



Welcome to the sixth bulletin from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID19 vaccination programme. Bulletins will be published every week or more frequently, if required.

COVID-19 Vaccine AstraZeneca® and pregnancy



The National immunisation Advisory Committee has updated their guidelines in relation to the use of COVID-19 Vaccine AstraZeneca®. The recommendation for the use of COVID-19 Vaccine AstraZeneca® is now consistent with the recommendations for mRNA COVID-19 vaccines.

Recommendation is as follows;

There is limited experience with the use of this vaccine in pregnant women. Animal reproductive toxicity studies have not yet been completed. Based upon results from the preliminary study, no effects are expected on development of the foetus. Although the available data do not indicate any safety concerns or harm to pregnancy, there is currently insufficient evidence to recommend routine use of this vaccine during pregnancy.

Administration of this vaccine in pregnancy should be considered when the potential benefits outweigh any potential risks for the mother (e.g. at high risk of severe disease, HCW) and foetus. Pregnant women who meet the priority criteria for vaccination and their obstetric caregivers should engage in shared decision-making in advance of vaccination. Counselling should balance available data on vaccine safety. Risks to pregnant women from SARS-CoV-2 infection, and a woman's individual risk for infection and severe disease.

When COVID-19 Vaccine AstraZeneca® is being administered in pregnancy, the two dose schedule should be given 12 weeks apart if possible. However, as the two dose schedule should be given between 14 and 33 completed weeks of gestation, a shorter interval can be used, 4-12 weeks apart.

There is no requirement to check a pregnancy test prior to the administration of any COVID-19 vaccine.

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Quick Reference Guide of the key differences between COVID-19 vaccines

Vaccinations of people aged 85 years and older are starting this coming week in general practice. We have developed a quick reference guide for COVID-19 vaccines. A summary of the mRNA vaccines which will be administered in general practice is in the table below:

administered in general practice is in the table below:		
Name of Vaccine	Comirnaty®	COVID-19 Vaccine Moderna®
Manufacturer	Pfizer/BioNTech	Moderna
Number of doses	2	2
Interval	28 days	28 days
Indicated for	Age 16 and older	Age 18 and older
Supplied by National Cold Chain Service (NCCS)	At +2°C to +8°C with limited shelf life (<120 hours)	Frozen at -25° to -15°C Thaw prior to use: In the fridge at +2 °C to +8 °C for 2 hours and 30 minutes* OR at room temperature +8 °C to +25 °C for 1 hour
Dilution	Yes with 1.8ml of 0.9% sodium chloride (supplied separately)	DO NOT DILUTE
Handling	DO NOT SHAKE Invert vial 10 times prior to dilution	DO NOT SHAKE Gently swirl vial prior to withdrawing each dose
Shelf life of an to to unopened vial NOTE must be stored upright) +2°C to +8°C	Undiluted vaccine until "use by time and date" (120 hours from removal of vial from ULT freezer in NCCS)	30 days ('use by' time and date)
Shelf life once vial is opened "discard time"	6 hours after dilution	6 hours after first puncture
Dose	0.3ml	0.5ml
Number of doses per vial	6 doses If more than six 0.3ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses.	10 doses If more than ten 0.5ml doses can be safely and accurately withdrawn from a multidose vial, they can be used as valid doses.

^{*}Keep at room temperature for 15 minutes prior to administration



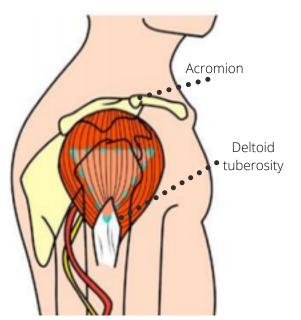






Intramuscular (IM) injection technique

All vaccinators must be competent in IM injection technique. Below is a reminder of IM injection technique. Note: COVID-19 vaccine should be given IM only.





- 2. **It is not necessary to use gloves** if the vaccinator's and patient's skin is intact.

1. Apply standard aseptic technique throughout the procedure.

- 3. It is not necessary to use a skin disinfectant e.g. alcohol swabs.
- If the skin at the injection site is visibly dirty, clean with soap and water.
- If an alcohol swab is used, delay injection for ≥30 seconds, to ensure the alcohol will have evaporated.
- 4. Land mark the injection site in the deltoid muscle:
 - Two finger widths down from the acromion process; the bottom edge is at an imaginary line drawn from the axilla
 - Injection site: 5cms below acromion process
- 5. 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.

NOTE: COVID-19 vaccine should be given by IM only.

- 6. Use the dominant hand to inject the medication. This ensures control of the needle and syringe during the procedure.
- 7. 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.
- 8. Insert the needle smoothly and swiftly.
- 9. Inject at a 90-degree angle, to ensure the medication reaches the muscle. Inject medication over 1-2 seconds.
- 10. After removing the needle, use gentle pressure with a cotton ball or gauze. Do not massage the injection site.
- 11. If there is a leakage at the injection site after withdrawal of needle: appl light pressure with gauze.

Swift needle entry

Slow injection of medication

Swift needle withdrawal



Less pain

NIAC recommendations:

"It is not necessary to use gloves for vaccine injections, unless contact with potentially infectious body fluids is possible, or unless the health care worker has an infected lesion on the hand. If gloves are worn they should be changed for each patient. If the skin at the injection site is visibly dirty it should be cleaned with soap and water. There is no need to use a disinfectant e.g. alcohol swabs.

If an alcohol swab is used, injection should be delayed for ≥30 seconds, to ensure the alcohol will have evaporated".









How to manage, store and handle vaccines

Comirnaty® and COVID-19 Vaccine Moderna® are mRNA vaccines and are very fragile.

- Vaccines must be stored upright during refrigerated storage.
- They should not be stored upside down or on their side.
- Pfizer/BioNTech has no stability data for thawed vials stored on their side for a prolonged period and cannot support the use of these vials.
- If a vial falls on its side for a short period during handling and is on its side for a short period then it should be righted and can be used.
- If a vial falls to the floor, there is the risk of hairline fractures that may not be visible to the naked eye. For this reason the manufacturer recommends it should not to be used.
- Do not shake vaccine vials.

Please refer to Clinical Guidance on COVID-19 Vaccination for details of vaccine preparation:

Read It Here

See Pfizer/BioNTech video for preparation of Comirnaty® vaccine

Watch It Here

Hand hygiene practice for safe vaccination

"Clean hands save lives"

Vaccination is a clean /aseptic procedure so performing hand hygiene is vital as per the WHO hand hygiene practice to prevent the risk of cross infection.



- Use an alcohol hand rub for hand hygiene when hands are visibly clean.
- When hands are visibly soiled use soap & water.

Basic hand hygiene rules as listed below must be followed when preparing & administering a vaccine

- Bare the wrists (e.g., short sleeved top or rolled up sleeves)
- · Remove all wrist jewellery, including wristwatch
- Remove all hand jewellery (a single plain band may be worn)
- Keep fingernails short (tips less than 0.5cm)
- Do not wear false nails or nail enhancements (e.g., gel nails)
- Do not wear nail varnish
- Cover cuts and abrasions with a waterproof dressing

Click to understand the importance of hand hygiene

Click to perform proper hand washing









Basic Life Support (BLS) and anaphylaxis training for vaccinators

We want to remind all vaccinators who are administering COVID-19 vaccines that they should be trained and competent in BLS and in the recognition and management of anaphylaxis. This is not unique to COVID-19 vaccines, and applies to all vaccines.

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Fever after COVID-19 vaccines

The National Immunisation Advisory Committee has issued a statement regarding fever after COVID-19 immunisation:

Vaccinated individuals should be advised that COVID-19 vaccines may cause a fever which usually resolves within 48 hours. This is a common, expected reaction. Isolation and further investigation are not generally required. Fever may be managed symptomatically with an antipyretic, provided there are no other concerns. Clinical judgement should be used based on the individual case. Carers and patients should be advised that if they have any concerns, they should seek advice from their GP.

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Latest monitoring data from the UK's Medicines and Health Products Regulatory Authority (MHRA)

The UK's MHRA have published an analysis of reports of suspected adverse events from members of the public public and healthcare professionals between 9th December 2020 and the 31st January 2021. An extract of the report is below:

The overall safety experience with both vaccines is so far as expected from the clinical trials. Based on current experience, the expected benefits of both COVID-19 vaccines in preventing COVID-19 and its serious complications far outweigh any known side effects.

Bell's Palsy

Up to the 31 January 2021 the MHRA have received 99 reports of facial paralysis or paresis with Pfizer/BioNTech vaccine. This is currently listed as a possible side effect in the Pfizer/BioNTech vaccine based on a small number of reports in the trials, but because this can also occur naturally an association with the vaccine is not yet confirmed. 15 reports of facial paralysis have been received for the COVID-19 Oxford University/AstraZeneca vaccine.

As well as individual clinical review of such reports, we are analysing these against the number of reports we would expect to occur in the absence of vaccination (the 'natural rate'). **Based on this review, the number of reports of facial paralysis received so far is similar to the expected natural rate and does not currently suggest an increased risk following the vaccines.** We will continue to monitor these events, including through evaluation of electronic healthcare record data.

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HSELand COVID-19 Webinar Series



6,200 people have now completed the COVID-19 Vaccine Webinar Series.

There are 2 Webinar Series available on www.hseland.ie for learners

- COVID-19 Vaccine Webinars for vaccinators who are trained and competent in immunisation practice
- COVID-19 Vaccination Programme for Nurses and Midwives

To access the series for your profession, log into your account on www.hseland.ie, click Education and Training Programmes and Resources for staff in the fight against COVID-19 in the green box on the homepage and then select the series for your profession on the right hand panel and follow the instructions on screen to begin the series.

The series includes information on Covid-19 Vaccine AstraZeneca. Please note that the updated information on administration of this vaccine in pregnancy contained in this bulletin will be included in the training video in the coming days.

To access these sections, log into your account on <u>www.hseland.ie</u> click *Certificates* along the top ribbon and then select *Learning Record*. The COVID-19 Vaccine Webinar Series should appear on your screen. Select one of the titles listed above and click *Launch* to view the additional or updated video.

If you are having difficulties accessing these updates, contact HSELand by email support@hseland.ie or phone 01 963 8272.

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



