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

15th November 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

I have this evening received further recommendations from the National Immunisation Advisory Committee (NIAC) regarding booster doses of COVID-19 vaccines for those with underlying conditions and those aged 50-59 years old. The accompanying document (see enclosed) provides a comprehensive account of the evidence underpinning these recommendations as well as the previous NIAC recommendation (Nov 1st) *re* boosters for healthcare workers.

In coming to these recommendations, NIAC reviewed the latest epidemiology of COVID-19 in Ireland including in relation to breakthrough infections, hospitalisations and ICU admissions and deaths; the evidence in relation to duration of protective immunity following COVID-19 vaccination and data from clinical trials and observational studies on the safety and immunological impact of booster vaccination.

NIAC continues to strongly recommend that all individuals should be immunised with a primary series of an authorised COVID-19 vaccine. Unvaccinated individuals have much higher rates of infection, hospitalisation, ICU admission and mortality compared to those who are fully vaccinated. Those fully vaccinated against SARS-CoV-2 continue to demonstrate significantly lower odds of infection compared to those who remain unvaccinated and, when breakthrough infections do occur, symptoms tend to be milder in vaccinated individuals. Notwithstanding the significant protective effects of COVID-19 vaccines, NIAC notes that vaccines are but one element of a multi-pronged approach necessary to control the level of circulating virus in the community and in limiting harm from disease.

Evidence suggests that vaccine effectiveness against infection and mild disease decreases over time following completion of the primary vaccination series, and that authorised vaccines are less effective against the highly transmissible Delta variant which could contribute to increased transmission of SARS-CoV-2 infection. However, to date, vaccines have been shown to maintain high vaccine effectiveness against serious illness, hospitalisation and death in most populations. There are data supporting that a decrease in protection may be greater in older age groups, the immunocompromised and in individuals with clinical risk factors for more severe outcomes.

A review undertaken by the Health Information and Quality Authority (HIQA) to assess the duration of vaccine efficacy and effectiveness against COVID-19 specifically in individuals with underlying health conditions found limited and inconsistent evidence regarding vaccine efficacy and effectiveness in those with underlying conditions. There was, however, some evidence from observational studies that vaccine effectiveness, particularly against infection, waned over time in those with underlying conditions. A study conducted by Public Health England observed greater reductions in vaccine effectiveness against hospitalisation in those in a clinical risk group, compared with those not in a clinical risk group, albeit only in those who were 65 years and older. Data from the REACT study in Scotland demonstrated that the rate ratios for severe COVID were higher for those with moderate risk conditions and highest for the clinically extremely vulnerable. Further, a study based on national Swedish registry data with up to nine months follow-up reported greater reductions in vaccine effectiveness, particularly against infection, in those with underlying conditions, compared with the general population. It is also noted by NIAC that in Ireland, 81% of those aged 15 years and older admitted to ICU with COVID during the period June 27th to October 30th had an underlying condition. Similarly, data from the US and Israel show a high percentage of those hospitalised or admitted to ICU as a result of COVID had at least one underlying condition.

Thus, given the higher risk of severe disease outcomes in those with underlying conditions, any additional reduction in vaccine effectiveness may be of concern and, on that basis, **NIAC has today recommended a booster dose of an mRNA vaccine for those aged 16-59 years who have an underlying condition (as outlined in Table 5a.2 of the Immunisation Guidelines) and all residents in long-term healthcare facilities, irrespective of age, many if not all of whom will have an underlying condition.**

Next in order of priority for booster vaccination, **NIAC has recommended that a booster dose of an mRNA vaccine be offered to those aged 50-59 years.** NIAC point out that the risk of vaccinated people aged 50-59 years requiring hospitalisation and becoming seriously ill and dying is higher than in younger age groups. Moreover, as age increases, the strength and durability of neutralising antibody response decreases. There is emerging evidence which supports that neutralising antibodies (which are increased following a booster dose of a COVID-19 vaccine) are an important correlate of protection against SARS-CoV-2. Further, NIAC note the adeno-viral vector vaccines (which many in this age group will have received) have a lower initial vaccine efficacy against infection compared with mRNA vaccines and there are some data to suggest protection against infection and symptomatic disease (as distinct from severe disease) decreases more quickly with adeno-viral vector vaccines.

For all the aforementioned groups, NIAC has recommended a full dose of Comirnaty© or a half dose of Spikevax© be given six months (minimum five-month interval) following completion of the primary vaccination schedule with any authorised COVID-19 vaccine. Recipients of COVID-19 vaccine Janssen© as their primary vaccine should receive an mRNA booster dose after an interval of three months. On a precautionary basis, due to preliminary data indicating an increased frequency of myocarditis and pericarditis following a second dose of a COVID-19 mRNA vaccine in younger males and adolescents, in particular for Spikevax©, NIAC has recommended a booster dose of Comirnaty© exclusively for those aged 16-29 years.

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

The rate of myocarditis and pericarditis following a booster dose of COVID-19 mRNA vaccine is currently unknown, although initial data from Israel has shown a lower rate of myocarditis following a booster dose than with the second dose of the primary vaccine series. Unpublished data from the Cov-Boost trial conducted in the UK suggest that mRNA booster doses are well tolerated and provide a strong booster effect, irrespective of the vaccine used in the primary series.

In line with previous NIAC recommendations on booster doses, where an individual has had a breakthrough infection, the booster dose should be deferred for a least six months following onset of the infection. In cases where an mRNA vaccine is contraindicated, NIAC has stated that consideration can be given to boosting with an authorised non-mRNA vaccine following an individual risk-benefit assessment.

Evidence from clinical trials indicate that booster doses of mRNA vaccines given six months after the primary series elicits a robust immune response, including against the Delta variant, and has a safety profile comparable to that observed after the primary vaccination series. The risk of myocarditis or other rare adverse reaction following an mRNA booster dose has yet to be characterised and will be closely monitored. Emerging real-world evidence from Israel's booster program indicates that a third dose of Comirnaty© resulted in improved short-term vaccine effectiveness against infection and severe illness. Indeed, in the Irish context, booster doses given to those aged 80 years and older have been followed by a sharp decline in case numbers in that age group. There are currently no data on the long-term effectiveness of booster doses, so it remains unclear how long the benefit of boosters may persist, or the magnitude of the effect boosters have on transmission of the virus.

I am endorsing the NIAC recommendations as set out above, and NIAC has advised that it continue to examine new evidence regarding the durability of protection of the primary vaccine series in other groups, including younger age groups who received adenoviral vector vaccines. You will be aware that last week I corresponded with NIAC and asked for the Committee to consider the likely requirements of the national programme for the coming six months in the interests of facilitating logistical planning.

Yours sincerely

Dr Tony Holohan
Chief Medical Officer

Designated Public Official under Regulation of Lobbying Act 2015

Bloc 1, Plaza Míseach, 50 - 58 Sráid Bhagóid Íochtarach, Baile Átha Cliath 2, D02 XW14
Block 1, Miesian Plaza, 50 - 58 Lower Baggot Street, Dublin 2, D02 XW14
T +353 1 635 4251 | info@health.gov.ie
www.health.gov.ie