COVID-19 VACCINE BULLETIN 22

Welcome to Bulletin 22 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme. Bulletins will be published every week or more frequently, if required.

Updates to the Vaccination Programme and Safety Updates

Reminder to vaccinators

A few common enquires sent to the National Immunisation Office include:

1. **Interchangeability of COVID-19 vaccines:** The current National Immunisation Advisory Committee (NIAC) recommendation is that we do not have enough data to support using different COVID-19 vaccines as part of a two-dose schedule. The same vaccine should be used for both doses.

Read more here

2. **Before giving the second dose:**

- Check with the individual being vaccinated and on COVAX which vaccine was given as a first dose and when they were given it (to ensure they receive the correct vaccine at the right dose interval).
- Check if there is a history of allergic reaction to the vaccine after first dose (or any new allergic reactions since first dose)
- Ensure those receiving Vaxzevria® are aware of the risk of Thrombosis with Thrombocytopenia Syndrome (TTS) and importance of seeking medical attention if they notice sign of TTS within 3 weeks after vaccination.
- If pregnant since the first dose - delay the second dose until at least 14 weeks of pregnancy.

Read more here

3. **Your vaccinator PIN** used in the COVAX system is your professional membership or registration number from your professional or regulatory body (e.g. Nursing and Midwifery Board of Ireland or Irish Medical Council).

4. **Operationally COVID-19 Vaccine Janssen® is to be used in those aged 50 years and over only:** Due to the small risk of TTS associated with the COVID-19 Vaccine Janssen®, NIAC as a precaution, have advised that those under the age of 50 should be given the mRNA vaccines. In addition, NIAC does advise that where a two-dose mRNA vaccine schedule is not feasible the COVID-19 Vaccine Janssen ® can be used in those aged 18-49. However, currently the HSE is only supporting the use of the COVID-19 Vaccine Janssen in those aged 50 year and over.

Read more here

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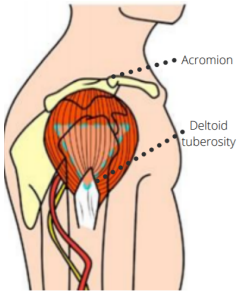
5 **COVID-19 vaccines post-partum:** Postpartum women who have not had one dose of COVID-19 vaccine in pregnancy should be vaccinated in line with the current prioritisation schedule based on age and other medical conditions.

Read more here

6 **COVID-19 vaccine doses in those who have previously had COVID-19:** Previously NIAC have recommended that those with a laboratory confirmed COVID-19 infection in the previous 6 months and are under the age of 50 and immunocompetent can receive only 1 dose of a COVID-19 vaccine to be considered fully immunised. However, the HSE is not currently operationalising this. Everyone will be offered two appointments at the appropriate interval for a two dose COVID-19 vaccine regardless of prior COVID-19 infection status.

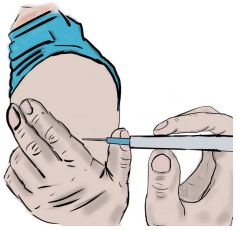
Read more here

7 **Intramuscular (IM) injection techniques:** All vaccinators must be competent in IM injection technique into the deltoid muscle.



Incorrect IM injection technique can result in the vaccine being administered into the subcutaneous tissue, and not the muscle, which can render the vaccine ineffective.

Administration of the vaccine in the incorrect site of the deltoid muscle can result in injury. For example if the vaccine is injected too high, it may inadvertently be injected into the synovial tissues of the shoulder joint, resulting in an immune-mediated inflammatory reaction. This is called Shoulder Injury Related to Vaccine Administration (SIRVA) which can lead to prolonged pain and dysfunction.



Read more here

We encourage vaccination leads in clinics to remind vaccinators of the requirement for competency in the correct IM injection technique and of the training and supporting materials that are available:

- Summary sheet outlining the IM injection technique **Click here**
- Training video **Click here**

8 **Follow the clinical guidance when preparing, diluting (if needed) and withdrawing vaccines from multi-dose vials**

Read more here

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EMA approves Comirnaty® (Pfizer/BioNTech) COVID-19 vaccine for adolescents

The European Medicines Agency (EMA) has approved Comirnaty® (Pfizer/BioNTech) to be used in those aged 12-15. Previously it was only approved for use in those aged 16 and over.

They reviewed trial data which is summarized in the next section. During the clinical trial the vaccine was found to be 100% effective against symptomatic disease. The side effect profile was similar to those experienced by adults (most being mild to moderate).

Currently the National Immunisation Advisory Committee (NIAC) have not issued recommendations on the use of Pfizer vaccine in 12-15 year olds and so Pfizer vaccine should continue to be given to those aged 16 years and above in Ireland.

Read more here

Cases of Myocarditis and Pericarditis post vaccination with mRNA vaccines being investigated

The EMA's safety committee is investigating a very small number of reports of myocarditis and pericarditis mainly after the Comirnaty vaccine in young adults. They are also closely monitoring for any similar cases after COVID-19 Vaccine Moderna. There are no indications that these cases are caused by the vaccine and the EMA safety committee is reviewing the matter.

The World Health Organisation (WHO) and the Centers for Disease Control and Prevention (CDC) from the United States are also investigating similar reports following mRNA vaccines.

- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 3-6 May 2021 — **Read more here**
- Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults — **Read more here**
- Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination — **Read more here**
- COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) reviews cases of mild myocarditis reported with COVID-19 mRNA vaccines — **Read more here**

WHO labelling of COVID-19 variants

For common use, to reduce the stigma and for ease of reference, the WHO has recommended using the greek alphabets to represent the variants of concerns and interest.
There are 4 variants of concerns including:

WHO label	Variant (first discovered in)
Alpha	B.1.1.7 (United Kingdom)
Beta	B.1.351 (South Africa)
Gamma	P.1 (Brazil)
Delta	B.1.617.2 (India)

Read more here

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Latest from research

Pfizer-BioNTech COVID-19 clinical trial finds effectiveness in children aged 12-15

This phase 3 clinical trial involved over 2200 children aged 12-15 who received two doses of the Pfizer-BioNTech COVID-19 vaccine 3 weeks apart. They compared the efficacy, safety and the immune response when compared to those aged 16-25.

Most of the side effects reported were mild to moderate and short lived (similar to those seen in older age cohorts). Furthermore laboratory tests confirmed that children aged 12-15 mounted a greater immune response when compared to young adults aged 16-25. 100% (95% CI, 75.3 to 100) efficacy is noted against symptomatic disease in children aged 12-15 after 7 days after the second dose.

Read more here

Ischaemic stroke and TTS

A letter published in the Journal of Neurology, Neurosurgery & Psychiatry contains a clinical case series describing 3 patients who developed an arterial thrombosis (presenting as ischemic stroke) within the context of TTS following vaccination with Vaxzevria® in the United Kingdom. Another commentary published in the same journal places the risk of stroke in context - comparing the incidence after vaccination which is lower than after COVID-19 infection.

The National Immunisation Office/Health Service Executive is aware of the reports of strokes in a very small number of people in the UK after Vaxzevria (AstraZeneca) COVID-19 vaccination. These cases are similar to the very rare unusual blood clots with low platelets that have been seen in people after Vaxzevria vaccination. These blood clots and strokes are much more common after COVID-19 infection. The safety of COVID-19 vaccines is continuously monitored by the European Medicines Agency (EMA), the Health Products Regulatory Authority (HPRA) and the National Immunisation Advisory Committee (NIAC). The benefits from receiving the Vaxzevria vaccine outweigh the risks for adults of all age groups.

Read more here **Read more here**

A hypothesis exploring the pathogenesis of thromboembolism post vaccination with viral vector vaccines

This preprint paper from Germany outlines one hypothesis for the blood clots seen after vaccination with viral vector vaccines. They hypothesize that a delivery mechanism using adenoviral vectors to deliver the viral spike protein DNA to be transcribed in the nucleus is the issue as DNA derived from the RNA virus is not best transcribed in the nucleus and may result in production of variations of spike protein. These variants of the spike protein may induce the thromboembolic events . They tested their hypothesis using laboratory experiments.

Read more here

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Small German study on mixing vaccine schedules

A pre-print from Germany describes results from a very small trial involving just 26 individuals under the age of 50. All participants received a dose of AstraZeneca COVID-19 vaccine followed by a booster of Pfizer-BioNTech COVID-19 vaccine after 8 weeks. A strong immune response was noted after the booster dose including increased levels of antibodies after 2 weeks, better neutralising effect on 3 variants of concern tested and increased T cell response. Furthermore no significant adverse reactions were reported.

Read more here

Spanish CombivacS trial

There is currently a clinical trial ongoing in Spain investigating the effectiveness of giving an mRNA vaccine after a first dose of COVID-19 Vaccine from AstraZeneca in those under the age of 60. The trail includes over 600 participants. Unpublished early data presented at a conference indicates that, when compared to individuals who did not receive any booster after the first dose of AstraZeneca vaccine, those who received a booster of Pfizer-BioNTech vaccine showed a greater antibody response. Further published data is awaited.

Read more here

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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

COVID-19 Vaccination Training Programme

While HSeLand is unavailable you can access the National Immunisation Office COVID-19 vaccinator training by registering through the interim HSeLand solution:

Register here

You must register on this platform to complete training if you previously registered on HSeLand. HSeLand recommend downloading your certificates of completion from the interim HSeLand platform so you can load them to your learning record when HSeLand is available again.

Do you have queries?

Due to a recent cyberattack against the HSE we are unable to access our HSE Emails at this time. We apologise for any inconvenience this may cause.

A new email address for **healthcare professionals only** to direct any urgent clinical or technical queries to. Please **do not send any patient identifiable information** to this email address as the email will be deleted and you will be asked to resend without this information.

Send your query

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

- Achal Gupta: 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.

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

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.