

COVID-19 VACCINE BULLETIN 11

Welcome to the updated eleventh bulletin 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.

COVID-19 Vaccine AstraZeneca®

The National Immunisation Advisory Committee (NIAC) has recommended that administration of COVID-19 Vaccine AstraZeneca® is recommended for use in all those aged 18 and over.

The administration of the vaccine had been paused until the outcome of a preliminary review by the European Medicines Agency (EMA) of a signal of blood clots in people vaccinated with COVID-19 Vaccine AstraZeneca®.

The EMA published the outcome of its review on the 19/03/2021. The findings of the review are as follows;

- the benefits of the vaccine in combating the still widespread threat of COVID-19 (which itself can cause clotting problems and may be fatal) continue to outweigh the risk of side effects;
- the vaccine is not associated with an increase in the overall risk of blood clots (thromboembolic events) in those who receive it. Overall, the number of thromboembolic events reported after vaccination was lower than that expected in the general population;
- there is no evidence of a problem related to specific batches of the vaccine
- however, the vaccine may be associated with **very rare** cases of unusual blood clots which are associated with thrombocytopenia, with or without bleeding. These include very rare cases of cerebral venous sinus thrombosis (CVST) and Disseminated Intravascular Coagulation (DIC).
- These are **very rare cases** – around 20 million people in the UK and EEA had received the vaccine as of March 16 2021 and the EMA had reviewed only **7** cases of blood clots in multiple blood vessels (DIC) and **18** cases of CVST.
- It has not been established if there is a causal link between the vaccine and these very rare unusual events. But because the numbers reported are higher than those that would be expected in the population, this can't be excluded. The EMA is continuing to investigate this possible association, and is closely monitoring the safety of all COVID-19 vaccines.

[**Read the EMA Published Outcome here**](#)

The EMA stated that the vaccine's proven efficacy in preventing hospitalisation and death from COVID-19 outweighs the extremely small possibility of developing DIC or CVST.

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Statement from the WHO GACVS COVID-19 subcommittee

On 19th March 2021 the WHO Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 subcommittee issued a statement on safety signals related to the AstraZeneca COVID-19 vaccine which states

The AstraZeneca COVID-19 vaccine continues to have a positive benefit-risk profile, with tremendous potential to prevent infections and reduce deaths across the world.

The available data do not suggest any overall increase in clotting conditions such as deep venous thrombosis or pulmonary embolism following administration of COVID-19 vaccines. Reported rates of thromboembolic events after COVID-19 vaccines are in line with the expected number of diagnoses of these conditions. Both conditions occur naturally and are not uncommon. They also occur as a result of COVID-19. The observed rates have been fewer than expected for such events.

While very rare and unique thromboembolic events in combination with thrombocytopenia, such as cerebral venous sinus thrombosis (CVST), have also been reported following vaccination with the AstraZeneca COVID-19 vaccine in Europe, it is not certain that they have been caused by vaccination. The European Medicines Agency's Pharmacovigilance and Risk Assessment Committee has reviewed 18 cases of CVST out of a total of more than 20 million vaccinations with the AstraZeneca COVID-19 vaccine in Europe. A causal relationship between these rare events has not been established at this time.

The GACVS subcommittee recommends that countries continue to monitor the safety of all COVID-19 vaccines and promote reporting of suspected adverse events.

The GACVS subcommittee also agrees with the European Medicines Agency's plans to further investigate and monitor for these events.

[***Read the WHO GACVS statement here***](#)

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COVID-19 Vaccine AstraZeneca®

The **National Immunisation Advisory Committee** has issued the following recommendations:

Recommendation 1

The administration of COVID-19 Vaccine AstraZeneca® should be recommended for use in all those aged 18 and over.

Recommendation 2

Healthcare professionals and vaccine recipients should be informed that very rare, complicated thromboembolic events have been reported in a small number of people who have recently received COVID-19 Vaccine AstraZeneca®.

They should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia and report any suspected adverse reactions to the Health Products Regulatory Authority.

Recommendation 3

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia and report any suspected adverse reactions to the Health Products Regulatory Authority.

Recommendation 4

Recipients of COVID-19 Vaccine AstraZeneca® should be instructed to seek immediate medical attention if they develop symptoms such as: shortness of breath, chest pain, leg swelling and/or persistent abdominal pain within weeks of vaccination.

Additionally, anyone with neurological symptoms including severe or persistent headaches (particularly 3 or more days after vaccination), blurred vision, or who develop bruising or petechiae beyond the site of vaccination, should seek prompt medical attention. These rare events that have been reported have usually occurred within 14 days of the COVID-19 Vaccine AstraZeneca®.

Recommendation 5

Healthcare professionals should seek early expert advice from the National Coagulation Centre about specialized 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 with COVID-19 Vaccine AstraZeneca®.

[*Read the NIAC recommendations here*](#)

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COVID-19 Vaccine AstraZeneca®

What advice should healthcare professionals give a person receiving COVID-19 Vaccine AstraZeneca®?

Prior to vaccination, healthcare professionals should inform the person of the extremely small possibility of developing DIC or CVST following vaccination, the symptoms and signs to be aware of after vaccination, and to seek prompt medical advice should these symptoms and signs develop.

The person to be vaccinated should be provided with the updated Patient Information Leaflet and HSE leaflet prior to vaccination. They should also be provided with the updated aftercare advice leaflet.

Please destroy any stock of previous versions of the EMA Patient Information Leaflet (PIL), the HSE Information leaflet and the HSE Aftercare Advice for COVID-19 Vaccine AstraZeneca®.

Healthcare professionals should report suspected adverse reactions to the HPRA

[Report a side effect with HPRA](#)

The following updated information is available on COVID-19 Vaccine AstraZeneca®:

Members of the public

- [Updated HSE Information leaflets](#) (available online)
- [Updated Patient information leaflet from EMA.](#) (see from page 25)
- [Recommendation from the National Immunisation Advisory Committee](#)
- [Frequently asked questions developed by the HSE](#)
- [Aftercare leaflet that includes information on signs and symptoms of thromboembolism and/or thrombocytopenia and what to do should these develop](#) (available online)

Healthcare professionals

- [National Immunisation Advisory Committee guidelines](#)
- [Updated Summary of Product Characteristics from EMA](#)
- [National Immunisation Advisory committee statement](#)
- [Recommendation from the National Immunisation Advisory Committee](#)
- [Link for reporting suspected adverse reaction to the HPRA](#)

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Covid-19 vaccines linked to a reduction in transmission

Public Health Scotland have announced the results of a study of healthcare workers employed by the NHS and their households (which has not yet been peer-reviewed).

[Read the Public Health Scotland Announcement](#)

The research involved over 300,000 people and ran between 8 December 2020 and 3 March 2021. The study compared cases and hospitalisations due to Covid-19 in household members of both vaccinated and unvaccinated health care workers.

The rate of infection with Covid-19 for people that live with healthcare workers was found to be at least 30% lower when the worker has been vaccinated with a single dose. Where healthcare workers had received a second dose of the vaccine at least 14 days before, their household members had a rate of Covid-19 which was at least 54% lower than household members where healthcare workers had not been vaccinated.

Despite this good news, it is important to remember that infection prevention and control practices in healthcare settings remain extremely important, as do the preventative measures we take to prevent spread of COVID-19 in our daily lives.

Effect of vaccination on transmission of COVID-19: an observational study in healthcare workers and their households will be available online.

[Read the study here](#)

Consent to Vaccination

Guidance and resource packs are available to support the consent process in disability services, and vaccination of people who may lack the capacity to consent.

- [Guidance and practical resource pack in preparation for Covid-19 vaccination programme in disability services](#)
- [Resources to Support the COVID-19 Vaccination Roll-out - dementia services](#)
- [Memo - Guidance regarding Consent for COVID 19 Vaccination](#)
- [Guidance Note - Supporting the consent process in those who lack capacity and are anxious / or refusing vaccination Version 1.1](#)
- [Consent for vaccination for COVID-19: Guiding Principles](#)

Queries regarding potential challenges related to vaccination and obtaining a consent, please email lead.integratedcare@hse.ie and dervelagrady@rcpi.ie

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Vaccine tracability forms in General Practice

Please **DO NOT** email your vaccine traceability forms to the NIO.

The NIO is not involved in the scheduling or delivery of vaccines.

These forms should be emailed to gpvaccines@hse.ie

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 now contains updated information for COVID-19 Vaccine AstraZeneca®

- Information from the National Immunisation Advisory Committee
- Clinical guidelines
- Medicine Protocol
- FAQs

[View Here](#)

Clinical Guidance for COVID-19 Vaccination

Quick Reference Guide to COVID-19 Vaccines

Name of Vaccine	Comirnaty® (Pfizer/BioNTech) COVID-19 mRNA Vaccine	COVID-19 Vaccine Moderna®	COVID-19 Vaccine AstraZeneca®
Type of Vaccine	mRNA vaccine	mRNA vaccine	Whole virus vaccine
Number of doses required	2	2	2
Interval	28 days	28 days	12 weeks
Minimum Interval	14 days	14 days	14 days
Indicated for	Age 16 and older	Age 18 and older	Age 18 and older
Supplied by National Cold Chain Service (NCCS)	Yes	Yes	Yes
Storage	-20°C to -80°C with initial dilution (120 hours from removal from ultra low temperature (ULT) in NCCS)	Freezer at -20°C to -15°C. Then cold to ice.	+2°C to +8°C
Stability	Yes, with 1.5mL of 0.9% sodium chloride	DO NOT DILUTE	DO NOT DILUTE
Handling	DO NOT SHAKE	DO NOT SHAKE	DO NOT SHAKE
Shelf life of unopened vial	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
Temperature	+2°C to +8°C	+2°C to +8°C	+2°C to +8°C
Stability of reconstituted vaccine	4 hours after dilution	6 hours after first puncture	6 hours after first puncture
Number of doses per vial	0.5 dose	0.5 dose	0.5 dose

Chapter 5a COVID-19
26 February 2021
5a COVID-19
SEVERE ACUTE RESPIRATORY SYNDROME
CORONAVIRUS 2, SARS-COV-2

NOTIFIABLE

In some circumstances, advice in these guidelines may differ from that in the Summary of Product Characteristics (SmPC) of the vaccines. When this occurs, the recommendations in these guidelines, which are based on current expert advice from NIAC, should be followed.

NOTE:
This chapter will be updated as new evidence becomes available.
Acronyms used in this document

IM injection technique. Note:

- Throughout the procedure, vaccinator's and patient's skin contact e.g. alcohol swabs, dry, clean with soap and water, for ≥30 seconds, to ensure
- old muscle: process, the bottom edge is
- At the injection site spread the skin taut between the thumb and forefinger with the non-dominant hand.
 - Do NOT bunch up the skin as this leads to administering the vaccine into subcutaneous tissue inadvertently.
- Use the dominant hand to inject the medication. This ensures control of the needle and syringe during the procedure.
- Hold the syringe firmly between thumb and forefinger, with heel of hand resting on the thumb of the non-dominant hand. This ensures a 90-degree angle is achieved and the correct site is targeted.
- Insert the needle smoothly and swiftly.
- Inject at a 90-degree angle, to ensure the medication reaches the muscle. Inject medication over 1-2 seconds.
- After removing the needle, use gentle pressure with a cotton ball or gauze. Do not massage the injection site.
- If there is a leakage at the injection site after withdrawal of needle: apply light pressure with gauze.

Swift needle entry
Slow injection of medication
Less pain

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COVID-19 Vaccination Training Programme

There are now nearly **11,000** 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

[Register Here](#)

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.

HSeLand will be temporarily unavailable from 23.00hrs Friday 26 March to the morning of Monday 29 March to perform an essential upgrade to their infrastructure to ensure better uptime and the stability of HSeLand .

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](#) for the most up to date information.