COVID-19 VACCINE BULLETIN 35

Welcome to Bulletin 35 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

NIAC Recommendations

The National Immunisation Advisory Committee (NIAC) has extended its recommendations for booster doses to people aged 60 and older. This recommendation has been accepted by the Department of Health.

No other groups are recommended booster doses at this time.

The recommended interval between completion of primary vaccination course and the booster dose is 5-6 months (a 6 month interval is preferred). The 6 months interval is preferred to provide maximum efficacy for the longest possible time. If required the booster dose may be given at a 5 month interval. This applies whether the primary course was an mRNA or viral vector vaccine.

The minimum interval of 2 months can be used in exceptional circumstances. The minimum interval recommended is 2 months but this is only in exceptional circumstances e.g. before international travel or if the person cannot have the vaccine at 6 months and there is no other opportunity to provide the vaccine.

Read more here

This extension of the booster programme has not yet been operationalised by the HSE. Planning is underway. A number of changes are needed including the statutory instrument, medicines protocols, IT system etc. Further information will be issued in due course. Clinical guidance, FAQs training etc. are being updated.

COVID-19 vaccines given before the recommended or minimum interval

It is very important to check on COVAX or the practice records the date when the person received their last dose of COVID-19 vaccine to ensure that the next dose is not given before the recommended interval. We have been asked about the need for a repeat dose of booster or an additional dose in immunocompromised people, when vaccines are given in error before the minimum interval of 2 months. The National Immunisation Committee advises that there is currently no evidence for the efficacy and safety of administration of a further dose of vaccine in these circumstances, therefore the dose should not be repeated.

Frequently Asked Questions about COVID-19 Vaccines

We have included below some questions you may be asked about COVID-19 vaccines:

Can COVID-19 vaccines cause menstrual disturbances?

The EMA's safety committee have reviewed reports of menstrual disturbances for all COVID-19 vaccines authorised in the EU. The review for Comirnaty®, Spikevax® and Vaxzevria® was recently completed, and in conclusion, no specific pattern of menstrual disturbances could be found, with no evidence of a causal association or link between menstrual disturbances and vaccination.

Read more here

Are there any concerns about female fertility and COVID-19 vaccines?

No. It is biologically implausible that a COVID-19 vaccine (or any vaccine) would affect fertility. Reports claiming that COVID-19 vaccines cause female infertility are unfounded. mRNA contained in COVID-19 vaccines cannot interact with DNA. In September a study published in the American Society for Reproductive Medicine (ASRM) Fertility & Sterility Reports, documented that seropositivity to the SARS-CoV-2 spike protein - whether from vaccination or COVID infection - does not prevent embryo implantation or early pregnancy development.

Read more here

Frequently Asked Questions are continued on page 2

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Frequently Asked Questions about COVID-19 Vaccines (continued from page 1)

What about male fertility and COVID-19 vaccines?

Reports claiming that COVID-19 vaccines affect sperm count are also unfounded. There is no biologically plausible reason why a COVID-19 vaccine (or any vaccine) would affect fertility. It is biologically implausible that the vaccine would affect sperm parameters.

A study of sperm parameters in 45 men before and after 2 doses of a COVID-19 mRNA vaccine, showed there were no significant decreases in any sperm parameter among a small cohort of healthy men.

Read more here

What do we know about the safety of COVID-19 vaccines and pregnancy?

Pregnant women with COVID-19 infection are more likely to be admitted to ICU or to die than either pregnant women without COVID-19 or similar aged non-pregnant women with COVID-19. Poor foetal outcomes including pre-term delivery and stillbirth are also associated with COVID-19 infection in pregnancy.

Pregnant women (and pregnant adolescents from 12 years of age) should be offered COVID-19 vaccination at any stage in pregnancy following an individual benefit/ risk discussion with their obstetric caregiver.

Pregnant women were not included in the original vaccine trials (although are being included in subsequent studies). Animal studies of the mRNA vaccines did not show any potential risks. There is no known plausible biological mechanism through which the vaccines would affect the foetus. Hundreds of thousands of mRNA COVID-19 vaccines have been given in pregnancy in the USA, Israel and other countries. All data to date shows pregnancy complications rates in women who received mRNA vaccines to be the same as what would normally be expected. None of the currently available COVID-19 vaccines reach or cross the placenta. The intramuscularly administered vaccine mRNA remains in the deltoid muscle cell cytoplasm for just a few days before it is destroyed.

Read more here

However, protective antibodies to COVID19 have been shown to cross the placenta and may confer protection to the baby after delivery.

Read more here

What if the vaccine leaks from the syringe while it is been given?

When some of the vaccine is lost (patient moves, syringe leaks), it is difficult to judge how much vaccine the patient received. You should not count this as a valid vaccination.

As the COVID-19 vaccine is non-live, you should re-immunise the person as soon as possible, even at the same visit.

Should pregnant women receive an additional dose of a COVID-19 vaccine?

Pregnant women should receive a course of 2 doses of an mRNA vaccine, which can be given at any stage of pregnancy. There is no recommendation for pregnant women to receive an additional dose of a COVID-19 vaccine to complete their primary course. This is because they are expected to have an adequate immune response to the primary vaccination course. However, if a pregnant women has immunosuppression due to disease or treatment, as outlined in the NIAC guidelines, she should receive an additional dose of an mRNA vaccine.

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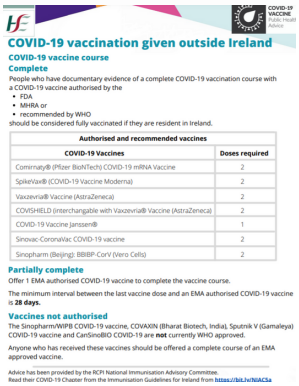
COVID-19 vaccination given outside Ireland

A Reference Guide for COVID-19 vaccination given outside Ireland is now available from our website.

This information provides guidance to vaccinators when providing additional COVID-19 vaccines to people who have received COVID-19 vaccines outside of Ireland which have or have not been approved by the World Health Organization (WHO).

This information is valid at the time of sharing. It is based on guidance from NIAC and the WHO.


COVID-19 vaccination given outside Ireland

COVID-19 vaccine course

Complete

People 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 if they are resident in Ireland.

Authorised and recommended vaccines

COVID-19 Vaccines	Doses required
Comirnaty® (Pfizer BioNTech) COVID-19 mRNA Vaccine	2
SpikeVax® (COVID-19 Vaccine Moderna)	2
Vaxzevria® Vaccine (AstraZeneca)	2
COVISHIELD (interchangable with Vaxzevria® Vaccine (AstraZeneca)	2
COVID-19 Vaccine Janssen®	1
Sinovac-CoronaVac COVID-19 vaccine	2
Sinopharm (Beijing): BBIBP-CorV (Vero Cells)	2

Partially complete

Offer 1 EMA authorised COVID-19 vaccine to complete the vaccine course.

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

Vaccines not authorised

The Sinopharm/WIPB COVID-19 vaccine, COVAXIN (Bharat Biotech, India), Sputnik V (Gamaleya) COVID-19 vaccine and CanSinoBIO COVID-19 are **not** currently WHO approved.

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

Advice has been provided by the RCPI National Immunisation Advisory Committee.
Read their COVID-19 Chapter from the Immunisation Guidelines for Ireland from https://bit.ly/NIAC5a

Download it here

COVID-19 Vaccine Janssen® SmPC has been updated

The update includes the extension of the shelf life of the COVID-19 vaccine Janssen from 3 months to 4.5 months once removed from the freezer and when stored between +2°C and +8°C. This also applies to already thawed batches of the vaccine currently stored between +2°C and +8°C. Any settings that continue to store the COVID-19 Vaccine Janssen consistently between +2°C and +8°C must extend the "Use Before Date" of their stock by **45 days.**

Read more here

Extended shelf-life of Comirnaty®

The shelf-life of Comirnaty has been extended by the manufacturer (Pfizer BioNTech) by 3 months (from 6 months to 9 months) and it applies to all current stock in the ultra low storage freezers in NCCS. Therefore, there will be a 3 month discrepancy between the printed label on the vial and the paperwork. The printed label on the vial is incorrect and the expiry date on the paperwork is correct.

EMA Updates

EMA starts evaluating use of COVID-19 vaccine Comirnaty® in children aged 5 to 11

The EMA have started evaluating an application to extend the use of BioNTech/Pfizer's COVID-19 vaccine, Comirnaty® to children aged 5 to 11.

At this time Comirnaty® is only licensed for use in people aged 12 years and over.

Read more here

New formulation approved for COVID-19 vaccine from BioNTech/Pfizer

The EMA, Committee for Medicinal Products for Human Use (CHMP) has approved a ready-to-use formulation of Comirnaty.

The new formulation is not yet available and will be available in a phased rollout starting in early 2022.

Read more here

Until the HSE notifies vaccinators of the introduction of the new Comirnaty® (Pfizer BioNTech) formulation, vaccinators must continue to follow HSE protocols to prepare Comirnaty® (Pfizer BioNTech).

Watch this short video from Pfizer for a reminder about preparing Comirnaty® (Pfizer BioNTech) for administration — **Click here**

Additional information is available in the NIO Clinical Guidance for COVID-19 Vaccination — **Click here**

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Research

BNT162b2 and ChAdOx1 nCoV-19 Vaccine Effectiveness against Death from the Delta Variant

A Review of a Scotland-wide surveillance platform which includes 5.4 million people has been published in the New England Journal of Medicine. This showed that BNT162b2 vaccine (Pfizer–BioNTech) and the ChAdOx1 nCoV-19 vaccine (AstraZeneca) were 90% effective in preventing death 14 or more days after the second vaccine dose.

Among persons 16 to 39 years of age who had infections caused by Delta variant, no deaths occurred among those who were fully vaccinated, as compared with 17 deaths among those who were unvaccinated.

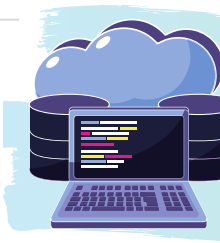
Among those who were 40 to 59 years of age, vaccine effectiveness against death from Covid-19 was 88% (Astra Zeneca vaccine) and 95% (Pfizer–BioNTech) vaccine).

Among those 60 years of age or older vaccine effectiveness against death was 90% (Astra Zeneca vaccine) and 87% (Pfizer–BioNTech vaccine). Overall, vaccine effectiveness against death from the delta variant 14 or more days after the second vaccine dose was 90%.

NEJM (October 21st 2021)

Read more here

CoVax System Updates



Sprint 15 is planned for the 31st October and brings many changes to HSECOVAX

The core change in Sprint 15 is the new logic of the 'Vaccine Courses' tab which was previously named vaccine schedule.

The Vaccine Courses tab is the launch point to assign, record, change, view 'vaccine courses' or record adverse events.

Booster and Additional Dose courses will also launch from this new starting point. The primary course must be completed before extra doses can be assigned.

Please note that this change impacts all vaccinators and many of the operations administrator standing operating practices have been updated. All content will be updated on the HSE myTrailhead training site late next week.

There will also be a Sprint 15 recorded webinar as well as communication release notes. (Dates TBC)

Summary of changes in Sprint 15 include

1. New Vaccine course functionality
2. New 'Add Course' Button to Assign Vaccine Courses to a Person Account
3. New vaccine Course selection Screen prior to the normal Immunisation Consent and Administer Vaccine flows
4. All COVID-19 Vaccination, Boosters and Additional Doses now flow through the Vaccine Course Tab
5. Person Account Banner Statuses changes
6. New Reset consent and Reset Edibility Button for Operations Administrators on vaccine Course Object

These changes see the HSECOVAX system changing to support multiple vaccine courses and vaccines.

Influenza

If Fluenz Tetra (LAIV) has been exposed to a temperature deviation >8°C to ≤25°C for less than 12 hours, then it should be administered as soon as possible and within the 12 hour period. At the end of this period, Fluenz Tetra should be used immediately or discarded.

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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.