

# COVID-19 VACCINE BULLETIN 24

Welcome to Bulletin 24 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 and Reminders on the Vaccination Programme

### Individuals being vaccinated should be provided with the manufacturer's patient information leaflet

The Patient Information Leaflet, PIL, is produced by the manufacturers. It contains detailed information about the vaccine, potential side effects and ingredients.

Please ensure that people being vaccinated are provided with the PIL produced by the manufacturer in addition to any HSE leaflets and aftercare materials. This is an important requirement specified by the Health Products Regulatory Agency (HPRA). Do ensure that you accept delivery of any new PILs that are delivered to your setting by the cold chain service as it will contain the most up-to-date information from the manufacturer including any new added adverse events. When a new version of the information is received, please ensure older versions are destroyed so that people are given the correct version.

[Read more here](#)

### HPRA safety update June 2021

This monthly report highlights any safety issues reported to the HPRA on COVID-19 vaccines including adverse events reported by healthcare professionals. To date the HPRA has had nearly 9500 suspected side effects reported in the context of 3 million doses of COVID-19 vaccines administered (a third of which are second doses) - most adverse events were mild to moderate. There have been 7 reports of suspected Thrombosis with Thrombocytopenia Syndrome (TTS) reported to HPRA which have occurred 1-3 weeks after the first dose of Vaxzevria- all individuals are recovering or discharged.

The report also summarises the latest EMA safety updates including:

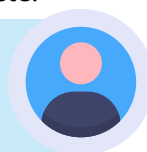
- Health care professionals should be aware of clinical care guidance on the management of TTS e.g. in countries where local guidance isn't available they suggest using the guidance produced by the International Society on Thrombosis and Haemostasis. The Irish Haematology Society Coagulation Special Interest Group has produced **national guidance** on this subject.
- Safety update for Vaxzevria around capillary leak syndrome (CLS). CLS has been added as a new side effect for Vaxzevria and a previous history of CLS is a contraindication to the vaccine.
- There is an ongoing EMA review of pericarditis and myocarditis post vaccination. Health professionals should report any suspected cases. Individuals should seek medical attention if they notice symptoms after vaccination (such as shortness of breath, a forceful heartbeat that may be irregular, and chest pain).

[Read more here](#)

### Ensure vaccinator details on COVAX are accurate and complete

As a COVAX application user, it is essential to check and ensure all vaccinator details are accurate and complete.

- ✓ Check your user profile to ensure your vaccinator name, professional number type and professional identification number (PIN) are accurate
- ✓ Ensure vaccinator profession type and professional number type are complete
- ✓ Ensure correct and complete vaccinator details are recorded on immunisation records after vaccination.
- ✓ Accurate and complete vaccinator details must be recorded on all immunisation records



Why are vaccinator details important?

1. It is a legal requirement - vaccinator name, professional number type and professional identification number should be recorded according to Statutory Instruments (S.I.No.698 of 2020, 4F)
2. Vaccinator details are required on immunisation records for a complete vaccination history.



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## Latest in Research

### Safety of mRNA vaccines in pregnant women

Recent data has shown that getting COVID-19 during pregnancy results in poorer maternal and fetal outcomes. Therefore pregnant women have been prioritised for vaccination in many countries including Ireland and the United States (US).

This real world study from the US analyses reports of suspected side effects to surveillance databases between mid December and end of February 2021. There were no increased reports of local and systemic adverse events following vaccination in pregnant women compared to non-pregnant women. 827 of the vaccinated participants (who received one or two doses of an mRNA vaccine) that were followed up had a completed pregnancy. Adverse pregnancy related and neonatal outcomes in the vaccinated group were in keeping with the general expected background pre-pandemic rate.

[Read more here](#)

### Importance of the second dose in preventing hospitalisation from the Delta variant

The latest analysis (published as a pre-print) from Public Health England provides further evidence that the vaccines are highly effective against preventing hospitalisation from the Delta variant (B.1.617.2) in England after 2 doses: Comirnaty (Pfizer BioNTech) is 96% effective and Vaxzevria (AstraZeneca) is 92% effective. The vaccines have a similar effectiveness against the Alpha variant (B.1.1.7). Further analysis is underway to understand the impact of vaccination on deaths due to the Delta variant (it is expected to offer a high level of protection similar to other variants).

It is important that individuals receive both doses of the same vaccine (unless there is a clinical contraindication) as it provides increased and longer lasting protection against COVID-19 including the Delta variant now circulating widely in the United Kingdom.

The contraindications and precautions to vaccination are detailed in the clinical guidance and National Immunisation Advisory Committee (NIAC) immunisation guidelines on COVID-19 vaccines. If someone has had a reaction to the first dose of vaccine but it is not listed as a contraindication, then they can receive the second dose of the vaccine.

[Read more here](#)

### Scottish study on the Delta variant

This correspondence published in the Lancet compares the demographics, risk of hospitalisation and vaccine effectiveness for the Delta (B.1.617.2) variant when compared with the Alpha (B.1.1.7) variant.

The Delta variant was found to be prevalent across all ages but particularly in children aged 5-9 years and higher socioeconomic groups. The Delta variant was also associated with a significantly increased risk of hospitalisation (nearly twice that compared to the Alpha variant) particularly in those with multiple comorbidities.

Vaccination (two weeks after the second dose) was effective at reducing hospitalisation:

- Comirnaty (Pfizer/BioNTech) was 92% effective against hospitalisation with the Alpha variant and 79% effective against hospitalisation with the Delta variant.
- Vaxzevria (AstraZeneca) was 73% effective against hospitalisation with the Alpha variant and 60% effective against hospitalisation with the Delta variant.

[Read more here](#)

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## Impact of mixing vaccine schedules in healthcare workers

This preprint describes a prospective cohort study that followed up 340 healthcare workers in Germany in one center. The participants either received two doses of Comirnaty 3 weeks apart or one dose of Vaxzevria followed by one dose of Comirnaty (10-12 weeks later).

They reviewed reactogenicity and immunogenicity data. Interim analysis shows the reactogenicity between the heterologous prime-boost vaccine schedule was similar to those who received two doses of the Comirnaty. Good immune response was noted from both vaccine schedules with slightly better T-cell response and higher serum antibody avidity following the heterologous prime-boost vaccine schedule.

[Read more here](#)

## Impact of vaccination on unvaccinated cohorts

Publication from Israel studies the impact on infection rates in children under the age of 16 (who are unvaccinated) from vaccinating adults with the Pfizer-BioNTech COVID-19 vaccine.

They studied the impact of vaccination on 177 communities with low underlying natural immunity.

They found a correlation between high vaccination rates and lower infection rates later in unvaccinated children within the same community. They estimate that by vaccinating an additional fifth of the population in a community (aged 16-50) this results in nearly a two-fold reduction in positive test fraction within the unvaccinated cohort (children under 16 years of age).

[Read more 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](#)

## 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.