CIDR extract 13/06/2023.[5]



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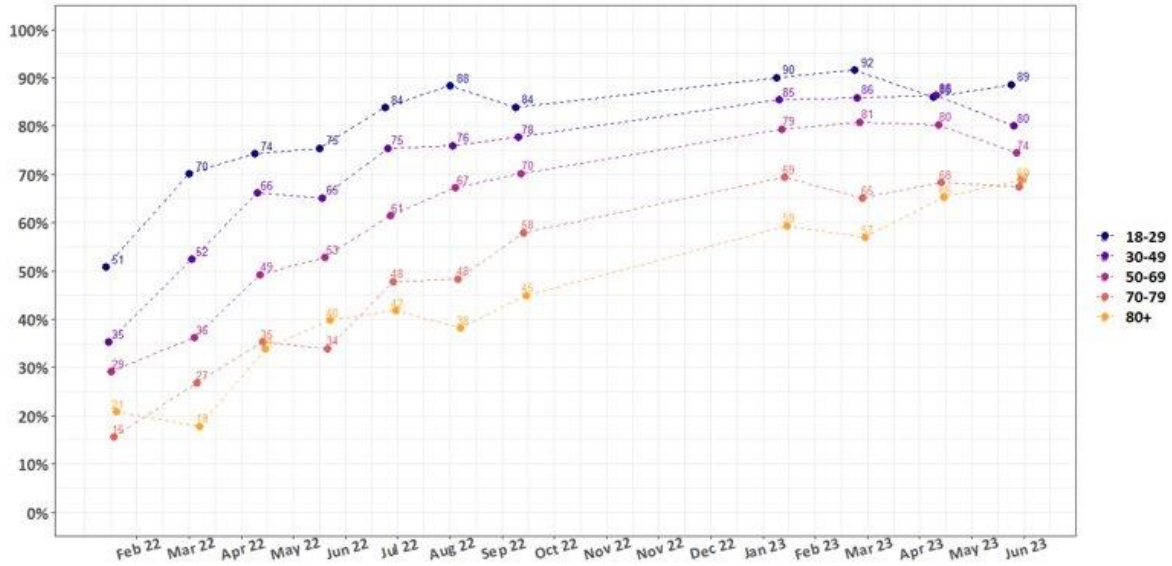
Omicron SARS-CoV-2 subvariants continue to dominate the SARS-CoV-2 virological landscape in Europe and globally, however new mutations continue to emerge as the virus evolves. Since February 2023, recombinants of the Omicron variant, specifically the XBB.1 sublineage (XBB1.9, XBB1.16 and XBB 1.5) accounted for the majority of cases sequenced in Ireland. In recent weeks a new sublineage EG.5.1 has emerged, accounting for 28% of variants sequenced in Ireland from week 26 to week 31. EG.5.1 has shown a significant growth advantage compared to its prevailing XBB variant precursors.[6] The rise in EG.5.1 has also been observed in other European countries including the UK as well as in the US.[6-9] It was declared a variant of interest by the WHO on 9 August 2023.[9] This new subvariant contains a mutated spike protein, F456L, which is leading to increased immune evasion however, as yet it is unclear whether this new mutation will cause greater severity of disease or whether it is linked to the latest upward trend in COVID-19 cases and hospitalisations globally. With respect to vaccine effectiveness against this new sublineage, it should be noted that there is very close alignment between XBB.1.5 and EG.5.1 except for two new mutations in EG.5.1. Accordingly, the new adapted monovalent booster formulations are expected to be effective against severe COVID-19 disease caused by EG.5.1.

Seroprevalence and vaccine uptake

Serological evidence of previous natural infection is still relatively high, although it has decreased modestly in those aged less than 70 years, it has increased slightly in those aged 80 years and older in June 2023. (Figure 4) Those aged 70 years and above still have the lowest levels of natural protection at 69% and therefore are more reliant solely on vaccination for protection than younger cohorts.[10] With respect to population coverage from vaccination, uptake has decreased with each subsequent booster dose offered and with decreasing age. By June 2023, 39% of adults aged 70 years and above had availed of the spring 2023 booster (4th booster). As of April 2023, a third booster dose, which had been offered since Autumn 2022, had been received by 45% of adults aged 65 years and above but only 23% of adults aged 50 years and above.[1]

Figure 4. Percentage of people with evidence of prior SARS-CoV-2 infection from February 2022 to June 2023. Source: Seroepidemiology Unit.[10]



Vaccine effectiveness

Since October 2022, bivalent mRNA vaccines targeting the original SARS-CoV-2 viral strain and the Omicron BA1 or BA.4/5 variants have been the recommended booster vaccines in Ireland. Recent data on the duration of effectiveness of bivalent vaccines against newer XBB variants indicate that the level of protection they provide against hospitalisation is lower and wanes more quickly compared to the protection observed against BA.4/5 variants.[11 12] Data from both the UK and USA estimate that the protection against XBB-related hospitalisation declined from approximately 51-57% at 1-12 weeks after receiving a bivalent booster vaccine, to 0-20% at 12-25 weeks post bivalent booster dose.[12 13] However, it is important to acknowledge that several studies have reported slower waning of protection against more severe outcomes such as critical illness and death, with effectiveness of 43-48% reported at 12-16 weeks post bivalent booster dose.[12 13]

Interdose intervals for booster vaccination

Vaccine induced or natural immunity against COVID-19 wanes over time, however immunity can be restored by booster vaccination.[14-16] As discussed in previous NIAC recommendations, the frequency of booster vaccination needs to be carefully considered to balance the risk of immune imprinting from boosting too frequently, and the vulnerability to COVID-19 that may arise due to extended time lapses between booster doses.[17] In those at high risk of severe disease, such as those of more advanced age, even a minor decrease in vaccine effectiveness with time can translate into a rise in severe disease and death, reinforcing their need for more frequent booster vaccination. In addition, evidence

suggests that immunity, whether acquired through vaccination, natural infection or both (i.e., hybrid immunity), tends to be more robust and longer lasting in younger age cohorts.[18] Therefore, the recommended intervals between booster doses of COVID-19 vaccines remain at six months for those aged 50 years and above, and nine months for those aged less than 50 years without immunocompromise.

Timing of booster doses and co-administration with influenza vaccines

A predictable pattern of seasonality of COVID-19 has not yet been established. However, in Ireland, there have been distinct waves of SARS-CoV-2 infection during the winter months since 2020.[1] These winter waves have resulted in higher rates of hospitalisations at a time when the health care system is already under pressure due to surges in other respiratory viruses such as influenza and RSV.[19] Timing booster doses of COVID-19 vaccine to occur in advance of the winter season can offer several benefits. First, it provides individuals with maximum protection against COVID-19 when SARS-CoV-2 circulation is likely to increase. Second, it can minimise the impact of co-infection for individuals with COVID-19 and other respiratory viruses like influenza and RSV. Third it may reduce the burden on healthcare systems. And finally, by facilitating co-administration with influenza vaccine the uptake of both vaccines can be increased and protection against both illnesses can be achieved faster than sequential delivery, while also optimising the efficiency of vaccine delivery.

Recently published studies compared the immune response in those who were co-administered COVID-19 and influenza vaccines on the same day versus those who received either vaccine alone or sequentially at least three weeks apart. The studies showed that co-administration may reduce the immune response to the COVID-19 vaccine but does not affect the immunogenicity of the influenza vaccine. In the co-administered groups, there were significant increases in SARS-CoV-2 antibody levels, but the increase was less than in the groups who received the COVID-19 vaccine alone or sequentially. The difference in antibody response was not statistically significant in all studies, but the trend of reduced response in the co-administered groups was consistent across all studies. However, these studies did not measure differences in clinical outcomes over time. Additionally, there is no universally agreed threshold of SARS-CoV-2 antibody level that confers immunity. Therefore, the clinical impact of co-administration on COVID-19 vaccine effectiveness remains unclear. Importantly, the co-administration of COVID-19 and influenza vaccines was found to be safe, with similar reactogenicity and side effect profiles compared to sequential administration.[20-23] In agreement with advice from many other health authorities including WHO and European Centre for Disease Prevention and Control (ECDC), the potential risk of a small reduction in COVID-19 immunogenicity is considered to be outweighed by the broader population health benefits of co-administration.[24-26]

Vaccine safety

Since the publication of NIAC's 2023 COVID-19 recommendations, no new safety concerns have emerged regarding COVID-19 vaccinations in use in Ireland. The safety profile of the bivalent mRNA COVID-19 booster vaccines is comparable to that of original mRNA COVID-19 booster vaccines. The risk of myocarditis and/or pericarditis after receipt of mRNA COVID-19 vaccines in adolescents and young adults, particularly males, is significantly reduced for the booster doses compared to primary series vaccination.[27]

Updated variant vaccines

In spring 2023, as XBB recombinant subvariants of SARS-CoV-2 became dominant worldwide, the WHO and international regulators recommended manufacturers focus efforts on developing vaccine formulations which aim to induce antibody responses that neutralise XBB descendent lineages.[28 29] Minimal antigenic differences have been observed across the existing XBB.1 descendent lineages which suggests that a vaccine containing an XBB.1 subvariant such as XBB.1.5 is likely to provide good protection against other XBB.1 subvariants.

Following review of available preclinical and clinical data, the EMA-ECDC released a joint statement in which XBB.1.5 containing monovalent vaccines were considered a reasonable choice of COVID-19 vaccine formulation for authorisation autumn 2023.[24]

These vaccines have been shown in preclinical trials to yield higher neutralising antibody titres than the current bivalent BA.4/5 vaccines against XBB subvariants (Figures 5 and 6).[24 30]

Figure 5. Neutralising antibody titres against BA.4/5 and XBB subvariants in mice 14 days after bivalent BA.4/5 or new monovalent XBB.1.5 or new bivalent BA.4/5 + XBB.1.5 booster vaccination. Source: Moderna preclinical study.[31]

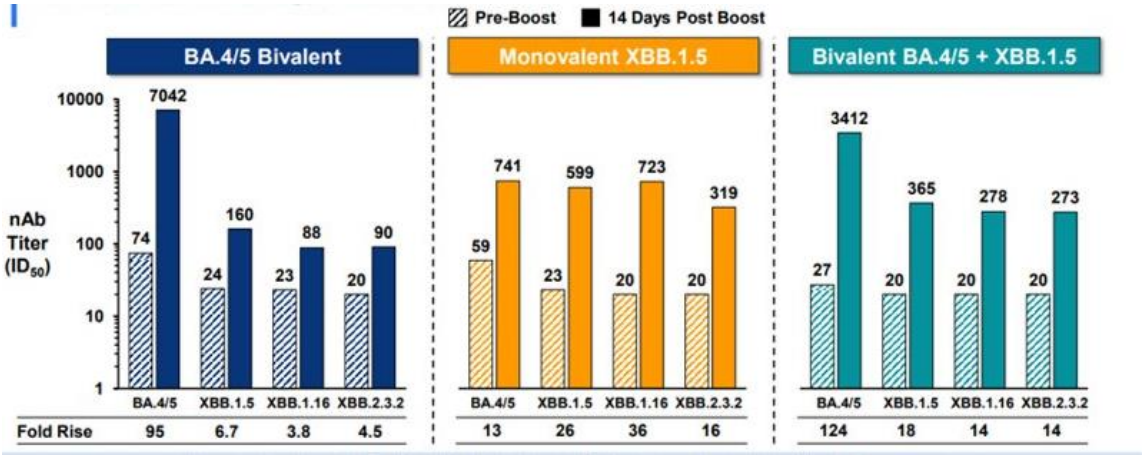
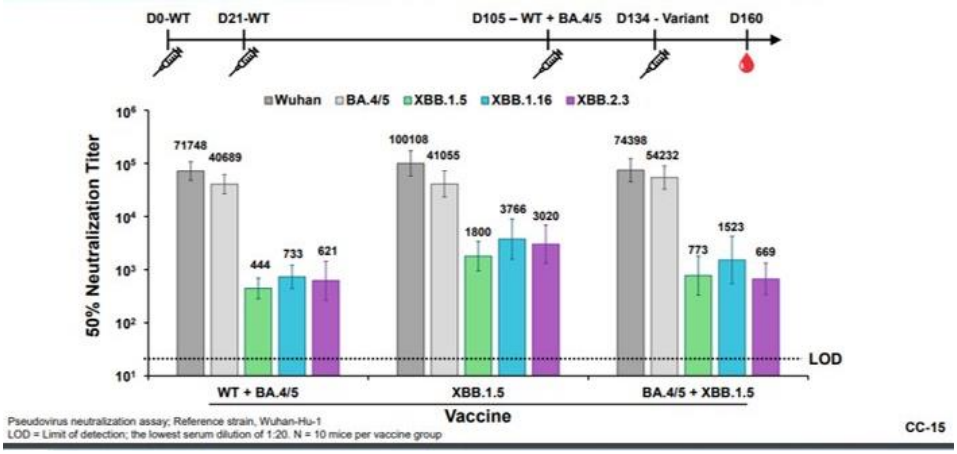
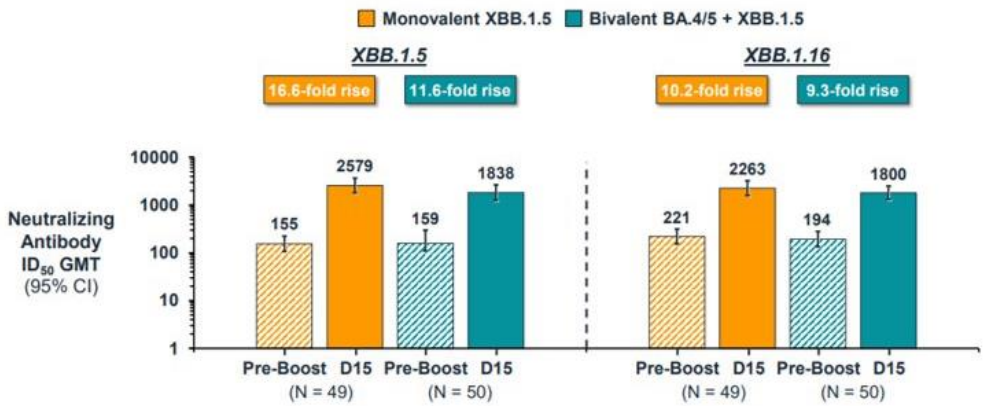


Figure 6. Neutralising antibody titres against BA.4/5 and XBB subvariants in mice 26 days after bivalent BA.4/5 or new monovalent XBB.1.5 or new bivalent BA.4/5 + XBB.1.5 booster dose. Source: Pfizer preclinical study.[30]



This improved immune response was also observed in a small (n=101) clinical study of Moderna's XBB.1.5 monovalent vaccine candidate. (Figure 7)[31] Safety data from the trial indicated that the reactogenicity profile was similar to previously approved mRNA monovalent and bivalent vaccines, however it must be noted that this small sample size is not powered to detect uncommon adverse events.[31] Preclinical and clinical data indicate that XBB.1.5 monovalent mRNA vaccines are expected to offer enhanced protection against circulating subvariants of SARS-CoV-2, and therefore will likely be the preferred choice of COVID-19 vaccine for winter 2022/2023 once available. The updated mRNA vaccines (Comirnaty, Pfizer-BioNTech and Spikevax, Moderna) are pending regulatory approval in Europe ahead of winter 2023.

Figure 7. Neutralising antibody titres against XBB.1.5 and XBB.1.16 in adults 15 days after new monovalent XBB.1.5 or new bivalent BA.4/5 + XBB.1.5 booster dose. Source: Moderna clinical study.[31]



International recommendations

In March and June 2023 respectively, the WHO and the ECDC/EMA advised that COVID-19 vaccination campaigns ahead of this winter should prioritise people who are most at risk of severe disease. These include older adults (WHO recognises that 50 or 60 years are commonly used cut-offs for identifying "older adults" but leaves it to countries to make the decision regarding specific age cut-offs, EMA classify older adults as 60 years and older), people with weakened immune systems, people with underlying medical conditions putting them at higher risk of severe COVID-19 irrespective of age, and those who are pregnant.[24 32] Healthcare workers are also considered a priority group for vaccination. Concomitant vaccination for COVID-19 and influenza is recommended considering vaccine specific available information on the co-administration with influenza vaccines.[24 32] In August 2023, the WHO further recommended integrating COVID-19 vaccination into National Immunisation Programmes and broader health care delivery mechanisms.[26] International recommendations for 2023 COVID-19 booster vaccination strategies are summarised in Table 1.

Table 1. 2023 International COVID-19 booster recommendations for 2023

Country	Spring 2023	Autumn 2023
Denmark[33]	• No vaccination programme • Certain groups at increased risk	• ≥65 years • Persons <65 years at increased risk
France[34]	• ≥80 years • Immunocompromise • Those deemed high risk as part of a shared medical decision with health care team	• ≥65 years • Residents: ≥85 years or resident of nursing home or long-term care unit regardless of age • Immunocompromise: ≥6 months of age • Medical conditions: ≥6 months of age
Netherlands[35]	• People in certain at-risk groups may require an extra repeat dose and can be referred by their attending doctor	• ≥60 years • Adults in a risk group who are offered influenza vaccine annually • Children and adults in a high risk group • Healthcare workers
Sweden[36]	**Recommended to those:** • ≥80 years • Living in care homes for the elderly **Available to those:** • 65-79 years • 18-64 years with risk factors	**Recommended to those:** • ≥50 years • Living in care homes for the elderly • 18-49 with risk factors **Available to those:** • 18-49 years without risk factors
UK[37]	• ≥75 years • Residents in care home for older people • Immunocompromise: 5 years	• ≥65 years • Residents in care home for older adults • 6 months-64 years in a clinical risk group • Health and care workers • 12-64 household contacts of immunocompromised • 16-64 carers of older adults

Canada[38]	• ≥80 years • 65-79 years, particularly without a history of COVID-19 infection • Adult residents of long-term care homes and other congregate living settings for seniors or those with complex medical care needs • Moderate-severe immunocompromise: ≥12 years	• ≥65 years • Residents of long-term care home and other congregate living settings for seniors or those with complex medical care needs • Immunocompromise: ≥12 years • Medical conditions: ≥12 years • Certain ethnic groups • Essential community services providers
Interval of 6 months is recommended for all cohorts in the countries listed above except Sweden. Sweden recommends a 9 month interval for those aged 18-64 years without risk factors and a 6 month interval for all other cohorts.		
Germany[39]	• ≥ 60 years • Residents of long-term care facilities • Immunocompromise: ≥ 6 months of age • Medical conditions: ≥ 6 months of age • Family members and close contacts of those unlikely to produce a protective immune response • Medical and nursing staff	
In Germany an interval of 12 months is recommended for all except immunocompromised for whom a shorter interval may be considered - shorter intervals may also be considered for others, as determined by attending physician.		

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APPENDIX 2. 2023 COVID-19 VACCINE RECOMMENDATIONS V1.2 (ISSUED 17 AUG 2023)

Version 1.2

Updated text

9. XBB.1.5 monovalent mRNA COVID-19 vaccines are preferred for use as boosters once available, until that time bivalent mRNA COVID-19 vaccines should continue to be used as boosters. Spikevax vaccines should not be administered to those aged under 30 years. For those aged 5-29 years, Comirnaty vaccines at the age-appropriate doses are recommended.

Original text Version 1.1 (11 April 2023)

9. mRNA COVID-19 bivalent vaccines are preferred for use as boosters however, Spikevax bivalent Original/Omicron BA.4-5 should not be administered to those aged under 30 years. For those aged 5-29 years, Comirnaty Original/Omicron BA.4-5 vaccines at the age appropriate dose is recommended

2023 COVID-19 VACCINE RECOMMENDATIONS

A. RECOMMENDATIONS FOR 2023 COVID-19 BOOSTER VACCINES

1. A spring COVID-19 booster vaccine is recommended for:
   - those aged 70 years and older
   - those living in long term care facilities for older adults
   - those aged 5 years and older with immunocompromise associated with a suboptimal response to vaccination.

2. The spring COVID-19 booster vaccination campaign should aim for completion by end May.

3. An autumn COVID-19 booster vaccine is recommended for:
   - those aged 50 years and older
   - those aged 5-49 years with immunocompromise associated with a suboptimal response to vaccination
   - those aged 5-49 years with medical conditions associated with a higher risk of COVID-19 hospitalisation, severe disease or death
   - health and care workers.

4. For pregnant adolescents and adults a COVID-19 booster vaccine once in pregnancy is recommended if it is more than six months since their previous COVID-19 vaccine or infection.
   - COVID-19 vaccine can be given at any stage in pregnancy

- the booster is ideally given between 20-34 weeks' gestation
- if it is more than 12 months since their previous COVID-19 vaccine or infection administration earlier in pregnancy should be considered.

5. For those healthy aged 18-49 years and who are up to date with their vaccines (primary schedule and first booster)
    - an autumn booster vaccine is not routinely recommended
    - access to an autumn booster vaccine should be available for those who, following discussion of their reasons with a health care provider (e.g., GP, pharmacist or vaccination centre), request vaccination.

6. For those healthy aged 12-17 years and who are up to date with their vaccines (primary schedule and first booster) an additional booster vaccine is not routinely recommended.

7. For those healthy aged under 12 years COVID-19 booster vaccination is not recommended.

8. COVID-19 booster vaccines as outlined above may be given irrespective of the number of previous booster doses or types of COVID-19 vaccines received as follows:
    - for those aged 50 years and older an interval of six months is recommended following any previous COVID-19 vaccine dose or infection
    - for those aged 5 years and older with immunocompromise associated with a suboptimal response to vaccination, an interval of six months is recommended following any previous COVID-19 vaccine dose or infection
    - for those aged less than 49 years an interval of nine months is recommended following any previous COVID-19 vaccine dose or infection
    - a minimum interval of three months is permissible in exceptional circumstances e.g., heightened epidemiologic risk or for operational reasons.

9. XBB.1.5 monovalent mRNA COVID-19 vaccines are preferred for use as boosters once available, until that time bivalent mRNA COVID-19 vaccines should continue to be used as boosters. Spikevax vaccines should not be administered to those aged under 30 years. For those aged 5-29 years, Comirnaty vaccines at the age-appropriate dose are recommended.

10. Protein based vaccines (Nuvaxovid and VidPrevtyn Beta) may be used as alternatives for those for whom an mRNA vaccine is contraindicated or declined.
    - Nuvaxovid is the preferred alternate and can be used for primary and booster vaccination.
    - Data on VidPrevtyn Beta are more limited. It is only authorised as a booster.

11. The autumn campaign should coincide with the seasonal influenza vaccination campaign. COVID-19 booster and influenza vaccines may be administered at the same time with one vaccine in each arm.

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