COVID-19 VACCINE BULLETIN 29

Welcome to Bulletin 29 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

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

Heterologous/mixed schedules of COVID-19 vaccines

The National Immunisation Advisory Committee (NIAC) has issued recommendations to the Department of Health regarding heterologous/mixed schedules of COVID-19 vaccines in certain circumstances. The Department of Health has announced a change in policy based on these recommendations.

The HSE is planning the implementation of this change in policy (including the provision of information to those being vaccinated) and more information will be issued. Clinical guidance, training materials etc. will also be updated.

A summary of NIAC recommendations is below:

Current homologous vaccine schedules including Vaxzevria® are proven highly effective against COVID-19 hospitalisation and severe disease including that caused by the Alpha and Delta variants.

Early studies indicated that heterologous combinations are highly immunogenic. For those who received a 1st dose of Vaxzevria®, an mRNA vaccine as the second vaccine dose can result in excellent humoral and enhanced cellular immunity. It remains to be proven that the augmented immunogenicity translates into better clinical effectiveness against COVID-19, because we do not yet have data that this schedule results in clinical effectiveness (i.e. prevention of COVID-19).

While there are no immediate serious safety concerns with heterologous vaccine schedules, current data indicates that the rates of side effects following the second dose may be higher. Further monitoring is required to determine the long-term and overall safety profile of these schedules.

Given the impact of the Delta variant and the rapidly rising case numbers, there is an urgency to get everyone vaccinated as safely and as quickly as possible. Available evidence supports the use of heterologous vaccination schedules in some circumstances to maximise vaccine uptake.

Recommendations

1. Given the proven real-world effectiveness of the currently authorised homologous schedules, including effectiveness against the Delta variant, **NIAC continues to preferentially recommend homologous schedules for all age groups.**
2. Homologous mRNA vaccine schedules are preferred for those under 50 years of age.
3. Where a second vaccine dose of a homologous schedules is contraindicated, a heterologous vaccine schedule can be used, irrespective of whether the first dose was an mRNA or adenoviral vector vaccine.
4. For those who have already had a first dose of Vaxzevria® and who did not complete the vaccination schedule as recommended, an mRNA vaccine should be offered in line with their priority grouping or age cohort.

Read more here

Recommendations are continued on page 2

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Heterologous/mixed schedules of COVID-19 vaccines

Recommendations (continued from page 1)

5 Those 18 - 34 years of age who opt for Vaxzevria® as a sooner alternative to an mRNA vaccine are recommended to complete that vaccine course with Vaxzevria®.

5.1 If they decline the offer of a second dose of Vaxzevria®, they should be afforded the option of completing vaccination with an mRNA vaccine along with their age cohort. They should be informed that this may delay optimising their protection.

5.2 If there are sufficient supplies of mRNA vaccines, individuals who receive a first dose of Vaxzevria® should be offered the option of a second vaccine of either Vaxzevria® or an mRNA vaccine.

6 Those who have received a heterologous schedule should be considered fully vaccinated after their second vaccine (7 days after Comirnaty®, 14 days after Spikevax® and 15 days after Vaxzevria®).

Read more here

Vaccination of young people aged 12-15 years

Administration of COVID-19 vaccines with vaccines included in the schools immunisation programme

We have had several queries about whether there is a need for an interval between COVID-19 vaccines and other vaccines such as HPV and Tdap.

NIAC advises 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

Advice for vaccinators when there is a disagreement between parents regarding vaccination of their children

The **document** "**Who can give consent for vaccination of a young person aged under 16 years?**" has been updated to include information about "Disagreement between parents about Covid vaccination" which might be useful for vaccinators.

A summary is below:

Although the consent of one person with parental responsibility is sufficient to authorise vaccination for a child aged 12-15 years, if the vaccinator has been specifically notified by either parent/legal guardian that one parent/legal guardian objects to vaccination, the vaccination should not be carried out, even though the other parent/legal guardian consents.

In such situations, the parents/legal guardians should be advised to discuss matters among themselves to seek to resolve their dispute. Parents/legal guardians should be encouraged to discuss the matter with their child's General Practitioner to address any concerns regarding the vaccine. The parents/legal guardians should also be encouraged to discuss vaccination with their child, whose own views are also important. Ultimately, the matter may need to be resolved by the parents through the courts.

Every reasonable effort should be made to avoid vaccination of a child where one parent/legal guardian has indicated that s/he objects to vaccination. The onus as per the HSE National Consent Policy is on the objecting parent/legal guardian to make this objection known to the service in question. A parent/ guardian may make an objection known by contacting a local vaccination centre or the child's General Practitioner. When this happens, they should be asked for the child's PPSN which will enable the objection to be registered on the information system.

Read more here

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Information and Communication Resources for members of the Travelling Community and Migrants

The HSE has worked with the World COVID-19 Service to develop videos in different languages to support communities whose first language is not English. Information is available in written format in 26 languages including Albanian, Pashto and Zulu.

Read more here

Information is also available in accessible and easy read format

Read more here

Pavee point have also created videos and resources to support the Travelling and Roma communities in Ireland

Read more here

Materials are updated as new information becomes available.

Updates to the product information for COVID-19 Vaccine Janssen® from the European Medicines Agency

The European Medicines Agency's safety committee has recommended amending the product information for COVID-19 vaccine Janssen to include immune thrombocytopenia (ITP) as a side effect, together with a warning to alert healthcare professionals and people taking the vaccine. ITP is a condition in which the immune system mistakenly attacks and destroys blood cells called platelets that are needed for normal blood clotting. The licensed documentation for the product will be amended with these changes.

These cases were reported very rarely. The safety committee of EMA reviewed 120 worldwide cases of suspected ITP by 18 June 2021; of these, 4 cases had a fatal outcome. As of 30 June 2021, over 21 million people had received the vaccine globally (equivalent to 1 case reported per 210,000 doses).

The EMA also recommended to add dizziness and tinnitus as adverse reactions to alert healthcare professionals and people taking the vaccine of these potential side effects.

The EMA reviewed 1,183 cases of dizziness identified as part of spontaneous reports on anxiety-related reactions to immunisation.

Regarding tinnitus, EMA investigated 6 cases observed in clinical trials and 108 cases identified by the company during monitoring spontaneous reports.

The benefit-risk balance of the vaccine remains unchanged.

EMA will continue to closely monitor this issue and will communicate further when new information becomes available.

Read more here

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Withdrawing doses from a vial of Comirnaty® (Pfizer BioNTech)

After dilution, each vial contains 6 doses. If a seventh dose of 0.3ml can be safely and accurately withdrawn from a diluted vial, it is a valid dose.

In CVCs where doses may be withdrawn in advance, if eight doses have been obtained from a vial, each of the syringes must be examined by another person to identify the syringe with less than 0.3ml. If all syringes contain 0.3ml then more than 1.8ml must have been added and the vial has been over-diluted.

Read more here

Myocarditis and Pericarditis pathway post mRNA vaccination

Cases of myocarditis and pericarditis have been reported very rarely following vaccination with the COVID-19 mRNA vaccines Comirnaty™ (BioNTech/Pfizer) and Spikevax (Moderna).

A pathway has been developed by the National Clinical Advisors and Group Leads (NCAGL) to support clinicians who are dealing with suspected cases of myocarditis and pericarditis after mRNA vaccination. Key points :

- Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis and where clinically suspected, should refer individuals to the Emergency Department/Acute Medical Assessment Unit for investigations including ECG and troponin.
- Patients with a confirmed or probable myocarditis should not receive another dose of mRNA vaccine. If they are aged 18 years and over they may be given a viral vector vaccine (provided there are no contraindications) 28 days after the first dose.
- Following a diagnosis of confirmed pericarditis, the GP and patient/parent/guardian should liaise with the treating Cardiologist to make a joint decision as to whether the patient can attend for a subsequent dose of mRNA COVID-19 vaccine.

Read more here

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HSeLanD is back online

Following the cyber-attack, HSeLanD has been fully restored and is back online.

You can now access the National Immunisation Office COVID-19 Vaccination Training Programme for Pfizer, Moderna, AstraZeneca and Janssen vaccine through your HSeLanD account.

Visit HSeLanD

Important reminders for learners

- If you have an existing account for HSeLanD, you MUST use your original account details. DO NOT create a new account unless you have never used HSeLanD.

- If you completed COVID-19 Vaccination Training on the interim HSeLanD solution, remember to load your certificate to your learning record on your HSeLanD account.

- 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).

We would encourage you to log in and complete the updated content in each programme to refresh your knowledge and ensure you are up to date with your COVID-19 Vaccination Training.

If you have any issues with the platform please contact HSeLand directly.

Contact HSeLanD

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Latest in Research

Vaccine administration at a higher location than recommended and supraclavicular lymphadenopathy

This case series published in Eurosurveillance, highlights the importance of correct intramuscular injection technique and the administration of the vaccine in the correct site.

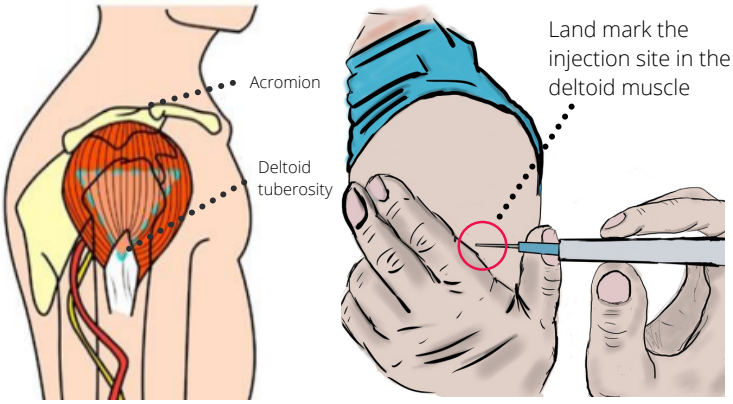
The authors report on 20 cases of acute onset of single supraclavicular lymphadenopathy coinciding with administration of a dose of an mRNA vaccine on the same side. While axillary lymphadenopathy had been reported as a recognised adverse reaction following mRNA vaccines, supraclavicular lymphadenopathy had not, and therefore this finding prompted concern amongst recipients and healthcare professionals about other possible cause, including malignancy.

Twelve of the 20 patients in the case series spontaneously reported that the intramuscular injection point was unusually high, and nearly all (17/20) acknowledged a similar perception when they were asked about this specifically (either compared with the previous dose administration or in relation to their theoretical expectation about the exact location of the point of injection).

The authors' report that if the vaccine was given at a higher location than recommended, the supraclavicular lymph nodes and not the axillary nodes is the most frequent drainage area and therefore this may have resulted in supraclavicular lymphadenopathy.

Land marking the injection site is a crucial step to ensure administration of the vaccine at the correct site of the Deltoid muscle. This has been highlighted in this bulletin, and through training and guidance. See immunisation.ie for further details.

Read more here



Summary sheet outlining the IM injection technique

Click here

Training video

Click here

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Latest in Research

Clinical Features of Vaccine-Induced Immune Thrombocytopenia and Thrombosis

This prospective cohort study was carried out among 294 patients with suspected vaccine induced thrombocytopenia and thrombosis (VITT) over a three-month period in the UK. There were 170 definite and 50 probable cases if VITT. All patients had received the first dose of the Oxford-AstraZeneca adenoviral vector vaccine. The median number of days following administration of the vaccine to presentation with suspected VITT was 14 days (Range 5-48 days) and the median age was 48 years (Range 18 to 79 years). There was no sex difference and no identifiable medical risk factors. There was a high mortality rate among those with VTTT (22% overall). Mortality was higher among those with lower platelet counts, lower fibrinogen counts, intracranial haemorrhage and cerebral venous sinus thrombosis. Treatment remains uncertain however identification of prognostic markers may help to guide effective management.

Read more here

Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK

This large community-based survey of randomly selected households across the UK examined vaccine effectiveness against the COVID-19 Delta variant in those aged 18 years and older. This study found that the effectiveness of the Pfizer-BioNTech and Oxford-AstraZeneca vaccines is reduced with the Delta variant. Two doses of the Pfizer-BioNTech or Oxford-AstraZeneca vaccine provided the same protection as having previous infection. Those who were vaccinated after infection had more protection than those vaccinated without having had prior infection. Protection was higher among younger age groups and the time between vaccine doses did not affect effectiveness. Compared to Oxford-AstraZeneca vaccines, the Pfizer-BioNTech vaccine has greater initial effectiveness but this declines faster than Oxford-AstraZeneca. A single dose of the Moderna vaccine had similar or greater effectiveness compared to a single dose of the Pfizer-BioNTech or Oxford-AstraZeneca vaccines. For those who were infected with the Delta variant after vaccination, peak levels of virus were similar to those in unvaccinated individuals. Overall, this study found that obtaining two vaccine doses is the most effective way to ensure protection against the COVID-19 Delta variant, however vaccine effectiveness is reduced and peak viral load is higher with the Delta variant.

Read more here

Risk of Myocarditis from COVID-19 Infection in People Under Age 20: A Population-Based Analysis (Pre-print)

This US study examined medical records from 48 healthcare organisations and included patients aged less than 20 years who had a COVID-19 diagnosis between April 2020 and March 2021. The primary outcome was a diagnosis of myocarditis within 90 days of a diagnosis of COVID-19 or a positive COVID-19 test. In total 14,207 patients aged 12-17 years were included in the study. This study found that for males aged 12-17 years, the adjusted rate of myocarditis was 450 per million cases of COVID-19. For females aged 12-17 years, the adjusted rate of myocarditis was 213 cases per million cases of COVID-19. Myocarditis occurred within 5 days in 40% or from 19-82 days in 60%. Two patients were hospitalised and there were no deaths reported. There is a risk of myocarditis associated with receiving an mRNA COVID-19 vaccine. This risk is highest in those aged 12-17 years and is higher in males compared to females. Overall, this study concluded that young males aged 12-17 years infected with the virus are up to 6 times more likely to develop myocarditis as those who receive the vaccine and that young females aged 12-17 years infected with the virus are up to 21 times more likely to develop myocarditis as those who receive the vaccine.

Read more here

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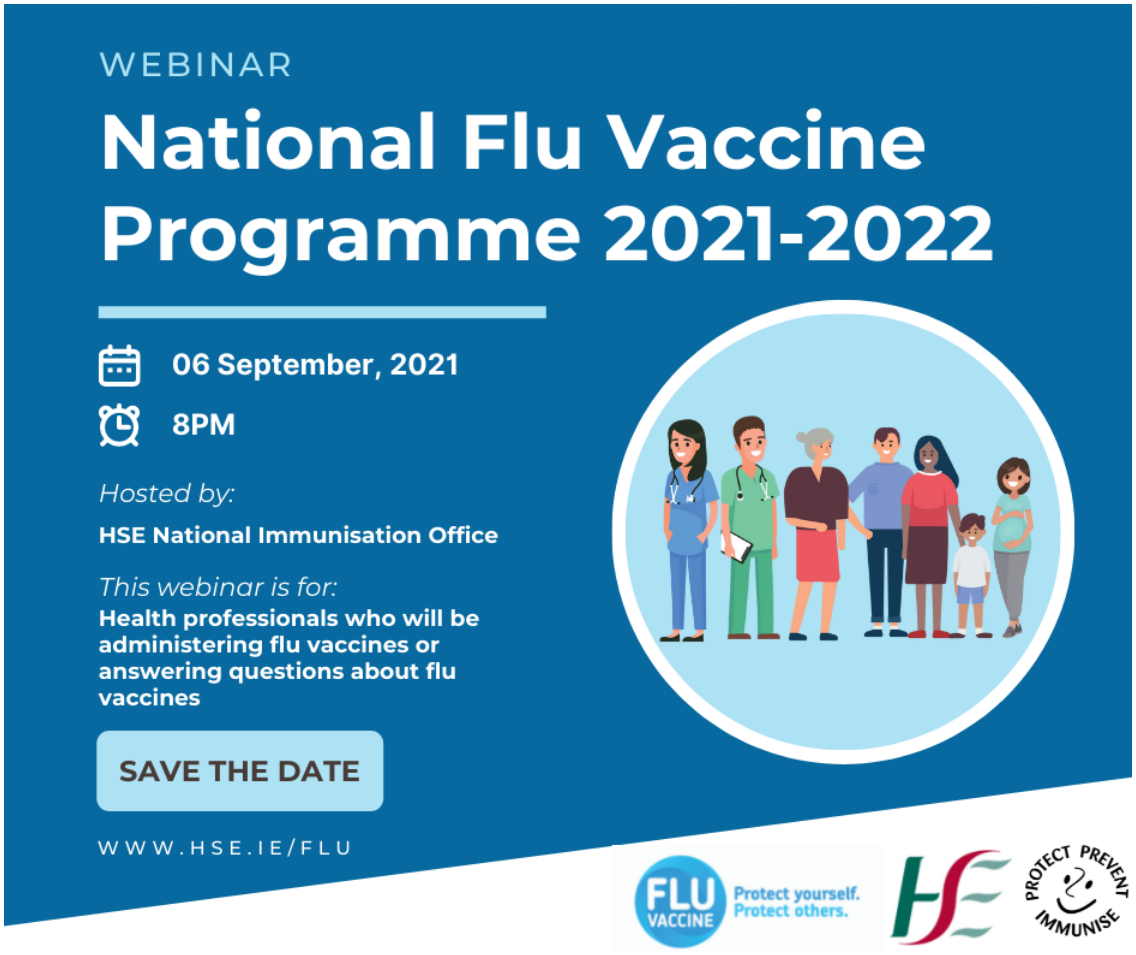

Save the Date - Live Webinar for 2021/22 National Flu Vaccine Programme

The NIO will be hosting a live webinar on **6th September at 8.00PM** on the **2021/22 National Flu Vaccine Programme** for the upcoming flu season.

We recommend this webinar for health professionals who will be

- administering flu vaccines
- answering questions about flu vaccines

Registration details will be released in due course. Even if you cannot join live, we recommend you still register and we will send you the recorded webinar to watch at your convenience.

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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

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.