COVID-19 VACCINE BULLETIN 17

Welcome to Bulletin 17 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.

Shelf life of vaccines

COVID-19 vaccines used in the programme have different shelf-lives. Please refer to Clinical Guidance for Vaccinators for details.

See Clinical Guidance here

We have developed a quick-reference guide for vaccinators, an extract of which is shown below.

See Quick Reference Guide here

A summary sheet for each vaccine is also available.

See Summary Sheets here

	Cominaty® (Pfizer BioNTech)	COVID-19 Vaccine Moderna®	Vaxzevria® (AstraZeneca)
Supplied by National Cold Chain Service (NCCS)	+2°C to +8°C with a limited shelf life (<120 hours after removal from ultra-low temperature freezer in National cold chain service)	Frozen at -25°to -15°C Thaw prior to use (see www.immunisation.ie for details)	+2°C to +8°C
Shelf life of an unopened vial at between +2°C to +8°C (NOTE must be stored upright)	Until "use before" time and date (**120 hours** from removal of vial from ULT freezer in NCCS)	**30 days** (until "use before" time and date)	Until expiry date
Shelf life once vial is opened "discard time"	6 hours after dilution	6 hours after first puncture	6 hours after first puncture

Please record "use before" date rather than manufacturer expiry date in the COVAX or GP IT system for the Comirnaty and Moderna vaccines.

Any expired unused vaccines should be returned to NCCS with your next delivery.

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Safety Updates

EMA lists unusual blood clots with low blood platelets as a very rare side effects of the COVID-19 vaccine Janssen

COVID-19 Vaccine Janssen was authorised in the EU on 11 March 2021; the rollout of the vaccine in the EU was temporarily delayed by the company.

This vaccine is not yet being used in our COVID-19 immunisation programme in Ireland. The National Immunisation Advisory Committee (NIAC) is currently reviewing the EMA findings and other evidence and will be issuing revised recommendations on the use of the COVID-19 Vaccine Janssen in Ireland shortly.

The European Medicines Agency (EMA) has reported on the conclusions of their safety committee regarding reports of unusual blood clots associated with COVID-19 vaccine Janssen® (Johnson and Johnson).

At its meeting of 20 April 2021, after reviewing all available evidence, the EMA safety committee concluded that the benefits of the vaccine in preventing COVID-19 outweigh the risks of very rare clotting events. However, they have advised that unusual blood clots with low blood platelets should be listed as very rare side effects of the vaccine.

During its investigation, the committee reviewed eight reports (from the USA) of serious cases of unusual blood clots associated with low levels of blood platelets, one of which had a fatal outcome. These very rare blood clots were associated with low levels of blood platelets with or without bleeding. Often these rare blood clots were in unusual locations including in the vessels draining blood from the brain (cerebral venous sinus thrombosis, CVST), the abdomen (splanchnic vein thrombosis) and in arteries. By the middle of April over 7 million people in the USA had the COVID-19 vaccine Janssen®.Most of these rare events occurred within 3 weeks of receiving the first dose of the vaccine and in women under the age of 60. The EMA has not specified any particular groups at higher risk of these rare side effects. A possible link was concluded by the EMA with similar rare side effects with another adenovirus based COVID-19 vaccine; Vaxzevria® (from AstraZeneca).

The EMA suggested that a potential biological mechanism for these rare side effects is due to the vaccine causing an immune response similar to that seen in another rare condition following injection with heparin (heparin induced thrombocytopenia, HIT). Health professionals and those being vaccinated with COVID-19 vaccine Janssen® should be informed that unusual blood clots with low blood platelets are very rare side effects of the vaccine. Healthcare professionals in Ireland should seek early expert advice from the National Coagulation Centre about the specialised testing and treatment options for patients presenting with thromboembolic events that are associated with thrombocytopenia, (including Disseminated Intravascular Coagulation (DIC) or Cerebral venous sinus thrombosis (CVST)) occurring within weeks following vaccination. Any suspected side effect linked to a COVID-19 vaccine should be reported to the Health Products Regulatory Authority (HPRA).

COVID-19 is associated with a risk of hospitalisation and death. The reported combination of unusual blood clots and low blood platelets is very rare, and the EMA concluded the overall benefits of COVID-19 Vaccine Janssen in preventing COVID-19 outweigh the risks of side effects.

Read more here

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Draft case definition from the Brighton collaboration

In light of these unusual cases of blood clots with low blood platelets following vaccination with Vaxzevria® and COVID-19 Vaccine Janssen the Brighton collaboration (consisting of a group of experts) released a draft case definition of the term "Thrombosis or Thromboembolism" to be used to identify confirmed, probable and possible cases in such situations.

Read more here

Statement from the World Health Organization (WHO)

The WHO's Global Advisory Committee on Vaccine Safety (GACVS) released their review of unusual blood clotting events with low platelets or Thrombosis with Thrombocytopenia Syndrome (TTS) with AstraZeneca COVID-19 vaccines (Vaxzevria® and Covishield®).They reiterate that the causal link hasn't yet been fully established. They recommended that all adenovirus based vaccines be included in the ongoing analysis of TTS. Furthermore the risk of TTS is low following vaccination and this needs to be considered in relation to local factors such as vaccine supply and case rates when deciding on the use of the vaccine in individual countries. More research is being done to identify if there is stronger evidence for risk factors for TTS including age or sex. They encourage all countries to investigate suspected cases of TTS.

The WHO recommends health care providers to be alert to the signs and symptoms of TTS 4-20 days after vaccination. In suspected cases a platelet count and appropriate imaging should be requested. Furthermore, they warn clinicians that the use of heparin in cases of TTS could be dangerous. As previously recommended by NIAC specialist expert advice should be sought in such cases.

Read more here

HPRA Safety Update: COVID-19 Vaccines, Overview of National Reporting Experience

The Health Protection Regulatory Agency (HPRA) is responsible for the monitoring and regulating all medicines including vaccines in Ireland. They released their latest update on COVID-19 vaccines use in Ireland.

By the middle of April the HPRA received over 6,600 reports of side-effects following vaccination in the context of nearly 1.2 million doses of vaccines given. The majority of side-effects are mild-moderate. They highlight the EMA findings in relation to TTS and the two adenovirus based COVID-19 vaccines (Vaxzevria® and COVID-19 Vaccine Janssen®). In Ireland, by the middle of April 2021, there were 29 cases of thrombosis like events reported to the HPRA following vaccination with Vaxzevria® - of which only few were associated with thrombocytopenia. In majority of cases of thrombosis without thrombocytopenia the clots were not in unusual locations.

Read more here

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Latest from Research

Results from Israel's national vaccination programme using the Comirnaty vaccine

The study uses data from Israel's largest health organisation to assess the real world effectiveness of Comirnaty® (Pfizer/BioNTech vaccine). The vaccine was given as two doses 21 days apart. A matched cohort study was undertaken involving nearly 1.2 million people (half of whom were vaccinated). Outcomes were measured after the first dose (day 14-20) and second dose (on or after day 7). This study provides real-world evidence of effectiveness of Comirnaty® vaccine against a number of clinical outcomes as summarised in Table 1. Subgroup analysis showed similar effectiveness across the ages. However, there may be marginally lower effectiveness in those with underlying health conditions. During the study period the incidence of COVID-19 was high and the dominant strain was the highly transmissible B.1.1.7 variant which is the dominant strain in Ireland.

Table 1: Summary of vaccine effectiveness based on published results from the study

Effectiveness against the following COVID-19 outcomes	14-20 days after the first dose of vaccine	≥7 days after second dose of vaccine
Documented COVID-19	46% (95% CI 40- 51)	92% (95% CI, 88- 95)
Symptomatic COVID-19	57% (95% CI, 50- 63)	94% (95% CI, 87- 98)
Hospitalisation	74% (95% CI, 56- 86)	87% (95% CI, 55- 100)
Severe disease	62% (95% CI, 39- 80)	92% (95% CI, 75- 100)
Death	72% (95% CI, 19- 100)	-

Read more here

Impact of Israel's national COVID-19 vaccination programme

This study reviews the impact of the vaccine at a population level in Israel over time. They retrospectively reviewed COVID-19 data for 6 months from end of August 2020. The vaccination programme started at the end of December 2020 using Comirnaty® vaccine (Pfizer/BioNTech) prioritising those at high risk. By the end of the study period nearly half of the population had received at least 1 dose of the vaccine. Over a third had received their second dose. Older adults are particular at higher risk and were initially prioritised; nearly 9 in 10 people aged over 60 years have received at least 1 dose at the end of the study period. Two months after the start of the vaccination programme which began with older adults, there was a concomitant drop in this age group in COVID-19 case rates, positivity rates, hospitalisation and severe cases. These trends were noticeable from 3-4 weeks after the vaccination programme started. This is largely attributed to the vaccination programme although other public health measures would have had an impact. This study demonstrates the real-world vaccine impact at a population level.

Read more here

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Training Updates

Approved training programmes on COVID-19 vaccines

Training for the COVID-19 vaccination programme is available on HSELand and is regularly updated by the National Immunisation Office as per the latest National Immunisation Advisory Committee (NIAC) recommendations.

This training developed by the National Immunisation Office in also included in the training developed by the ONMSD for nurses and midwives vaccinating under a medicines protocol, and the training programmes for registered Physiotherapists and Optometrists.

These training programmes on HSELanD are approved by the professional regulatory bodies for the professions involved in vaccination.

There are very frequent changes to guidelines, and the training is continually reviewed and updated to reflect these changes. It is important that all vaccinators are trained with up to date and consistent clinical information from a single source.

The training programmes on HSELanD are approved by the professional regulatory bodies for the professions involved in vaccination.

It is advised NOT to deliver separate training sessions on COVID-19 vaccines to vaccinators, as this can quickly be out of date, and can cause confusion.

Approved training programmes available from HSELand are:

- **COVID-19 Vaccination Training Programme**
- **COVID-19 Vaccination Programme for Nurses and Midwives**
- **COVD-19 Vaccination Programme for Registered Physiotherapists**
- **COVID-19 Vaccination Programme for Registered Optometrists**

Register here

COVAX updates

Covax Upgrade Sprint 8 was delayed it is now planned to go live on the 28th/29th April

PIN - there is a legal requirement to add the Vaccinator PIN to a client vaccination record. When you get set up on Covax you must enter your PIN on the registration page.

On the HSE Training site, under **"Module 0 - First Time HSE CoVax Registration"**, there is a short demo clip showing the steps to register and to also set their vaccinator pin / type.

See Module 0 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

Do you have queries?

For questions about the COVID-19 Vaccination programme

- COVID-19 vaccine orders or deliveries to GPs, please email gpvaccines@hse.ie
- Health Professionals for your own COVID-19 vaccination appointments, please email Covid19.support@hse.ie
- Legal queries, potential challenges related to vaccination and obtaining a consent, please email lead.integratedcare@hse.ie and dervelagray@rcpi.ie
- For clinical queries and queries relating to cold chain maintenance or breakdown, please email immunisation@hse.ie

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

- Achal Gupta: achal.gupta@hse.ie mobile 087 4064810
- Mariangela Toma: mariangela.toma@hse.ie mobile 087 7575679
- Cliona Kiersey: cliona.kiersey@hse.ie mobile 087 9915452
- Email the immunisation inbox: immunisation@hse.ie

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

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