



8<sup>th</sup> September 2021

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

As you will be aware, on 22<sup>nd</sup> June 2021 I sought advice from the National Immunisation Advisory Committee (NIAC) in respect of the potential need for booster doses of COVID-19 vaccines. On 19<sup>th</sup> July 2021, NIAC indicated in preliminary advices that those who were immunocompromised, residents of long-term care facilities (LTRC), those 80 years and older in the community and frontline healthcare workers were to be considered as a priority should the need for booster doses arise. On 25<sup>th</sup> August 2021, I wrote to NIAC to establish if there had been any further consideration of booster doses, in particular in respect of the aforementioned priority groups. Yesterday I received advice from NIAC (see attached) in respect of that request, in which they recommend a booster dose for residents aged 65 years and older in LTRC and those aged 80 years and older living in the community. In coming to their recommendations, NIAC considered the emerging evidence pertaining to waning immunity, vaccine effectiveness of a booster dose against Delta in protecting against serious disease (hospitalisations, ICU admissions and death), as well as safety data in respect of a booster dose. Consideration was also given to global vaccine equity and upholding the principles of minimising harm, fairness and moral equality as part of the National Vaccine Allocation Framework.

In their recommendations, NIAC note that a number of countries have reported an increase in breakthrough infections in fully vaccinated individuals. The relative contributions of vaccine effectiveness against the Delta variant, waning vaccine mediated immunity, and relaxation of non-pharmaceutical measures leading to an increase in community transmission remains to be clarified. Importantly, recent studies have indicated that high levels of vaccine effectiveness against hospitalisation, severe disease and death, the primary objective of the vaccination programme, have been sustained throughout the period during which the Delta strain has been predominant. There is however, some attenuation of vaccine effectiveness in protecting against infection and mild symptomatic disease. Moreover, data emerging from Israel, Italy and the UK indicates that vaccine effectiveness may diminish or wane over time. A number of studies have documented a decline in neutralising antibodies six months following completion of the primary vaccination schedule. It is important to note that at this juncture it remains unclear whether this decrease in neutralising antibody titers correlates with a decrease in vaccine effectiveness against disease. Preliminary real-world data from Israel does however show a correlation between time from vaccination and an increase in breakthrough infections.



In their advices, NIAC specifically examine the data on vaccine effectiveness relating to older persons and those individuals who reside in LTRC. Data from the US and Canada signal a concerning trend whereby the proportion of breakthrough cases increases with age and are highest in those aged over 80 years, with protection against hospitalisation as a result of COVID-19 reduced in those over 75 years. This decline may be due to waning immunity in older persons over time; data from Israel indicates that those aged 60 years or older who were fully vaccinated in March 2021 were 1.7 times more protected against severe COVID-19 compared to those who were fully vaccinated in January 2021. As noted by NIAC, those residing in LTRC aged over 65 years may also have altered vaccine protection due to their age and underlying conditions which put them at increased risk of severe disease should they contract SARS-CoV2. While there is evidence of high vaccine effectiveness against severe disease in this group against the Alpha variant, it is slightly lower when compared with estimates of vaccine effectiveness in the general population. To date there is limited data available in respect of vaccine effectiveness against Delta in residents of LTRC. This coupled with the current high levels of community transmission in Ireland increases the risk of breakthrough infections in this group who are particularly vulnerable to severe disease. In recommending a booster dose for residents of LTRC, NIAC were also mindful of the disruption to and curtailment of visitor access and other activities in LTRC should an outbreak occur, which significantly negatively impacts the wellbeing of residents.

There is limited data on the safety and efficacy of booster doses of COVID-19 vaccination, although booster doses have in studies, elicited significant increases in neutralising antibodies against Beta and Delta and Gamma variants compared to wild-type following primary immunisation. Crucially, there appears to be a favourable safety profile and over 1.5 million booster doses of Comirnaty® have been administered in Israel to date, with no safety concerns and a lower rate of systemic and local reactions observed than after the first or second doses of that vaccine.

In light of the above, **NIAC have recommended a booster dose of an mRNA vaccine (irrespective of whether primary vaccination course was of an mRNA or adeno-viral vector) for residents aged 65 years and older in LTRC and for those aged 80 years and older living in the community. The booster dose can be given after a minimal interval of six months following completion of the primary vaccination schedule. The mRNA COVID-19 vaccine can be co-administered or given at any interval before or after administration of the seasonal influenza vaccine.** Further, NIAC observe that in addition to provision of a booster dose to these groups, all recommended public health and infection control measures should continue to be observed by these groups and by those caring for them. In the current advices, NIAC reiterate the importance of encouraging all unvaccinated or incompletely vaccinated people of any age, particularly those aged 80 years and older, as well as those living in LTRC aged 65 and older and those living with and/or caring for them to complete the primary vaccination course.



I note that the European Centre for Disease Control (ECDC) in their interim public health considerations for the provision of additional COVID-19 vaccine doses, published on 1<sup>st</sup> September 2021, recommend that consideration be given to providing an additional dose as a precautionary measure to older frail individuals, in particular to those living in closed setting, citing resident of LTC as an example. The European Medicines Agency (EMA) has not authorised additional or booster doses for any COVID-19 vaccine to date. However, the EMA has begun assessing data on booster doses to be given six months after the second dose of Comirnaty® and will consider whether to update the licensed product information to allow for booster doses in near future. In light of the current epidemiological situation, and in order to provide earliest protection to the groups identified by NIAC as requiring a booster dose, implementation of these recommendations may require an off-label use of mRNA Covid-19 vaccines. In this case, it is important that recipients of a booster dose would be provided with information regarding the evidence available (and as yet unknown) in regard to the safety and efficacy of a booster dose as part of the informed consent procedure.

NIAC have indicated that these recommendations are interim in nature and that they will continue to actively examine the evidence regarding waning immunity and reduced vaccine effectiveness in other groups, including older persons (under 80 years), those with underlying medical conditions, as well as health care workers. The current advices find that there is consistent evidence currently of continued vaccine effectiveness against breakthrough infections in healthcare workers.

I am endorsing the NIAC recommendations as set out above, which will be updated as required, based on any further NIAC advice.

Yours sincerely

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Dr Tony Holohan  
Chief Medical Officer