

# COVID-19 VACCINE BULLETIN 44

Welcome to Bulletin 44 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

## Changes to guidance regarding the observation period after COVID-19 vaccination

The National Immunisation Advisory Committee has changed their recommendations regarding the required period of observation after COVID-19 vaccination.

### Recommendations are as follows:

#### Post vaccination observation period

- Vaccine recipients: 15 minutes. This can be waived for those receiving a homologous or heterologous mRNA booster vaccine.
- Those with a history of mastocytosis: 30 minutes
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

The requirement for a 30 minute observation period for individuals who have a history of anaphylaxis from any cause has been removed.

Training and supporting materials are being updated to reflect this change.

## Frequently asked questions

**? Should people with at-risk conditions who are NOT immunocompromised at the time of vaccination receive an additional dose of an mRNA vaccine as well as a booster dose?**

**No.** Only people who are immunocompromised at the time of vaccination are recommended an additional dose (immunocompromising conditions are shaded in blue in table 5a.2 in immunisation Guidelines). The additional dose should be given 2 months after the last vaccine dose. The additional dose is recommended because the immune response to the primary vaccination course may be inadequate. Immunocompromised individuals aged 16 and older, are also recommended a booster dose which should be given 3 months after the additional dose

People with conditions that put them at high or very high risk of severe COVID-19 but who are not immunocompromised at the time of vaccination (shaded in white in [Table 5a.2](#)), do not need an additional dose. This is because they mount an adequate immune response to the primary vaccination course. If they are aged 16 years and older, they are recommended a booster dose 3 months after the primary course.

	Immunosuppression at the time of vaccination (shaded in blue in table 5a.2)	High or very high risk condition but not immunosuppressed at the time of vaccination (shaded in white Table 5a.2)
Primary vaccination course	✓	✓
Additional dose	✓	no
Booster dose if aged 16 and older	✓	✓

[Read NIAC chapter here](#)

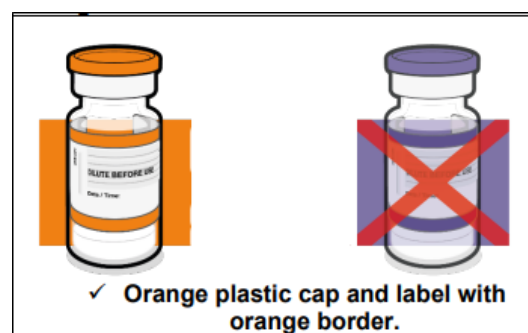
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## Frequently asked questions (continued from page 1)

**? Comirnaty® vaccine for children aged 5-11 years (orange cap) contains 10 micrograms of mRNA vaccine in each dose. The vaccine for people aged 12 years and older (purple cap) contains 30 micrograms in each 0.3ml dose. Can I use 0.1 mls of the purple cap vaccine to vaccinate a child who is aged 5-11 years?**

No. You cannot use the vaccine for people aged 12 years and older (purple cap) to vaccinate children aged 5-11 years.

Although it might appear that 0.1ml of the purple cap formulation would be equivalent to a 10 microgram dose of the orange cap formulation, the correct concentration of mRNA vaccine cannot be guaranteed in such a small volume of vaccine.



**? Can other vaccines be co-administered with Comirnaty 10 micograms/dose vaccine in children aged 5-11?**

No. As a precaution, it is advised to separate **Comirnaty 10 micograms/dose** vaccine, administration in children aged 5-11 years from any other vaccine for a period of 14 days both before or after COVID-19 vaccine.

However, the National Immunisation Advisory Committee has advised that it is no longer necessary to leave a 14 day interval before or after **Comirnaty 30 micograms/dose** vaccine licensed for use in any one aged 12 or older.

## Updates to SMPC for Comirnaty® and COVID-19 vaccine Janssen®

The product information for **Comirnaty®** and **COVID-19 vaccine Janssen®** have been updated.

**Comirnaty®**

[See SMPC](#)

**COVID-19 vaccine Janssen®**

[See SMPC](#)

- Following a review by the European Medicine Agency of very rare cases, transverse myelitis has been added as an adverse reaction for Covid-19 Vaccine Janssen® (and Vaxzevria®). It is also included under the warning on neurological events in section 4.4. The frequency category is unknown (In total, 38 globally reported cases were considered, 25 cases with Vaxzevria® and 13 with COVID-19 Vaccine Janssen®. Respectively, global exposure to the vaccines was estimated at 1.3 billion doses for Vaxzevria® and at 33.5 million for COVID-19 Vaccine Janssen®).
- Paraesthesia and hypoaesthesia have been added as adverse events for Comirnaty®, with a frequency unknown. They are also be listed under the 'anxiety-related reactions' warning in 4.4.
- Thrombosis and thrombocytopenia syndrome (TTS) and COVID-19 vaccine Janssen®: the warning has been be updated to remove the reference to most cases being reported in women, as it is now more balanced male:female in EU reports.

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## COVID-19 vaccination in pregnancy

A number of recent publications support the importance of COVID-19 vaccination in pregnancy and add to the evidence of the safety of mRNA vaccines.



### Effectiveness of Maternal Vaccination with mRNA COVID-19 Vaccine During Pregnancy Against COVID-19-Associated Hospitalization in Infants Aged <6 Months

[Read study here](#)

COVID-19 vaccination during pregnancy is recommended to prevent severe illness and death in pregnant women. Infants are at risk for COVID-19-associated complications, including respiratory failure and other life-threatening complications.

This study conducted in 17 states of the US, was a test-negative, case-control study at 20 paediatric hospitals during July 1, 2021-January 17, 2022. The study assessed the effectiveness of 2-dose primary mRNA COVID-19 vaccination during pregnancy, against COVID-19 hospitalization in infants aged <6 months.

Effectiveness of maternal completion of 2-dose primary mRNA vaccination during pregnancy against COVID-19 hospitalization among infants was 61% (95% CI = 31% to 78%). Effectiveness of completion of the primary COVID-19 vaccine series early and later in pregnancy was 32% (95% CI = -43% to 68%) and 80% (95% CI = 55% to 91%), respectively.

Completion of a 2-dose mRNA COVID-19 vaccination series during pregnancy might help prevent COVID-19 hospitalization among infants aged <6 months

### Pregnant and Post-Partum women admitted to Intensive Care with confirmed COVID-19 infection in Ireland

[Read report here](#)

This report from the Health Protection Surveillance Centre published in Epi-insight, is of Pregnant and Post-Partum women admitted to Intensive Care with confirmed COVID-19 infection - 1st March 2020 to 31st December 2021.

Over one third of women aged 15-44 years admitted to ICU due to confirmed COVID-19 infection were reported as being pregnant or less than 6 weeks post-partum

Very low vaccination uptake rates were reported in this group of women as none of the 33 women admitted to ICU between 1st January and 31st August 2021 were reported as having received COVID-19 vaccination or were registered as vaccinated on COVAX and 88% (n=22) of the 25 women admitted to ICU since September 2021 had not received COVID-19 vaccine or were not registered as vaccinated.

### Association of Comirnaty® COVID-19 Vaccination During Pregnancy With Neonatal and Early Infant Outcomes

[Read study here](#)

In this large population-based study from Israel including 24 288 singleton live births, the risks of preterm birth and small birth weight were examined between newborns whose mothers received Comirnaty® in pregnancy and those who didn't. There was no evidence of differences between newborns of women who received Comirnaty® vaccination during pregnancy, and those of women who were not vaccinated. This study further contributes to current evidence on the safety of maternal COVID-19 vaccination.

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## COVID-19 vaccination in pregnancy (continued from page 3)

### COVID-19 infection causing placental tissue destruction and Stillbirth and Neonatal Death

[Read study here](#)

The study from Ireland and 11 other countries, reported on the effects of COVID-19 on the placenta. Placentas were examined from 68 stillborn and neonatal deaths where mothers were infected with COVID-19.

All 68 placentas had evidence of SARS-CoV-2 placentitis. Placentitis resulted in widespread and severe placental destruction, with placental malperfusion and insufficiency. In these cases, intrauterine and perinatal death likely resulted directly from placental insufficiency and fetal hypoxic-ischemic injury.

## Other research

### A UK review shows vaccinated people are less likely to have long COVID than unvaccinated

[Read study here](#)



A new evidence review by UK Health security agency shows that people who have had one or more doses of a coronavirus (COVID-19) vaccine are less likely to develop long COVID or experience symptoms for a shorter time, compared with those unvaccinated.

Individuals who received a vaccination after being infected with COVID-19 also reported that the duration of post-COVID symptoms was less than for those who were unvaccinated. Two doses of the COVID-19 vaccination provide a high level of protection against long COVID, compared to one dose or no doses.

### Effectiveness of a third dose of mRNA vaccine in Immunocompetent and Immunocompromised Adults—United States, August–December 2021” published in MMWR

[Read article here](#)

The US CDC published Effectiveness of a Third Dose of Pfizer-BioNTech and Moderna Vaccines in Preventing COVID-19 Hospitalization among Immunocompetent and Immunocompromised Adults—United States, August–December 2021 on January 28 in *MMWR*. The study was performed during August 19–December 15, 2021, a period in which the SARS-CoV-2 Delta variant was predominant.

Portions of the abstract appear below.

In a study of hospitalized adults, compared with receipt of 2 mRNA COVID-19 vaccine doses, receipt of a third dose increased vaccine effectiveness against hospitalization among adults without and with immunocompromising conditions, from 82% to 97% and from 69% to 88%, respectively. [...]

Administration of a third COVID-19 mRNA vaccine dose as part of a primary series among immunocompromised adults, or as a booster dose among immunocompetent adults, provides improved protection against COVID-19-associated hospitalization.

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## COVID-19 vaccines for people with a weak immune system

### Watch NEW Q&A series from Dr Eimear Hayes, NIO

We asked Dr Eimear Hayes, Senior Medical Officer from our office, to answer some common questions about the **additional dose** and the **booster dose** of the COVID-19 vaccine for people with a weak immune system.



[Watch full video here](#)

Completing your COVID-19  
primary vaccine course



Who should get an additional dose  
of the COVID-19 vaccine?



When should I get an additional dose  
of the COVID-19 vaccine?



I tested positive for COVID-19.  
When should I get my additional dose  
of the COVID-19 vaccine?



What is the difference between  
the additional dose and the booster  
dose of the COVID-19 vaccine?



Who should get a booster dose  
of the COVID-19 vaccine?



I tested positive for COVID-19.  
When should I get my booster dose  
of the COVID-19 vaccine?



[Click here for more info](#)

# COVID-19 VACCINE BULLETIN 44

## Toolkit to increase uptake of childhood vaccinations in General Practice

You may have read that during the COVID-19 pandemic, there has been a decrease in the uptake of childhood immunisations in several countries in Europe, including the UK and Ireland.

This leaves young babies vulnerable to vaccine preventable diseases including meningococcal infection and measles. WHO has warned there is a risk of outbreaks of vaccine preventable diseases like measles in the European region, due to cross-border spread, especially as international travel returns to normal.

**We have developed a toolkit to support GPs and Practice nurses to achieve high uptake of primary childhood immunisations in General Practice.**

**This includes:**

- **Tips for catch-up vaccination, measures to increase vaccine uptake in GP practices, and supports for communicating with people who might be hesitant about vaccines**



## Toolkit for GP Practices to increase primary childhood vaccine uptake

HSE National Immunisation Office



[Download toolkit here](#)



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## Website

Visit our website [www.immunisation.ie](http://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

You can access updates to the National Immunisation Office COVID-19 Vaccination Training Programme for

- Children 5 to 11
- Pfizer,
- Moderna, and
- Janssen vaccine

through your HSeLand account.

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.

[Visit HSeLand](#)

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:

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

**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.