COVID-19 VACCINE BULLETIN 30

Welcome to Bulletin 30 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 dosing of COVID-19 vaccines

In Bulletin 29 we highlighted that the National immunisation Advisory Committee (NIAC) has advised that heterologous COVID-19 vaccines schedules (i.e. a different vaccine given as a 2nd dose to complete the schedule) may be administered in some circumstances, and that this has been accepted by the Department of Health.

Training materials, medicines protocols and clinical guidance have been updated and are available on our website (links available on page 2).

Information for people getting vaccinated will be available on **www.hse.ie/COVID19Vaccine** and shared across the HSE channels. It is important that vaccine recipients have information on heterologous dosing prior to vaccination.

The implementation of heterologous schedules is expected to begin very soon, and more information will be issued shortly.

What recommendations have NIAC made?

NIAC recommends that the currently authorised homologous schedules (2 doses of the same vaccine) of vaccines are preferred for all age groups. This is because of the proven real-world effectiveness of homologous schedules, including effectiveness against the Delta variant.

- 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.
- People who have received a 1st dose of Vaxzevria® (AstraZeneca) and have decided not to receive a 2nd dose, can receive an mRNA vaccine (Comirnaty® (Pfizer/BioNTech) or Spikevax® (Moderna) as a 2nd dose

Following a 1st dose of a COVID-19 vaccine, one dose of a different vaccine only is required to complete the heterologous vaccine schedule e.g. 1 dose of Vaxzevria® and 1 dose of Comirnaty®. The 2nd dose should be given 28 days or more after the 1st dose.

We have developed frequently asked questions for healthcare professionals who may be advising people considering a 2nd dose of an mRNA vaccine following a 1st dose of Vaxzevria®.

Read the FAQs here

FAQs are continued on page 2

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Heterologous dosing of COVID-19 vaccines

What recommendations have NIAC made? (continued from page 1)

What do we know about the efficacy and effectiveness of heterologous vaccination schedules?

Early studies have indicated that heterologous vaccination schedules are highly immunogenic. These studies have shown that Vaxzevria®, followed by an mRNA vaccine elicited a stronger immune response when compared to two doses of Vaxzevria. It remains to be proven that the augmented immunogenicity translates into better efficacy or effectiveness against COVID-19. It is likely that heterologous vaccination schedules will prove to be effective, however, clinical effectiveness data are lacking.

What do we know about the safety of heterologous vaccination schedules?

There is limited evidence about the safety of heterologous vaccination schedules however so far there are no immediate serious safety concerns. Rates of side effects following administration of the second dose may be higher. Studies suggest that adverse reactions like pain at the injection site, headache, myalgia, chills and fever may be more common. The longer-term safety profile remains to be assessed and further monitoring is required to determine the overall safety profile of these schedules.

What is the advice for pregnant women who have received a 1st dose of Vaxzevria® in relation to heterologous vaccination?

Pregnant women should be advised that the advice from NIAC is that homologous vaccination schedules are preferred. However, if the pregnant woman does not wish to receive the second dose, she can receive an mRNA vaccine, Comirnaty® (Pfizer BioNTech) or Spikevax® (COVID-19 Vaccine Moderna) as the second dose. Vaccines should be given between 14 and 36 completed weeks of gestation.

Has the European Medicines Agency granted conditional marketing authorisation for heterologous vaccination?

No, heterologous vaccination schedules have not yet received conditional marketing authorisation by the European Medicines Agency.

Read more:

- Information for the public will be available from the HSE website — Click here
- Chapter 5A from the National Immunisation Advisory Committee — Click here
- Clinical guidance for vaccinators — Click here
- Medicines protocols — Click here
- Training has been updated — Visit HSeLanD

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Administration of COVID-19 vaccines with other vaccines in pregnancy

We have had several queries about whether there is a need for an interval between COVID-19 vaccines and other vaccines including those given in pregnancy.

NIAC advises that other vaccines, including pertussis vaccine and influenza vaccine 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.

We have received several questions about the administration of COVID-19 vaccines as booster doses

Are there any recommendations about booster COVID-19 vaccines yet?

No. No recommendations have been issued to date by the National Immunisation Advisory Committee regarding COVID-19 booster vaccinations, nor have any policy decisions been made by the Department of Health.

Administration of COVID-19 vaccines as booster doses is therefore not part of the COVID-19 vaccination programme at this time.

Therefore at present any administration of booster doses of COVID-19 vaccines is outside the recommendations of the National Immunisation Advisory Committee and outside of the COVID-19 vaccination programme and relevant indemnity.

Booster doses have not received conditional marketing authorisation by the European Medicines Agency.

Coring issues with Comirnaty® (Pfizer BioNTech) reconstitution

A number of complaints have been submitted to Pfizer regarding the presence of rubber stopper particles inside the solution. Investigation of the complaint samples at the Pfizer manufacturing site has established that the following factors can cause rubber particles to be removed from the stopper:

- When the needle is not inserted in the centre ring of the top plug;
- When the end of the needle scrapes rubber off the inner wall of the small channel of the stopper due to non-vertical insertion of the needle;
- When the needle is rotated or twisted during piercing of the stopper, resulting in a particle cored out of the stopper. This damage is enlarged when a wider bore needle is used.
- The needle used for reconstitution should be 21G or narrower.
- The presence of rubber stopper particles inside the solution maybe due to incorrect technique used during product administration.

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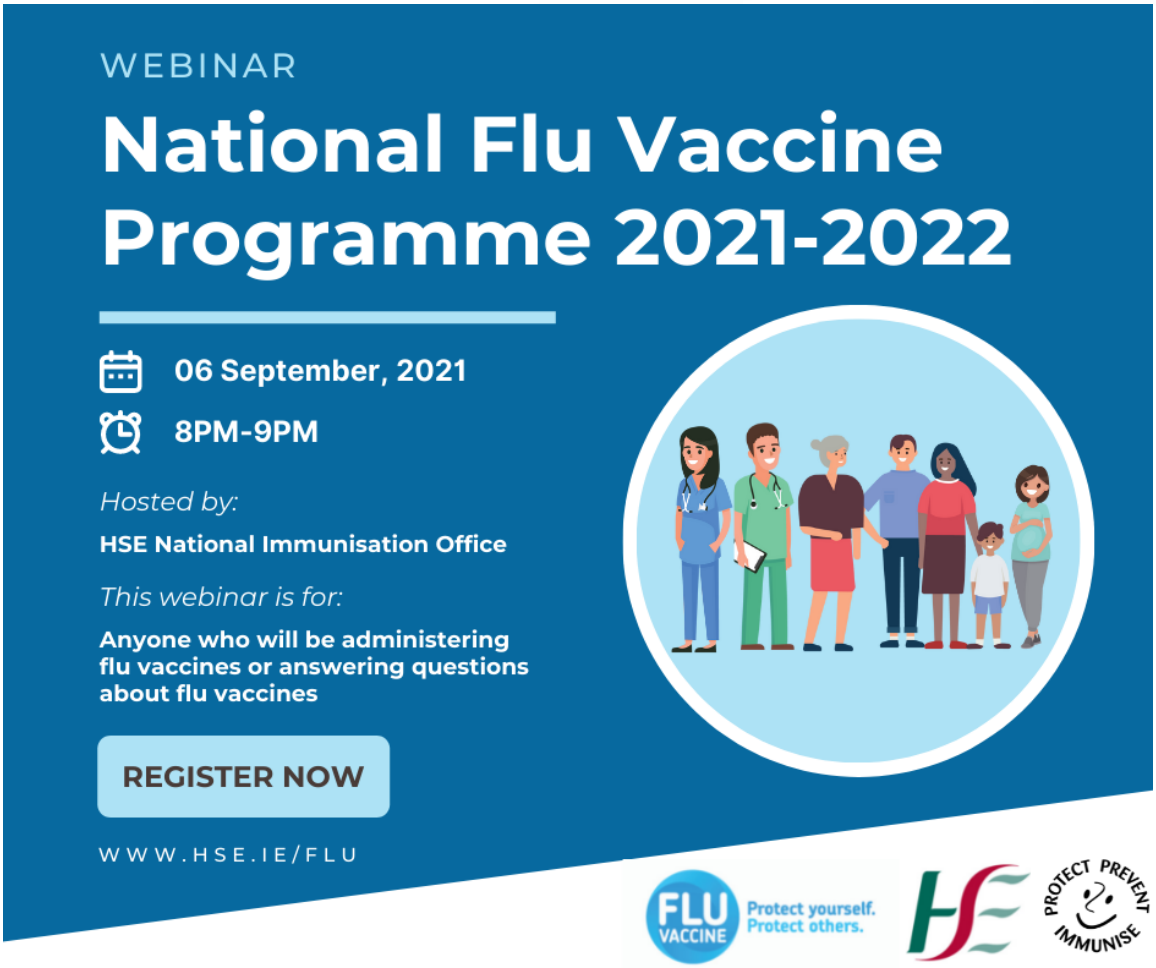

REGISTER NOW - Live Webinar on the Flu Vaccine for 2021/22 flu season

The HSE National Immunisation Office (NIO) will be hosting a live webinar on 6th September at 8:00PM on the Flu Vaccine for the upcoming 2021/2022 flu season.

This is a free event to support the rollout of the 2021/2022 National Influenza Vaccine Programme in Ireland.
This live webinar will provide up to date clinical information to support health professionals who will be

- administering flu vaccines
- answering questions about flu vaccines

You can **register here.**

This event has been CPD approved.

Spaces are limited. Confirmation will be sent to attendees when registration closes.
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

HSeLanD COVID-19 Vaccination Training Programme

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

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

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.