COVID-19 VACCINE FREQUENTLY ASKED QUESTIONS
FOR
HEALTH CARE PROFESSIONALS

Update 15/03/2021

Updates include:

- **Simplification of "How the Vaccines Work" – Page 6**
- **New information on Covid-19 vaccine Janssen (Johnson & Johnson) – throughout**
- **Updated "Vaccines at a Glance" – Page 34**

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COVID-19 vaccines – FAQs for Healthcare Workers

This document will be regularly updated as the situation evolves, and new evidence emerges.

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Can you give me some information about Covid-19 vaccines?

Yes. There are four COVID-19 vaccines which have already been authorised by the European Medicines Agency for use in the European Union. some countries. Pfizer/BioNTech's vaccine Comirnaty™ was given conditional approval on the 21st December 2020, the Moderna vaccine on the 6th January 2021, the AstraZeneca vaccine on the 29th January 2021 and on the 11th March 2021 the EMA approved the use of the Janssen vaccine.

Once vaccines are demonstrated to be safe and efficacious, they must be approved by national regulators, manufactured to exacting standards, and distributed. WHO is working with partners around the world to help coordinate key steps in this process, including to facilitate equitable access to safe and effective COVID-19 vaccines for the billions of people who will need them.

What are the stages of vaccine development?

The general stages of the development cycle of a vaccine are:

- Exploratory stage
- Pre-clinical stage
- Clinical development
- Regulatory review and approval
- Manufacturing
- Quality control
- Post marketing surveillance

Clinical development is a three-phase process. During Phase I, small groups of people receive the trial vaccine. In Phase II, the clinical study is expanded, and the vaccine is given to people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended. In Phase III, the vaccine is given to thousands of people and tested for efficacy and safety.

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Many vaccines undergo Phase IV- formal, ongoing studies after the vaccine is approved and licensed.

How are new vaccines approved in the European Union?

The regulation of vaccines falls under the scope of medicines regulation, which includes several mutually reinforcing activities all aimed at promoting and protecting public health. In the European Union, once sufficient data is available from research and clinical trials, companies can apply to the **European Medicines Agency (EMA)** for authorisation to place their vaccine on the EU market.

The EMA then evaluates all the data and carries out a rigorous, independent scientific assessment of the candidate vaccine. Based on result of the EMA's assessment, the European Commission grants a marketing authorisation in the EU. The vaccine can then be used. Each country has its own Medicines Regulatory Authority but countries within the European Community must first wait for direction from the European Medicines Agency before approving a medicine locally.

During a public health emergency, the EMA may grant a **conditional marketing authorisation** for a vaccine. This may happen when the benefit of immediate provision outweighs the risk of having less complete data than would normally be requested for authorisation. A conditional marketing authorisation allows prompt response to a public health threat such as the COVID-19 pandemic. In these cases, the producer commits to providing further data according to an agreed timeline.

In any case, the European Commission will only grant a marketing authorisation once the European Medicines Agency's assessment shows that the vaccine is both safe and effective. Once a new vaccine is placed on the market, EU authorities will carry out continuous monitoring and evaluation of new data on the vaccine, including monthly safety reports from vaccine producers and results of further studies. The **EU safety monitoring plan for COVID-**

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19 vaccines[1] entails more frequent monitoring than usual as well as monitoring activities specifically tailored to COVID-19 vaccines.

Since the vaccines are being produced at record speed should I worry about safety?

The normal time frame for producing a vaccine is usually 10-15 years. COVID vaccines however are being produced in less than 12 months, so the question regarding safety is a pertinent question. There are a number of important factors that explain why the vaccine has been produced in such a short period of time but not at the expense of safety.

These include:

- unprecedented cooperation between stake holders such as governments, private industry and NGOs to come up with an effective, safe vaccine
- massive financial commitment of industry and governments to develop the vaccines
- researchers were able to build on work that had already been done. For example, techniques for using mRNA in vaccines had already been developed for cancer therapy, and a large amount of research had been carried out on other Coronaviruses
- The regulatory agencies responsible for vaccine approval have been reviewing the data from the trials on a rolling basis instead of reviewing all the data at the end
- Some companies have taken the risk of producing large amounts of their vaccine before obtaining approval, so the vaccine would be available straight away once approved

These factors have been crucial in shortening the time from the development of COVID-19 vaccines without compromising safety. There are many strict measures in place to help ensure that COVID-19 vaccines will be safe. All COVID-19 vaccines applying for marketing authorization on the EU market need to go through the usual rigorous, independent scientific

[1] The plan can be accessed here: https://www.ema.europa.eu/en/news/ema-publishes-safety-monitoring-plan-guidance-risk-management-planning-covid-19-vaccines

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assessment of the European Medicines Agency (as described in the previous question) before being approved for use.

Comirnaty™ (the Pfizer/BioNTech vaccine), Moderna, AstraZeneca and Janssen (Johnson & Johnson) vaccines have all gone through all the required phases of vaccine development and evaluation process, including initial laboratory studies and Phase 1, 2 and 3 clinical trials in humans. The phase 3 trial for Comirnaty™ involves over 40,000 participants across 6 countries, that for COVID-19 vaccine Moderna involves around 30,000 participants, the phase 3 trial for AstraZeneca vaccine has 23,700 participants in three countries, and the Janssen vaccine phase 3 trial involves 44,000 persons across the United States, South Africa and Latin America. All the trials include people at high risk for COVID-19 and even those with co-morbidities, and were specifically designed to identify any common side effects or other safety concerns. Further monitoring and studies are ongoing for all the vaccines.

More information about development, evaluation, approval and monitoring of COVID-19 vaccines in the EU is available at:

https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-development-evaluation-approval-monitoring

What types of Covid-19 vaccines are being developed and how do they work?

Scientists around the world are developing many potential vaccines for COVID-19. These vaccines are all designed to teach the body's immune system to safely recognize and block SARS-CoV-2, the virus that causes COVID-19.

Several different types of potential vaccines for COVID-19 are in development, including:

- ***Inactivated or weakened virus vaccines***, which use a form of the virus that has been inactivated or weakened so it does not cause disease, but still generates an immune response.
- ***Protein-based vaccines***, which use harmless fragments of proteins or protein shells that mimic the COVID-19 virus to safely generate an immune response.

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- ***Viral vector vaccines***, which use a virus that has been genetically engineered so that it cannot cause disease, but produces coronavirus proteins to safely generate an immune response.
- ***RNA and DNA vaccines***, a cutting-edge approach that uses genetically engineered RNA or DNA to generate a protein that itself safely prompts an immune response.

The great majority of vaccines that are currently being developed all require that they be given in 2 doses.

Can you explain in more detail how the vaccines work?

Pfizer/BioNTech - COMIRNATY® is a messenger RNA (mRNA) based vaccine against coronavirus disease 2019 (COVID-19). mRNA or messenger ribonucleic acid consists of transcripts of genetic material that are used to guide protein synthesis in the cell.The mRNA instructs the cell to produce proteins of the S antigen which is part of the spike protein unique to SARS-CoV-2. The spike protein is involved in the process of viral attachment and entry into human cells. The presence of the spike protein will stimulate the body to produce an immune response and to retain that information in memory immune cells. The mRNA from the vaccine is broken down by the body within a few days.

Efficacy shown in clinical trials in participants with or without evidence of prior infection with SARS-CoV-2 and who received the full series of vaccine (2 doses) was approximately 95% based on a median follow-up of two months.

Moderna - The Moderna COVID-19 vaccine is a messenger RNA (mRNA) based vaccine against coronavirus disease 2019 (COVID-19). The host cells receive the instruction from the mRNA to produce protein of the S-antigen unique to SARS-CoV-2, allowing the body to generate an immune response and to retain that information in memory immune cells. Efficacy shown in clinical trials in participants who received the full series of vaccine (2 doses) and had negative baseline SARS-CoV-2 status, was approximately 94% based on a median follow-up of 9 weeks.
risks

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Suggested reading for those interested in a detailed review of mRNA vaccines: 'mRNA vaccines — a new era in vaccinology' by Pardi et al.[2]

Oxford/AstraZeneca - The ChAdOx1-S/nCoV-19 [recombinant] vaccine consists of an adenoviral vector (carrier) which cannot replicate. The vaccine expresses the SARS-CoV-2 spike protein gene, which instructs the host cells to produce the protein of the S-antigen unique to SARS-CoV-2. This allows the body to generate an immune response and to retain that information in memory immune cells. Efficacy shown in clinical trials in participants who received the full series of vaccine (2 doses) irrespective of interval between the doses was 63.1%, based on a median follow-up of 80 days, but tended to be higher when the dose interval was longer.

Janssen (Johnson & Johnson) - COVID-19 Vaccine Janssen is composed of a recombinant, human adenovirus type 26 vector that cannot replicate and that encodes a SARS-CoV-2 full-length spike (S) glycoprotein in a stabilised conformation. Following administration, the S glycoprotein of SARS-CoV-2 is transiently expressed, stimulating both neutralising and other functional S-specific antibodies, as well as cellular immune responses directed against the S antigen, which may contribute to protection against COVID-19.

Who will get the vaccine?

Now that the European Medicines Agency has granted marketing approval for four vaccines, the manufacturing companies will distribute their vaccines to the different countries in the EU. Distribution of the Pfizer vaccine started on 26th December 2020, that of the Moderna vaccine started on the 10th January 2021, distribution of the AstraZeneca vaccine started on the 30th January 2021 and stocks of the Janssen vaccine are expected towards the end of March+/ beginning of April. Once other vaccines are approved, their distribution will follow. Each country will have a priority list of who should get the vaccine first. In Malta the priority list will include:

[2] Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5906799/pdf/nihms955599.pdf

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First Group

- healthcare workers and long-term care facility workers (public and private sector)
- persons living in long-term care facilities – elderly and mental health
- persons aged 85 and over.

Second Group

- All other front liners;
- persons 80-85 years of age.

Third Group

- persons with chronic illness whose state of health makes them particularly at risk-elevated risk of severe disease or death;
- persons 70-80 years of age;
- staff at schools and child-care centres

Fourth Group

- rest of population

The timing of the roll out will depend on the speed of production and supply of the vaccines.

Who is eligible for the COVID-19 vaccine?

All Maltese citizens and all residents of Malta with a valid residency card are eligible for the vaccine.

With what efficacy will COVID-19 vaccines reduce the risk of COVID-19 and its complications?

The WHO had originally set as an expectation that a COVID-19 vaccine would prevent disease or decrease its severity in at least 50% of people who are vaccinated. However, clinical trials have shown that some vaccines are registering a vaccine efficacy of 90% to 95%. This means that the vaccine will prevent serious disease and complications from Covid-19 in at least 90-95% of cases.

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Efficacy of Pfizer/BioNTech vaccine:

Part of the Phase 3 trial of this vaccine involved 36,621 individuals at high risk of infection with COVID-19. They were randomly split into two equal groups to receive either the vaccine or a placebo.

Of all the participants who were still negative for COVID-19 7 days after the second dose, 162 individuals from the placebo group got COVID-19, while only 8 individuals from the vaccine group got COVID-19.

This makes the vaccine 95% efficacious at preventing symptomatic COVID-19 from 7 days after the 2nd dose in participants without evidence of SARS-CoV-2 infection before and during vaccination regimen.

For participants with and without evidence of SARS-CoV-2 infection before and during vaccination regimen, efficacy against confirmed COVID-19 occurring at least 7 days after Dose 2 was 94.6%, with 9 and 169 cases in the vaccine and placebo groups respectively. It was similarly effective across different age groups, genders, racial/ethnic groups and in people with medical conditions that put them at greater risk of severe COVID-19.

With respect to secondary efficacy endpoints of the trial, when it comes to severe COVID-19 disease, ten participants had severe COVID-19 disease after Dose 1 (one subject who received the vaccine and nine participants who received placebo). The vaccine recipient who met criteria for severe disease did so because of oxygen saturations of 93% on room air but did not require hospitalisation or further medical care. Of the 9 placebo recipients who met criteria for severe COVID-19 disease, only 2 did not require hospitalisation. The rest required hospital treatment including one participant who required non-invasive positive pressure ventilation for bilateral pneumonia and 3 who required admission to intensive care. While the number of severe cases is too small to draw more definitive conclusions, this case split does suggest protection from severe COVID-19 disease.

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Efficacy of COVID-19 Vaccine Moderna:

The Phase 3 trial of this vaccine involved 28207 participants with a negative SARS-CoV-2 baseline status that received two doses of either COVID19 vaccine Moderna (n=14134) or placebo (n=14073). 25.3% of the participants were aged 65 years and over. 18.5% of these participants were at risk of severe COVID-19 due to at least one pre-existing medical condition (irrespective of age). The case definition of COVID-19 used in the trial included both clinical and laboratory criteria. In the primary efficacy analysis where the median length of follow-up was 9 weeks post-Dose 2, there were 11 cases of COVID-19 in the COVID-19 vaccine Moderna group and 185 cases in the placebo group. This represents an overall vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%). There were no cases of severe COVID-19 in the COVID-19 vaccine Moderna group while there were 30 cases in the placebo group.

Efficacy of Covid-19 vaccine AstraZeneca

Four randomised control trials were carried out in the UK, Brazil and South Africa. The data analysis of 17 178 participants is ongoing and is being updated as more results are obtained. The pooled results from these trials showed an overall vaccine efficacy against symptomatic COVID-19 more than 14 days after the second dose of 66·7% (95% CI 57·4–74·0). Vaccine efficacy was 63·1% (51·8–71·7) in those who received two standard doses and 80·7% (62·1–90·2) in those who received the low dose plus standard dose. Notably, in exploratory analyses, vaccine efficacy after a single standard dose was 76·0% (59·3–85·9) from day 22 to day 90, and antibody levels were maintained during this period with minimal waning. Supporting a longer-interval immunisation strategy, vaccine efficacy was significantly higher at 81·3% (60·3–91·2) after two standard doses given at an interval of 12 weeks or longer, compared with 55·1% (33·0–69·9) when given less than 6 weeks apart. These findings were supported by immunogenicity studies done in participants who were younger than 55 years, showing anti-SARS-CoV-2 spike IgG antibody responses more than two-fold higher in those who had a dose interval of at least 12 weeks than in those who had an interval of less than 6 weeks (geometric mean ratio 2·32 [95% CI 2·01–2·68]).

Overall, the value of this study is in providing evidence that a single dose of the ChAdOx1 nCoV-19 vaccine is highly efficacious in the 90 days after vaccination, that a longer prime-boost interval results

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in higher vaccine efficacy, and that protection against symptomatic COVID-19 is maintained despite a longer dosing interval.

Efficacy of Covid-19 vaccine Janssen (Johnson & Johnson)

An ongoing, multicentre, randomised, double-blind, placebo-controlled phase 3 study (COV3001) is being conducted in the United States, South Africa and Latin American countries to assess the efficacy, safety, and immunogenicity of a single-dose of COVID-19 Vaccine Janssen for the prevention of COVID-19 in adults aged 18 years and older. A total of 44 325 individuals were randomised in parallel in a 1:1 ratio to receive an intramuscular injection of COVID-19 Vaccine Janssen or placebo. A total of 21 895 adults received COVID-19 Vaccine Janssen and 21 888 adults received placebo. Participants were followed for a median of 58 days (range: 1-124 days) after vaccination.

The primary efficacy analysis population of 39 321 individuals included 38 059 SARS-CoV-2 seronegative individuals at baseline and 1 262 individuals with an unknown serostatus. From the group that received the vaccine (n= 19630), 116 persons tested positive for Covid-19, 14 days after receiving the vaccine as opposed to 348 persons from the placebo group (n=19691). This gives an overall efficacy of 66.9% at 14 days post-vaccination. At the endpoint of 28 days post-vaccination, there were 66 PCR-positive persons in the vaccine group and 193 in the placebo group, giving an overall efficacy of 66.1% at 28 days post-vaccination.

When analysing efficacy against severe Covid disease, there were 14 cases classified as severe in the vaccine group and 60 in the placebo group at 14 days post-vaccine (efficacy 76.7%). At the 28-day endpoint, there were 5 cases in the vaccine group and 34 in the placebo group (efficacy 85.4%). There were 4 hospitalisations in the vaccine group and 14 in the placebo group resulting in 3 deaths. There were no deaths in the vaccine group.

Note that (as for all vaccines) since efficacy is not 100%, vaccination cannot provide a guarantee that an individual is fully protected from COVID-19.

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Will the vaccine stop the pandemic? Can vaccinated people still transmit COVID-19?

While vaccines in general will help protect individual patients and those around them, a large proportion of the population must be immunised and protected before transmission is substantially reduced. Vaccinating whole populations will take several months. We do not yet have data to indicate whether the vaccine prevents asymptomatic COVID-19. It may be the case that vaccinated people can still get asymptomatic COVID-19 and pass it to others.

Hence it is crucial that the public health measures currently in place to reduce COVID-19 transmission continue to be adhered to even after getting vaccinated, as COVID-19 will remain a continuing concern. Effective public health measures, such as social distancing, limiting the size of gatherings, and wearing masks, will still be needed for at least several more months, and potentially longer before these measures can start to be eased gradually. Also, in view of the fact that asymptomatic transmission from vaccinated persons has not been excluded, vaccinated persons are NOT exempt from quarantine e.g. if they have close contact with a positive case.

What level of population coverage is required to achieve herd immunity?

Herd immunity is a term used to describe when sufficient people have protection—either from previous infection or vaccination—to make it unlikely for a pathogen to continue spreading within a community. As a result, herd immunity protects a community even if some people do not have individual protection themselves. The percentage of people that need to be immune to obtain herd immunity in the case of COVID-19 is still unknown. Mathematical modelling has shown it to be around 80%

Does immunity from getting Covid-19 last longer than from vaccination?

The protection natural immunity gained from having been infected with COVID-19 varies from person to person. We do not yet know how long natural immunity lasts and some cases of re-infection with COVID-19 have been documented. The vaccines being developed, however, are showing a very strong immune response which may provide better and longer protection than natural immunity. More studies and more time are required before these questions may be

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answered. Thus far the follow-up data available has confirmed sustained vaccine efficacy for a 3-month period with no waning of protection for all the Covid-19 vaccines. Monitoring will be ongoing to provide further data regarding duration of protection down the line.

Will a coronavirus vaccine need to be given annually?

When a vaccine is licensed, only information about the length of immunity for that particular period of time included in the trial is available. For example, if the first people in the study were vaccinated in July 2020 and the vaccine is licensed in December 2020, we will only have information about the immune response up to 5 months after vaccination. The vaccine manufacturer will continue to monitor vaccine recipients for several months or more, so that over time, we will continue to get a better picture of the duration of immunity. With this information, we will be better able to understand whether vaccines against COVID-19 will require annual dosing like influenza. The emergence of Covid-19 variants will also determine whether booster doses of vaccine will be necessary.

How long before a coronavirus vaccine takes effect?

It usually takes a week or two for immunity to develop following vaccination, but the specific timeline for any coronavirus vaccine will depend to some extent on the specific type of vaccines that are licensed. Ongoing studies for all vaccines in use are indicating that maximum efficacy is achieved 10-14 days after the 2nd dose.

Will there be different vaccines which are more suited for different medical conditions?

No. All the Covid-19 vaccines which are being administered have the aim of preventing serious disease caused by Covid-19 infection. The vaccine brands may have different mechanisms for producing antibodies against Covid-19 but they can all be given to persons suffering from various types of medical conditions.

Are there contraindications to vaccination?

- Minor illnesses without fever or systemic symptoms are not valid reasons to postpone vaccination. If someone is acutely unwell, immunisation may be postponed until they

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have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.

- Severe allergic reaction (e.g., anaphylaxis) to any component of the COVID-19 vaccine is a contraindication to vaccination. While reports of allergic reactions following vaccination outside the clinical trials are further investigated, persons with a history of severe allergic reaction (anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) or specific food or drug should have a risk assessment to determine the risk benefit risk ratio of taking the vaccine .

Should one still get vaccinated if there is previous or ongoing infection with COVID-19?

There is no evidence of any safety concerns from vaccinating individuals that have a past history of COVID-19 infection, or who have detectable levels of COVID-19 antibodies. Based on the current evidence, we do not know how long the immunity from natural infection lasts. Phase 3 trials involving 2 doses of Covid-19 vaccine have shown that immunity from the vaccine tends to last longer than that from natural infection. Therefore, all those who have been infected are advised to take the vaccine. There is no need to wait for a period of time before taking the vaccine after Covid-19 infection. However it is prudent to wait **4 weeks from the start of symptoms or a positive PCR** before taking the vaccine**.** This is to avoid confusion between Covid-19 symptoms and vaccine side effects which may be similar. The same applies if Covid infection occurs after taking the first vaccine dose. The second dose should be taken from 4 weeks after start of symptoms of positive PCR.

Inadvertently vaccinating individuals who are potentially infected/ asymptomatic/ incubating COVID-19 infection is unlikely to have a detrimental effect on their illness.

Having prolonged COVID-19 symptoms (long COVID) is not a contraindication to receiving the vaccine. However, if a patient is seriously debilitated, still actively being investigated, or has recently deteriorated, postponement of vaccination may be considered to avoid incorrect attribution of changes in the patient's underlying condition to the vaccine.

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Can persons who are in preventive quarantine (travel quarantine, contact with a known positive case) still take the vaccine?

Vaccination appointments should be deferred until the quarantine period is over. After the quarantine period is over, then there should be no delay in taking the vaccine.

How will people know when to attend for vaccination?

A letter with an appointment for the vaccine will be sent to groups of people at a time so that they can take the vaccine. It is important to wait for this letter, as the vaccine will not be given to anyone without an appointment. This is done to make sure that those people who are most at risk are protected from the complications of COVID-19 infection.

Those who have received an appointment but need to reschedule it for any reason are kindly requested to inform the covid19 vaccine helpline on Tel. 145. Any healthcare professional who counsels a patient to defer or refrain from vaccination is kindly asked to remind patients to inform the **145 Covid-19 vaccine helpline** or write to covid-vaccine@gov.mt that they will not be attending for their vaccination. This will help to avoid wastage of vaccines.

Will the vaccine be available in private practice?

For the time being the vaccine will be given free of charge and will be available from dedicated centres only. The vaccine is not available on the private market. Beware of any individuals or websites selling the vaccine. Vaccines being sold online or by unauthorised persons may be fraudulent and there is no way of knowing if they were kept under the required standards.

Dosage and Schedules

What is the dose and administration schedule for Comirnaty™ (the Pfizer/BioNTech vaccine? How is the vaccine presented?

A single vaccine dose is 0.3 ml (30 mcgs), given as an intramuscular injection in the upper arm in the deltoid muscle. Two doses of Pfizer/BioNTech vaccine are required with a minimum 21-day interval between doses. The vaccine is supplied as a multi-dose phial of frozen solution

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that requires thawing and dilution prior to administration. Each phial was initially said to contain sufficient solution for 5 doses but the European Medicines Agency has confirmed that a phial contains sufficient solution for 6 doses if low dead-volume syringes/needles are used for extraction (dead volume of no more than 35 microliters). However, if the amount that remains in the phial after extraction of the 5th dose is not sufficient for a full dose (0.3ml), both vial and contents should be discarded. One should never pool remains of multiple vials to make up a full dose.

What is the dose and administration schedule for COVID-19 Vaccine Moderna? How is the vaccine presented?

A dose of the Moderna vaccine is 0.5 ml, given as an intramuscular injection in the upper arm in the deltoid muscle. Two doses of the vaccine are required with a minimum 28-day interval between doses. The vaccine is supplied as a multi-dose phial of 10 doses which are ready constituted but require thawing prior to administration.

What is the dose and administration schedule for COVID-19 Vaccine AstraZeneca? How is the vaccine presented?

The recommended schedule is two doses (0.5 ml) given intramuscularly into the deltoid muscle. According to the manufacturer's product label, the vaccine can be administered with an interval of 4-12 weeks (6). In light of the observation that two-dose efficacy and immunogenicity increase with a longer interdose interval, WHO recommends an interval of 8 to 12 weeks between the doses. If the second dose is inadvertently administered less than 4 weeks after the first, the dose does not need to be repeated. If administration of the second dose is inadvertently delayed beyond 12 weeks, it should be given at the earliest possible opportunity. It is recommended that all vaccinated individuals receive two doses.

The vaccine is presented as a multidose vial containing 11 doses and is stored at 2 – 8 Celsius. Once a vial is punctured, the 11 doses must be utilised within 6 hours.

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What is the dose and administration schedule for COVID-19 Vaccine Janssen (Johnson & Johnson)? How is the vaccine presented?

The Covid-19 vaccine Janssen is administered as a single 0.5ml dose given as an intramuscular injection in the deltoid muscle. It is presented as a multidose vial containing 5 doses. It can be stored at a temperature of -20 Celsius, then thawed and placed at 2 – 8 Celsius where it has a shelf life of 3 months. Once the vial is punctured the 5 doses must be administered within 3 hours at room temperature or 6 hours if placed in a refrigerator at 2 – 8 Celsius.

Booster doses

There is currently no evidence indicating a need for further doses once an individual has received the course of vaccine. The need for, and timing of, additional doses will be evaluated as further data accumulate.

Interchangeability with COVID-19 vaccines

No data are available on the interchangeability of doses of this vaccine with other COVID-19 vaccines. It is currently recommended that the same product should be used for both doses. Recommendations may be updated as further information becomes available on interchangeability.

Co-administration with other vaccines

There should be a minimum interval of 14 days between administration of Covid vaccine and any other vaccine against other conditions. This recommendation may be amended as data on co-administration with other vaccines become available.

Contents of the Vaccines

What does Comirnaty™ (the Pfizer/BioNTech vaccine) contain?

Vaccine ingredient	
BNT162b2 RNA	This is the mRNA that codes for the COVID-19 virus spike protein. This is the active ingredient.

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ALC-0315	These are lipids that surround the mRNA in the form of lipid nanoparticles. This protects the mRNA and helps it enter cells through microporation.
ALC-0159 (contains polyethylene glycol/macrogol (PEG))	
1,2-Distearoyl-sn-glycero-3-phosphocholine	
potassium chloride	These are the constituents of phosphate-buffered saline which helps control the pH of the vaccine
potassium dihydrogen phosphate	
sodium chloride	
disodium hydrogen phosphate dihydrate	
sucrose	Acts as a cryoprotectant to protect the lipid nanoparticles and prevent them from sticking together
water for injection	Before being injected, the vaccine is mixed with 0.9% sodium chloride solution

The vaccine is **egg-free** so may be used by those with an egg allergy. There are **no animal products or preservatives** in the vaccine.The vaccine is administered from vial with a synthetic rubber (bromobutyl) stopper that **does not contain latex** so is safe in those with latex allergies.

What does COVID-19 Vaccine Moderna contain?

Vaccine ingredient	
Single-stranded, 5'-capped messenger RNA (mRNA) encoding the viral spike (S) protein of SARS-CoV-2	This is the active ingredient.
Lipid SM-102	A proprietary phospholipid that forms the basic structure of the lipid nanoparticle that encases the mRNA
Cholesterol	Improves the stability of the lipid nanoparticle

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DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine)	A commercially used phospholipid that forms part of the nanoparticle wall structure
PEG2000 DMG (1,2-Dimyristoyl-rac-glycero-3 methoxypolyethylene glycol-2000)	A lipid fused with polyethylene glycol (PEG) that aids the formation of lipid nanoparticles
Tromethamol/TRIS	These are the constituents of a buffer solution which helps control the pH of the vaccine
Tromethamol hydrochloride	
Acetic acid	
Sodium acetate trihydrate	
Sucrose	Increases stability of the lipid nanoparticles

What does the Covid-19 vaccine AstraZeneca contain?

Chimpanzee Adenovirus encoding the SARS-CoV-2 Spike glycoprotein (ChAdOx1-S)

*Produced in genetically modified human cells and by recombinant DNA technology.

Histidine

L-Histidine hydrochloride monohydrate

Magnesium chloride hexahydrate

Polysorbate 80 (E 433)

Ethanol

Sucrose

Sodium chloride

Disodium edetate (dihydrate)

Water for injections

What does the Covid-19 vaccine Janssen (Johnson & Johnson) contain?

Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein* (Ad26.COV2-S).

* Produced in the PER.C6 TetR Cell Line and by recombinant DNA technology.

2-hydroxypropyl-β-cyclodextrin (HBCD)

Citric acid monohydrate

Ethanol

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Hydrochloric acid

Polysorbate-80

Sodium chloride

Sodium hydroxide

Trisodium citrate dihydrate

Water for injections

Specific Contraindications and Precautions

The Pfizer BioNTech and Moderna COVID-19 mRNA Vaccines contain polyethylene glycol (PEG), a known potential allergen commonly found in medicines and also in household goods and cosmetics (forms part of the lipo-nano particle coating of the mRNA). Known allergy to PEG is extremely rare but would contraindicate receipt of this vaccine. Patients with undiagnosed PEG allergy may have a history of unexplained anaphylaxis or of anaphylaxis to multiple classes of drugs.

A history of mild allergic reaction to a vaccine or injectable therapy, such as urticaria alone without signs or symptoms of anaphylaxis, is not a contraindication or precaution to these vaccines.

Vaccine recipients will be monitored for around 15 minutes after being vaccinated in case of a rare anaphylactic event following the administration of the vaccine. Appropriate medical treatment for anaphylaxis will be available at vaccination centres.

Individuals who have queries regarding the safety of vaccine regarding their medical condition should discuss with their GP or call 145 or send an email to covid-vaccine@gov.mt

- **Pregnant and breast-feeding women**

As is usual in initial trials for new vaccinations/medicines, none of the authorized vaccines have been specifically tested in pregnant and breast-feeding women.

Evidence from *non-clinical* studies of all four vaccines has been evaluated by the World Health Organization and other regulatory agencies and has not raised concerns about safety in

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pregnancy. Note that the vaccine does not contain live virus and so cannot replicate in the body and infect the unborn baby in utero. Based on how they work, experts do not think it likely that mRNA vaccines have specific pregnancy-related risks. Although the available data do not indicate any safety concern or harm to the baby, there is currently insufficient evidence to recommend routine administration of this vaccine in pregnant women since animal reproductive toxicity studies are still underway. That being said, the potential benefits of vaccination may be especially important for certain pregnant women, such as those who have a high risk of severe complications from COVID-19 or those who have a high risk of catching COVID-19. These women are advised to discuss with their doctor and may decide to receive the vaccine.

Pregnant women who are not at high risk of catching COVID-19/experiencing serious complications from COVID-19 are advised to postpone vaccination until their pregnancy is over. Women who become pregnant after receiving the first dose of Comirnaty™ are advised to delay receiving the 2nd dose until after their pregnancy is over, unless they are at high risk of catching COVID-19/experiencing serious complications from COVID-19.

The Royal College of Obstetrics and Gynaecology (UK) and the Joint Committee for Vaccination and Immunisation (US) have both confirmed that women in preparation for pregnancy may take the vaccine and do not need to avoid pregnancy following vaccination.

On the other hand, women who are trying for IVF should avoid vaccination because there is not enough safety evidence as yet.

Key points that healthcare professionals counselling pregnant women deciding whether to take the vaccine should make them aware of/discuss include:

- That pregnant people have an increased risk of severe illness from COVID-19. While the risk of severe complications from COVID-19 is still low, it is higher than that of women in the reproductive age group who are not pregnant. Pregnant people with COVID-19 also have a greater risk of pregnancy complications/adverse outcomes including preterm birth.

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- Data about the safety of COVID-19 vaccines for people who are pregnant is limited. Studies in pregnant people are planned and researchers are monitoring participants who became pregnant during the clinical trial.
- The individual's personal risk of exposure to COVID-19 (e.g. due to their occupation) and risk of experiencing severe illness if infected with COVID-19 (e.g. due to medical conditions)

Regarding breast-feeding, as stated above there are no safety data available regarding the use of vaccines during breastfeeding. Despite this, the vaccine is not thought to be a risk to the breast-feeding infant and vaccination with any type of the authorized vaccines is not considered a contraindication. Women who are breast-feeding may decide to receive the vaccine.

- **Age limitations**

Initially Comirnaty™ (the Pfizer/BioNTech) vaccine will not be licenced for use in children under 16 years of age because safety trials on this group have not yet been carried out. Currently we know that children (<16 years) comprise a small proportion of the total population who contract COVID-19 (<5%). This data tallies both locally and with European data. They are also more likely to have mild illness with uncomplicated recovery. As a result, vaccination among children is currently not routinely recommended for children and young persons below aged 16. The vaccination of children with underlying conditions will be considered after initial roll-out when more evidence on risk and benefit will be available.

The safety and efficacy of COVID-19 Vaccine Moderna, AstraZeneca and Janssen (Johnson&Johnson) in children and adolescents less than 18 years of age have not yet been established. No data are available. The three vaccines are licenced for use in individuals aged 18 years and over.

Note on the use of AstraZeneca vaccine in the elderly: Because a relatively small number of participants aged 65 years or over were recruited into the original clinical trials, there were few cases of COVID-19 in either the vaccine or the control group in this age category, and thus the confidence interval on the efficacy estimate was very wide. More precise efficacy

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estimates for this age group were carried out in both the trials and real world studies in countries that are using this vaccine. Immune responses induced by the vaccine in older persons are well documented and similar to those in other age groups. The trials data indicate that the vaccine is safe for this age group. The risk of severe disease and death due to COVID-19 increases steeply with age but results of studies carried out Public Health England and published on the 4th March, 2021 show that the AstraZeneca vaccine significantly reduces severe illness, hospitalisation and death in older adults. Taking the totality of available evidence into account, WHO recommends that the vaccine should be used in persons aged 65 years and older.

- **Immunocompromised individuals and immunosuppressant therapy**

Immunocompromised persons are at higher risk of severe COVID-19. Available data are currently insufficient to assess vaccine efficacy or vaccine-associated risks in severely immunocompromised persons, including those receiving immunosuppressant therapy. It is possible that the immune response to the vaccine may be reduced, which may lower its clinical effectiveness. In the interim, given that all the authorised vaccines are nonreplicating, immunocompromised persons who are part of a group recommended for vaccination may be vaccinated. Information and, where possible, counselling about vaccine safety and efficacy profiles in immunocompromised persons should be provided to inform individual benefit–risk assessment.

No data are available about concomitant use of immunosuppressants and individuals with stable HIV infection on treatment. Again, given that the vaccines are non-replicating, persons with HIV or on immunosuppressant therapy may be given the vaccine.

- **Persons with comorbidities**

Certain comorbidities have been identified as increasing the risk of severe COVID-19 disease and death. The clinical trials demonstrated that the vaccines have similar safety and efficacy profiles in persons with various underlying medical conditions, including those that place them at increased risk for severe COVID-19. The comorbidities studied in the clinical trials

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included obesity, cardiovascular disease, respiratory disease and diabetes. Vaccination is recommended for persons with comorbidities that have been identified as increasing the risk of severe COVID-19.

- **Persons with bleeding disorders and those taking anticoagulant therapy**

Precautions for patients with bleeding disorders apply to all vaccines and IM medication. Since there has not been any significant ill reactions up to now to the Covid vaccines in people on anticoagulants and those with bleeding disorders, receiving these vaccines outweighs the risks and is considered to be safe. The main potential contraindication is in those with a history of significant allergic reactions. In this case, patients are advised to contact their respective physicians.

Otherwise, the main issue is that since this is an intramuscular injection, the needle could cause bleeding in similar patients. Hence the advice below.

The smallest gauge needle (23 or 25 gauge) should be used for the vaccination. The patient is advised to inform the person who is administering the vaccine that they have an increased risk of bleeding before they prepare to inject.

- This is followed by firm pressure applied to the site without rubbing for at least 5 minutes after the inoculation. The individual/ carer should be informed about the risk of haematoma from the injection.
- In the case of a large haematoma/bruise, patients are advised to consult their doctor.

Patients on Anticoagulant therapy

Warfarin

Ideally, people on Warfarin should check their INR blood test a few days before having their vaccine. However, in those patients who have very stable INRs, this is not an absolute requirement. If the INR is less than 4.0, it should be safe to proceed with the vaccine. In cases, of INRs greater than 4.0, patients are advised to consult their local Anticoagulation Clinic.

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Rivaroxaban

Rivaroxaban or the brand name Xarelto is typically administered as 10 or 20mg once a day. For those patients who take the drug in the morning, it would be safe to delay the dose on the day of the vaccine and restart 6 hours after the vaccine. For those who take the drug in the afternoon/evening, continue as normal and then on the day of the vaccine, delay the next dose of Rivaroxaban by at least 6 hours after the vaccine. Like this, the patient would not have missed any doses.

Those patients taking 2.5mg twice a day, can just omit the morning dose on the day of the vaccine. Those cases with acute thrombosis who are receiving the highest dose of Rivaroxaban i.e. 15mg twice a day should ideally delay the vaccine until they decrease the dose to 20mg daily.

Enoxaparin

Enoxaparin or the brand name Clexane is typically administered as 40mg once a day. For those patients who take the Clexane™ injection in the morning, it would be safe to delay the dose on the day of the vaccine and restart 6 hours after the vaccine. For those who take the Clexane dose in the afternoon/evening, continue as normal and then on the day of the vaccine, delay the next dose of Clexane by at least 6 hours after the vaccine. Like this, the patient would not have missed any doses.

Patients taking 2 doses of Clexane™ daily are advised to miss the morning dose on the day of the vaccine and take the evening dose not before 6 hours from the vaccine.

Apixaban

Apixaban or the brand name Eliquis is administered as 5mg or 2.5mg twice a day. One can just omit the morning dose on the day of the vaccine and then continue as normal. Those patients with acute thrombosis who are on the higher dose of Apixaban i.e. 10mg twice a day should ideally delay the vaccine until they decrease the dose to 5mg twice a day.

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Dabigatran

Dabigatran or the brand name Pradaxa is typically administered as 75mg, 110mg or 150mg twice daily. One can just omit the morning dose on the day of the vaccine and then continue as normal. **Antiplatelet Agents e.g. Aspirin and Clopidogrel**

Many people are on Aspirin or Clopidogrel or sometimes both drugs together. In these cases, it is advisable that they carry on taking their antiplatelet drugs as normal. The patient must be reminded to press for 5 minutes on the inoculation site after the injection.

Inherited Bleeding Disorders

These include Haemophilia, Von Willebrand's Disease and other inherited or acquired bleeding disorders. Specific advice has been issued by the major bleeding disorders organisations like the World Federation of Haemophilia (WFH) and this can be found on the Facebook page of the Malta Bleeding Disorders Society which is freely available online or the WFH website. (https://news.wfh.org/covid-19-vaccination-guidance-for-people-with-bleeding-disorders/)

A summary of the locally adapted recommendations follows below:

1. The vaccine should be administered intramuscularly. The smallest gauge needle available (23-25 gauge) should be used, if possible. Some vaccines must be administered using the accompanying needle–syringe combination, and so the use of an alternative needle may not be possible or desirable. Pressure should be applied to the site for at least 10 minutes post-injection to reduce bleeding and swelling. Additionally, self-inspection/palpation of the injection area several minutes and 2-4 hours later is recommended to ensure that there is no delayed hematoma. Discomfort

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in the arm felt for 1-2 days after injection should not be alarming unless it worsens and is accompanied by swelling. Any adverse events (e.g., hematoma, allergic reaction) should be reported to the haemophilia treatment centre.

2. . Patients with a history of allergic reactions to extended half-life clotting factor concentrates containing polyethylene glycol (PEG) should discuss vaccine choice with their physician because some vaccines contain PEG as an excipient. These products are not typically available in Malta.
3. For patients with severe/moderate haemophilia on prophylaxis, the vaccine should be given after a factor VIII (FVIII) or factor IX (FIX) injection. For patients with a basal FVIII or FIX level above 10%, no haemostatic precautions are required but apply at least 5-minute pressure on the injection site. Those who are on FEIBA should also take a dose prior to the vaccine injection.
4. Patients with Willebrand disease (VWD), depending on their baseline von Willebrand factor (VWF) activity levels, should use therapies (i.e., DDAVP if available, tranexamic acid), in consultation with the Malta Centre for Bleeding and Thrombotic Disorders which is an EU accredited Haemophilia treatment centre.
5. Patients with severe FXIII deficiency and those with afibrinogenemia should ideally receive the vaccine immediately after their routine prophylactic dose of FXIII or fibrinogen concentrate respectively.
6. There are no specific contraindications to vaccination related to complications of haemophilia and other bleeding disorders or their therapies.

<u>Patients with low platelets e.g. ITP</u>

Those people who suffer from low platelets or some platelet function defect could also be vaccinated. So long that the platelet count is not less than 20 x 109/L, one can proceed with the vaccine and then apply pressure for 5 minutes after the injection. The vaccine is also indicated in those suffering from Immune Thrombocytopenia Purpura (ITP). It might be prudent to check a CBC blood test in those with a history of low platelets prior to vaccination.

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What are the side-effects for the different vaccines?

Fever is a common side effect for all the vaccines. This may be prevented by taking paracetamol around 8 hours after vaccination and continue taking it regularly for 48 hours if fever persists.

Side effects associated with Comirnaty™ (Pfizer-BioNTech)

During trials (including a phase 3 trial with around 44,000 participants equally divided between the vaccine and placebo groups), the vaccine has been shown to elicit increased local and systemic adverse reactions as compared to placebo for the most part mild to moderate and usually lasting up to a few days. The most common solicited adverse reactions were:

- injection site reactions (84.1%)
- fatigue (62.9%)
- headache (55.1%)
- muscle pain (38.3%)
- chills (31.9%)
- joint pain (23.6%)
- fever (14.2%).

The above adverse reactions reflect reactogenicity (inflammatory response to the vaccine) which commonly occurs after most vaccinations. These side-effects were generally mild to moderate, resolving without complication or injury. Vaccine recipients can be advised to use anti-pyretics and/or analgesics to control these symptoms as appropriate.

The number of trial participants reporting hypersensitivity-related adverse events (allergic reactions) was numerically higher in the vaccine group compared with the placebo group (137 [0.63%] vs. 111 [0.51%]). (Contraindication and precautions related to allergic reactions are discussed separately in the relevant section.)

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Lymphadenopathy is an adverse reaction that occurred significantly more frequently in the vaccine group than in the placebo group and was considered plausibly related to vaccination. This adverse event occurred uncommonly (>=1/1000 to <1/100).

As for the concern regarding facial palsy following vaccination with Pfizer-BioNTech vaccine, the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) has reviewed the data submitted to the U.S. Food and Drug Administration (FDA) that reported four and three cases of facial paralysis (Bell's palsy) respectively in patients who were vaccinated and one patient who received the placebo. Normal background incidence of idiopathic facial paralysis is around 15-30 per 100,000. Using the reported data for those who received either vaccine, the equivalent combined incidence of idiopathic facial paralysis is 17.7 per 100,000. While there appears to be a greater number of individuals who developed facial paralysis in the vaccine group, it does not appear to be greater than the expected background rate. Thus, there is no clear basis upon which to conclude a causal relationship at this time. These rare events should not dissuade healthcare personnel or patients from receiving these critical vaccines.

Subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection did not reveal any specific safety concerns for these sub-groups. Side effects were less common in those aged over 55 than those aged 16 to 55 years.

What are the side-effects of COVID-19 Vaccine Moderna?

The COVID-19 Vaccine Moderna safety profile was evaluated in an ongoing randomised, placebo-controlled, observer-blind Phase 3 clinical trial that is being carried out in the USA. The trial included 30,351 participants aged 18 and over. Of these, 15185 received at least one dose of COVID-19 Vaccine Moderna and 15166 received a placebo.

The most frequently reported adverse reactions were:

- pain at the injection site (92%)
- fatigue (70%)
- headache (64.7%)

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- myalgia (61.5%)
- arthralgia (46.4%)
- chills (45.4%)
- nausea/vomiting (23%)
- axillary swelling/tenderness (19.8%)
- fever (15.5%)
- injection site swelling (14.7%)
- redness (10%).

Adverse reactions were usually mild or moderate in intensity and resolved within a few days after vaccination. Reactogenicity events (reflecting inflammatory response to the vaccine that is common after many immunisations) occurred slightly less frequently in older age groups.

The incidence of axillary swelling/tenderness, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting and fever was higher in adults aged 18 to less than 65 years than in those aged 65 years and over.

Local and systemic adverse reactions were more frequently reported after the second dose of the vaccine than after the first dose.

The reactogenicity and safety profile in the 343 trial participants receiving COVID-19 Vaccine Moderna that were seropositive for SARS-CoV-2 at baseline was comparable to that in the participants seronegative for SARS-CoV-2 at baseline.

Hypersensitivity-related adverse events (allergic reactions) were reported by 1.5% of vaccine recipients and 1.1% of placebo recipients.

During the Phase 3 trial of the Moderna vaccine, 3 participants with dermal fillers that received the vaccine experienced localised swelling – two reported facial swelling while another reported lip angioedema. All cases resolved with steroid and/or antihistamine treatment. These events were rare and effects were mild – none of the affected individuals required adrenaline or hospitalisation. The adverse events in question were not considered

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life-threatening and resolved with no long-term complications. Monitoring for similar reactions is ongoing.

Having dermal fillers should not exclude an individual from receiving a COVID-19 vaccine. The risks of contracting COVID-19 are considered to far outweigh the risk of having a reaction to a COVID-19 vaccine, as noted also by The Aesthetic Society (professional organization of plastic surgeons in the U.S.) in a recent statement.

No other noteworthy patterns or numerical imbalances between the vaccine and placebo groups were recorded for specific categories of adverse events (such as other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to the Moderna COVID-19 Vaccine.

What are the side effects of Covid-19 vaccine AstraZeneca?

The COVID-19 Vaccine AstraZeneca safety profile was evaluated in an ongoing randomised, placebo-controlled, observer-blind Phase 3 clinical trial carried out in the UK, Brazil and South Africa. The study included 12000 participants who received at least 1 dose of the vaccine.
The most frequently reported adverse reactions were:
injection site tenderness (63.7%),
injection site pain (54.2%),
headache (52.6%),
fatigue (53.1%),
myalgia (44.0%),
malaise (44.2%),
pyrexia (includes feverishness (33.6%) and fever >38°C (7.9%)),
chills (31.9%),
arthralgia (26.4%)
nausea (21.9%).
The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination. When compared with the first dose, adverse reactions reported after the second dose were milder and reported less frequently.

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Reactogenicity was generally milder and reported less frequently in older adults (≥65 years old).

The safety profile was consistent across participants with or without prior evidence of SARS-CoV-2 infection at baseline; the number of seropositive participants at baseline was 718 (3.0%).

What are the side effects of Covid-19 vaccine Janssen (Johnson and Johnson)?

The safety of COVID-19 Vaccine Janssen was evaluated in an ongoing phase 3 study (COV3001). A total of 21 895 adults aged 18 years and older received COVID-19 Vaccine Janssen. The median age of individuals was 52 years (range 18-100 years). The safety analysis was performed once the median follow-up duration of 2 months after vaccination was reached. Longer safety follow-up of >2 months is available for 11 948 adults who received COVID-19 Vaccine Janssen.

In study COV3001, the most common local adverse reactions reported were:

- injection site pain (48.6%).
- headache (38.9%),
- fatigue (38.2%),
- myalgia (33.2%) and
- nausea (14.2%).
- Pyrexia (defined as body temperature ≥38.0°C) was observed in 9% of participants.

Most adverse reactions occurred within 1–2 days following vaccination and were mild to moderate in severity and of short duration (1–2 days). Reactogenicity was generally milder and reported less frequently in older adults (763 adults ≥65 years old).

The safety profile was generally consistent across participants with or without prior evidence of SARS-CoV-2 infection at baseline; a total of 2 151 adults seropositive at baseline received COVID-19 Vaccine Janssen (9.8%).

Reporting of suspected adverse reactions

Adverse events should be reported to Medicines Authority on their online Adverse Reaction Reporting Form. This can be downloaded from: http://www.medicinesauthority.gov.mt/reportingadversereactions?l=1

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COMPARING COVID-19 VACCINES

	PFIZER/BIONTECH	MODERNA	ASTRAZENECA	JANSSEN
Age limits	16+	18+	18 - 70	Over 18 years
Vaccine type	mRNA	mRNA	Inactivated virus vector	Inactivated virus vector
Transport and storage	-70°c	-20°c	2°c – 8°c	-20°c and 2°c - 8°c
Preventing severe Covid-19 disease, hospitalisation and death	90%	100%	100%	89%
Dosage	2 doses	2 doses	2 doses	1 dose
Dose interval	3 weeks	4 weeks	8 - 12 weeks	Not applicable
Contingency plan for variants	Developing booster	Developing booster	Developing updated vaccine	Developing booster
Pregnant?	Not recommended	Not recommended	Not recommended	Not recommended
Pause breastfeeding?	No	No	No	No
Risk for persons with severe allergies	Rare	Rare	None	None
Common side effects	Local pain, redness, swelling, fever, chills, muscle pains, headache	Local pain, redness, swelling, fever, chills, muscle pains, headache	Local pain, redness, swelling, fever, chills, muscle pains, headache	Local pain, redness, swelling, fever, chills, muscle pains, headache
Duration of side effects	24 - 48 hours	24 - 48 hours	24 - 48 hours	24 - 48 hours

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MINISTRY FOR HEALTH

Health Promotion & Disease Prevention Directorate

COVID-19 vaccine myths and misinformation

The volume of misinformation and disinformation that has accompanied the COVID-19 pandemic has been unprecedented, thanks in part to the new technologies and social media platforms that are available. This includes a large amount of false information being circulated by members of the anti-vaccine community in response to the development of COVID-19 vaccines. Healthcare professionals have an important role to play in managing this infodemic, as they are often looked up to by their community as a source of reliable information. We are including below some of the myths that have been circulating about the vaccine below along with the information that debunks them. For more information about infodemic management and guidance on risk communication with the public, visit:

https://www.who.int/teams/risk-communication

Vaccine myth: The m-RNA Covid-19 vaccine will alter the body's genetic make-up

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No. The vaccine is made up of lipid mRNA nanoparticles. These do not enter the host's cell nucleus and so will not change the host's genetic makeup. These nanoparticles are broken down by the body after a few days.

Vaccine myth: Covid-19 vaccines are made from foetal cells

The mRNA vaccines that have reached Phase 3 trials were not created with and do not require the use of foetal cell cultures in the production process. The AtraZeneca vaccine was developed using genetically modified human embryo kidney cells.

Vaccine myth: More people will die as a result of a negative side effect to the COVID-19 vaccine than would die from the virus.

Fact: A claim circulating on social media is that the COVID-19 mortality rate is 1%–2% and that people should not be vaccinated against a virus with a high survival rate. However, a 1% mortality rate is 10 times more lethal than the seasonal flu. In addition, the mortality rate can vary widely based on age, sex and underlying health conditions.

In contrast, clinical trials of COVID-19 vaccines have shown only short-term mild or moderate vaccine reactions that resolve without complication or injury.

While some people who receive the vaccine may develop symptoms as their immune system responds, this is common when receiving any vaccine, and these symptoms are not considered serious or life-threatening. And you cannot become infected with COVID-19 from COVID-19 vaccines. These are inactivated vaccines, not live-virus vaccines.

While no vaccine is 100% effective, getting vaccinated is far better than not getting vaccinated. The benefits outweigh the risks in healthy people.

Vaccine Myth: COVID-19 vaccines were developed to control the population through microchip tracking or "nanotransducers" in the human brain.

There is no vaccine microchip, and the vaccine will not track people or gather personal information into a database.

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This myth started after comments made by Bill Gates from the Bill & Melinda Gates Foundation about a digital certificate of vaccine records. The technology he was referencing is not a microchip, has not been implemented in any manner and is not tied to the development, testing or distribution of COVID-19 vaccines.

Vaccine Myth: COVID-19 vaccines cause infertility or miscarriage.

No, COVID-19 vaccines have not been linked to infertility or miscarriage.

A sophisticated disinformation campaign has been circulating online, claiming that antibodies to the spike protein of COVID-19 produced from these vaccines will bind to placental proteins and prevent pregnancy. This disinformation is thought to originate from internet postings by a former scientist known to hold anti-vaccine views.

These postings are not scientifically plausible, as COVID-19 infection has not been linked to infertility. Also, no other viral infection or vaccination-inducing immunity by similar mechanisms has been shown to cause infertility. Antibodies to the spike protein have not been linked to infertility after COVID-19 infection. There is no scientific reason to believe this will change after vaccination for COVID-19. While there are no formal studies, the best evidence comes from women who got sick with COVID-19 while pregnant. While data clearly indicate pregnant women are at higher risk of hospitalization due to COVID-19 infection, there is no evidence of increased miscarriage rates.

During natural infection, the immune system generates the same antibodies to the spike protein that COVID-19 vaccines would. Thus, if COVID-19 affected fertility, there already would be an increase in miscarriage rates in women infected with COVID-19. This has not happened.

Vaccine Myth: COVID-19 vaccines must be stored at extremely low temperatures because of preservatives in the vaccines**.**

Pfizer/BioNTech, Moderna, AstraZeneca and Janssen vaccines do not contain any preservatives.

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Different vaccines have different storage requirements. For instance, Comirnaty™ (the Pfizer/BioNTech vaccine) must be stored at minus 70 degrees Celsius, while the Moderna vaccine needs to be stored at minus 20 degrees Celsius. Both of these vaccines are mRNA vaccines. mRNA is fragile and can break down easily. Storing mRNA vaccines, like these COVID-19 vaccines, in an ultracold environment keeps them stable and safe. The AstraZeneca vaccine is not an mRNA vaccine and it can be stored at 2 to 8 degrees Celsius, the same as other normally used vaccines. The Janssen vaccine can be stored at minus 20 Celsius for long-term storage (2 years) but can be thawed and kept at 2 – 8 Celsius for 3 months.

For further information or queries:

A Covid 19 vaccine helpline **145** has been set up as well as an email address covid-vaccine@gov.mt

Acknowledgement

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