# COVID-19 VACCINE BULLETIN 20

**Welcome to Bulletin 20 from the HSE National Immunisation Office which highlights changes in clinical guidance for the COVID-19 vaccination programme. Bulletins will be published every week or more frequently, if required.**

## Latest Updates on Vaccination Guidance

### Interim arrangements for the NIO during the HSE IT system outage

Following the cyberattack on the HSE IT systems, the National Immunisation Office has very limited access to its emails and IT systems.

We are unable to access emails sent to our usual HSE inbox and have limited access to edit documents uploaded onto our www.immunisation.ie website.

During this period interim arrangements have been put in place including:

1. A new email address for **healthcare professionals only** to direct any urgent clinical or technical queries to. Please **do not send any patient identifiable information** to this email address as the email will be deleted and you will be asked to resend without this information.

**Email queries**

2. While HSELand is unavailable and while we explore other options you can access COVID-19 vaccinator training by registering through the following eventbrite links:

**Pfizer** **Moderna** **AstraZeneca** **Janssen**

3. During this period, we will be focused on keeping our quick reference guide documents updated with others to follow in due course. The weekly bulletins will also be uploaded on a regular basis.

**Quick Reference Guide** **Weekly Bulletins**

4. The COVAX system may not be updated from the GP systems regularly. A reminder to all vaccinators it is good practice in general to check with the person being vaccinated if they have received a COVID-19 vaccine before (if so, confirm the brand and timing of that vaccine before proceeding).

# COVID-19 VACCINE BULLETIN 20

## Comirnaty® (Pfizer/BioNTech)- changes to enable more flexible storage conditions

The longer USE BEFORE date (expiry date after thaw) has now been implemented. All deliveries of Comirnaty will now display the extended "Use Before" date and the delivery will have a month's shelf-life.

If you have any unopened vials that were delivered this week (on or since Monday 17th) and have exceeded the "Use Before" date, the new extended date can be applied to these vials by adding 26 days to the printed "Use Before" provided that they were maintained between +2°C and +8°C.

If there are unopened vials in the fridge delivered before Monday 17th please contact NIO directly and you will be advised. Please use the **temporary email address** for the NIO until HSE emails are restored. Please note that no patient identifiable details should be sent to this email address.

**Read more here** **Read more here**

## HPRA COVID-19 vaccine safety and EMA updates

The Health Products Regulatory Agency (HPRA) has released a further update on suspected side-effects from COVID-19 vaccines reported to its database so far. By the middle of May nearly 7900 suspected side-effects were reported to the HPRA ( in the context of over 1.9m doses of COVID-19 vaccines administered in Ireland.) Most reported side effects were mild to moderate and self-limiting.

They highlight additional messages from the EMA safety committee around the very rare side effect of thrombosis with thrombocytopenia syndrome (TTS) post vaccination with adenoviral vector vaccines. Health care professionals and individuals receiving the vaccine should be made aware of these additional signs or symptoms to those previously mentioned (that would trigger urgent medical review for TTS within 3 weeks post vaccination): mental status change , seizures or leg swelling. Furthermore the EMA has advised people diagnosed with low platelets 3 weeks post vaccination should be assessed for blood clots and vice versa. The product information for COVID-19 vaccine Janssen® is updated and is due to be updated for Vaxzevria® too.

**Read more here** **Read more here**

## TrackVax - Vaccine Reconciliation

TrackVax is an App to reconcile usage and manage vials and doses within a clinic. Therefore it allows interrogation of the status of the doses from delivery to the vaccination site to the point of doses administered or disposed. All vaccine wastage, i.e. not used for any reason, must be reconciled. The current reconciliation (vaccine specific) form, available on the NIO website, must be completed and returned to the specified email address. This has not changed. Central Vaccination Clinics (CVC) using Trackvax will shortly have the TrackVax application updated to version 21. The updated version, among new features, will also perform a daily and automatic vaccine vials/ doses reconciliation. Once version 21 has been installed in the site, then return of the completed Vaccine Reconciliation form will no longer be a requirement. The installation of TrackVax in the CVCs is proceeding at good pace and centres that have expressed interest in the app, will benefit from it.

If not already done so, expression of interest to have TrackVax installed can be sent to this temporary email address:

**Email queries**

Vaccine specific reconciliation forms are available on the following NIO webpages:

**Pfizer** **Moderna** **AstraZeneca** **Janssen**

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## Updated guidance on consent for vaccination of young people 16-17 years

The HSE guidance has been updated regarding consent for vaccinating young people aged 16-17 to support the COVID-19 vaccination roll out.

Four factors to consider when deciding if a person aged 16-17 has capacity to consent:

1. Does the young person understand the information relevant to the decision, including the risks of refusing vaccination?
2. Is the young person able to retain the information long enough to make a decision?
3. Can the young person use and weigh the information to make a decision? This may involve enabling another person to help the individual.
4. Can the young person communicate their decision? Communication can be verbal, using sign language or any other means of communication. A person must fulfil all of these criteria in order to be determined to have capacity to make a decision.

The guidance provides advice for healthcare providers on different scenarios where a young person does and does not have capacity to consent to vaccination.

**Read more here**

## Prophylactic use of paracetamol pre-vaccination is not recommended

It is not recommended that over-the-counter medicines such as paracetamol or ibuprofen are taken before COVID-19 vaccination to prevent potential vaccine related side effects. However, if you are taking any of these medications regularly as prescribed by a doctor, do continue to take them as usual.

## Timing of corticosteroids or immunomodulatory treatment and COVID-19 vaccines

There is no recommendation to delay corticosteroid or immunomodulatory treatment before or after any of the COVID-19 vaccines which are all non-live vaccines.

However, if someone has planned immunosuppressive treatment they should try and complete the COVID-19 vaccination schedule two weeks before it starts ideally. The advice from the National Immunisation Advisory Committee is:

"Patients with planned immunosuppressive therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used. Specialists should consider the individual's risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of the patient's immune status and likely immune response to vaccination."

**Read more here**

# COVID-19 VACCINE BULLETIN 20

## Vaxzevria® (COVID-19 Vaccine AstraZeneca) second dose interval at 12 weeks for all

In the recent NIAC guidance for Vaxzevria® it was recommended that people under the age of 50 without underlying health conditions that puts them at high or very high risk of severe COVID-19 and have received one dose of the vaccine could wait up to 16 weeks for their second while awaiting more evidence.

After reviewing the latest data, all individuals who have received a previous dose of Vaxzevria® should receive their second dose ideally 12 weeks later. The HSE is working to operationalise this over the next few weeks. Anyone who has a second dose scheduled between 13 and 16 weeks later should attend when scheduled, because it is known that immunity does not reduce within the 16 weeks after the first dose.

## COVID-19 vaccine doses after confirmed infection

Recent NIAC recommendations advise that those under the age of 50 and immunocompetent who have a laboratory confirmed COVID-19 infection in the previous 6 months only need one dose of the COVID-19 vaccines to be considered fully vaccinated.

However infection records are not currently linked with the vaccination system therefore vaccinators are not able to confirm previous infection. If a person has evidence of a laboratory confirmed COVID-19 infection in the last 6 months (and the individual is immunocompetent and under the age of 50), they may choose to receive only one dose of a COVID-19 vaccine. However, they will continue to be scheduled to receive a second dose of the COVID-19 vaccine if it is part of the vaccine's routine schedule and they can receive this. The rules around the EU vaccine certificate are being finalised and so we cannot advise about this at present.

**Read more here**

## PHE COVID-19 vaccine surveillance data

This surveillance report from the UK summarises the impact of their COVID-19 vaccination roll out on the population and provides real-world estimates of vaccine effectiveness. They estimate the vaccine effectiveness for a single dose of any of the three vaccines used in their programme is between 55-70% against symptomatic infection; with effectiveness increasing to 85-90% with the second dose of the Pfizer vaccine (data from other vaccines is not available for second doses).

Furthermore nearly half of their adult population has received at least one dose of the vaccine by mid-May. And surveillance data suggests nearly all older adults (over the age of 60) are protected with antibodies against the virus. They estimate nearly 35,000 hospitalisations and 10,000 deaths have been averted due to the vaccines.

**Read more here**

# COVID-19 VACCINE BULLETIN 20

## Latest from research

### Public health impact of delaying second dose of BNT162b2 or mRNA-1273 COVID-19 vaccine: simulation agent based modeling study

This was a modelling study which compared the impact of the delayed second dose versus standard dosing vaccination strategies on SARS-CoV-2 infections and COVID-19 related hospital admissions and deaths. The authors included models with different vaccine efficacies, as well as different infection dynamics in the population. The study suggests a reduction in mortality, hospital admissions and deaths with a delayed vaccine strategy, particularly when delayed in the population under 65 years. The study however noted that this was found under conditions of vaccination rates being below 1% per day, and when vaccine rates were higher than 1% per day there was no difference in mortality and hospital admissions for delayed vaccine strategy. This modelling study provides evidence of benefit of a delayed second dose of mRNA vaccine strategy in the context of low vaccination rates or low supply of vaccine.

**Read more here**

### Extended interval BNT162b2 vaccination enhances peak antibody generation in older people

This was a cohort study in the UK, including 172 participants aged 80 and older. 99 participants received two doses 3 weeks apart (standard interval). 73 participants received the two doses 11-12 weeks apart (extended interval). 15 participants were excluded as serology indicated they had previous SARS-CoV-2 infection. Antibody responses were compared in both groups. Spike-specific antibodies were detected in 100% of participants in both groups 2-3 weeks after the second dose.The magnitude of the antibody response was compared in the two groups. Antibody titres in the standard-interval regimen peaked at 1138 U/ml after the second dose and then fell by 2.6-fold over the subsequent weeks ($p<0.0001$). Within the extended-interval cohort the median antibody titre was 17 U/ml at 5-6 weeks weeks after the first vaccine but showed a substantial 242-fold increase to reach 4030 after the second boost ($p<0.0001$). A comparison of the median magnitude of peak cellular responses after the second vaccine in the two schedules showed that these were higher for donors in the standard-interval regime (72 vs 20 spots/million; $p<0.0001$).

**Read more here**

### Heterologous prime-boost COVID-19 vaccination: initial reactogenicity data

This correspondence printed in the Lancet from the Com-COV study, a UK multicentre, participant-masked, randomised heterologous prime-boost COVID-19 vaccination study comparing different regimes of vaccination with AstraZeneca and Pfizer vaccination (receiving either both doses of same vaccine (homologous), or prime dose of one vaccine with second dose of different vaccine (heterologous). They found that those who received heterologous regime (different vaccine for second dose) reported more systematic reactions following second dose compared to those who received the same vaccine for their boost dose. Increased rates of fever, chills, fatigue, headache, joint pain, malaise, and muscle ache were reported in this group, compared to those reported after the second dose in homologous regime, along with increased use of paracetamol. The reactogenicity tended to resolve within 48 hours and was not associated with any adverse safety outcomes.

**Read more here**

# COVID-19 VACCINE BULLETIN 20

## Effectiveness of BNT162b2 mRNA vaccine and ChAdOx1 adenovirus vector vaccine on mortality following COVID-19

This study looked at real world mortality data in England, estimating risk of mortality by vaccination status. Survival analysis showed an additional 44% protection against death after the first dose of Pfizer vaccine, 55% after the first dose of AstraZeneca vaccine, and 69% after the second dose of Pfizer vaccine. A single dose of either vaccine provided an efficacy of 80% against mortality and 97% for 2 doses of Pfizer vaccine. The study was not able to estimate efficacy of the second dose of AstraZeneca vaccine due to later rollout of that vaccine. This large observational study shows significant protection against mortality provided by these vaccines.

**Read more here**

## Effectiveness of BNT162b2 mRNA and ChAdOx1 adenovirus vector COVID-19 vaccines on risk of hospitalisation among older adults in England: an observational study using surveillance data

This study looked at the risk of hospitalisation, comparing those who are vaccinated and unvaccinated in England, using surveillance data for the first four months of the vaccination programme. In those aged 80 years and over, vaccine efficacy against hospitalisation was 73% following the first dose of AstraZeneca vaccine and 81% following the first dose of the Pfizer vaccine, and 93% following the second dose of the Pfizer vaccine. In those aged 70-79 years, vaccine effectiveness against hospitalisation was 84% following the first dose of Astrazeneca vaccine and 81% following the first dose of the Pfizer vaccine. This large observational study provides further real world effectiveness data for the Pfizer and Astrazeneca vaccines.

**Read more here**

## Real-world effectiveness of Ad26.COV2.S adenoviral vector vaccine for COVID-19

This study used surveillance data in the USA comparing those who had received one dose of Janssen vaccine to unvaccinated individuals, comparing outcomes. It estimates a vaccine effectiveness of 76.7% in preventing SARS-CoV-2 infection with onset at least two weeks after vaccination. Due to this vaccine being introduced relatively recently, data was not available to robustly study the effect of the Janssen vaccine on outcomes of mortality, hospitalisation and ICU admissions. This study provides real world data on the effectiveness of Janssen vaccine in preventing COVID-19 infection.

**Read more here**

## Association Between Vaccination With BNT162b2 and Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infections Among Health Care Workers

This retrospective single site cohort study in Israel estimated the effect of Pfizer vaccine on SARS-CoV-2 infection in healthcare workers (symptomatic and asymptomatic). They estimated vaccine efficacy of 97% for preventing symptomatic infection and 86% for asymptomatic infection. This study provides further evidence that the vaccine is highly effective in preventing SARS-CoV-2 infection.

**Read more here**

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## National Immunisation Office (NIO) COVID-19 Vaccination Programme Update

We asked the NIO team to reflect on their milestones over the last 6 months to support the roll-out of the COVID-19 Vaccination Programme.

The NIO has been tasked with providing training and developing clinical information for vaccinators, responding to clinical queries and supporting the HSE in the development of materials for people getting vaccinated.

## NIO Representation

Since the beginning of 2021, our Director Dr Lucy Jessop has attended **Department of Health NPHET briefings** on four occasions and has presented at **Joint Health Select Committees, HSE press briefings**, and **the European Congress of Clinical Microbiology** to provide updates and answer questions about the COVID-19 vaccination programme.

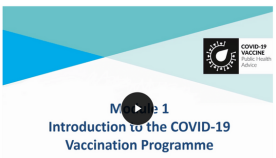
NIO clinical staff have provided clinical updates and responded to queries at **over 20 webinars** with **over 1,000** participants.

**20+ webinars**
**1000+ participants**

## COVID-19 Vaccine Training

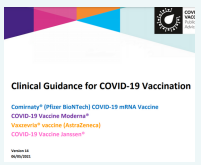
**12,000+ people** have completed the **HSeLand** COVID-19 Vaccination Training Programme developed by the NIO.

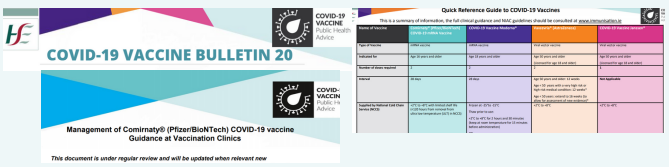
Learners also complete updated content to ensure they are aware of the most up to date information.




## COVID-19 Vaccine Materials

**15+** **COVID-19 Clinical Vaccine materials** have been developed by the NIO to support vaccinators

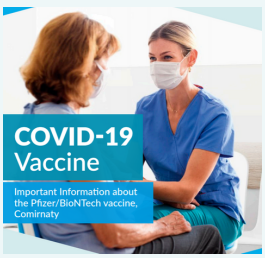



A recent survey found the following materials were most used by health professionals

- COVID-19 Vaccine Bulletins
- HSeLand COVID-19 Vaccination Programmes
- NIAC Immunisation Guidelines
- Clinical Guidance COVID-19 Vaccination
- Quick Reference Guide to COVID-19 Vaccines

NIO provides clinical oversight to HSE communications to develop COVID-19 vaccine information leaflets, post vaccination advice and record cards.

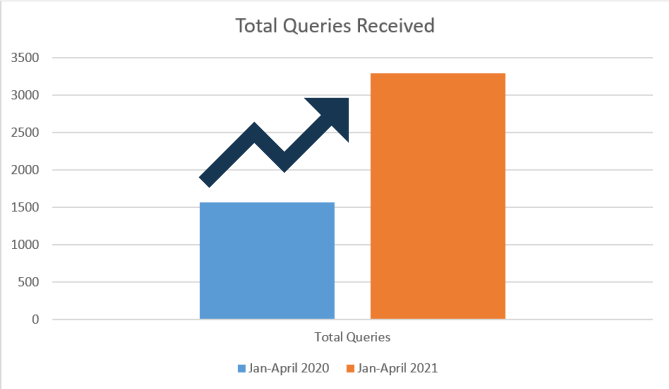



NIO has printed and distributed **over 1 million copies** of information materials for people getting vaccinated to vaccination clinics, primary care settings, hospitals and nursing homes across the country.

NIO have provided content to Social Inclusion and Translate Ireland to help in the development of COVID-19 scripts in **36 languages**

# COVID-19 VACCINE BULLETIN 20

## COVID-19 Clinical Queries




**2,111** **COVID-19 specific** queries dealt with

Topics include

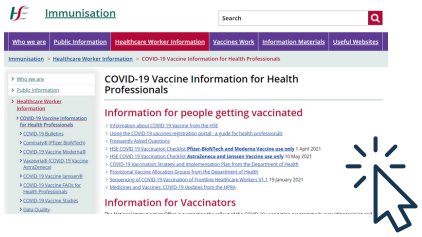
- Cold Chain
- Intervals between vaccine doses
- Vaccine side-effects
- Categorisation of high risk group
- Concerns about allergies
- People who have had COVID-19 enquiring should they have the vaccine

## Website & Social Media

PROTECT PREVENT IMMUNISE

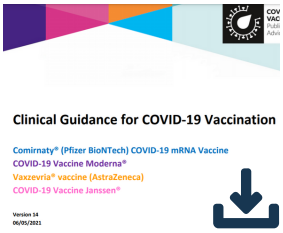
**750,000+ users**

have visited the NIO website




**150,000+ times**

the NIO webpage COVID-19 Vaccine Information for Healthcare Professionals has been viewed




**3,550+ times**

Clinical Guidance for Vaccinators has been downloaded

**More followers** across all Social Media channels

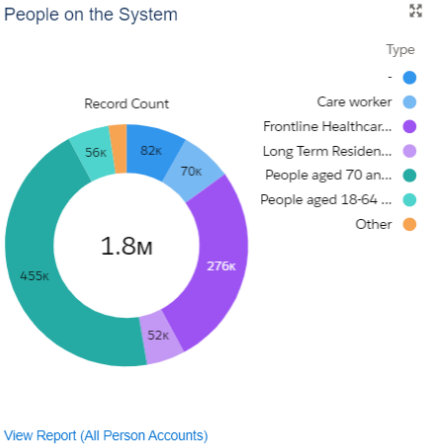
reached **5K+ Twitter followers, 400+ Instagram followers, 100+ YouTube subscribers**

## IT: CoVax

The CoVax system has been live since 28th December 2020. The system has a Public Portal, Healthcare Worker Portal, Application, and GP interfaces from 4 national GP systems as well as Clinic Appointments management.

**Since December 2020,** there are **approx. 2 weekly software releases** which involves a team of staff from both NIO and Office of the Chief Information Officer (OoCIO) testing the software releases and doing sanity testing before it goes live.

A team from both NIO and OoCIO also produce reports to anaylse user profiles registered through the public portal, to track pattern changes and to identify any quality issues.



# COVID-19 VACCINE BULLETIN 20

## 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**

## Do you have queries?

Due to a recent cyberattack against the HSE we are unable to access our HSE Emails at this time. We apologise for any inconvenience this may cause.

Should vaccines be exposed to temperatures outside of parameters please contact the National Immunisation Office immediately. Contacts include:

- Achal Gupta: 087 4064810
- 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.**

**The National Immunisation Office is not involved in the allocation or delivery of COVID-19 Vaccines.**

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