An Roinn Sláinte
Department of Health
Office of the Chief Medical Officer

22nd July 2022

Mr Stephen Donnelly TD
Minister for Health
Department of Health
Block 1, Miesian Plaza
50-58 Lower Baggot Street
Dublin 2

Via email to Private Secretary to the Minister for Health

Dear Minister

I have today received recommendations from the National Immunisation Advisory Committee (NIAC) regarding additional booster doses of COVID-19 vaccines (see attached). On April 5th, NIAC recommended a second mRNA booster dose for the highest risk groups; those aged 65 years and older and those aged 12 years and older who were immunocompromised. In this updated advice, **an additional second mRNA booster (4th dose for most people) is now also recommended for individuals aged 50-64 years, those aged 12-49 years who have underlying medical conditions associated with a higher risk of severe COVID-19, or who reside in long-term residential care facilities.** The Committee recommends that booster doses should be given at an interval of four months since previous COVID-19 vaccine dose or SARS-CoV2 infection (a minimal three-month interval may be exceptionally applied). Longer intervals between doses have been shown to result in a stronger and more durable immune response. Given that most individuals in the aforementioned groups will have received their first booster dose over four months ago, they are now due for their second booster. NIAC has indicated that it will keep under review the need for any further boosters for these groups during the Winter months.

Further, **a third booster dose (5th dose for most people) has also been recommended for those aged 65 years and older, and those aged 12 years and older who are immunocompromised**. Where practicable, NIAC recommends that the third booster be co-administered with the flu vaccine. In light of the four-month interval since previous booster/infection and the availability of the flu vaccine, it is anticipated a third booster will be rolled out to these groups from October onwards. Regardless of vaccination status, age remains the greatest risk factor for severe outcomes of COVID-19. Patients with immunocompromise have a weaker initial immune response to vaccination and more rapid waning of vaccine associated protection against severe outcomes than other patients.

In its current advice, NIAC has also **recommended a first booster (3rd dose) for 5-11 year olds who are immunocompromised** which can be administered now**.** The Minister will be aware that as yet, a booster COVID-19 vaccine dose has not been authorised by the European Medicines Agency (EMA) for 5-11 year olds, although the issue is currently under review.

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The Committee considered that given that these children are at increased risk of severe illness from COVID-19 and in the context of the circulating Omicron variant (which demonstrates some immune escape from current vaccines), that a booster dose for children in this age group can help boost protection and the benefits outweigh the risks.

Moreover, **an additional booster dose (4th dose for most people) has been recommended for pregnant women from 16 weeks gestation onwards if they have not previously received a booster dose in their current pregnancy.** Booster vaccination in pregnancy has been associated with a reduced risk of hospitalisation for both mother and infants under six months of age. No particular maternal or fetal safety concerns from use of COVID-19 vaccines in pregnant women have been identified.

As described by NIAC, there is some evidence on the short-term benefit (up to 45 days) of a second booster dose in reducing infection rates. Given that the Autumn and Winter months are expected to be associated with a resurgence of SARS-CoV-2 community transmission, as well as an increase in the incidence of other respiratory infections which will lead to increase pressure on the health service, NIAC has recommended that **healthcare workers receive a second booster dose and that, where practicable, this be co-administered with the flu vaccine.** This is likely to offer a modest benefit in terms of limiting the risks of transmission to vulnerable people in their care.

Healthy individuals aged 12-49 years old who do not have risk factors for severe COVID-19 are not recommended to receive an additional booster dose at this time as their risk of severe illness after their first booster dose is very low. NIAC will continue to closely follow vaccine effectiveness and epidemiological data and will update advice on second boosters during the Winter period for this group, as required.

In keeping with the primary objectives of the COVID-19 immunisation programme, NIAC's current recommendations for an additional booster dose focus on key populations at increased risk of severe illness and death from COVID-19. Booster vaccination with mRNA vaccines provides significant protection against hospitalisation and death in breakthrough Omicron infections. However, there is some evidence of waning protection against severe disease, particularly in higher risk groups and preliminary data indicates that a second booster dose provides additional protection compared to a first booster. Restoration of high levels of protection can be achieved by booster vaccination. A second booster in those aged 60 years and older in Israel resulted in a fourfold reduction in severe COVID-19, while recent data from the US demonstrates in those aged 50 years and older, those who were fully vaccinated and in receipt of one booster had four times the risk of dying from COVID-19 compared to those fully vaccinated and in receipt of two or more booster doses. Though data are limited, a second booster dose of an mRNA vaccine has been shown to be safe and well tolerated with no new safety signals being identified.

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In their current advice, NIAC emphasises the importance of primary and booster vaccination and notes that a substantial proportion of eligible people have not yet received their first or second booster doses. For example, only 25% of those aged 12-17 years have received a first booster while 58% of those aged 65 years and older have received a second booster. NIAC continues to strongly recommend that those who are eligible for COVID-19 vaccination but have not yet received their recommended doses (primary or booster) come forward promptly to maximise their protection against SARS-CoV-2 prior to the Winter period. Even for those who may have had a previous infection, there is an additional value of availing of a booster dose if indicated for their age group. Available evidence shows that hybrid immunity resulting from infection and booster vaccination confers stronger protection than infection alone. The combination of vaccination and infection can result in greater immunogenicity with higher antibody levels with greater durability and wider breadth of protection than that afforded by either alone. However, hybrid immunity waning also occurs and can be boosted by a further vaccine dose. Emerging evidence suggests that hybrid immunity resulting from previous infection and then booster vaccination confers the strongest protection.

Finally, NIAC continues to monitor the rapidly evolving scientific data in relation to the level and duration of protection conferred by vaccine-induced immunity, SARS-CoV-2 infection-induced immunity and hybrid immunity as well as multivalent COVID-19 vaccines. Manufacturers are working on new adapted vaccines including multivalent vaccines and these are currently under review by the EMA who have indicated they are likely to give a view on authorisation of such vaccines in September. The precise characteristics of these vaccines and the timing of their availability is not yet known. Updated recommendations from NIAC will be made as necessary.

I am endorsing the NIAC recommendations as detailed above.

Yours sincerely

Breda Smyth

Prof. Breda Smyth
Interim Chief Medical Officer

Designated Public Official under Regulation of Lobbying Act 2015

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