COVID-19 VACCINE BULLETIN 34

Welcome to Bulletin 34 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

COVID-19 Vaccines for people who are immunocompromised

EMA recommendations on extra doses of COVID-19 vaccine for those with immunocompromised and on boosters

The EMA's human medicines committee (CHMP) has concluded that an extra dose of the COVID-19 vaccines Comirnaty® (Pfizer BioNTech) COVID-19 mRNA Vaccine and SpikeVax® (COVID-19 Vaccine Moderna) may be given to people with severely weakened immune systems, at least 28 days after their second dose.

The recommendation comes after studies showed that an extra dose of these vaccines increased the ability to produce antibodies against the virus that causes COVID-19 in organ transplant patients with weakened immune systems.

The product information of both vaccines will be updated in due course to include this recommendation.
EMA has also recommended Comirnaty can be used as a booster for persons aged 18 and over at least 6 months after their second dose. The EMA is currently reviewing the data for Spikevax.

Read more here

Please note that where EMA recommendations differ from NIAC advice, in Ireland we follow NIAC recommendations regarding groups who are eligible for a booster or extra dose and at what interval.

Read NIAC guidelines here

NIAC advice on the required interval for an extra mRNA vaccine

The National Immunisation Advisory Committee (NIAC) have advised one COVID-19 vaccine dose for all aged 12 and older with immunocompromise who have received a COVID-19 vaccine course with either an mRNA (Pfizer or Moderna) or an adenoviral vector vaccine (AstraZeneca or Janssen) to complete their primary immunisation course. NIAC still advise the mRNA vaccine should be given after a minimum interval of two months following the recommended COVID-19 vaccine course. This dose is now approved by the EMA.

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

Third dose after breakthrough infection for people who are immunocompromised

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.

However if it is not possible to establish if breakthrough COVID-19 infection occurred within this timeframe, the individual may be vaccinated.

People with 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 area only, 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.

Please see detailed information on such conditions and treatment: **Click here**

We have developed FAQs for healthcare professionals: **Click here**

COVID-19 VACCINE BULLETIN 34

EMA Safety Committee (PRAC) Updates on COVID-19 Vaccines

Released 1st October 2021

Rare cases of Venous Thromboembolism (VTE) after COVID-19 Vaccine Janssen®

VTE (which is different from TTS or Thrombosis with Thrombocytopenia syndrome) was added a rare (frequency >1/10,000 to <1/1,000) side effect of COVID-19 vaccine Janssen based on data from clinical trials and post marketing surveillance. Healthcare professionals and individual receiving the vaccine should be aware of this risk, especially in those who may have an increased risk of VTE.

Immune Thrombocytopenia (ITP) with Vaxzevria® Vaccine (AstraZeneca) and COVID-19 Vaccine Janssen®

ITP is a condition in which the immune system mistakenly targets blood cells called platelets that are needed for normal blood clotting. It can cause bleeding and can sometimes be fatal.

Very few cases of ITP have occurred after both Vaxzevria and COVID-19 Vaccine Janssen. It has usually occurred within 4 weeks of vaccination and will be added as a side effect for both vaccines (frequency unknown).

If an individual has a history of thrombocytopenic disorder, the risk of developing low platelet levels such as ITP should be considered before vaccination, and platelet monitoring is recommended after vaccination with either of these vaccines in an individual who has a history of ITP.

Read more here

Updated Adverse Reactions for COVID-19 Vaccines

The following side effects are to be/added to the product information for COVID-19 vaccines.

Comirnaty® (Pfizer BioNTech) COVID-19 mRNA Vaccine	Uncommon: Hyperhidrosis (night sweats), decreased appetite, asthenia and lethargy Frequency unknown: Erythema Mulitforme
SpikeVax® (COVID-19 Vaccine Moderna)	Frequency unknown: Erythema Mulitforme
Vaxzevria® Vaccine (AstraZeneca)	Common: pain in extremity, influenza-like illness, asthenia Uncommon: lethargy, urticaria , abdominal pain
COVID-19 Vaccine Janssen®	Uncommon: diarrhoea and paraesthesia Rare: hypoesthesia, lymphadenopathy, vomiting and tinnitus Frequency unknown: Transverse Myelitis

Find the updated product information for COVID-19 vaccines here: **Read more here**

Training, clinical guidance, medicines protocols and supporting documents are being updated to reflect these changes.

COVID-19 VACCINE BULLETIN 34

Completing a vaccination course after 1 dose of SpikeVax® (COVID-19 Vaccine Moderna)

People who received SpikeVax® (COVID-19 Vaccine Moderna) as dose 1 who are not yet "Course Complete" can now receive a Comirnaty® (Pfizer BioNTech) COVID-19 mRNA Vaccine as dose 2 if SpikeVax® (COVID-19 Vaccine Moderna) is not available.

NIAC have advised the National Immunisation Office that

"*in exceptional situations where the mRNA vaccine product given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series.*"

If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time. Such persons are considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the second dose of an mRNA vaccine.

COVID-19 vaccination outside Ireland

NIAC guidance advises:

"*Those who have documentary evidence of a complete COVID-19 vaccination course with a COVID-19 vaccine authorised by the FDA, MHRA or recommended by WHO should be considered fully vaccinated.*

People who have partially completed a COVID-19 vaccine course with a vaccine authorised by the FDA, MHRA or recommended by WHO should be offered an EMA authorised COVID-19 vaccine to complete the series, and then should be considered fully vaccinated.

The minimum interval between the last vaccine dose and an EMA authorised COVID-19 vaccine is 28 days."

Read more here

Anyone who has documentation showing completion of the following vaccine courses, requires no further COVID-19 vaccines if they are resident in Ireland.

Approved COVID-19 Vaccines	Doses required
Comirnaty® (Pfizer BioNTech) COVID-19 mRNA Vaccine	2
SpikeVax® (COVID-19 Vaccine Moderna)	2
Vaxzevria® Vaccine (AstraZeneca)	2
COVISHIELD (interchangeable with Vaxzevria® Vaccine (AstraZeneca))	2
COVID-19 Vaccine Janssen®	1
Sinovac-CoronaVac COVID-19 vaccine	2
Sinopharm (Beijing)	2

WHO COVID-19 Approved vaccines

Click here

WHO advice

Click here

The Sinopharm (Wuhan): Inactivated (Vero Cells) and Sputnik V COVID-19 vaccine are not not currently WHO approved.

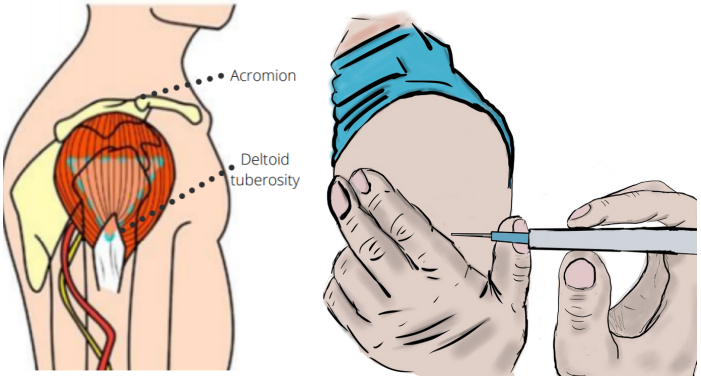
Anyone who has received these vaccines should be offered a complete course of an EMA approved vaccine.

COVID-19 VACCINE BULLETIN 34

Reminder about IM Injection Technique

All vaccinators must be competent in IM injection technique which includes correct landmarking of the injection site to ensure the vaccine is given in the correct area of the Deltoid muscle.

Below is a reminder of IM injection technique. **Note: COVID-19 vaccine should be given IM only.**



Summary sheet outlining the IM injection technique

Click here

When vaccinating adolescents aged 12-15 years, the same intramuscular injection technique should be followed as for adults.

The injection site must be landmarked correctly to avoid injury associated with administration of the vaccine in the wrong site.

Several supporting documents, training videos and modules are available on correct IM injection technique.

Watch Training video

Click here

Training is also included in HSELand modules

Click here

More IM Injection Technique materials

Click here

Please contact your clinical lead or line manager if you need additional support or training.

COVID-19 VACCINE BULLETIN 34

Frequently asked questions

Who should receive a booster dose of COVID-19 vaccine?

The National Immunisation Advisory Committee has advised the following:

One booster dose of an mRNA vaccine is recommended for all those aged 80 and older and those aged 65 years and older who are living in long term care facilities (LTCFs), who have already completed their primary course with any COVID-19 vaccine type.

Can booster COVID-19 vaccine be given to other groups?

Booster doses should not be administered to anyone who it has not been recommended for by NIAC. There is currently no recommendation for booster doses in any other groups. NIAC continues to review evidence regarding the duration of immunity and the durability of vaccine effectiveness in other groups.

What interval should be used when giving the booster dose COVID-19 vaccine for eligible groups?

The booster dose should be given after an interval of six months following the last dose of an authorised COVID-19 vaccine.

The 6 months interval is recommended to provide maximum efficacy for the longest possible time. The booster dose is still effective when given before a 6 months interval however following a the 6 months interval maximises the protection provided by the booster dose after completion of the Primary COVID-19 vaccine schedule.

Can boosters be given less than 6 months since last COVID-19 vaccine dose?

NIAC have advised that in exceptional circumstances a minimum interval of 2 months after the last dose may be used.

The Statutory Instrument (SI) to enable non-medical vaccinators to provide COVID-19 vaccines in HSE CVC's states an interval of 6 months, so vaccines given before 6 months must be given by a doctor or otherwise on prescription. Practice nurses administering vaccines in general practice are acting under the instruction of their GP rather than the SI, as is the case for other vaccines.

Who is recommended to get an additional COVID-19 vaccine?

NIAC have advised that people aged 12 years and older who are immunocompromised at the time of vaccination, due to disease or treatment, should receive one additional dose of a COVID-19 vaccine.

Frequently asked questions are continued on page 7

COVID-19 VACCINE BULLETIN 34

Frequently asked questions (continued from page 6)

What is the difference between a booster dose and an additional primary dose of COVID-19 vaccine?

An additional dose of COVID-19 is only recommended for those with immunocompromise in order for them to complete primary immunisation.

A booster dose is recommended for groups where a number of breakthrough cases have been observed to protect them from COVID-19.

The Pfizer vaccine being used for the booster and additional doses is the same vaccine and dosage as used for the primary course.

Can other vaccines be given at same time as COVID-19 vaccine?

COVID-19 vaccines can be given on same day or at any time interval from other vaccines including the seasonal flu vaccine so there is no need to delay any vaccinations after the COVID-19 vaccine unless the patient has an acute febrile illness.

See advice below from NIAC:

Co-administration

COVID-19 vaccines and other vaccines may be administered at the same time or at any interval.
As it is not known if COVID-19 vaccine reactogenicity is increased with co-administration, vaccines should preferably be given in different limbs.

Read more here

Do sites need to order a new supply COVID-19 vaccine before offering booster or additional primary doses of COVID-19 vaccine?

Sites who have a supply of Comirnaty® (Pfizer BioNTech) COVID-19 mRNA Vaccine that is in date and stored appropriately can use this supply for patients who need a booster dose or an additional primary dose of COVID-19 vaccine.

Monthly Safety Update Report from the HPRA

The HPRA have released their regular monthly safety update for COVID-19 vaccines.

To date there have been nearly 15,500 adverse events reported to the HPRA regarding COVID-19 vaccines – this is in the context of over 7 million doses administered. Most side effects reported are mild to moderate.

The report also highlights some of the recent EMA updates from the safety committee meetings and safety update reports.

Read more here

COVID-19 VACCINE BULLETIN 34

Research

The Safety and Immunogenicity of Concomitant Administration of COVID-19 Vaccines (ChAdOx1 or BNT162b2) with Seasonal Influenza Vaccines in Adults: A Phase IV, Multicentre Randomised Controlled Trial with Blinding (ComFluCOV)

This preprint from The Lancet states "Concomitant vaccination raises no safety concerns and preserves the immune response to both vaccines."

Adults in receipt of a single dose of ChAdOx1 (Vaxzevria) or BNT162b2 (Comirnaty) were enrolled at 12 UK sites and randomised 1:1 to receive concomitant administration of either age-appropriate influenza or placebo alongside second COVID-19 vaccine.

Between 1st April and 26th June 2021, 679 participants were recruited. Overall, 340 participants were randomised to concomitant administration of influenza and COVID-19 vaccine and 339 were randomised to placebo and COVID-19 vaccine. Rates of local and unsolicited systemic reactions were similar between randomised groups.

Concomitant vaccination raises no safety concerns and preserves the immune response to both vaccines.

Read more here

Safety Monitoring of an Additional Dose of COVID-19 Vaccine — United States, August 12– September 19, 2021

As of September 19, 2021, approximately 2.21 million persons in the United States had received additional doses of COVID-19 vaccines after completion of a primary series. During August 12–September 19, no unexpected patterns of adverse reactions were observed among 22,191 who received an additional dose of COVID-19 vaccine. Most reported local and systemic reactions were mild to moderate, transient, and most frequently reported the day after vaccination. No unexpected patterns of adverse reactions were identified; those reported were mild to moderate and transient.

A study conducted among immunocompromised hemodialysis patients also reported that local and systemic reactions after dose 3 of Pfizer-BioNTech vaccine were similar to those after dose.

Read more here

COVID-19 VACCINE BULLETIN 34

GP and Pharmacies can now order LAIV

Fluenz Tetra, the live attenuated influenza vaccine (LAIV) is now available to order for 2-17 year olds for the 2021/2022 influenza season.

LAIV is given intra nasally and is the recommended for all children aged 2 to 17 years at the time of vaccination. It is also the recommended vaccine for children who are considered medically at risk.

QIV vaccine should only be offered to children who have a contraindication to LAIV vaccine.

The ideal time for vaccination in Ireland is before the influenza season, e.g. in October.

The LAIV protects children and reduces the spread of flu to other high-risk persons.

Place your order for the LAIV through your national cold chain account today.

Order LAIV Vaccine — **Click here**

Learn more about HSE 2021/2022 Seasonal Influenza Vaccination Programme — **Click here**

COVID-19 VACCINE BULLETIN 34

Website

Visit our website **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

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.