COVID-19 VACCINE BULLETIN 15

National Immunisation Advisory Committee (NIAC) recommendations on Vaxzevria® (COVID-19 Vaccine AstraZeneca)

The National Immunisation Advisory Committee (NIAC) has issued new recommendations in relation to Vaxzevria® vaccine (COVID-19 Vaccine AstraZeneca) following the report of the European Medicines Agency (EMA) on rare thromboembolic events associated with thrombocytopenia after vaccination.

These events are very rare, and estimated to occur between 4 and 10 in every 1 million people, one of whom may die. Because so few events have been reported, there is a high level of uncertainty about whether these events happen more frequently in any particular age group or gender.

Although most cases occurred in women under 60 years of age, this may be because of the higher rate of vaccination in healthcare workers who are mostly female. In the UK the rate of events reported was similar in men and women.

A UK suggestion of a possible increasing incidence of this adverse event in the younger age groups has not been confirmed, based on available European Economic Area (EEA) data. The EMA has requested more information through new and ongoing studies.
While thromboembolic events associated with thrombocytopenia are extremely rare, they have a very high risk of death or severe outcome.

Risk and benefits of vaccination with Vaxzevria®

NIAC considered the risk of these extremely rare clotting events and compared them to the risks of COVID-19.

The estimated risk of death from COVID-19 in those aged 20-34 is twice the risk of a thromoboembolic event with thrombocytopenia. This compares with a risk of death from COVID-19 that is 85 times higher than the risk of a clotting event for those aged 60 and older.

Age group (in years)	Likelihood of death from COVID-19 disease **V** adverse clotting events
0-19	1
20-34	2
35-44	6
45-49	12
50-54	23
55-59	48
60-64	85

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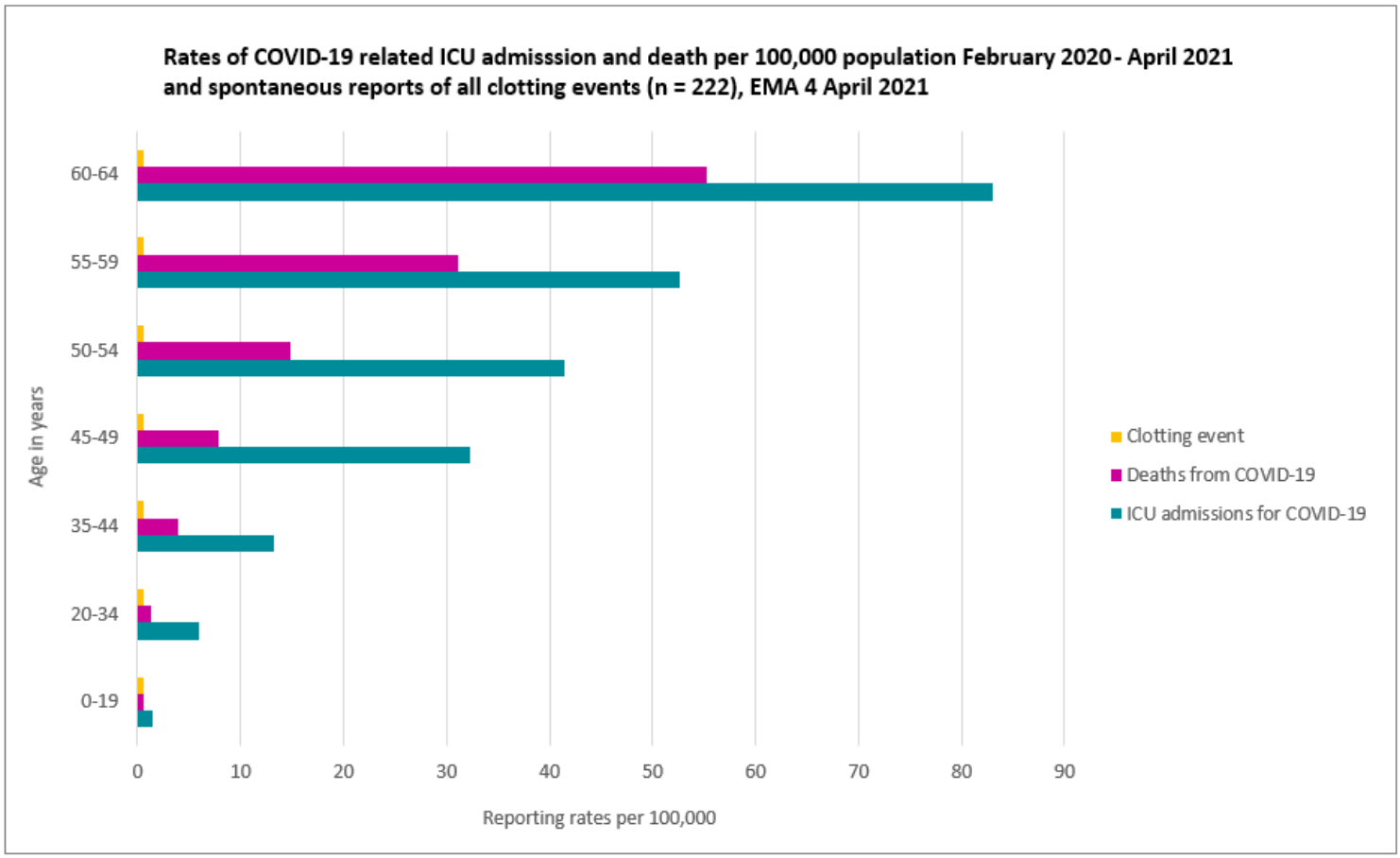
The figure below shows the numbers of rare thromboembolic events reported compared to ICU admissions and deaths from COVID-19 per 100,000 of the population.



Source: Health Protection Surveillance Centre (HSPC) Computerised Infectious Disease Reporting (CIDR)

Because older age groups have a higher risk of the serious consequences of COVID-19 and alternative COVID-19 vaccines are available, NIAC has revised the recommendations for use of this vaccine.

Recommendations

- Any authorised COVID-19 vaccine, including Vaxzevria®, is recommended for those aged 60 years and older including those with medical conditions with very high or high risk of severe COVID-19 disease

- **Vaxzevria® is not recommended for those aged under 60 years** including those with medical conditions with very high or high risk of severe COVID-19 disease

- A second dose of Vaxzevria® should not be given to anyone who developed unusual blood clots with low platelets after the first dose

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Recommendations for people who have already received a dose of Vaxzevria®

- Aged 60 and older should receive their second dose 12 weeks later as scheduled
- Aged under 60 years
    - **with a very high risk or high-risk medical condition** should receive their second dose 12 weeks later as scheduled (for details of very high risk and high risk medical conditions, please see **the guidelines** of the National Immunisation Advisory Committee)
    - **without** a very high risk or high-risk medical condition should have the scheduled interval between doses extended to **16 weeks** to allow further assessment of the benefits and risks as more evidence becomes available. (Clinical trial data has shown that the Vaxzevria® is efficacious, with no waning of immunity, up to at least 12 weeks after the first dose. Data supports evidence of protective immunity for at least 16 weeks following a first dose of the vaccine)**.**

No specific risk factors for these rare thromboembolic events associated with thrombocytopenia have been confirmed.

There is no evidence of an increased risk for those with clotting or platelet disorders e.g. idiopathic or heparin induced thrombocytopenia, autoimmune conditions, history of cerebral venous sinus thrombosis unrelated to vaccination, acquired or hereditary thrombophilia, or antiphospholipid syndrome.

People with these conditions may be vaccinated with Vaxzevria® (provided there are no contraindications).

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Resources

For details of the NIAC recommendations **Click here**

The following table outlines the vaccines used in the HSE COVID-19 vaccination programme by age group

	Cominaty® (Pfizer BioNTech)	COVID-19 Vaccine Moderna®	Vaxzevria® (AstraZeneca)	COVID-19 Vaccine Janssen®
Age 16-<18	√	Unlicensed	Unlicensed	Unlicensed
18-59	√	√	Not recommended	√
60-69	√	√	√	√
70 years and older	√	√	Offer a mRNA vaccine (Comirnaty® or Moderna®)	Offer a mRNA vaccine (Comirnaty® or Moderna®)

Clinical guidance for vaccinators and other materials are being updated with these new recommendations and will shortly be available on **www.immunisation.ie**

Training on HSELand will also be updated **www.HSEland.ie**