COVID-19 VACCINE BULLETIN 21

Welcome to Bulletin 21 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.

Updates to the Vaccination Programme and Safety Updates

Updated Clinical Guidance Version 15

Following the release of the new NIAC recommendations the 'Clinical Guidance for COVID-19 Vaccination' has been updated. Version 15 is now live on the website.

The key updates include:

- Updated shelf life of thawed undiluted vials of Comirnaty® (Pfizer/BioNTech) at +2°C to +8°C is now 1 month (31 days) instead of 120 hours
- Vaxzevria® (COVID-19 Vaccine AstraZeneca) second dose interval has been moved to 12 weeks for all who have received a previous dose
- Other vaccines may be administered with COVID-19 vaccines at the same time or at any interval. If other vaccines are being given at the same time as COVID-19 vaccines it is preferable to give them in different limbs

Due to the outage resulting from the cyberattack on the HSE IT systems we are unable to update the vaccination training videos for vaccinators at present. However, updates have been written onto the training websites where relevant. You can access these video training modules through our Eventbrite pages listed at the end of this bulletin.

The master medicines protocols for the COVID-19 vaccines have been updated on our website too

Click here

To review further updates read the full guidance here

Read Clinical Guidance here

Comirnaty® (Pfizer/BioNTech) and facial swelling in those with dermal fillers

The European Medicines Agency's (EMA) safety committee has reviewed evidence and cases reported to their European pharmacovigilance database. Based on this review they have recommended that "facial swelling in people with a history of injections with dermal fillers" be added as a potential side effect of the Comirnaty® (Pfizer/BioNTech) vaccine. The product information is due to be updated shortly.

Read more here

Urticaria and angioedema to be included as side effects of Vaxzevria® (COVID-19 Vaccine AstraZeneca)

The EMA safety committee reviewed reported cases of hypersensitivity reactions after Vaxzevria® (COVID-19 Vaccine AstraZeneca). The product information will be updated to have a hypersensitivity reaction of urticaria as a new uncommon side effect and angioedema too (frequency to be determined). Hypersensitivity, rash, pruritus and anaphylaxis were already included in the product information.

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New FAQ: Can I just give the Comirnaty® (Pfizer/BioNTech) vaccine as a one-off single dose?

No this is not recommended. You do not have the maximum protection against the virus until 7 days after the second dose of the Comirnaty® (Pfizer/BioNTech) vaccine. There is insufficient data on how long the protection from the first dose lasts. Furthermore, the Comirnaty® (Pfizer/BioNTech) vaccine has been licensed for use by the European Medicines Agency as a two-dose product. Therefore, unless there are clinical reasons or contraindications to the vaccine it is recommended that the person complete the two-dose vaccine schedule.

COVID-19 Vaccine Janssen® is the only authorised single dose COVID-19 vaccine.

Read more here

COVID-19 Vaccination in Pregnancy

Following the recently updated NIAC recommendations on COVID-19 vaccinations in pregnancy, The National Immunisation Office has produced a summary sheet to aid vaccinators on the different scenarios they might encounter when vaccinating pregnant women in various stages of pregnancy.

Read more here

The Institute of Obstetricians and Gynaecologists, the Irish Medicines in Pregnancy Service at the Rotunda Hospital and the National Immunisation Advisory Committee (NIAC) have updated the following document: **"Questions and Answers for pregnant or breastfeeding women about COVID- 19 vaccination".**

It aims to answer common questions around COVID-19 vaccination for these women. For example it includes the updated guidance from NIAC allowing co-administration of other vaccines with COVID-19 vaccines.

Read more here

For more information on how pregnant women are being contacted **Click here**

Updated Immunisation Guidelines

NIAC produces the immunisation guidelines for Ireland. On 25 May 2021 the following chapters of the immunisation guidelines (including on COVID-19 vaccines) have also been updated:

- Chapter 2 - General Immunisation Procedures
- Chapter 5a - COVID-19
- Chapter 9 - Hepatitis B
- Chapter 10 - Human Papillomavirus
- Chapter 12 - Measles

Read more here

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Latest from research

UK Data on the Effectiveness of the Pfizer-BioNTech and AstraZeneca COVID-19 Vaccines Against the B.1.617.2 variant

This study looked at the effectiveness of COVID-19 vaccines against the B.1.617.2 variant (India). The study was conducted using UK data and had 2 parts. First was a test negative case control study (comparing vaccination status in symptomatic cases to those who report symptoms but test negative).

Second, they compared the proportion of cases with the B.1.617.2 variant relative to the main circulating virus (the B.1.1.7 variant, Kent) by vaccination status. 12,675 sequenced cases were included in the analysis of which 11,621 had B.1.1.7 detected and 1,054 had B.1.617.2 detected.
They found a reduction in effectiveness of one dose of vaccine against symptomatic disease with the B.1.617.2 variant.

Vaccine effectiveness against symptomatic disease with B.1.617.2 for a single dose of either vaccine was approximately 33%, for two doses of Pfizer vaccine effectiveness was approximately 88% and for two doses of AstraZeneca is approximately 60%.

This study estimates that there is reduced effectiveness of COVID-19 vaccines after one dose of Pfizer or AstraZeneca vaccine, however two doses of vaccine appeared to provide significant protection. Of note there was a limited follow up period in this study so they were unable to estimate effectiveness against severe illness, hospitalisation and death. However, previous vaccine effectiveness estimates with other variants have shown higher levels of effectiveness against more severe outcomes, so higher levels of effectiveness against severe disease may be anticipated with the B.1.617.2 variant.

Read more here

Vaccine Effectiveness of mRNA COVID-19 Vaccines in Healthcare Workers (HCW) from the United States

This was a negative case control study, which estimates real world effectiveness of mRNA vaccines (Pfizer-BioNTech and Moderna® COVID-19 Vaccines) in HCWs in the USA. This paper reports results up to March 18 2021, at this point 623 case-patients and 1,220 controls had been enrolled. The majority of cases worked in direct patient contact roles and were aged between 19-49 years.

This study estimates a 2 dose effectiveness of mRNA vaccines of 94% (95% CI = 87%–97%) against symptomatic COVID-19. This was measured from 7 days after the second dose of vaccine. They also estimated a 1 dose effectiveness of 82% (95% confidence interval [CI] = 74%–87%), adjusted for age, race/ethnicity, and underlying medical conditions, this was measured from 14 days after first dose of vaccine.

This study among HCWs, which is ongoing, provides reassuring evidence that mRNA vaccines are highly effective in preventing symptomatic COVID-19 and correlate with trial data estimates.

Read more here

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TeenCOVE Study (Moderna) Releases Data on Effectiveness in Adolescents

Moderna have released Phase 2/3 study results for use of their mRNA vaccine in adolescents. Their study involved 3,732 adolescent participants ages 12 to less than 18 years. They were randomised to receive either 2 doses of mRNA vaccine or placebo. After two doses, no cases of COVID-19 were observed in the vaccine group using the case definition from the adult Phase 3 COVE study, compared to 4 cases in the placebo group, resulting in a vaccine efficacy of 100% starting 14 days after the second dose. Because symptoms in adolescents have been reported to be milder they also looked at those with mild symptoms, and created a case definition for testing of those people with milder symptoms for the adolescent trial. Using this case definition a vaccine efficacy of 93% was observed.

The vaccine was generally well tolerated in the population, and adverse events reported were similar to those in the adult trials. No significant safety concerns were identified. The majority of adverse events were mild or moderate in severity. The most common solicited local adverse event was injection site pain. The most common solicited systemic adverse events after the second dose of vaccine were headache, fatigue, myalgia and chills.

This study provides evidence that the Moderna COVID-19 vaccine is safe and effective in people ages 12 to 18, whereas the initial clinical trials only included those over 18 years of age. The company will now submit this data to the relevant authorities in various jurisdictions and seek approval for use of the vaccine in those aged 12 and over.

Read more here

UK COVID-19 vaccine Booster Study Launched

The UK health secretary announced a large study which is to begin recruiting. The Cov-Boost study aims to identify find out which COVID-19 vaccines are most effective as a booster vaccination, depending on which vaccine was used to provide the initial prime-boost course. They are currently enrolling men and women over the age of 30 who received their initial prime-boost course of vaccination against COVID-19 in December 2020 or January 2021.

The study will evaluate the effect of a third/booster dose of one of seven different COVID-19 vaccines compared to a control group, who will receive a MenACWY vaccine. People are eligible to participate in the study if they have already received a COVID-19 vaccine.
The COVID-19 vaccines used in the study will be ChadOx1 nCoV-19 (Oxford/AstraZeneca), BNT162b2 (Pfizer BioNTech), mRNA-1273 (Moderna), NVX-CoV2373 (Novavax), VLA2001 (Valneva), CVnCoV (Curevac) and Ad26.COV2.S (Janssen).

Results are expected in 2022.

Read more here

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Moderna Booster Study Initial Data

In early May Moderna also announced initial phase 2 clinical trial data from a booster dose. The initial data indicates that a booster dose given to people who have previously been vaccinated increases antibody response against variants of concern (VOC)- B.1.351 (South Africa) and P.1 (Brazil). 3 booster vaccines are going to be studied: the original licensed vaccine from Moderna, a vaccine strain-matched to the VOC B.1.351 and a multivalent vaccine (combining the two aforementioned vaccines). Initial data shows the strain matched booster produced a higher antibody response against the VOC B.1.351 when compared with the original licensed vaccine as a booster.

Read more here

Combining Influenza and COVID-19 Vaccination (ComFluCOV) study

The ComFluCOV trial is a study currently under way in the United Kingdom. It aims to examine the safety, as well as the immune responses, of administering the currently approved COVID-19 vaccines at the same time as the recommended influenza vaccines. It will include healthy adult volunteers, who will receive either influenza vaccine (Flucelvax QIV if the participant is less than 65 years old, or FluAd if the participant is aged 65 years or older) or control (saline), at the same time as receiving their second dose of COVID-19 vaccine (either Vaxzevria® or Comirnaty®).

Results are expected later this year.

Read more here

Ipsos MRBI/IPHA survey on attitudes towards the COVID-19 vaccine - Update May 2021

The latest Ipsos MRBI (Market Research Bureau Ireland) survey undertaken for the Irish Pharmaceutical Healthcare Association (IPHA) shows an increase in the number of people who would wish to take a COVID-19 vaccine when one becomes available to them, and a decline in the number of people who say they would not take the vaccine, compared to results in survey taken in January 2021.

63% of people reported they would take the COVID-19 vaccine and 26% had already received the vaccine, which means 89% of people overall in the survey were willing to take COVID-19 vaccine. In January, 7% of respondents said they would refuse a COVID-19 vaccine and 18% were unsure. This month, 4% overall say they will refuse a COVID-19 vaccine and 7% are unsure.

Read more here

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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

COVID-19 Vaccination Training Programme

While HSeLand is unavailable you can access the National Immunisation Office COVID-19 vaccinator training by registering through the Eventbrite links here:

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

Please note these links provide vaccinator training - some professions such as nurses, midwives, optometrists and physiotherapists need to undertake a tailored vaccinator training programmes- we are working with partners to make those modules available to individuals soon.

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.

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

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.

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.