

# COVID-19 VACCINE BULLETIN 33

Welcome to Bulletin 33 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

Bulletins will be published **FORTNIGHTLY** or more frequently, if required.

## Covered in this bulletin:

- ▶ Booster doses of COVID-19
- ▶ Updated list of immunocompromise associated with suboptimal response to vaccines
- ▶ Extended primary course for immunocompromised
- ▶ FAQ re extended primary course and booster doses

Completing a primary vaccination course remains key to the prevention of COVID-19. There is evidence of high effectiveness of all authorised COVID-19 vaccines against severe COVID-19 disease, including that caused by the Delta variant.

The National Immunisation Advisory Committee has recommended booster doses of vaccination in older people in specific groups; they have also recommended an additional dose of vaccine for people who are immunocompromised due to disease or treatment at the time of primary vaccination, to complete the primary vaccination course.

## Booster doses for older people

NIAC has recommended that a booster dose of mRNA vaccine be given to all those

- Age 80 years and older
- Age 65 years and older living in a long term residential care facility

**No other groups are recommended to receive a booster dose of vaccine at this time. Booster doses should not be given to anyone outside of these groups.**

A single dose of an mRNA vaccine is recommended as a booster dose irrespective of what type of vaccine they received for their primary course.

The booster dose should be given after an interval of six months or more following the last dose of an authorised COVID-19 vaccine (in exceptional circumstances, a minimum interval of two months can be used between the booster dose and the last dose of an authorised COVID-19 vaccine).

The booster dose can be given at the same time or at any interval before or after seasonal influenza vaccine, or other vaccines such as PPV23.

If a person has had a laboratory-confirmed COVID-19 breakthrough infection since completing their primary COVID-19 vaccine course, then the booster dose should be delayed for 6 months following the onset of infection. This is because vaccination following infection is highly immunogenic and recent evidence indicates that a breakthrough infection results in a strong booster response in fully vaccinated older people.

**It is not recommended to perform serological testing prior to administering a booster dose of vaccine.**

We have developed FAQs to support vaccinators who will be administering booster doses

[Click here](#)

**Operational guidance will be issued separately once these recommendations are operational.**

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## Immunocompromise associated with suboptimal response to vaccines

NIAC have updated the table 5.a.2 in chapter 5a COVID-19 vaccine. Those with conditions listed in the shaded areas, **at the time of vaccination**, may be associated with a suboptimal response to vaccines and patients with these conditions should be given an additional dose of mRNA vaccine.

Medical condition	Very high risk	High risk
<b>Cancer</b>	Receiving or within 6 weeks of receiving systemic cytotoxic chemotherapy, targeted therapy, monoclonal antibodies or immunotherapies  Receiving treatment or pending treatment for a haematological cancer  Undergoing or within 6 weeks of surgery or radical radiotherapy for lung or head and neck cancer  Advanced/ metastatic cancer	Haematological <sup>1</sup> - within 5 years of treatment  Non haematological cancer within 1 year following immunomodulating treatment  All other cancers being treated (excluding hormonal treatment)
<b>Chronic heart and vascular disease</b>		e.g. heart failure, hypertensive cardiac disease
<b>Chronic kidney disease</b>	On dialysis, or eGFR <15 ml/min	eGFR <30ml/min
<b>Chronic liver disease</b>		e.g. cirrhosis or fibrosis
<b>Chronic neurological disease or condition</b>	With evolving respiratory failure requiring non-invasive ventilation e.g. motor neurone disease, spinal muscular atrophy	Significantly compromised respiratory function and/or the ability to clear secretions e.g. Parkinson's disease, cerebral palsy
<b>Chronic respiratory disease</b>	Severe e.g. severe cystic fibrosis, severe COPD, severe pulmonary fibrosis	Other conditions e.g. stable cystic fibrosis, severe asthma (continuous or repeated use of systemic corticosteroids), moderate COPD
<b>Diabetes</b>	HbA1c ≥58mmol/mol	All other diabetes (Type 1 and 2)
<b>Immunocompromise due to disease or treatment</b>	Severe e.g. <b>Transplantation:</b> - Listed for solid organ or haematopoietic stem cell transplant (HSCT) - Post solid organ transplant at any time - Post HSCT within 12 months <b>Genetic diseases:</b> - APECED <sup>2</sup> - Inborn errors in the interferon pathway <b>Treatment:</b> - including but not limited to Cyclophosphamide, Rituximab, Alemtuzumab, Cladribine or Ocrelizumab in the last 6 months	Other e.g. High dose systemic steroids <sup>3</sup>  HIV, not on treatment or CD4 count <200 x10 <sup>6</sup> /L for adults
<b>Inherited metabolic diseases</b>	Disorders of intermediary metabolism/at risk of acute decompensation e.g. Maple Syrup Urine Disease	Disorders of intermediary metabolism not fulfilling criteria for very high risk
<b>Intellectual disability</b>	Down Syndrome	Intellectual disability excluding Down Syndrome
<b>Obesity</b>	BMI >40 Kg/m <sup>2</sup>	BMI >35 Kg/m <sup>2</sup>
<b>Severe mental illness</b>		e.g. schizophrenia, bipolar disorder, severe depression
<b>Sickle cell disease</b>	Sickle cell disease	

<sup>1</sup> Includes e.g., leukaemia, lymphomas, blood dyscrasias or other malignant neoplasms affecting the bone marrow or lymphatic systems

<sup>2</sup> APECED - autoimmune polyendocrinopathy candidiasis ectodermal dystrophy

<sup>3</sup> The following doses of prednisolone (or equivalent dose of other glucocorticoid) are likely to be immunosuppressive:

- Adults and children ≥10kg: ≥40mg/day for more than 1 week, or ≥20mg/day for 2 weeks or longer
- Children <10 kg: 2mg/kg/day for 2 weeks or longer

[Read more here](#)

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## Extended primary schedule for immunocompromised people

NIAC have recommended an extended primary schedule for individuals who are immunocompromised at the time of vaccination which is associated with suboptimal response.

- one mRNA vaccine dose is recommended for all aged 12 and older with immunocompromise at the time of vaccination, who have completed a COVID-19 vaccine course with either an mRNA or an adenoviral vector vaccine
- the mRNA vaccine should be given after a minimum interval of two months following the last dose of an authorised COVID-19 vaccine. This additional dose is to allow them to mount an adequate immune response to the primary vaccination schedule.

If a person has had a laboratory-confirmed breakthrough infection since their last dose of COVID-19 vaccine, then the additional dose should be delayed for 6 months following the onset of confirmed COVID-19 infection. This is because vaccination following infection is highly immunogenic.

**It is not recommended to perform serological testing prior to administering an additional dose of vaccine.**

There is limited data available on this extended primary course, but NIAC will continue to monitor the evidence. This is an off label use of the vaccine but no safety concerns have been raised in the reviewed data.

**Operational guidance will be issued separately, however when recording the extended primary course dose please remember that this is part of the primary course and it is not a booster dose. This is important as booster doses may be needed in future.**

We have developed FAQs for healthcare professionals

[Click here](#)



**Why it is an additional primary dose recommended for people who are immunocompromised at the time of vaccination?**

There is evidence of an inadequate response to the COVID-19 vaccination course for these groups who are immunocompromised due to disease or treatment.

Those with immunocompromise with a suboptimal response to vaccines are particularly vulnerable to SARS-CoV-2 infections. They are more likely to get severely ill from COVID-19 and they are at risk of prolonged viral shedding.

While overall vaccine effectiveness against hospitalisation for COVID-19 was 86% in a US study, it was 90% among the immunocompetent compared with 63% in the immunocompromised. Forty to 44% of hospitalised breakthrough infections were in the immunocompromised.

A report from the European Centre for Disease Prevention and Control (ECDC) advises that additional doses should be considered for people with severely weakened immune systems as part of their primary vaccination.

**Frequently asked questions are continued on page 4** 

# COVID-19 VACCINE BULLETIN 33

## **FAQs on people who are immunocompromised who require an extended COVID-19 vaccination course**

(continued from page 3)



### **Which COVID-19 vaccine is recommended as an additional primary dose?**

One dose of an mRNA vaccine is recommended to complete the primary COVID-19 vaccine course. This advice is the same regardless of the vaccine(s) that was previously administered. In the HSE programme, a dose of Comirnaty® (Pfizer/BioNTech) will be offered.



### **How soon after completing a course should the additional dose be given?**

The mRNA vaccine should be given after a minimum interval of two months following the last vaccine administered.



### **Is there scientific evidence of benefit and safety?**

Pfizer/BioNTech reported that data in individuals who received a third dose of Comirnaty® show a favourable safety profile and robust immune responses. The additional dose elicited significantly higher neutralising antibody titres against the initial SARS-CoV-2 virus (wild type), and the Beta and Delta variants, compared to the levels observed after the two-dose primary series.

Two reports of successful enhancement of immune response in solid organ transplant recipients have been reported. In a randomised controlled trial with 120 organ transplant recipients, median age 66 years, an additional dose of Spikevax® (Moderna) was given two months after the second dose and resulted in significant increases in antibody levels and neutralising antibody activity.

There is also preliminary evidence of the safety of giving a 3rd mRNA vaccine dose from Israel where a population based booster programme of Comirnaty® administered to the approximately one million people has already taken place. Data shared by the Israeli Health Ministry reported that no safety concerns were identified with similar safety profile but lower rates of systemic and local reactions than following the first or second doses.



### **Is it recommended to check serology before administering an additional primary dose?**

No. This is not recommended. There is no agreed or recommended correlate of protection (there is no agreed or recommended antibody level above which you would not vaccinate, or below which you would vaccinate).

**Frequently asked questions are continued on page 5**



# COVID-19 VACCINE BULLETIN 33

## FAQs on people who are immunocompromised who require an extended COVID-19 vaccination course

(continued from page 4)



**What is the recommended timing of the additional primary dose in immunocompromised people who have had laboratory-conformed breakthrough infection since they completed their COVID-19 vaccination course?**

The additional primary dose should be delayed for at least six months after the laboratory-conformed COVID-19 infection was diagnosed. Serological testing prior to giving a dose is not recommended. If it is not possible to establish if breakthrough COVID-19 infection occurred within this timeframe, the individual may be vaccinated.



**What vaccine is recommended if someone has a contraindication to an mRNA vaccine?**

An additional adenoviral vector vaccine (Vaxzevria® (Astrazeneca) or COVID-19 Vaccine Janssen®) can be considered for those with a contraindication or precaution to an mRNA vaccine.



**Why aren't other people with underlying conditions recommended to get an additional primary dose of COVID-19 vaccine?**

A third primary dose of an mRNA vaccine is only recommended for those with immunocompromise in order for them to complete primary immunisation. This is not a booster dose, but an additional dose to allow them to mount an adequate primary immune response to vaccination.

Other groups do not have a suboptimal response to vaccines and therefore do not require an additional to complete primary immunisation.

**For more information**

[Click here](#)

**Clinical Guidance for COVID-19 Vaccination**

[Click here](#)

## New Resource - Talking to healthcare workers about COVID-19 vaccines

Talking to healthcare workers about COVID-19 vaccines" a video from Dr Chantal Migone, Specialist in Public Health Medicine, National Immunisation Office.

### Learning Objectives:

At the end of the video, you will

- Understand the principles of communicating with people who are undecided or "hesitant" about vaccines
- Learn skills to listen and engage in conversation aimed at building trust in vaccines
- Be able to respond to common concerns about COVID-19 vaccines



[Click here](#)

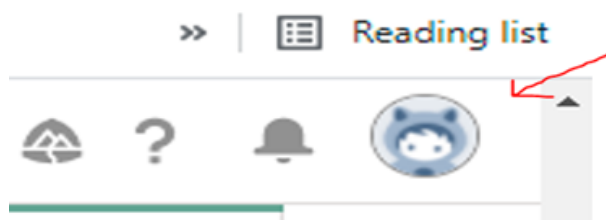
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## Resetting your Vaccinator Pin or Medical Council Number on the HSE COVAX System

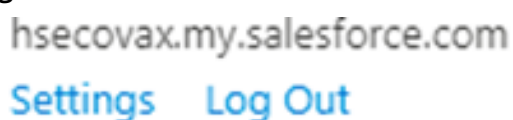
It is a legal requirement if you are a COVID-19 Vaccinator that you record your Professional Registration and relevant Pin Number or Medical Council Number for Doctors.

To check that your details are correct please go into Settings on COVAX:

- 1 Click on the person icon at the top right hand corner of the COVAX page

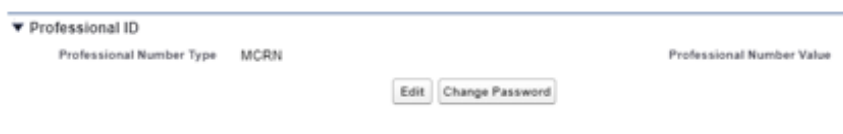


- 2 Go to Settings

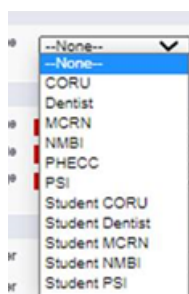


- 3 Search for Advanced User Details

- 4 Click on Advanced User section and scroll down and you can now add your pin and registration details and then SAVE



- 5 If you are a student pick the list that applies to you as listed below



- 6 Input the number you have been advised to use for this section if you are a student and for all other make sure you have a pin or medical council number here



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## Website

Visit our website [www.immunisation.ie](http://www.immunisation.ie) regularly for the most up to date information to support vaccinators and health professionals responding to queries.

Our dedicated COVID-19 Vaccination section contains

- Information from the National Immunisation Advisory Committee
- Clinical guidelines
- COVID-19 vaccine studies
- IM injection technique reminders
- Dedicated pages for the licensed COVID-19 vaccines

[Visit here](#)

## HSeLand COVID-19 Vaccination Training Programme

You can access updates to the National Immunisation Office COVID-19 Vaccination Training Programme for Pfizer, Moderna, AstraZeneca and Janssen vaccine through your HSeLand account.

[Visit HSeLand](#)

We would encourage you to log in and complete the updated content in each programme to refresh your knowledge and ensure you are up to date with your COVID-19 Vaccination Training.

If you have any issues with the platform please contact HSeLand directly.

[Contact HSeLand](#)

## Do you have queries?

Clinical queries from healthcare professionals can be directed to our HSE email address.

[Send your query](#)



Should vaccines be exposed to temperatures outside of parameters please contact the National Immunisation Office pharmacists immediately. Contacts include:

- Achal Gupta: mobile 087 4064810
- Mariangela Toma: mobile 087 7575679
- Cliona Kiersey: mobile 087 9915452

**The National Immunisation Office is not involved in the allocation or delivery of COVID-19 Vaccines.**

**Queries that are not clinical or technical cannot be answered by the National Immunisation Office**

Read about the role of the National Immunisation Office in supporting the COVID-19 vaccination programme on our [website](#).

Recommendations about COVID-19 vaccine are changing as more information becomes available so please visit our [website](#) for the most up to date information.