

COVID-19 VACCINE BULLETIN 5

Welcome to the fifth bulletin from the HSE National Immunisation Office. Bulletins will be published every week or more frequently, if required.

COVID-19 Vaccine AstraZeneca

On the 29th January 2021, the European Medicines Agency (EMA) recommended a conditional marketing authorisation for COVID-19 Vaccine AstraZeneca® in those 18 years and over. The EMA licensing is for a two-dose schedule 4-12 weeks apart.

Evidence shows that protection starts from approximately 3 weeks after first dose of vaccine and persists up to 12 weeks. Studies show 76% protection overall against symptomatic COVID-19 disease in the first 90 days. Modelling showed no evidence of waning of protection in the first three months after vaccination. Higher efficacy of 82% after the second dose was found if the booster dose was given at 12 weeks.

There was insufficient clinical data to allow reliable calculation of efficacy in those aged 55 and older.

The National immunisation Advisory Committee (NIAC) has updated their guidelines:

1. Any currently authorised COVID-19 vaccine including COVID-19 Vaccine AstraZeneca® can be given to adults of all ages, including those aged 70 and older.
2. Vaccination of those aged 70 and older should not be delayed. Where practicable and timely, those aged 70 and older should be given an mRNA vaccine. Recommendations for those aged 65-69 will be made when impending new evidence has been reviewed

[Read More Here](#)

The next priority group to be vaccinated in the Government's COVID-19 Vaccination strategy are people aged 70 years and older.

Based on the recommendations of NIAC, the Department of Health's policy is that people **aged 70 years and older** will be offered mRNA vaccines (Comirnaty® and COVID-19 Vaccine Moderna®).

COVID-19 Vaccine AstraZeneca® will be offered to other people in the priority groups vaccination i.e. healthcare workers.

As there is evidence to show there is an increased immune response with a longer interval in those **under 65 years of age**, the two doses of 0.5mls should be given 12 weeks apart (NIAC recommendations are that for people aged less than 65 years, two doses are given 4-12 weeks apart).

For people **aged 65-69 years**, two doses should be given 6 weeks apart (NIAC recommendations are that for people aged 65 and older, two doses are given 4-6 weeks apart).

Check www.hseland.ie for updated training and www.immunisation.ie for updated Clinical guidance on COVID-19 Vaccination.

COVID-19 VACCINE BULLETIN 5

Allergies and mRNA COVID-19 vaccines

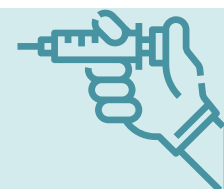
NIAC recommendations regarding contraindications to COVID-19 mRNA vaccines should be followed.

Comirnaty® and COVID-19 Vaccine Moderna® are contraindicated in people with a history of anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polyethylene glycol (PEG)).

Advice from a relevant specialist should be sought for a person with a history of an immediate systemic allergic reaction to any other vaccine, injectable therapy or polysorbate 80 (because of the cross reactivity with polyethylene glycol). The risks should be weighed against the benefits of vaccination. They should be observed for 30 minutes after vaccination.

Regarding post-vaccine observation, the following is advised:

- Those with no history of anaphylaxis from any cause: 15 minutes
- Those with a history of anaphylaxis from any cause: 30 minutes
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated



NIAC does not recommend vaccination in a hospital setting for people with a history of allergies.

As stated above, advice from a relevant specialist should be sought for a person with a history of an immediate systemic allergic reaction to any other vaccine or injectable therapy.

For more information: [the National Immunisation Advisory Committee \(NIAC\)](#) together with the Irish Association of Allergy and Immunology (IAAI) have produced a Frequently Asked Questions (FAQ) document about COVID-19 vaccines for people with pre-existing allergic conditions.

[Read It Here](#)

Number of doses in each vial

Comirnaty® (Pfizer/BioNTech) vaccine

Each diluted vial of Comirnaty® (Pfizer/BioNTech) vaccine contains 6 doses. It may be possible to withdraw up to 7 doses of vaccine from each vial especially when a low dead space needle and/or syringe are used. If it is not possible to withdraw a 7th dose of vaccine from a diluted vial of Comirnaty® the vial should be discarded. There should be no pooling of vaccine from different vials.

COVID-19 Vaccine Moderna® and COVID-19 Vaccine AstraZeneca®

Each vial of COVID-19 Vaccine Moderna® and of COVID-19 vaccine AstraZeneca® contains 10 doses. It may be possible to withdraw 11 doses from each vial especially when low dead volume syringes and/or needles are used. If it is not possible to withdraw an 11th dose from a vial of COVID-19 Vaccine Moderna® or of COVID-19 vaccine AstraZeneca® the vaccine the vial should be discarded. There should be no pooling of vaccine from different vials.

[See Clinical Guidance](#)

[Read More Here](#)

COVID-19 VACCINE BULLETIN 5



Drawing up vaccines for administration

The HSE advice is that for Comirnaty® (Pfizer/BioNTech) vaccine and COVID-19 Vaccine Moderna® vaccine and COVID-19 vaccine AstraZeneca® doses should be drawn up in a syringe and administered immediately. One dose at a time should be withdrawn and administered immediately before another dose is drawn from the vial. This is consistent with the advice from the manufacturers.

Storage of mRNA Vaccines

Comirnaty® Pfizer-BioNTech and Covid-19 vaccine Moderna® are both mRNA vaccines and they have an extreme physical fragility. Storage conditions compliance is paramount to preserve this fragility and the ability of these vaccine to work. The manufacturers require the vaccine vials to be stored in an **upright** position. Prolonged storage of vials inverted or on their sides is incorrect and therefore it adversely affects the vaccine, rendering them unsuitable for use.

Please see the two photos clearly identifying the correct way the box must be positioned and the incorrect way which would necessitate the destruction of the vaccines. Storage with red stickers visible stating **'this way up'** is correct, and the incorrect position has the box on side, white sticker visible, red sticker not visible.



COVID-19 VACCINE BULLETIN 5

Safe disposal of empty/used vaccine vials

Do **NOT** leave the empty vaccine vials unattended as this poses a health & safety risk. The vaccinator should dispose the empty vaccine vials into a sharps bin safely as per the healthcare waste management policy. These healthcare risk waste bins must be stored safely with restricted public access. This measure can prevent the malpractice of empty vaccine vials turning up anywhere outside the clinic.

Vaccination of healthcare workers with Comirnaty®

Healthcare workers will be receiving their second dose of Comirnaty vaccine in the coming weeks. In clinical trials a higher rate of local and systemic adverse events were seen after the second dose. Staggering of staff vaccination for 2nd doses of vaccine may be considered to ensure adequate staffing due to possible adverse reactions .

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](#)

The 2nd safety report has been published by HPR

This update concluded that the safety data collected for Comirnaty® to date is consistent with the known safety profile of the vaccine and there were no changes to the recommended use of the vaccine.

[Read More Here](#)

COVID-19 VACCINE BULLETIN 5



Pregnant women attending for COVID-19 vaccination with an mRNA Vaccine (Comirnaty® and COVID-19 Vaccine Moderna®)

Pregnant women who are between 14 weeks and 33 weeks of gestation may receive COVID-19 mRNA vaccines. They should be advised to consult with their obstetric care giver (Obstetrician or GP) about the benefits and risks of vaccination. Counselling from their obstetric care giver 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.

If a woman is between 14 and 33 weeks gestation and has decided to receive a COVID-19 mRNA vaccine following a consultation with her Obstetrician or GP, she can be vaccinated. There is no longer a requirement for a pregnant woman to provide a letter from their obstetric care giver (Obstetrician or GP) prior to vaccination with an mRNA COVID-19 vaccine.

Women who are at less than 14 weeks or more than 33 weeks of gestation should not receive COVID-19 mRNA vaccines.

[Read More Here](#)

Please note that the advice of the National Immunisation Advisory Committee (NIAC) regarding vaccination of pregnant women with COVID-19 Vaccine AstraZeneca® is different to that for mRNA vaccines .

NIAC states in relation to COVID-19 Vaccine AstraZeneca: 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.

Therefore at present COVID-19 Vaccine AstraZeneca® should be deferred in women who are pregnant, until further advice is available from NIAC.

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