



31st August 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

On August 30th I received advice from the National Immunisation Advisory Committee (NIAC) regarding the need for an additional vaccine dose for those who are immunocompromised (see attached). This additional dose, intended to improve immunocompromised individual's response to their *initial* vaccine schedule, is distinguished from booster doses which may be required by some, or all of the population, as a result of waning immunity and vaccine effectiveness over time. In the latter regard, NIAC is actively reviewing the evidence regarding a waning of the immune response to a primary vaccine series and a decrease in vaccine effectiveness in a number of groups, including residents of long-term residential care facilities, older persons, those with underlying medical conditions and healthcare workers. It has been indicated by NIAC in the current advice that more evidence in respect of the safety and effectiveness of booster doses in these groups is expected in the coming days and weeks and that recommendations will follow.

There is now an accumulation of evidence that those who are immunocompromised mount a suboptimal response to COVID-19 vaccines, and data from the US indicates that 40-44% of breakthrough infections leading to hospitalisation are in the immunocompromised. This group are also at risk of severe disease and prolonged viral shedding during which variants can emerge which could prove to be vaccine resistant. There is currently limited evidence available on the effectiveness of an additional dose of COVID-19 vaccines, however, in studies following a third dose of Comirnaty® or Spikevax®, significantly higher levels of neutralising antibody titres were observed compared to those detected following a two-dose primary vaccination series. Higher levels of seroconversion have also been documented in immunocompromised patients following a third dose of Comirnaty®. Importantly, data from studies and real-world experience in Israel have not identified any safety concerns after administration of a third dose of an mRNA vaccine. In that context, **NIAC has recommended an extended primary vaccination course with an mRNA vaccine for immunocompromised individuals aged 12 years and older, regardless of whether the primary course was of an mRNA or an adenoviral vector vaccine.** The third dose of an mRNA vaccine should be given a minimum of two months after the last dose of the primary vaccination schedule. In addition, NIAC has reiterated the importance of those who are immunocompromised and those who are living and/or caring for them should observe all the recommended public health advice to limit their COVID-19 exposure.

The Centres for Disease Control (CDC) has recently recommended that individuals who are moderately to severely immunocompromised should receive an additional dose of mRNA COVID-19 vaccine after the initial two doses. The US Food and Drug Administration (FDA) has amended the use authorisations for both Comirnaty® and Spikevax® to allow for the use of an additional dose in immunocompromised individuals. A number of European countries, including Austria, Belgium, France, Hungary, Luxembourg, Lithuania and Slovenia, are also recommending the use of an additional vaccine dose for those who are immunocompromised. However, it should be noted that, to date, there has been no variation to the licence granted by the European Medicines Agency (EMA) to authorise a third dose for immunocompromised individuals, although the issue is under active consideration. Moreover, it is likely that the various statutory instruments governing the administration of COVID-19 vaccines will have to be amended to facilitate the administration of a third dose to those who are immunocompromised.



On a more general note, contained in current advices, NIAC has also recommended **that all those eligible for vaccination but who remain unvaccinated or indeed partially vaccinated should be strongly encouraged to initiate/complete their vaccination course.** Moreover, in an effort to minimise the risk of other respiratory infections, **the 2021/22 seasonal influenza vaccination programme should proceed as planned, and efforts enhanced to optimise uptake.**

In further advice also received yesterday (see attached), NIAC has updated its recommendations regarding vaccination for pregnant women. In April of this year, NIAC advised that pregnant women should be offered mRNA COVID-19 vaccination between 14-36 weeks' gestation following an individual benefit/risk discussion with their obstetric care giver. Following a review of the most recent evidence and in the context of the Delta variant, NIAC has recommended that the previous term limits for receiving a vaccine by a pregnant woman should be removed and **pregnant women and adolescents from 12 years and above should be offered an mRNA COVID-19 vaccine at any stage of pregnancy, following an individual benefit/risk discussion with their obstetric care giver.**

In its advice, NIAC point out that while pregnant women are not more likely to contract SARS-CoV-2 than non-pregnant women, if they do become infected, pregnant women are at increased risk of hospitalisation, and are at significantly higher risk of ICU admission. Data collected between late June and early August this year, when Delta has been the predominant variant circulating, shows an increase in hospitalisations and ICU admissions in pregnant/postpartum women compared to previous waves. Similar data are reported from the UK. Pregnant/recently postpartum women now represent 9.4% of ICU admissions in this country. NIAC also point to a growing accumulation of evidence on the safety and effectiveness of COVID-19 vaccination in this cohort, which indicate that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy. NIAC have also recommended **that there should be enhanced efforts to increase vaccine uptake in pregnant women, their partners and eligible household contacts,** in order to protect both mother and baby from serious harm as a result of COVID-19.

I am endorsing the recommendations as set out above.

Yours sincerely

Dr Tony Holohan
Chief Medical Officer