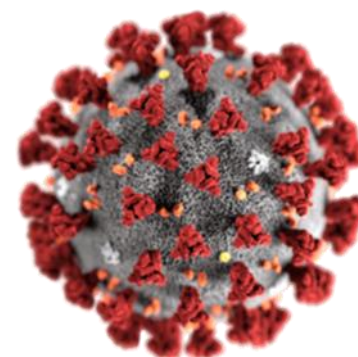




**COVID-19
VACCINE**
Public Health
Advice

The Covid-19 Vaccination Programme

Dr Lucy Jessop
Director of Public Health
National Immunisation Office

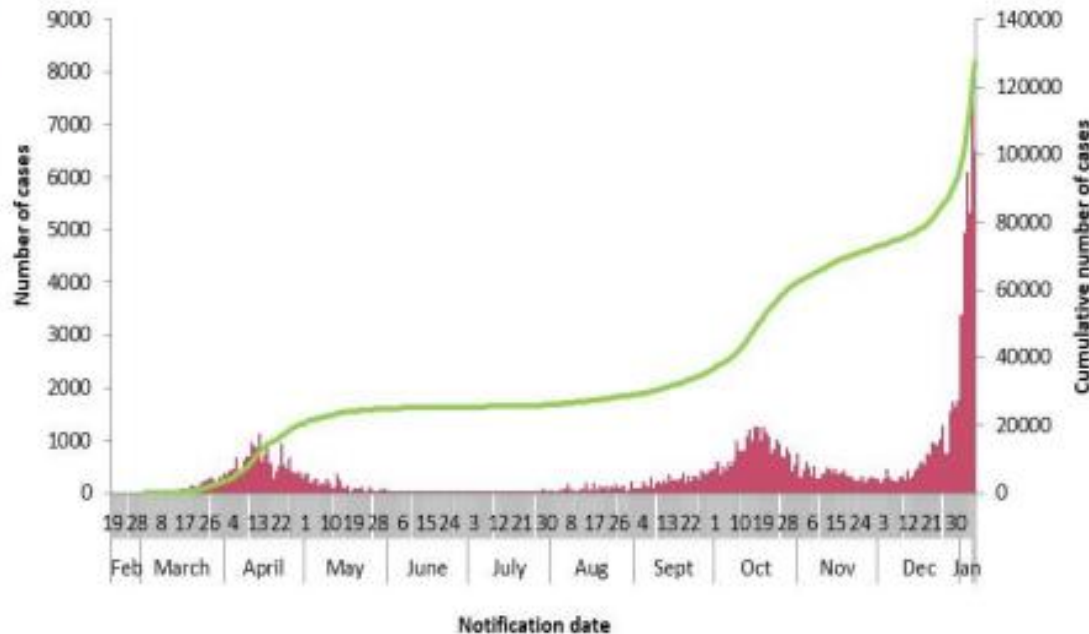




COVID-19 Natural History

- The most common symptoms are fever, dry cough, dyspnoea, fatigue,
- anorexia and loss or change of taste or smell
- Older people atypical symptoms
 - 80% of infections are asymptomatic or mild,
 - 15% moderate
 - 5% severe.
- Severe illness and death have been reported at all ages, the risk of severe outcome increases with age and for those with chronic medical conditions.
- Long term effects of Covid-19 reported, most commonly reported symptoms: Fatigue, SOB, Joint Pain, Chest Pain. Long-term significance of symptoms unknown.

COVID-19 Epidemiology Ireland



Total Confirmed Cases
127 657

Total Deaths
2,307

(07/01/2020)

Number and cumulative number of confirmed COVID-19 cases notified in Ireland by notification date

Source: HPSC



Healthcare workers account for 16% of all COVID-19 cases in Ireland

Table A: Summary of healthcare worker COVID-19 cases notified to HPSC, week 10 - week 51, Ireland, (n= 12,929)

Characteristic of HCW COVID-19 cases	Number	%
Total number of COVID-19 cases	80,099	-
Total number of HCW cases	12,929	16.1%
Median age (IQR)	40 (31-50) years	-
Total number hospitalised	418	3.2%
The median age (IQR) of hospital inpatient	45.5 (34-54) years	
Total number admitted to ICU	61	14.6%*
The median age (IQR) of HCW in ICU	51 (44-59) years	-
Total number of deaths	8**	0.06
The median age (range) for deaths	54 (30-68) years	-

*This relates to hospitalised cases and it is 0.5% of all HCW cases.

**Seven confirmed and 1 probable COVID-19 case.

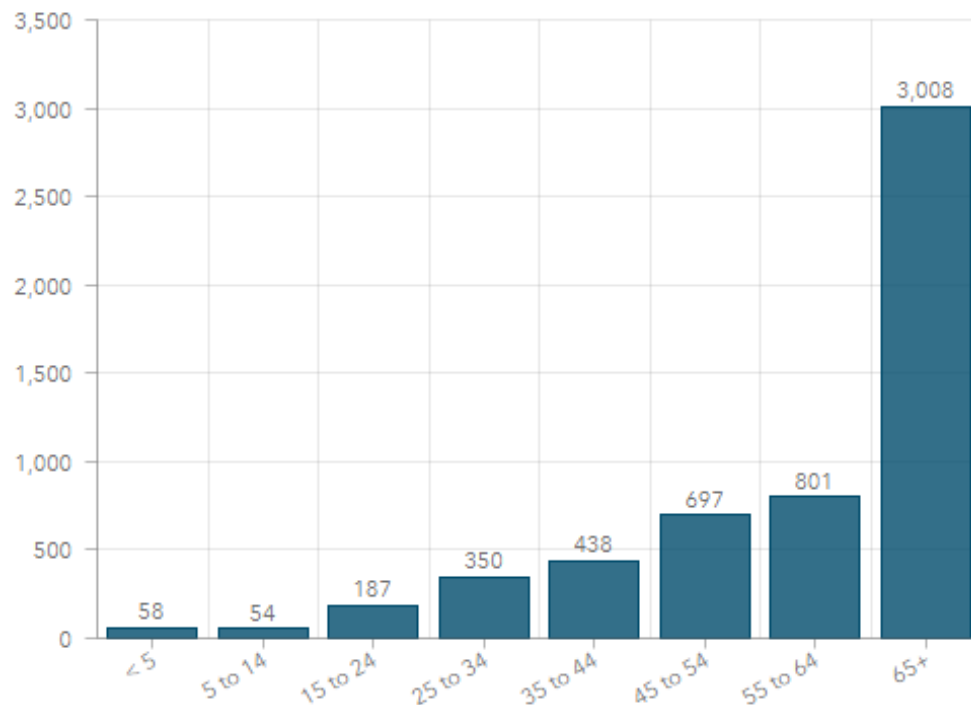
Of HCW cases- 25% nurses 24% HCA
23% of HCW cases work in nursing homes





Highest proportion of hospitalisations and deaths are in those aged 65 and older.

Total Confirmed Cases Hospitalised - Age Profile

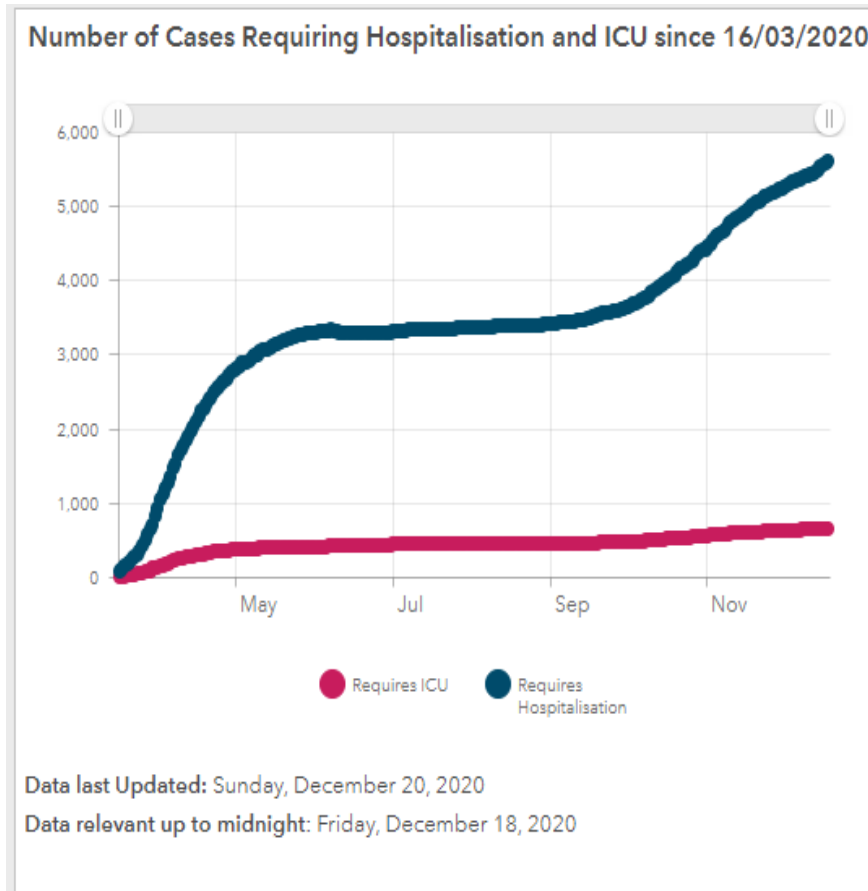


Data last Updated: Sunday, December 20, 2020

Data relevant up to midnight: Friday, December 18, 2020

**First wave,
56% of deaths occurred
among residents of
nursing homes and long-
term care facilities.**

Hospitalised and ICU cases



Hospitalised cases:

63% had an underlying medical condition.

Cases admitted to ICU

89% had an underlying medical condition.

Aims of Pandemic Vaccination Programme

PANDEMIC VACCINATION PROGRAMME

ETHICAL FRAMEWORK: MINIMISE HARM, FAIRNESS, MORAL EQUALITY, RECIPROCITY



1

Prevent
Morbidity &
Mortality



2

Protect
Healthcare
Capacity



3

Protect
Essential
Services



4

Minimise
social & economic
disruption



Priority Groups

Group
Adults aged ≥ 65 years who are residents of long-term care facilities. Consider offering vaccination to all residents and staff on site
Frontline HCW
Aged 70 and older in the following order: 85 and older 80-84 75-79 70-74
Other HCWs not in direct patient contact
Aged 65-69. Prioritise those with medical conditions** which put them at high risk of severe disease



Priority Groups cont.

Key workers (to be further refined)

Aged 18-64 years with medical conditions which put them at high risk of severe disease

Residents of long-term care facilities aged 18-64

Aged 18-64 years living or working in crowded settings where self-isolation and social distancing may be difficult to maintain

Key workers in essential jobs who cannot avoid a high risk of exposure to COVID-19.

Those who are essential to education and who face disease exposure -

Aged 55-64 years

Those in occupations important to the functioning of society, e.g., third level institutions, entertainment and goods-producing industries

Aged 18-54 years who did not have access to the vaccine in prior phases

Children, adolescents up to 18 years and pregnant women (to be refined)



TYPES OF COVID VACCINES

MRNA VACCINES



Pfizer / BioNtech
("Comirnaty")



Moderna



CureVac

VIRAL VECTOR VACCINES



Oxford /
Astra Zeneca



Johnson and
Johnson / Janssen

PROTEIN-BASED VACCINES



Protein sub-unit
vaccines:
Sanofi / GSK

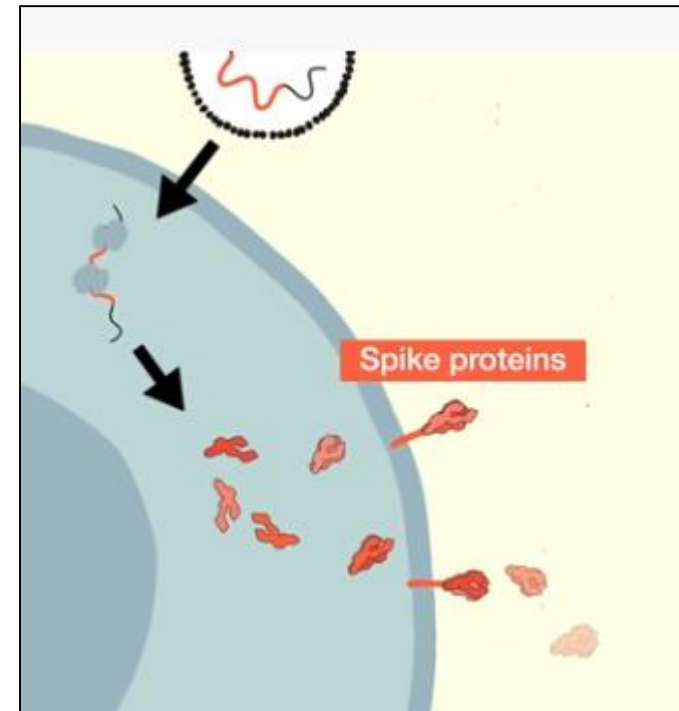


Viral-like particle
Novavax

Comirnaty® (Pfizer/BioNTech) received approval for conditional marketing authorisation on 21/12/2020 by EU,
following a recommendation by the European Medicines Agency
Moderna vaccine approved 6/1/21

mRNA Vaccines

- The spike protein is the target antigen of the vaccines. Covid-19 vaccines stimulate the immune response against the spike protein of the virus.
- Do not contain any part of a virus. Contain mRNA, the genetic code/ blueprint to make the spike protein of the Covid -19 virus
- mRNA is coated in lipid molecules to prevent it from degrading.
- When a person is vaccinated, mRNA enters human cells and stays in the cytoplasm (it doesn't enter the nucleus). It gives instructions to the cell (ribosome) to produce the spike protein of the virus
- The spike protein is then expelled from the cell and stimulates the immune response. Antibodies are produced against the spike protein.
- mRNA is broken down a few days after the vaccine is given.
- Not a live vaccine





Pfizer BioNTech BNT162b2

Phase 3 trial results (aged 16 and older)

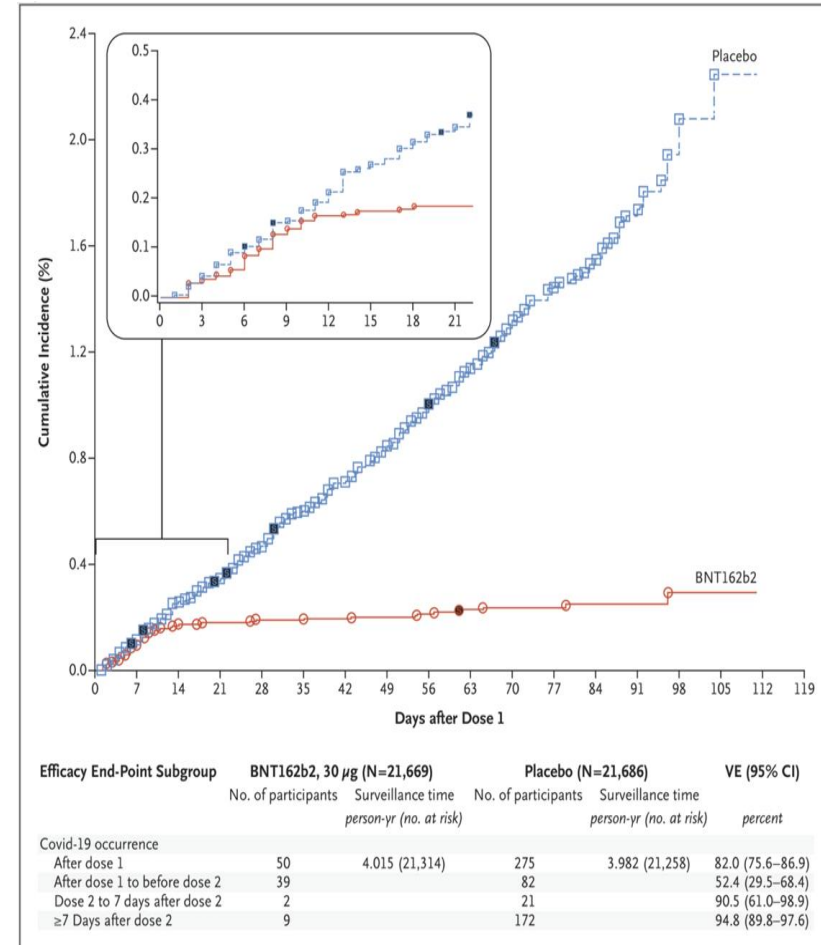
18, 198 received
2 doses of vaccine

18, 325 received
2 doses of placebo

Results: Vaccine efficacy : COVID-19
occurrence from 7 days after Dose 2

	BNT162b2 Vaccine	Placebo
Symptomatic Covid-19	8 N=18198	162 N=18325
Severe Covid-19	1 N=21669	9 N=21686

Vaccine efficacy of 95% (95% credible interval, 90.3–97.6%)



Efficacy similar in all age groups





Adverse Events Reported

Adverse events reported from 21,744 vaccine recipients Phase 2 and 3 trials

Pain at the injection site	84%	More after dose 2 > dose 1
Fatigue	63%	
Headache	55%	More in younger than older
Myalgia and chills	38%	
Arthralgia	24%	Usually mild or moderate in intensity
Pyrexia and injection site swelling	14%	
Other adverse events reported		Resolved within a few days after vaccination
Nausea	common ($\geq 1/100$ to $< 1/10$)	
Lymphadenopathy	0.3%	
Acute peripheral facial paralysis	rare ($\geq 1/10,000$ to $< 1/1000$)	



Contraindications

Anaphylaxis following a previous dose of the vaccine or any of its constituents.

Anaphylaxis - serious systemic allergic reaction requiring medical intervention

Precautions

- Acute severe febrile illness; defer until recovery (no need to check temperature)
- Deferred until clinical recovery from COVID-19
and
at least four weeks after diagnosis or onset of symptoms
or
four weeks from the first PCR positive specimen in those who are asymptomatic.
- Defer second dose if diagnosed with COVID19 between 1st and 2nd dose

Not contraindicated for those with persisting symptoms post COVID-19 unless evidence of recent clinical deterioration.

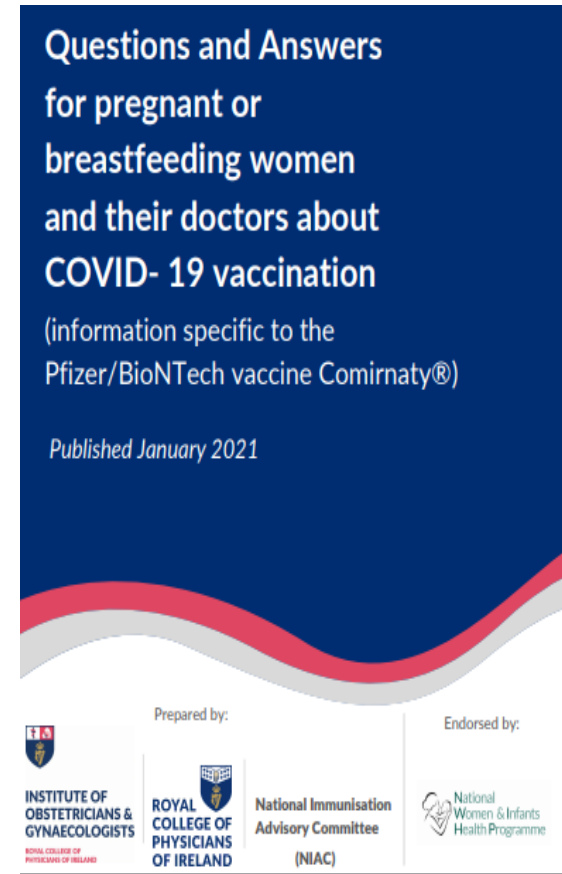
Appropriate support in case of anaphylaxis or fainting after vaccine administration.
Precautions in place to minimise injury from fainting.





Pregnancy, Breastfeeding And Fertility Treatment

- Limited experience in pregnant women. Animal studies do not indicate direct or indirect harmful effects
- NIAC recommends vaccine where it is decided that the risk/benefit is favourable. Pregnant women at high risk of severe disease and healthcare workers should discuss the risks and benefits of COVID-19 vaccine with their obstetrician or GP.
- The two dose schedule should not commence before 14 weeks gestation and should be completed by 33 weeks gestation (as a precaution to minimise any possible association with miscarriage or pre term birth).
- COVID-19 vaccine can be given to women who are breastfeeding.
- You do not need to leave any interval after having the COVID-19 vaccine and becoming pregnant. If you become pregnant following the first dose, you should wait until 14 weeks or after to get the second dose.
- There is no evidence the vaccine affects fertility. COVID-19 mRNA vaccines can't become part of your or your baby's DNA.
- You do not need to leave any interval after having the COVID-19 vaccine and starting to try to conceive or to have fertility treatment such as IVF. However, you may wish to defer it until you have completed the full course, in view of the risk of side effects such as fever in the 48 hours following the vaccine, especially the second dose.





Bleeding Disorders/ On Anti Coagulants

- Inform recipient they may develop haematomas in IM injection site.
- Consult re those with thrombocytopenia (platelet count $<50 \times 10^3/\text{ml}$).
- Those with inherited coagulopathies receiving factor replacement therapy should be given IM vaccination within a few days after treatment.
- Those on long term anticoagulation are not considered to be at higher risk of bleeding complications following immunisation.

Other Medical Conditions Or Medication

mRNA vaccines are not live vaccines- no issue with giving to immunocompromised people, but may not make full immune response

Do not need full medical or medication history of patients, only information as relevant to cautions and contraindications





Children

- Vaccine recommended for healthcare workers and those in priority groups from 16 years of age.
- Limited data on the safety and efficacy of the vaccine in children less than 16 years.
- Clinical trials ongoing.

Adverse Events

- Over 17 million doses of COVID-19 vaccine administered worldwide so far :in UK (1.3m) and US (5.9m) to date.
- *“Consider staggering healthcare worker vaccinations due to higher rate of pyrexia after 2nd dose.”* NIAC
- Small number of cases of anaphylaxis reported in UK and US.
- Observation time post vaccination
 - no history of anaphylaxis from any cause: 15 minutes
 - a history of anaphylaxis (serious systemic allergic reaction requiring medical intervention) from any cause: 30 minutes
 - those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated



Myths And Facts About COVID-19 mRNA Vaccines

Can mRNA vaccines cause people having a positive COVID-19 nose and throat swab test?

No. They do not affect a PCR swab test, which is the basis of diagnosing COVID-19 infection by detecting viral RNA in the nose and throat.

Work is on-going to determine if they may affect antibody tests

Will Comirnaty® protect against the new strains of SARS CoV-2 virus that have been identified in the UK and South Africa?

All the evidence is that the vaccine will protect against these strains of the virus. Work is on-going to confirm that this is the case.

Are foetal cell lines used to produce Comirnaty®?

No. Foetal cell lines are not used to produce Comirnaty®.



Other Issues

- Vaccination is not mandatory in Ireland
- You can't choose the type of vaccine you have
- At present no change in any guidelines for those who are vaccinated- e.g. travel, close contacts etc
- No change in serial testing at present
- When more information available on whether vaccine reduces transmission, this may change



More Information

NATIONAL IMMUNISATION OFFICE WEBSITE www.immunisation.ie

- **Clinical Guidance for Covid-19 Vaccination**
- **SOP vaccine management**
- **Medicines Protocol for Comirnaty® (Pfizer/BioNTech Covid-19 Vaccine)**
- **Links to primary research studies**
- **Link to NIAC guidelines**
- **Pregnancy, breastfeeding and fertility guidance**

HSELAND E-LEARNING PLATFORM www.HSEland.ie

- **Learning module slideset**
- **HSE website: : <https://www2.hse.ie/covid-19-vaccine/>**
- **Public information on the programme e.g. leaflet (translations, easy read coming soon)**

Email clinical queries to the NATIONAL IMMUNISATION OFFICE:
immunisation@hse.ie

