COVID-19 VACCINE BULLETIN 4

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

Changes to reporting suspected adverse reactions for Vaccinators

The requirement to enter suspected adverse reactions into the COVAX I.T. system no longer applies. Suspected adverse reactions should be reported directly to the HPRA following the instructions available on the HPRA website **www.hpra.ie**

As much information as is known should be provided, and where possible, the vaccine batch number should be included.

Number of doses to be withdrawn per vial

The National Immunisation Advisory Committee advises the following in relation to the number of doses per vial:

Comirnaty®: If more than six 0.3ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses.

COVID-19 Vaccine Moderna®: If more than ten 0.5ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid vaccines doses.

It may not always be possible to withdraw more than 6 doses per vial for Comirnaty® and more than 10 doses per vial for COVID-19 Vaccine Moderna®. Once all doses have been administered, discard the vial and record the time and date of discard. There should be no pooling of different vaccine vials.

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Frequently asked questions for COVID-19 vaccination in people with pre-existing allergies

A reminder that the Irish Association of Allergy and Immunology in conjunction with the National Immunisation Advisory Committee have produced a Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions.

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Can people with multiple antibiotic allergies receive a COVID-19 vaccine?

Yes. A person with a history of penicillin allergy or allergies to other antibiotics can be vaccinated. If they have a convincing history of anaphylaxis, then they should be observed for 30 minutes after receiving their vaccine.

Can people with a history of anaphylaxis to a specific foodstuff receive a COVID-19 vaccine?

Yes. People reporting immediate (IgE) food allergy, including a history of anaphylaxis, delayed (non IgE) mediated food allergy and food intolerance are all suitable candidates for this vaccine. Only those with a convincing history of anaphylaxis are required to wait 30 minutes after their vaccine.

A review of allergic reactions following COVID-19 Vaccine Moderna® including anaphylaxis

This review was based early monitoring data on anaphylaxis after receipt of COVID-19 Vaccine Moderna® in the US.

During December 21, 2020–January 10, 2021, monitoring by the Vaccine Adverse Event Reporting System detected 10 cases of anaphylaxis after administration of 4,041,396 first doses of COVID-19 Vaccine Moderna®. This is equivalent to 2.5 cases of anaphylaxis per million doses administered. Nine cases occurred in persons with a documented history of allergies or allergic reactions, five of whom had a previous history of anaphylaxis. In nine cases, onset occurred within 15 minutes of vaccination. No anaphylaxis-related deaths were reported.

The clinical and epidemiologic characteristics of anaphylaxis case reports after receipt of COVID-19 Vaccine Moderna®are similar to those reported after receipt of the Pfizer-BioNTech COVID-19 vaccine (Comirnaty®) with symptom onset after vaccination which occurred quickly, usually within minutes and a female predominance in anaphylaxis case reports for both vaccines.

For more information: The latest info from MMWR re allergic reactions including anaphylaxis after COVID-19 Vaccine Moderna®.

Read It Here

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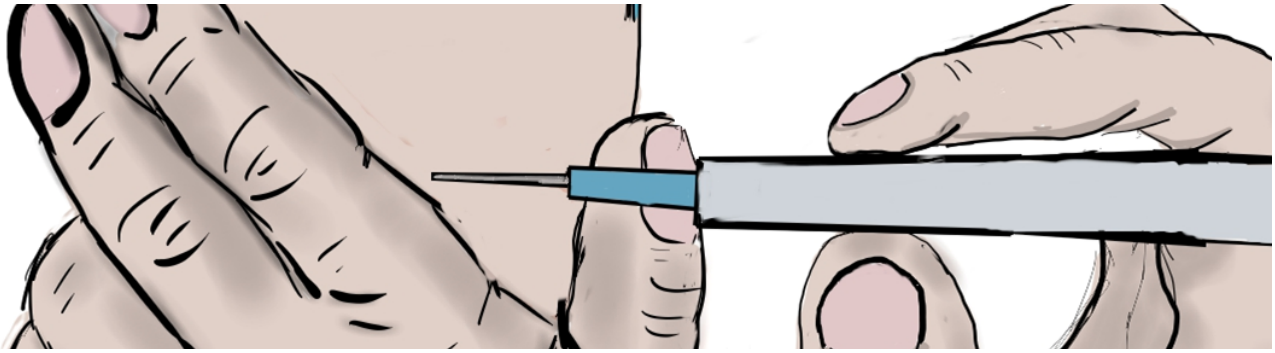

Vaccination of very frail older person patients with Cominarty®

The WHO released a safety statement regarding vaccination in this group, following reports of excess death in very frail older person patients after receipt of the Pfizer BioNTech (Comirnaty®) vaccine. A careful scientific review of the data and information was completed by WHO Global Advisory Committee on Vaccine (GACVS) COVID-19 Vaccine Safety subcommittee.

Their findings suggest that there is no unexpected or untoward increase in fatalities in this group. The reported data indicates that the deaths in this group post vaccination are in line with the expected all-cause mortality in this frail older person population.

The committee concluded that there is no evidence of the vaccine having a contributory role in these deaths. The committee concluded that the benefit-risk balance of the Pfizer BioNTech (Comirnaty®) vaccine remains favourable in older persons and does not suggest any revision, at present, to the recommendations around the safety of this vaccine.

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Reminder for nurses and midwives vaccinators, vaccinating under a medicines protocol

Nurses and midwives vaccinating under a medicines protocol must have completed the relevant training which has been developed by the Office of the Nursing and Midwifery Services Directorate and is available on HSELand **www.hseland.ie**

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