

Welcome to Bulletin 39 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme.

# Recommendations from the National Immunisation Advisory Committee for vaccination of children aged 5-11 years

COVID-19 vaccination is strongly recommended for those aged 5 to 11 years:

- with underlying conditions
- living with a younger child with complex medical needs
- living with a person who is immunocompromised

This group should be offered vaccination with the same priority as booster doses for those aged 16 to 49 years with an underlying condition.

COVID-19 vaccination should be offered to all other children aged 5 to 11 years with the same priority as boosters for those under 40 years old.

This is because of the favourable benefit risk profile of the vaccine, to protect them from severe disease, the consequences that can follow infection e.g. multisystem inflammatory syndrome in children (MIS-C), long COVID, psycho-social and developmental impacts.

Before vaccination, parents or guardians should be informed of the known benefits, risks and uncertainties of COVID-19 vaccination. The decision to accept, defer or refuse vaccination for a child should be respected.

#### Note the vaccine for children is a different vaccine formulation.

It contains a lower dose of antigen [10 micrograms per dose compared with 30 micrograms per dose in the formulation for people aged 12 years and older]. There are key difference between the recommendations for children aged 5-11 and those for people aged  $\geq$  12 years which are highlighted in this bulletin.



**Read NIAC guidelines here** 

Planning is underway and clinical guidance, training, medicines protocol and other supporting materials are being prepared.







### **Evidence and rationale for vaccination of children aged 5-11**

- In a vaccine trial involving children aged 5 11 years who were given the lower dose of Comirnaty, there were three COVID-19 cases in 1,305 children who received the vaccine, and 16 cases in 663 who received a placebo. The point estimate for vaccine efficacy was 90.7%. (95% CI 67.7, 98.3). The low dose vaccine demonstrated efficacy against the original and Delta strain.
- SARS-CoV-2 infection in those aged 5 to 11 years is usually asymptomatic or mild. Rates of hospitalisation and ICU admission are very low, and COVID-19 related death is extremely rare.
- Risk of hospitalisation is higher in children with underlying conditions but previously healthy children can also develop severe COVID-19; In the UK, between March 2020 and February 2021, 25 children and adolescents died of COVID-19. Of these six (24%) had no underlying condition. Five deaths (20%) were in those aged 5-9 years and nine (36%) in those aged 10-14 years.
- In Ireland, children aged 5 to 11 years have the highest rate of infection of all age groups, three times that of adolescents.
- As COVID-19 infections surge, rates in children also rise, with a proportionate increase in hospital and ICU admissions.
- Multisystem Inflammatory Syndrome in Children (MIS-C) is a rare complication after symptomatic or asymptomatic SARS-CoV-2 infection, including in those without an underlying condition.
- The risk of long COVID-19 is lower in children compared to adults although as case numbers increase there is likely to be a considerable health impact.
- Children have suffered significantly from both the direct and indirect effects of the COVID-19 pandemic (educational opportunities, psychosocial development)
- ECDC modelling data suggest that vaccinating children aged 5-11 years could reduce SARS-CoV-2 transmission in the whole population by up to 15% in a country with high adult (85%) and child (50-70%) vaccination rates.

## Safety of COVID-19 vaccine in children

The most frequent adverse reactions in children 5 to 11 years of age reported in the vaccine trials were:

- injection site pain (>80%),
- fatigue (>50%),
- headache (>30%),
- injection site redness and swelling (>20%),
- myalgia and chills (>10%).

These were usually mild or moderate in intensity and resolved within a few days after vaccination. A higher rate of pyrexia is seen after the second dose.

The safety profile in the clinical trials of children aged 5-11 years was similar to that seen in older trial participants. No new safety concerns were observed. The number of subjects in the vaccine trials does not allow detection of rare or very rare adverse events such as myocarditis and follow-up is ongoing.

More than four million first doses and approximately 450,000 second doses have been given to children in this age group in the US. No immediate safety issues have been notified but follow up time has been short.

### **Myocarditis and pericarditis**

The EMA has evaluated the occurrence of vaccine associated myocarditis as very rare. The risk is highest in younger males.

Two European studies have estimated the risk of myocarditis, after the second dose of the vaccine:

- One additional case for every 38,000 men aged 12 to 29 (within 7 days)
- One additional case for every 17,500 men aged 16-24 (within 28 days)

Data are very limited on those 5 to 11 years of age, however based on preliminary data from US and Israel, the incidence of myocarditis in those aged 12-15 years may be less than in those 16-24 years.





#### What is the dose of Comirnaty for children aged 5-11 years?

The dose of vaccine for those aged 5 to 11 years is **0.2 ml** intramuscularly (IM) into the deltoid muscle. Each dose contains 10 micrograms. Note that the dose volume, and the vaccine dose is different to that for  $\geq$ 12 years (0.3mls and 30 micrograms per dose).

### What volume of 0.9% saline should be used to dilute a vaccine vial?

The vaccine requires dilution with **1.3ml** of 0.9% sodium chloride. After dilution, the vaccine should be kept at  $+2^{\circ}$ C to  $+30^{\circ}$ C and used within 12 hours. Note that the dilution volume and the discard time is different.



#### How many doses of 0.2mls are in a diluted vial of the vaccine?

If more than ten 0.2ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses. There are a maximum of 12 doses in each vial.



#### What is the recommended interval between doses?

- The recommended interval is 21 days
- If the interval between doses is longer than 21 days, the second dose should be given as soon as possible. The course does not need to be restarted.
- The minimum interval is <u>19 days</u>. If the second dose is given between 19 and 20 days after the first dose, it is a valid dose. If the second dose is given before 19 days, this is not considered a valid dose. Note this is a different minimum interval compared to that for those aged ≥12 years.



#### What is the recommended timing after COVID-19 infection?

The vaccine can be administered 28 days after a laboratory-confirmed diagnosis of COVID-19 or the onset of COVID-19 symptoms.



# What are the recommendations regarding vaccination of immunocompromised children aged 5-11 years?

Children who are severely immunocompromised at the time of vaccination can have the 3rd dose <u>at least 28 days after</u> the second dose (this advice corresponds to the SMPC). [For all those aged 12 years or more with immunocompromised an interval of 2 months is still advised].









# What are the contraindications to Comirnaty vaccine for children aged 5-11 years?

• Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents\* (including polyethylene glycol (PEG)).

\*note that the constituents of the Comirnaty® formulation for children aged 5-11 years includes trometamol.

Read SmPC for details

- Myocarditis after a previous dose of Comirnaty®.
- Appropriate support should be available in case of anaphylaxis or fainting after vaccine administration. Precautions should be in place to minimise injury from fainting.



### What are the precautions to vaccination?

- Acute severe febrile illness; defer until recovery
- Pericarditis after a previous dose of Comirnaty® (seek specialist advice)
- <u>Vaccination should be postponed in children with a previous history of MIS-C, until clinical recovery</u> or until 90 days or more since diagnosis, whichever is the longer.
- If vaccination is advised for a child with prior anaphylaxis to an unrelated allergen, observe for 30 minutes after vaccination.



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#### What is the advice regarding co-administration with other vaccines?

- Until there is more evidence, it is prudent to <u>separate COVID-19 vaccine administration in children</u> <u>aged 5-11 years from any other vaccine for a period of 14 days.</u>
- This advice differs to that for people aged ≥ 12 years.

# What dose of Comirnaty should a child who turns 12 years of age between a 1st and second dose of vaccine receive?

The dose of Comirnaty depends on the age at the time of the first vaccine i.e. an 11 year old child who receives the first dose of 10 micrograms Comirnaty and who is 12 years of age at the time of their second dose, should receive a further dose of 10 micrograms Comirnaty.

#### As the COVID-19 vaccination programme now includes additional doses for those who are immunocompromised as well as booster doses, please check before each vaccination:

- Is this a primary course, an additional dose for a person who is immunocompromised or a booster dose?
- What is the age of the person?
- What is the recommended vaccine for this age-group?
- What is the recommended dose?
- What is the recommended interval since the last dose?
- Has the person had COVID-19 infection? What is the recommended interval since laboratory-confirmed COVID-19 infection?





#### **COVID-19 VACCINE** Public Health Advice

# **COVID-19 VACCINE BULLETIN 39**

### **Changes to recommendations on booster doses**

The National Immunisation Advisory Committee has issued the following recommendations regarding booster doses. These recommendations have been accepted by the Department of Health:

- In light of the Omicron variant, reducing the interval between the primary course and the booster dose should facilitate earlier protection. A booster dose of vaccine should now be given after a minimum interval of three months in the same order of priority as outlined in the Immunisation Guidelines for Ireland.
- Those aged 16 years and older with immunocompromised associated with a suboptimal response to vaccines who have completed a three dose primary series, should be given an mRNA booster vaccine after a minimum interval of three months. The booster dose is Comirnaty 30micrograms (for those aged 16 years and older) or Spikevax 50 micrograms (for those aged 30 years and older).
- Those who are fully vaccinated and have had breakthrough laboratory confirmed COVID-19 infection should delay their booster vaccination for at least six months in accordance with the Immunisation Guidelines for Ireland. There is preliminary evidence that fully vaccinated people with breakthrough infections are naturally boosted against the Omicron variant and so may not require a booster earlier than currently recommended.

#### **Read more here**

These recommendations are not yet operationalised. Planning is underway, including the preparation of public information, changes to the I.T system, medicines protocols, guidance, training.

[~ <b></b>	Quick Re	eference Guide to CO	VID-19 Vaccines	VACCINE Public Heal Advice	
~	This is a summary of information,	the full clinical guidance and NIAC guidelin	es should be consulted at www.immunisati	on.ie	
faccine	Comirnaty® Children's formulation	Comirnaty® (Pfizer BioNTech)	Spikevax* (Moderna)	COVID-19 Vaccine Janssen* (only if cannot receive an mRNA vaccine)	
	Primary vac	ination course (recommended for	people aged 12 years and older)		
4ge	5-11 years	212 years	a30 years	218 years	
lose	0.2mls	0.3mls	0.5mls	0.5mb	
nterval between dose 1 and dose 2	21 days	21-28 days	28 days	Not applicable	
iming since COVID-19	4 weeks	4 weeks	4 weeks	4 weeks	Ouick Reference Guide V15 has
	Additional dose for	immunocompromised (recommend	led for people aged 12 years and oli	Jer)	
48e	5-11 years	≥12 years	230 years	218 years	been updated to reflect this upda
lose	0.2mls	0.3mk	0.5mls	0.5mb	
terval since finishing mmary vaccination ourse	28 days	2 months	2 months	2 months	
iming since COVID-19 preakthrough infection	At least 6 months	At least 6 months	At least 6 months	At least 6 months	Click here
		Booster dose for eligible	groups*		
<b>1</b> 86	Not recommended	216 years	a30 years	a18 years	
lose		0.3mls	0.25mls	0.5mk	
ntonul since finishing		At least 3 months	At least 3 months	At least 3 months	
erimary vaccination ourse					

### **People with allergies**

The National Immunisation Advisory Committee (NIAC) together with the Irish Association of Allergy and Immunology (IAAI) have updated a Frequently Asked Questions (FAQ) document about COVID-19 vaccines for people with pre-existing allergic conditions.

Read more more

### Removal of requirement for pregnant women to discuss COVID-19 vaccination with an Obstetric Care giver

NIAC have removed the requirement for pregnant women to have a discussion with an obstetric care giver before vaccination- they can now attend for vaccination without the need to have discussed this with their Doctor or midwife.

Information and resources on vaccination in pregnancy:





14 December 2021





# EMA and ECDC recommendations on heterologous vaccination courses against COVID-19

- The currently available evidence consistently points towards an acceptable tolerability and enhanced immune responses with the heterologous regimen of vector vaccine followed by an mRNA vaccine versus the homologous vector vaccine regimen
- Some studies have reported higher reactogenicity (e.g. pain, fever, headache, fatigue) of heterologous vaccination but results are not consistent. With respect to infrequently occurring adverse reactions, there is insufficient data to draw conclusions;
- Overall the data presented support the use of mixed vector/mRNA schedules. Based on the evidence seen so far and on existing clinical knowledge, giving a second dose of mRNA vaccine to previous recipients of a single dose of vector vaccines is a vaccination strategy that is beneficial from an immunological perspective with a positive impact on the achieved level of protection from infection and disease.
- Giving an adenoviral vector vaccine as second dose after a mRNA vaccine might be considered if there is a problem with availability of mRNA vaccines, but based on the limited data available it may be less advantageous from an immunological point of view than the opposite sequence.

#### **Read more more**

# Sprint 17-511 brings changes to the HSECOVAX system to allow the administration of a new product Comirnaty children 5-11 years to children aged 5-11 years old

A new priority group has been created for children aged 5-11 years called 9h. A new course displays at the add course stage called Comirnaty children 5-11 years, 21 days for this age group is available in the course drop down menu at the add course stage. In addition, there are two new question on the medical eligibility assessment form.

#### **Question 1**

NIAC recommends separating COVID-19 vaccine administration in children aged 5-11 years from any other vaccine for a period of 14 days.

#### **Question 2**

NIAC recommends Vaccination should be postponed in children with a previous history of MIS-C, a rare but serious disorder after covid-19 infection until clinical recovery or until 90 days or more since diagnosis, whichever is the longer. This is the new, three part question in relation to MIS-C.

• Ha	ive you	had	another	vaccination	in	the	last	14 (	days?
	Yes								
	h l e								

	* Have you had multisystem inflammatory syndrome also called MIS-C (a rare syndrome usually treated in hospital) after a COVID-19 infection?
	● Yes ○ No
,	* Anyone receiving the Comirnaty Children vaccine will have to wait until they have clinically recovered from MIS-C before the vaccine is administered. Have you clinically recovered from MIS-C?
	If no, you will have to wait until you have clinically recovered.
	* Anyone receiving the Comirnaty Children vaccine will have to wait 90 days after the diagnosis of MIS-C before the vaccine is administered. Has it been over 90 days since MIS-C was diagnosed? Ves No
	If no, you will have to wait until it has been over 90 days since diagnosed with MIS-C.

#### Pregnancy Question for all ages

In relation to pregnant women, NIAC recommend COVID-19 vaccination at any stage of pregnancy. There is no longer a requirement for pregnant women to discuss vaccination with their obstetric care givers.

The pregnancy question on HSECOVAX is unchanged so you can ask are you pregnant but for second part for everyone who is pregnant tick yes to the have you talked with the obstetric care giver so they are eligible. You no longer need to ask this part of the question.

* Are you pregnant?
Yes
O No
If yes, you will be required to answer further questions to determine eligibility.
<ul> <li>Can you confirm that you have talked to your Obstetrician, Midwife or Doctor about the risks and benefits of getting the vaccine?</li> <li>Yes</li> <li>No</li> </ul>
If no, the COVID-19 vaccine can now be given at any stage of pregnancy. Please discuss with your Obstetrician, Midwife or Doctor first, and then if you decide to receive the vaccine, please call HSE Live to arrange to receive an appointment.



**Visit HSECovax Training** 

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**COVID-19 VACCINE** Public Health Advice

# **COVID-19 VACCINE BULLETIN 39**

# **Seasonal Influenza Vaccination Programme**

### Extension of free influenza vaccine for people aged 50-64 years

The Department of Health has announced the extension of the seasonal influenza programme to include all adults aged 50-64 years. The vaccine and vaccine administration is free for this group, through a participating GP or pharmacies.

The extension of the free flu vaccine for people aged 50 and over, for this season, will maximise the impact of the flu programme and reduce the risk of influenza compounding the winter pressures on our healthcare system due to COVID-19.

The change will be in place until the end of this influenza season in April 2022. This policy is line with National Immunisation Advisory Committee (NIAC) recommendations for the flu vaccine.

**The flu vaccine can be given at the same time or ay any interval between COVID-19 vaccines.** Those aged 50 and over coming forward for their COVID-19 booster vaccine can also avail of the free flu vaccine through participating GPs and pharmacies.

Please note: As a precaution, it is advised that for children aged 5-11 years the COVID-19 vaccine and any other vaccine, including LAIV (children's nasal flu vaccine), are separated by 14 days.

### Find a pharmacy giving Flu vaccines

A list of pharmacies giving COVID-19 and Flu vaccines is now available on the HSE website.

Find a pharmacy here

### **Reminder: GPs and Pharmacies can still order Flu vaccines**

Reminder that GPs and pharmacists can still order flu vaccines. There are no limitations on the quantities of Flu vaccines that can be ordered by GPs and Pharmacies.

The Flu vaccine provides the best protection from flu this winter.

## Place your orders for the LAIV and QIV vaccines through your national cold chain account today.

	Order Flu vaccines Download Children's Flu Vaccine Toolkit and Factsheet	Click here Click here
	Download Flu Vaccine for Pregnant Women Toolkit and Factsheet	Click here
140	Learn more about HSE 2021/2022 Seasonal Influenza Vaccination Programme	Click here



#### 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**

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

- Mariangela Toma: mobile 087 7575679
- Cliona Kiersey: mobile 087 9915452

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.

