COVID-19 VACCINE BULLETIN 26

Welcome to Bulletin 26 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

Bulletins will now be published FORTNIGHTLY or more frequently, if required.

Updates and Reminders for Vaccinators

Very rare cases of myocarditis and pericarditis after mRNA vaccine

The European Medicines Agency (EMA) safety committee (PRAC) have advised that myocarditis and pericarditis be added as a new side effect for the mRNA COVID-19 vaccines Comirnaty® (Pfizer BioNTech) or Spikevax® (COVID-19 Vaccine Moderna).

Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of the membrane around the heart. Symptoms can vary but often include breathlessness, palpitations, and (acute and persisting) chest pain.

The cases reviewed mainly occurred within 2 weeks after vaccination, more often after the second dose and in younger adult men. The cases of myocarditis and pericarditis after vaccination usually improve with rest or treatment- similar to cases of myocarditis and pericarditis that occur without vaccination.

Healthcare professionals should be aware of the signs and symptoms of myocarditis and pericarditis in people who have had these vaccines. Health professionals who encounter such cases should refer to appropriate guidance and/or consult specialists (e.g. cardiologists) to diagnose and treat these conditions.

Vaccinators should advise individuals receiving this vaccine to seek urgent medical attention if they notice symptoms suggestive of myocarditis and pericarditis post vaccination.

The overall benefits of the COVID-19 vaccines continue to outweigh their risks.

Read more here

History of Capillary leak syndrome is a new contraindication for COVID-19 Vaccine Janssen®

The EMA's safety committee (PRAC) has recommended that people who have previously had a very rare syndrome called capillary leak syndrome, must not be vaccinated with COVID-19 Vaccine Janssen®.

The Committee also concluded that capillary leak syndrome should be added to the product information as a new side effect of the vaccine, together with a warning to raise awareness among healthcare professionals and patients of this very rare risk.

Capillary leak syndrome is a very rare, serious condition that causes fluid leakage from small blood vessels (capillaries), resulting in swelling mainly in the arms and legs, low blood pressure, thickening of the blood and low blood levels of albumin.

The Committee carried out a review of 3 cases of capillary leak syndrome which occurred within 2 days of vaccination in people who had received COVID-19 Vaccine Janssen®. Two of these cases were fatal. The EMA advises that healthcare professionals should be aware of the signs and symptoms of capillary leak syndrome and of its risk of recurrence in people who have previously been diagnosed with the condition.

Healthcare professionals should tell people receiving the vaccine that they must seek urgent medical attention if they have the following symptoms in the days after vaccination, which may be associated with feeling faint (due to low blood pressure):

- oedema in the extremities
- sudden weight gain

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A new warning added for Vaxzevria® (COVID-19 Vaccine AstraZeneca) - Guillain-Barre syndrome

Guillain-Barre syndrome or GBS is an immune system disorder that causes nerve inflammation and can result in pain, numbness, muscle weakness and difficulty walking.

The EMA safety committee has reviewed the evidence around the link between GBS and vaccination with Vaxzevria®. Although a causal association with Vaxzevria® and GBS has not been established but due to the seriousness of the rare condition it is to be added as a warning to the product information.

People receiving the vaccine should be made aware to seek urgent medical attention if they notice symptoms of GBS after vaccination with Vaxzevria®. Healthcare professionals should be alert to signs and symptoms of GBS which includes weakness and paralysis in the extremities that can progress to the chest and face.

The overall benefits of the COVID-19 vaccines continue to outweigh their risks.

Read more here

Dose Interval for Vaxzevria® (COVID-19 Vaccine AstraZeneca) reduced to 4 weeks

Recent National Immunisation Advisory Committee (NIAC) recommendations advise that individuals who have received their first dose of Vaxzevria® should get their second dose 4-12 weeks later (4-week interval is preferred). The HSE is working to reduce the time between dose 1 and dose 2 to 4 weeks. This will take time to reduce everyone's appointment to a 4-week gap.

Previously the interval was 8- 12 weeks due to evidence of a better immune response at that interval. However, significantly enhanced protection against the Delta variant with two doses and the increased transmissibility of the Delta variant causing a rise in cases has meant the interval has been reduced to 4 weeks so that people can have the best protection quicker.

Read more here

COVID-19 Vaccine Janssen® to be offered to 18-34 year olds

mRNA COVID-19 vaccines (Comirnaty® (Pfizer BioNTech) or Spikevax® (COVID-19 Vaccine Moderna)) are the recommended vaccines for people under the age of 50. This is because of the slightly increased (although still very rare) risk of unusual blood clots linked to people in that age group who get Vaxzevria® (COVID-19 Vaccine AstraZeneca) or COVID-19 Vaccine Janssen®.

Due to rising case numbers, individuals aged 18-34 can now avail the single dose Janssen vaccine from local participating pharmacies so that they can get vaccinated quicker. The longer people have to wait until they are fully vaccinated, the more individuals are at risk from getting COVID-19, including the Delta variant. All COVID-19 vaccines give good protection from severe illness from COVID-19 after being fully vaccinated.

Before getting COVID-19 Vaccine Janssen®, the individuals will be informed of the risk and benefits of each option and a consent form will be signed. A decision aid and consent form has been developed to support this process in pharmacies.

Read more here

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NIAC Chapter 5a and FAQs Updated

The National Immunisation Advisory Committee (NIAC) immunisation guidelines chapter 5a (on COVID-19 vaccines) was updated again recently.

Please review the two tables (one for mRNA vaccines and another for viral vector vaccines) for actions to take for individuals with specific allergy history with regards to contraindications and precautions. The tables were developed by NIAC in consultation with allergy and immunology specialists and updated again recently on 5 July 2021.

mRNA vaccines

Table 5a.3: Vaccination of those due an mRNA COVID-19 vaccine

	History	Action
Contraindication	• Anaphylaxis after a previous dose of Comirnaty® or Spikevax® (formerly COVID-19 vaccine Moderna®) • Anaphylaxis after polyethylene glycol (PEG, e.g., some bowel preparations for endoscopy, certain laxatives such as Movicol®)	Consider vaccination with Vaxzevria® or COVID-19 vaccine Janssen® in a suitable facility Observe for 30 minutes or Discuss with allergist/ immunologist
	• Anaphylaxis after Trometamol®; Spikevax® (formerly COVID-19 vaccine Moderna®) is contraindicated	Vaccinate with alternate vaccine
Special precautions	• Anaphylaxis after multiple, different drug classes, with no identified allergen (may indicate PEG allergy) • Anaphylaxis after a vaccine, or a medicine known to contain PEG • Unexplained anaphylaxis (may indicate PEG allergy)	Clarify if PEG is tolerated (see FAQs) Discuss with allergist/ immunologist Consider vaccination with Vaxzevria® or COVID-19 vaccine Janssen® Observe for 30 minutes
	• Mastocytosis • Idiopathic anaphylaxis • Anaphylaxis after food, venom or medication	Vaccinate as scheduled Observe for 30 minutes
Not a contraindication or a precaution	• Non-anaphylactic food allergy • Family history of allergy, including anaphylaxis • Previous local reaction to any vaccine • Hereditary angioedema • Contact dermatitis to PEG containing cosmetic product • Underlying asthma • Hay fever • NSAID allergy • Chronic spontaneous urticaria	Vaccinate as scheduled Observe for 15 minutes

Viral vector vaccines

Table 5a.4: Vaccination of those due a COVID-19 viral vector vaccine

	History	Action
Contraindication	• Anaphylaxis after a previous dose of Vaxzevria® • Anaphylaxis after polysorbate 80	Consider vaccination with Comirnaty® or Spikevax® (formerly COVID-19 vaccine Moderna®) in a suitable facility Observe for 30 minutes or Discuss with allergist/ immunologist
Special precautions	• Anaphylaxis after a vaccine, injected antibody preparation, or a medicine known to contain polysorbate 80 • Unexplained anaphylaxis (may indicate polysorbate 80 allergy)	Clarify if polysorbate 80 is tolerated (see FAQs) Discuss with allergist/ immunologist Consider vaccination with Comirnaty® or Spikevax® (formerly COVID-19 vaccine Moderna®) Observe for 30 minutes
	• Mastocytosis • Idiopathic anaphylaxis • Anaphylaxis after food, venom or medication	Vaccinate as scheduled Observe for 30 minutes
Not a contraindication or a precaution	• Non-anaphylactic food allergy • Family history of allergy, including anaphylaxis • Previous local reaction to any vaccine • Hereditary angioedema • Contact dermatitis to polysorbate 80 containing cosmetic product • Underlying asthma • Hay fever • NSAID allergy • Chronic spontaneous urticaria	Vaccinate as scheduled Observe for 15 minutes

Read more here

To support vaccinators and other front-line healthcare professionals NIAC and Irish Association of Allergy and Immunology have produced an FAQ document that provides information on how to advise allergic individuals according to their specific allergy history. This has now been updated again on 7 July 2021.

Read more here

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Spikevax® (COVID-19 Vaccine Moderna) storage updates

The manufacturer has recently updated some of the product information in the Summary of Product Characteristics (SmPC) on 11th June.

Key Changes include:

Subject	Key update	Previous recommendation
Unopened Vials	The unopened vaccine may be stored at +8°C to +25°C up to 24 hours after removal from refrigerated conditions.	Unopened vials may be stored at +8°C and +25°C for up to 12 hours after removal from refrigerated conditions.
Transportation of thawed vials in liquid state at 2°C to 8°C	If transport at -50°C to -15°C is not feasible, available data support transportation of one or more thawed vials in liquid state for up to 12 hours at 2°C to 8°C (within the 30 days shelf life at 2°C to 8°C). Once thawed and transported in liquid state at 2°C to 8°C, vials should not be refrozen and should be stored at 2°C to 8°C until use.	Once thawed, Spikevax® (COVID-19 Vaccine Moderna) cannot be moved from one site to another. Within the same site or campus, it can only be hand carried once with shaking and vibration minimised. The duration of this single journey must not exceed 1 hour.
Punctured vials	Chemical and physical in-use stability has been demonstrated for 19 hours at +2°C to +25°C after initial puncture (within the allowed use period of 30 days at +2°C to +8°C and 24 hours at +8°C to +25°C). From a microbiological point of view, the product should be used immediately. If the vaccine is not used immediately, in-use storage times and conditions are the responsibility of the user.	Once the vaccine has been punctured for the first time it must be used within 6 hours (between +2°C and +25°C)

HSE clinical guidance, standard operating procedures and NIAC immunisation guidelines have been updated.

Read more here

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Dose Interval for a two dose COVID-19 vaccine

It is important that vaccinators keep in line with recommended clinical guidance on timing of the second dose for COVID-19 vaccines on a two dose schedule. In particular second doses should be administered at the recommended interval.

In the HSE two doses of Comirnaty® (Pfizer BioNTech) should be administered with an interval of 28 days between doses (the National Immunisation Advisory Committee recommends an interval of 21 to 28 days). You do not need to restart the course if the interval is longer than 28 days. However, it should be noted the product information states that the participants whose data was used to calculate efficacy received their second dose within 19 to 42 days after their first dose. There is currently no clinical data on the efficacy of the vaccine when administered beyond intervals used in the clinical trial. Therefore it is recommended that the second dose of Comirnaty® is administered as close to the recommended 28 day interval as possible.

Table 1: Interval between two doses of Comirnaty® (Pfizer BioNTech)

Interval between the 1st and 2nd dose	Action Required
Less than 17 days	This is not considered a valid dose. A third dose should be given 28 days after the second (invalid) vaccine.
17 to 27 days	No further action needed. (Evidence from trial data is that this is a valid vaccine).
Longer than 28 days	Give the 2nd dose at whatever interval. The course does not need to be restarted.

Procedure for vaccinators who are concerned about a potential defect regarding a vaccine vial

Vaccines undergo rigorous checks and quality steps prior to final release from the manufacturer. During the manufacturing process, approximately 75% of manufacturing time is in quality or regulatory steps, with continuous monitoring and checks until the vials are released.

The product information usually states: "The vaccine should be inspected visually for particulate matter and discolouration prior to administration. Discard the vial if the suspension is discoloured or visible particles are observed."

When a vaccinator is concerned regarding a vial the following steps should be followed:

- The vaccinator should contact another health care professional (HCP) who has experience in using this product and ask for a second opinion
- The affected vial should be returned to the fridge and kept there in quarantine (between +2°C and +8°C)
- The vial in quarantine should be placed in a clearly marked area in the fridge "Quarantine - do not use"
- The vaccinator and senior experienced HCP should check the other vials in this batch in their fridge by removing one vial at a time and ensuring that the duration out of the fridge is kept to a minimum (less than 2 minutes).
- If more vials are considered defective, they should calculate the impact of placing vials into quarantine and arrange for additional deliveries if required.
- The HPRA, manufacturer and NIO should be emailed with details of the issue and with a photograph of vial identifying the defect (if possible).
- The NIO will follow up and contact other locations where this batch has been delivered if necessary.

This advice is now in the clinical guidance document.

Read more here

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Preventing Dilution Errors

The clinical leads in vaccination centres and individual vaccinators must ensure that the NIO Clinical guidelines are followed at all times and vaccinators have undergone appropriate training. Vaccinators can revisit their training modules available on the HSELand interim solution.

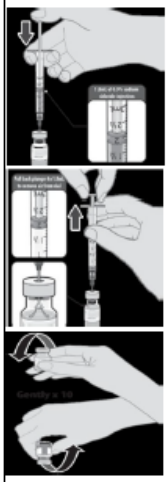
For vaccines such as Comirnaty® that require dilution it is important to check the product and expiry date of the diluent with a colleague as recommended in the clinical guidance before being used. Many products can look similar.

The following in an extract from our clinical guidance with relation to dilution of Comirnaty® (Pfizer BioNTech)

STEP 1. PREPARING FOR DILUTION

- Check the "use before" date and time on the box containing the vials with a colleague
- Remove the vial from the box in the fridge/ cool box
- Gently invert vial 10 times prior to dilution. Do not shake
- Inspect the liquid in the vial prior to dilution
- Should be an off-white solution. It may contain white to off-white amorphous particles.
- Remove cap
- Clean with 70% alcohol swab and allow it to air dry fully

STEP 2. DILUTION



- Twist to separate one ampoule of sodium chloride from other ampoules if attached
- Check product and expiry date with colleague
- Clean with a 70% alcohol swab
- Open the ampoule by twisting the cap using standard aseptic technique
- Connect syringe tightly to sodium chloride ampoule
- Withdraw 1.8ml of Sodium Chloride 0.9% Solution for Injection
- Cross check correct amount withdrawn with colleague
- Discard the ampoule and any remaining diluent in it into waste bin
- Using a 21 gauge green needle attached to the syringe,
- insert diluent slowly into the vaccine vial. You may feel some pressure in the vial as you add the diluent.
- Do not remove the needle from the vial. Keeping the needle above the level of the liquid, slowly withdraw 1.8 ml of air into the empty diluent syringe to equalise the pressure.
- Remove needle and syringe from vial.
- Dispose of the needle and syringe in a sharps bin.
- Gently invert the diluted solution 10 times. Do not shake.
- Diluted vaccine should be an off-white solution with no visible particles. Discard if particles present.
- Discard the diluted vaccine if particulates or discolouration are present

STEP 3. LABELLING THE VIAL

- Label the diluted vial with the date and "discard time" (6 hours after time of dilution) using a 24 hour format.
- Do not use the diluted vaccine after this date and time.
- e.g. vial diluted at 10.00 01/01/2021. Discard time is 16.00 01/01/2021
- After dilution, the vial contains 6 doses* of 0.3 ml
- Diluted vaccines can be stored at room temperature between +2°C and +30°C but must be used within 6 hours following dilution.
- Bring the vial to your vaccination table/site for vaccine preparation and administration

**If more than six 0.3ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses*

If clinical errors in the reconstitution or administration of the vaccines are made this should be reported immediately to senior staff on site, there should be an immediate risk assessment performed and the NIO should be contacted for advice around the validity of the dose.

Read more here

Vaxzevria name to now feature on deliveries

The product name for COVID-19 Vaccine AstraZeneca has changed some time ago on clinical guidance and product information to Vaxzevria®. The change in name will now be reflected on the product delivered from the National Cold Chain service. The Global Trade Item Number (GTIN) will still remain the same.

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Latest in Research

Preprint : Com-Cov study

What did the study examine:

This study examined whether a mixed vaccine schedule was at least as good as a standard vaccine schedule at producing higher levels of SARS CoV 2 antibodies 28 days after the booster vaccine dose.

Who was included in the study:

463 people who had never received a COVID-19 vaccine previously aged 50 years and over, with no or well-controlled mild-moderate comorbidities.

What does this mean?

The findings demonstrate that all the schedules studied (ChAd/BNT, BNT/BNT or BNT/ChAd) induced concentrations of antibodies to SARS CoV 2 at least as high as those induced after a licensed ChAd/ChAd schedule, which is effective in preventing symptomatic COVID-19 when administered at a 4-12 week prime-boost interval.

Administering a booster vaccine of either the same or alternative vaccines 28 days after the prime vaccination produced higher levels of SARS CoV 2 antibodies than a single dose of either vaccine alone.

Read more here

Although there may be recommendations made in external reports- they are for information only.
Please note that the **HSE clinical guidance on COVID-19 vaccines** should be referred to for up to date guidance for vaccinators in Ireland.

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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.

The training programmes have been extensively updated in recent weeks following updates from the National Immunisation Advisory Committee and the manufacturers. We would encourage you to log in and refresh your knowledge to ensure you are up to date with your COVID-19 training.

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.