COVID-19 VACCINE BULLETIN 28

Welcome to Bulletin 28 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.

Latest Updates for vaccinators

NIAC approves vaccination of adolescents aged 12-15

NIAC has reviewed the evidence in relation to vaccinating adolescents aged 12-15. The two mRNA COVID-19 vaccines (SpikeVax and Comirnaty) are approved by the EMA for use in this age group. Currently countries such as the United States, Israel, Germany and France are also vaccinating adolescents aged 12 and over.

In Ireland, NIAC has recommended that the vaccine be offered to this cohort to protect them from severe COVID-19 and rare but important consequences such as long COVID and Multisystem Inflammatory Syndrome in Children.

Vaccination should be strongly considered for those with underlying medical conditions and those living with people at high risk of severe COVID-19 e.g. a younger child with complex medical needs, or with an immunocompromised adult.

NIAC has also reviewed the data from the EMA and the United States on the risk of myocarditis and pericarditis following mRNA vaccines. The risk of these inflammatory conditions is higher in younger men and following the second dose.

Furthermore NIAC has provided some recommendations around informed consent from parents and guardians of children in this age cohort so that they are able to make the best decision for their child based on the available information.

The HSE is working to operationalise this recommendation. The registration portal is planned to open on Thursday August 12th for children aged 12-15.

Training, clinical guidance, medicines protocols and supporting documents are being updated.

A new module on HSEland has been developed to provide advice and guidance on the process for gaining consent from parents and legal guardians of 12-15 year olds to support the programme. We strongly recommend that any vaccinator offering vaccines to this age group views this module. (search for COVID-19 Vaccine Training Programmes and complete the video)

HSeLand

A webpage to help parents on this decision has also been created.

HSE Webpage

A webpage with resources to support health care professionals has been created including a decision aid to help you talk to parents about this choice. This will be updated with more materials next week including frequently asked questions and a consent form for general practice and pharmacies.

NIO Webpage

A Statutory Instrument has been signed extending the supply and administration of Comiranity and Spikevax to 12 years and over and the medicines protocols have been updated to reflect this.

NIO Webpage

Read the NIAC Recommendations

Read NIAC Chapter 5a - COVID-19

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Risk of myocarditis and pericarditis after mRNA vaccines updated by NIAC

In their recent updates to the immunisation guidelines on COVID-19 (Chapter 5a) NIAC have included an update on Myocarditis and Pericarditis in relation to vaccine safety.

Myocarditis is an inflammation of the heart muscle. Pericarditis is inflammation of the lining of the heart. They are listed as very rare side effect of mRNA vaccines. The symptoms can include breathlessness, palpitations and chest pain. Healthcare professionals and people receiving the vaccine should be aware of these symptoms in the days following vaccination.

Of the cases reported worldwide most have been self-limiting – meaning they tend to resolve with rest or some treatment. Some cases did require short hospital stays. Often, restriction of strenuous physical activity is advised for six months following myocarditis. We don't yet know if there are any long-term problems because of these side effects.

The EMA safety committee investigated cases of myocarditis and pericarditis reported after vaccination. Myocarditis has been reported in about 1 in 1,000,000 doses. Pericarditis has been reported in about 1 in 1,000,000 doses. EMA concluded that the cases primarily occurred within 14 days after vaccination, more often after the second dose of an mRNA vaccine and in younger adult men.

EMA concluded that the risk – benefit profile of the vaccine remains favourable.

However we have more data from the United States (US). The US Advisory Committee on Immunisation Practices concluded that the benefits of COVID-19 vaccines clearly outweighed the risks of vaccination. They estimated that in females aged 12-17 years, for each million second doses of vaccine administered, 8-10 cases of myocarditis might be anticipated, but 8,500 cases of COVID-19, 183 hospitalisations, 38 ICU admissions and one death would be prevented. In males aged 12-17 years, for each million second doses of vaccine administered, 56 -69 cases of myocarditis might be anticipated, but 5,700 cases of COVID-19, 215 hospitalisations, 71 ICU admissions and two deaths would be prevented.

A previous history of myocarditis after a dose of an mRNA vaccine is a contraindication to a second dose of an mRNA vaccine.

A precaution is included for both mRNA vaccines around pericarditis- those with previous history of pericarditis after a dose of an mRNA vaccine should seek specialist advice.

Read the COVID-19 Clinical Guidelines

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Individuals with a specific allergy history

A reminder to vaccinators that NIAC and 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. This was updated on 7th July.

The FAQ document has been created as supplemental information to aid vaccinators and other front-line healthcare professionals (GPs, Occupational Health etc.). The document provides information on how to advise individuals according to their specific allergy history.

Read the FAQs on the RCPI website

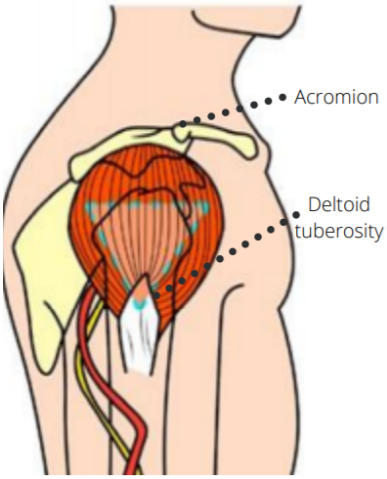
Intramuscular injection technique when vaccinating adolescents

When vaccinating adolescents aged 12-15 years, the same intramuscular injection technique should be followed as for adults.

The injection site must be landmarked correctly to avoid injury associated with administration of the vaccine in the wrong site.

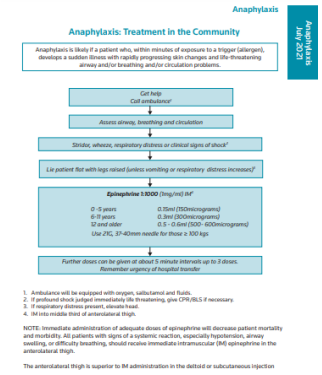
Several supporting documents, training videos and modules are available on correct IM injection technique.

Please contact your clinical lead or line manager if you need additional support or training.



IM Injection Technique

Adrenaline dose for management of anaphylaxis in adolescents aged 12-15.


Anaphylaxis

Anaphylaxis: Treatment in the Community

Anaphylaxis is likely if a patient who, within minutes of exposure to a trigger (allergen), develops a sudden illness with rapidly progressing skin changes and life-threatening airway and/or breathing and/or circulation problems.

Get help
Call ambulance[1]

Assess airway, breathing and circulation

Stridor, wheeze, respiratory distress or clinical signs of shock[2]

Lie patient flat with legs raised (unless vomiting or respiratory distress increases)[3]

Epinephrine 1:1000 (1mg/ml) IM[4]

0 -5 years	0.15ml (150micrograms)
6-11 years	0.3ml (300micrograms)
12 and older	0.5 - 0.6ml (500- 600micrograms)

Use 21G, 37-40mm needle for those ≥ 100 kgs

Further doses can be given at about 5-minute intervals up to 3 doses.
Remember urgency of hospital transfer

1. Ambulance will be equipped with oxygen, salbutamol and fluids.
2. If profound shock judged immediately life threatening, give CPR/BLS if necessary.
3. If respiratory distress present, elevate head.
4. IM into middle third of anterolateral thigh.

NOTE: Immediate administration of adequate doses of epinephrine will decrease patient mortality and morbidity. All patients with signs of a systemic reaction, especially hypotension, airway swelling, or difficulty breathing, should receive immediate intramuscular (IM) epinephrine in the anterolateral thigh.

The anterolateral thigh is superior to IM administration in the deltoid or subcutaneous injection

Anaphylaxis July 2021

The dose of Epinephrine 1:1000 (1mg/ml) IM recommended by the National Immunisation Advisory Committee for people aged 12 years and older is 0.5- 0.6ml (500- 600micrograms).

This is the same dose as for adults.

The NIAC section on anaphylaxis has recently been updated:

NIAC - Anaphylaxis

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Dose interval for mRNA Vaccines

Comirnaty

The recommended interval between two doses of Comirnaty vaccines is 21-28 days as per NIAC and SmPC. Previously due to supply issues, the interval was 28 days. Currently vaccination centres are able to provide the second dose between 21-28 days. While dose 2 of Comirnaty administered on 17-20 days is still valid - the programme guidance is to maintain the 21-28 day interval where possible.

Table 1: Interval between doses of Comirnaty and actions required.

Interval between 1st and 2nd doses	Action required
Less than 17 days	This this is not considered a valid vaccine. A third dose should be given 28 days after the second (invalid) vaccine.
17 to 21 days	No further action needed (Evidence from trial data is that this is a valid vaccine).
Longer than 21 days	Give the 2nd dose at whatever interval. The course does not need to be restarted.

Spikevax

The recommended interval for Spikevax (Moderna) is 28 days.

Table 2: Interval between doses of Spikevax and actions required.

Interval between 1st and 2nd doses	Action required
Less than 24 days	This is not considered a valid vaccine. A third dose should be given 28 days after the second (invalid) vaccine.
24-27 days	No further action needed (Evidence from trial data 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.

Read more here: **COVID-19 Clinical Guidelines**

Interrupted immunisation courses

If an immunisation course is interrupted, it should be resumed as soon as possible.

It is not necessary to repeat the course, regardless of the time interval from the previous incomplete course except cholera vaccine.

Read more here: **Chapter 2 - NIAC Guidelines**

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Heterologous vaccine schedules

The National Immunisation Advisory Committee (NIAC), does not recommend mixing COVID vaccines unless the 2nd dose of COVID vaccine is contraindicated.

NIAC has sent further recommendations on heterologous COVID-19 vaccine schedules to the Department of Health who are currently considering these recommendations.

Read more here: **COVID-19 Clinical Guidelines**

COVID-19 vaccines storage and handling

The storage and handling on COVID-19 vaccines must be maintained as per the individual Summary of Product Characteristics (SmPC) to ensure efficacy of the vaccine.

It is important to note that each brand of COVID-19 vaccine has specific room temperature parameters and available in the SmPC .

COVID-19 Vaccine	Maximum room temperature and duration
Comirnaty (Pfizer)	>8°C to +30°C for 2 hours prior to dilution
SpikeVax (Moderna)	>8°C to +25°C for 24 hours if unopened or 19 hours if punctured vial
Vaxzevria (AstraZeneca)	>8°C to +30°C for 12 unopened vial or 6 hours if punctured
COVID-19 Vaccine Janssen	>8°C to +25°C for 12 hours unopened or 3 hours if punctured

Read more here: **COVID-19 Clinical Guidelines**

Co-administration of COVID-19 vaccines with other inactivated or live vaccines

NIAC recommends that other vaccines may be administered with COVID-19 vaccines at the same time or at any interval. If other vaccines are being given at the same time as COVID-19 vaccines it is preferable to give them in different limbs.

If it is not possible to give the different vaccines in different limbs they should be administered at least 2.5cm apart.

Read more here: **COVID-19 Clinical Guidelines**

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Managing Expiry Dates in TrackVax

It is important to manage stock by rotating stock and using the shortest dated product first and in particular noting that stock received from other locations other than the National Cold Chain Service which can be short-dated stock.

1. A stock report can be run at any point within the 'CVC Reports' area of TrackVax. The report can be accessed by CVC Admin level and requires user login to access.
   - The report can be accessed via 'Current Stock' under the 'By Expiry Date' Tab. This report can be exported to Excel by clicking on 'Print Report' and then 'copy' to take the data and paste into Excel.
   - Note there are some issues with expiry dates on both Janssen and Moderna vaccine (any date that is beyond 3 months for Janssen and 30 days for Moderna is incorrect, the 'date received' can help establish estimated 'use before' /expiry date.
2. There will be an additional feature in Version 22 of TrackVax where the stock closest to expiry is shown in the Dashboard and will change to a white background when it is within 7 days of expiry.

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?

Clinical queries from healthcare professionals can be directed to our HSE email address.

Send your query

Should vaccines be exposed to temperatures outside of parameters please contact the National Immunisation Office pharmacists immediately. Contacts include:

- Achal Gupta: mobile 087 4064810
- Mariangela Toma: mobile 087 7575679
- Cliona Kiersey: mobile 087 9915452

The National Immunisation Office is not involved in the allocation or delivery of COVID-19 Vaccines.

Queries that are not clinical or technical cannot be answered by the National Immunisation Office

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.