

COVID-19 VACCINE BULLETIN 13

Welcome to Bulletin 13 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.

Updated product information for COVID-19 Vaccine AstraZeneca®

COVID-19 vaccine AstraZeneca® is now called Vaxzevria® COVID-19 Vaccine. Updated product information including a section on thrombocytopenia and coagulation disorders was published on 26 March 2021.

The public information leaflets will be updated with the name change at the next print run.

[Read More Here](#)

EMA COVID-19 Vaccine AstraZeneca®: review of very rare cases of unusual blood clots continues

On 31 March 2021 the EMA issued an update about their ongoing review of very rare cases of unusual blood clots associated with low numbers of platelets, in people vaccinated with AstraZeneca's COVID-19 vaccine (now called Vaxzevria®).

At present the review has not identified any specific risk factors, such as age, gender or a previous medical history of clotting disorders, for these very rare events. A causal link with the vaccine is not proven, but is possible and further analysis is continuing.

The EMA is of the view that the benefits of the AstraZeneca vaccine in preventing COVID-19, with its associated risk of hospitalisation and death, outweigh the risks of side effects.

The EMA Pharmacovigilance Risk Assessment Committee (PRAC) is expected to issue an updated recommendation during its April plenary meeting next week (6-9 April 2021).

[Read More Here](#)

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Vaccination in different settings

Vaccination with COVID-19 vaccines is happening in different settings including general practice, hospitals and clinics or hubs.

Before vaccination, please check if the person to be vaccinated has previously received a COVID-19 vaccine, and if so, which vaccine they received and when they received it. This is to ensure that the person receives the correct vaccine at the correct interval, and does not receive a third dose of vaccine in error. Remember, COVID-19 vaccines are not interchangeable.

Before administering a COVID-19 Vaccine, please remember to check the following:

Comirnaty® (Pfizer/BioNTech)	the <i>use before</i> date and time on the vaccine box and the <i>discard time and date</i> on the vial
COVID-19 Vaccine Moderna®	the <i>use before</i> date and time on the vaccine box and the <i>discard time and date</i> on the vial
Vaxzevria® (AstraZeneca)	the <i>expiry date</i> of the vaccine and the <i>discard time and date</i> on the vial

Lymphadenopathy after COVID-19 vaccines

Lymphadenopathy is listed among the expected adverse reactions following COVID-19 vaccines.

It is listed as very common after Moderna vaccine ($\geq 1/10$), and associated with axillary swelling and tenderness of the vaccination arm.

Lymphadenopathy has also been reported as uncommon ($\geq 1/1,000$ to $< 1/100$) after the Pfizer/BioNTech and AstraZeneca vaccines.

Adverse reactions reported have been mild to moderate and resolve spontaneously.

The vaccine programme is now being rolled out to people at high risk of severe complications of COVID-19, which includes people with cancer, who may be very concerned if this expected adverse reaction occurs. Clinicians should be aware of this expected adverse reaction in order to advise their patients who may present with concerns.

The information on expected adverse events is also included in the information materials for patients available:

[See Here](#)

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NIAC Update on COVID-19 Vaccine Prioritisation Groups

On March 29th 2021, the National Immunisation Advisory Committee (NIAC) issued updated evidence-based recommendations to the Department of Health on prioritisation groups for COVID-19 vaccination. The NIAC Guidance is available in full [here](#). The updated list is outlined below:

Group		
1	People aged 65 years and older who are residents of long-term care facilities (likely to include all staff and residents on site)	
2	Frontline healthcare workers	
3	People aged 70 and older	
4	People aged 16-69 with a medical condition that puts them at very high risk of severe disease and death	
5	People aged 65-69 whose underlying condition puts them at a high risk of severe disease and death	
6	Other people aged 65-69	Key workers essential to the vaccine programme
7	People aged 16-64 who have an underlying condition that puts them at high risk of severe disease and death	
8	Residents of long-term care facilities aged 16-64	
9	People aged 64 years and younger in the following order: i. 64-55 years ii. 54-45 years iii. 44-35 years iv. 34-25 years v. 24-16 years	People aged 16-64 living or working in crowded settings

HSE National Cold Chain Service

Please ensure vaccines are stored between +2°C and +8°C, however 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
- National Immunisation Office: immunisation@hse.ie

All COVID-19 vaccines currently in use in Ireland are delivered through the HSE National Cold Chain Service.

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Medical Product Alert N°2/2021: Falsified COVID-19 Vaccine CRM:0408811 identified in the WHO Region of the Americas

On the 28th of March the World Health Organization shared a Medical Product Alert which referred to a falsified Covid-19 vaccine detected in Mexico in February 2021 and recently confirmed as falsified. The falsified product was supplied and administered to patients outside authorised vaccination programs and may still be in circulation in the region and may continue to be offered to patients outside authorised vaccination programmes.

While the supply chain is secure for all those vaccinated through the HSE vaccination programme, there must be an equally secure process for disposal of empty vials / expired vials and ensure that these vials cannot be accessed by unauthorised personnel both at the clinic and after removal from the clinic.

It is absolutely paramount and everyone's responsibility to ensure that every vaccine vial is accounted for. Every vaccination clinic, regardless of the specific setting the clinic is held, should have a procedure in place to ensure that the number of vials used is equal to the number of vials disposed of at the end of the day.

This procedure should include:

- Ensure a physical stock count of COVID-19 vaccine vials is performed and in the HSE central vaccination clinic ensure this matches the stock count recorded on the IT system.
- Records of vial reconciliation should be maintained at all times
- Ensure that vials are stored securely at all points between receipt and use or disposal.
- Empty vials should be disposed safely into sharps bins and these bins must be tagged, safely stored and disposed as per the healthcare waste management policy.
- Deface original cartons labels using permanent black marker pens, and placed into appropriate waste sack for incineration, as soon as possible after they become empty.

Increased vigilance is required for each empty vial and it is everyone's responsibility to ensure that it cannot enter the falsified COVID -19 vaccine production.

[Read More Here](#)

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Public Health Advice should still be followed after vaccination

Post vaccination advice

A recent article in the British Medical Journal reported a rise in COVID-19 infections immediately after vaccination in the UK and Israel as people incorrectly assumed they were fully protected and reduced their adherence of public health measures.

The YouGov survey suggested that 29% of people would follow pandemic related rules and restrictions less strictly once they were vaccinated.

[Read More Here](#)

Please highlight to all vaccine recipients

- Vaccines do not provide immediate immunity
- They should follow **all current public health guidance** to protect themselves and others

Benefits of COVID-19 Vaccines in the prevention of SARS-CoV 2 infection

CDC study confirms protective benefits of mRNA COVID-19 Vaccines

The study looked at the effectiveness of Pfizer/BioNTech and Moderna mRNA vaccines in preventing SARS-CoV-2 infections among 3,950 healthcare workers and other essential workers over a 13-week period from December 14, 2020 to March 13, 2021.

Participants self-collected nasal swabs each week regardless of whether they had developed symptoms of illness. Researchers were able to look for evidence of SARS-CoV-2 infection irrespective of symptoms. A small number (11%) of infections in this study were asymptomatic. The majority of infections (58%) occurred among people whose infections were identified by testing before they developed symptoms or knew they were infected.

Following a single dose of either vaccine, the participants' risk of infection with SARS-CoV-2 was reduced by 80% two or more weeks after vaccination with a single dose. Results showed that following the second dose of vaccine, the risk of infection was reduced by 90% two or more weeks after vaccination.

The study demonstrates that these two mRNA vaccines can reduce the risk of all SARS-CoV-2 infections, not just symptomatic infections.

[Read More Here](#)

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Vaccine effectiveness of the first dose of AstraZeneca and Pfizer/BioNTech Vaccines against SARS-CoV-2 infection in residents of Long-Term Care Facilities (VIVALDI study)

This study from England is available as a pre-print so not yet peer-reviewed.

The study examined the effectiveness of a first dose of Pfizer/BioNTech vaccine and AstraZeneca vaccine against infection with SARS Co-V2 in residents of long-term care facilities.

They compared more than 10,000 vaccinated and unvaccinated residents, undergoing routine asymptomatic testing (8 December 2020 - 15 March 2021). The estimated vaccine effectiveness against asymptomatic infection was estimated as 56% at 28-34 days, and 62% at 35-48 days following a single dose of AstraZeneca or Pfizer/BioNTech vaccine.

The findings suggest that the risk of SARS-CoV-2 infection is substantially reduced from 4 weeks following the first dose of either vaccine and that this effect is maintained for at least 7 weeks, with similar protection offered by both vaccine types. The analysis period coincided with the rapid emergence of B.1.1.7 in England during the second wave of the pandemic.

[Read More Here](#)

Delayed reactions to mRNA-1273 (Moderna) Vaccine

Blumenthal et al reported on local reactions in 12 patients following administration of mRNA-1273 (Moderna) vaccine.

- Median onset of reactions occurred day 8 after the vaccine (range 4-11 days).
- Five of the reactions were grade 3 plaques (≥ 10 cm in diameter)
- Some patients had concurrent systemic adverse effects, and among these patients, 2 had additional skin findings.
- Most patients received treatment for their symptoms (e.g., with ice and antihistamines). Some patients received glucocorticoids (topical, oral, or both), and 1 patient received antibiotic therapy for presumptive cellulitis.
- The symptoms resolved a median of 6 days after onset (range, 2 to 11).

Given that neither local injection-site reactions nor delayed-type hypersensitivity reactions are contraindications to subsequent vaccination, all 12 patients were encouraged to receive the second dose and completed their mRNA-1273 vaccination course.

- Half the patients did not have a recurrence of large local reactions
- Three patients had recurrent reactions that were similar to those after the initial dose
- Three patients had recurrent reactions that were of a lower grade than those after the initial dose.
- The median onset of cutaneous symptoms after the second dose (day 2; range, 1 to 3) was earlier than that after the first dose

Given the up-scaling of COVID-19 vaccination programmes worldwide the presentation of delayed local reactions such as those described here will become more common. It is important that these presentations are always reported to the appropriate regulatory authorities (Health Product Regulatory Authority (**HPRA**) in Ireland).

[Read More Here](#)

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HSE Website Update

The [COVID-19 vaccines web page](#) on the HSE website has been restructured with a focus on the vaccines currently in use in Ireland: Comirnaty® Pfizer/BioNTech COVID-19 vaccine, COVID-19 vaccine Moderna® and COVID-19 vaccine AstraZeneca®.

Each vaccine now has a multi-page guide with a page for relevant subtopics, allowing people to easily access the facts about the COVID-19 vaccines they are offered.

The screenshot shows the HSE website's COVID-19 vaccines page. At the top left is the HSE logo and the text 'our health service'. To the right is a search bar with the word 'Search' and a magnifying glass icon. Below the logo is a breadcrumb trail: 'HSE.ie > COVID 19 vaccine'. The main heading is 'COVID-19 vaccines' with a sub-heading: 'Your COVID-19 vaccine will offer you protection from COVID-19 (coronavirus)'. The page features six content cards arranged in a 2x3 grid:

- Getting your vaccine**: People who are most at risk from COVID-19 will get their vaccine first
- Rollout**: Progress updates on the rollout of COVID-19 vaccines
- AstraZeneca COVID-19 vaccine**: Immunity, safety and side effects information about this vaccine
- Moderna COVID-19 vaccine**: Immunity, safety and side effects information about this vaccine
- Pfizer/BioNTech COVID-19 vaccine**: Immunity, safety and side effects information about this vaccine
- Leaflets**: HSE leaflets, vaccine manufacturer leaflets and other resources

At the bottom of the grid is a large teal button with the text 'Visit Here'.

CoVax System Update

The medicinal products (prescription and control of supply) (Amendment) (NO.7) Regulation S.I. No.698 of 2020 under Regulation 4E requires all vaccinators to keep records in relation to supply and administration of COVID-19 vaccination including the number of his or her certificate of registration issued by his or her professional regulatory body.

Please ensure your pin and name is correctly recorded on all vaccination records.

- Next Sprint upgrade planned for the **20th April**
- GP Interface delayed for further testing

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Useful Links

CDC study on protective benefits of mRNA COVID-19 Vaccines

https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm?s_cid=mm7013e3_w

Vaccine effectiveness of the first dose of AstraZeneca and Pfizer/BioNTech Vaccines against SARS-CoV-2 infection in residents of Long-Term Care Facilities (VIVALDI study)

<https://www.medrxiv.org/content/10.1101/2021.03.26.21254391v1?ct=>

Delayed reactions to mRNA-1273 (Moderna) Vaccine (NEJM)

<https://www.nejm.org/doi/full/10.1056/NEJMc2102131>



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COVID-19 Vaccination Training Programme

There are now **over 11,500** completions for the National Immunisation Office “COVID-19 Vaccination Training Programme” on HSELand.

The programme covers topics like

- Recommendations and contraindications
- Preparing vaccines for administration
- Communications and consent

The programme is updated regularly to include the most up to date information to support vaccinators who are competent in giving vaccinations.

You will be notified by email when new content is available for completion. Follow the instructions in the email to complete the updates. You do not need to redo the entire programme.

[Register Here](#)

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



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](http://www.immunisation.ie) for the most up to date information.