Moderna Covid-19 Vaccine
PATIENT INFORMATION LEAFLET

This leaflet should be used alongside the UKMFA general Covid-19 Vaccines Patient Information Leaflet[i]. It contains general medical information which is not advice and should not be treated as such.

The MHRA approved authorisation for **temporary supply of Covid-19 vaccine** (**Moderna mRNA-1273**) on 8[Th] January 2021.[iiiii] It does not have marketing authorisation, trials are active and set to conclude in late 2022 when participants complete their final assessment, 12 or 24 months following their last injection.[iv] Moderna's full trial data, including supporting clinical documents, will only be available upon request once the trial is completed. **Individuals who receive the vaccine should be aware that the Moderna mRNA-1273 vaccine will remain an investigational product until this time.[v]**

TYPE OF VACCINE & HOW IT WORKS

Vaccine Type

Covid mRNA-1273 is a rapid-response proprietary 'vaccine' based on an mRNA delivery system. The mRNA-1273 is a novel single messenger ribonucleic acid (mRNA)-based vaccine encapsulated in a lipid nanoparticle (LNP).[vi] This does not work in the same way as conventional vaccines.

How it works

Moderna's mRNA 'vaccine' contains a synthetic gene (mRNA) that codes for the SARS-CoV-2 spike protein. The mRNA is encapsulated in a lipid nanoparticle, which is the vehicle that delivers the mRNA into the cells of the recipient. Once inside the cell, the mRNA gene instructs the cell to make viral spike proteins, which then enter the bloodstream and are attacked by the immune system, producing antibodies to the viral spike protein.[vii] Moderna claims that the delivered mRNA will not enter the cell nucleus or interact with the recipient's genome.[viii]

Ingredients

The Moderna Covid-19 'Vaccine' is a white to off-white, sterile, preservative-free, frozen suspension produced for intramuscular injection which contains:

- synthetic mRNA encoding the pre-fusion stabilized spike glycoprotein (S) of SARS-CoV-2 virus (CX-024414 mRNA an active substance not intended for direct injection, the DNA template is produced from an Escherichia coli cell line)[ix]
- Lipids; SM-102, 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG], cholesterol and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]
- Trometamol (Tris), trometamol hydrochloride (Tris HCL), acetic acid, sodium acetate trihydrate, sucrose, water.[x]

DOSES & DURATION OF IMMUNITY

What do we know about immunity from the vaccine?

- It is unclear when immunity may start. Moderna has suggested that some asymptomatic infections ***may*** start to be prevented after the first dose, but this was not part of the Phase 3 trial, so the claim is yet to be proven.
- We do not know how long vaccine immunity will last, as the limited trial data available only covers 2 months after the second dose.
- It is not yet known whether this vaccine will prevent infection with, or transmission of, the virus.[xi]
- Trials have not been able to rule out the possibility of 'pathogenic priming' or vaccine-associated enhanced disease - a phenomenon where more severe illness occurs on exposure to wild virus due to the type of antibodies induced by vaccination (more information is available in the general vaccine sheet)[xii] [xiii]
- The trials did not rule out the potential risk of developing antibodies against PEG (which is a key ingredient in the vaccine). The PEGylated lipid

nanoparticle may cause unintended immune consequences, by triggering pre-existing anti-PEG antibodies instead of causing the immune system to make antibodies against SAR-Cov2 [xiv] [xv] [xvi] [xvii]

- None of the Covid vaccine trials are designed to detect a reduction in any serious outcome such as hospital admissions, use of intensive care or deaths.

Doses required

1 priming and 1 booster dose administered 28 days apart in an undiluted, one dose (0.5ml) containing 0.10mg of mRNA (embedded in lipid nanoparticles), intramuscular injection. [xviii]

ANIMAL TRIALS

It has been difficult to obtain clear sequential information about animal trials. Moderna were given approval to simultaneously overlap (rather than sequentially test) their vaccines. Animal data from the DART study was only available very recently [xix] whilst conducting Phase 1 trials on humans. Prior to the emergence of Covid-19 there had been efficacy studies conducted on non-human primates due to SARS-Cov-1 but these studies were limited. mRNA-1273 was tested on young and aged mice, Syrian golden hamsters, Sprague Dawley rats and non-human primates (rhesus macaque monkeys) for the purpose of identifying immunogenicity and efficacy. It is unclear exactly how many animals were involved in this testing.[xx] [xxi] [xxii] [xxiii]

HUMAN TRIALS

Phase 1, 2 and 3 trials were accelerated by performing them concurrently, alongside 'at risk' large scale vaccine production. There was a rolling regulatory review and simultaneous analysis. This protocol is unusual for vaccine trials.[xxiv] Trials remain active. Moderna must provide the interim and final study reports for study mRNA12-73 to the MHRA as soon as they become available.[XXV]

Phase 1 - **120 healthy adults** were placed in 3 age-stratified groups and given different doses of the vaccine or saline placebo: Age 18-55 years (n60) given doses (25, 50, 100, 250µm), Age 56-71 years (n30) given doses (25, 50, 100µm), Age >71years (n30) given doses (25, 50, 100µm). People with known underlying conditions were excluded from the trial.[xxvi]

Phase 2 - **600 healthy adults** divided into 2 cohorts - 300 participants aged 18-55 years and 300 participants >55years. Each cohort was divided into 2 groups and given either placebo or vaccine (50/100µm).

Phase 3 - 30,351 healthy, "medically stable" adults divided into 2 groups - 15,181 mRNA-1273 100µg vaccine group / 15,170 placebo group. The trial took place in 99 centres across the US. The trial was **randomised and placebo controlled**. 96% completed the second dose. Adults excluded from the trial if they were: **pregnant or breastfeeding, under 18 years of age, immunocompromised, or had a known history of SARS-CoV-2**. Symptomatic Covid-19 illness was confirmed in 185 participants in the placebo group and in 11 participants in the vaccine group.[xxvii]

Side Effects - Local (pain, redness, swelling of injection site) and Systemic (fever, chills, fatigue, muscle pain, etc.) reactions by age group:[xxviii]

Age 18-64 side effects reported:

- **1st Dose - 87.4% suffered local reaction** with 4% grade 3
- **2nd Dose - 90.5% suffered local reaction** with 7.4% grade 3
- **1st Dose - 57% suffered systemic reactions** with 3.2% grade 3 and 0.1% Grade 4 (hospital)
- **2nd Dose - 81.9% suffered systemic reactions** with 17.4% grade 3 (preventing daily activities) and 0.1% grade 4

Age 65+ side effects reported

- **1st Dose - 74.6% had local reaction** with 2% grade 3
- **2nd Dose - 83.9% had local reaction** with 5.9% grade 3
- **1st Dose - 48% had systemic reactions** with 2.2% grade 3

- **2nd Dose - 71.9% had systemic reactions** with 10.8% grade 3 and 0.1% grade 4

I**n both age groups, systemic reactions were more frequent after the second dose**. **Fatigue** was reported in 68% of 18-64 year olds and 58% 65+. **Severe fatigue** was reported in 11% of the younger and 7% of older age groups. **Severe pain in injection site** was reported in 5% of participants. There is reportedly **higher reactogenicity than is usually observed with flu vaccines**. 233 (1.5%) had **hypersensitivity**. 173 reported **lymphadenopathy**. **3 participants had Bell's Palsy** (1 in placebo group) where a causal relationship cannot be excluded. Serious adverse events included thrombosis, rheumatoid arthritis, cerebrovascular events (stroke) and activation of the inflammatory system.[xxix]

As of 3rd December 2020, **13 deaths were reported (6 in vaccine group, 7 in placebo group). Moderna vaccine mRNA1273 was linked to greater incidence of severe events such as fatigue and muscle pain after the second vaccination in comparison with Pfizer (BNT162b2).[xxx]**

Vaccine efficacy

Manufacturer's published interim analysis of trial data suggests **vaccine efficacy is higher (95.6%) in people under 65 years than >65 years (86.4%)**, as follows: 80.2% effective after first dose, 94.1% effective after second dose.[xxxi][xxxii] [xxxiii] [xxxiv]

Vaccine safety

No formal independent or peer reviewed publications are available to assess Moderna's claims of safety or efficacy. It must be pointed out that all trials were undertaken during a pandemic and as such, selected groups would not have been truly represented. The use of pain relief and fever medication was reported as having been used during the trials, which might have clouded or masked some of the symptoms. Safety concerns raised in the EMA, FDA and MHRA reports identified Anaphylaxis as an important risk.[xxxv] Important Potential Risks were vaccine-associated enhanced disease (VAED), including vaccine-associated enhanced respiratory disease (VAERD). Important missing information included use in pregnancy, use while breast-feeding, use in immunocompromised subjects, interactions with other vaccines, use in frail subjects with unstable health conditions and co-morbidities (e.g. chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease, cardiovascular disorders). Also, use in subjects with autoimmune or inflammatory disorders was lacking, including any long-term safety data - this information will not be fully reported until 31st December 2023.

Limitations of the trials:

To be enrolled in the study, female subjects had to have a **negative pregnancy test and agree to use effective contraception until at least 3 months after the final vaccination.** There is therefore **insufficient data to assess whether mRNA-1273 is safe for pregnant or breastfeeding women**. The trials did not measure drug interactions or the impact of other vaccines being administered in a close temporal relationship to mRNA-1273, (except for seasonal influenza vaccine, which is not permitted within 14 days). Data on long-term protection is expected, but the extent and quality of data that can be anticipated from the ongoing phase 3 study is uncertain, because participants in the placebo arm will be offered vaccination, which will unblind the study.

There is currently **insufficient data to draw conclusions about the safety of the vaccine for children under 18 years or in immunocompromised individuals**. There is also a **lack of data to support interchangeability of the Moderna Covid-19 vaccine with other Covid-19 vaccines** to complete the series of doses.[xxxvi]

Cost/Storage

Moderna vaccine needs to be stored frozen for transportation at -4°. Moderna has claimed that the vaccine remains stable at 2 to 8°C (a standard home/medical refrigerator will suffice for 30 days). It remains stable at -20°C (-4°F) for up to 7 months, unlike the Pfizer Covid-19 vaccine. [xxxvii]

UK Medical Freedom ALLIANCE

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The most expensive of the Covid-19 vaccines currently available - reported cost £28 per dose. The UK has ordered 17 million doses, available from Spring 2021.

PLEASE DO YOUR OWN RESEARCH AND SPEAK TO YOUR DOCTOR

For further information about Covid-19 vaccines you can go to:

- The full manufacturer's package insert for professionals (SmPC) (not the simplified Patient Leaflet) is available here: https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-epar-product-information_en.pdf
- UKMFA have published a Covid-19 Vaccine Consent Form to help support discussions between the patient and administering health professional about the benefits and risks of a Covid-19 vaccine, to protect both parties in this process www.ukmedfreedom.org/resources/vaccine-documents
- For more information about Medical Freedom, Informed Consent and Covid-19 vaccines, please visit our website www.ukmedfreedom.org

You must not rely on the information on our website as an alternative to medical advice from your doctor or other professional healthcare provider and if you have any specific questions about any medical matter, you should consult your doctor or other professional healthcare provider.

[i] https://uploads-ssl.webflow.com/5fa5866942937a4d73918723/5fdcb8da3e69e028e9fd95e8_UKMFA_COVID-19_Vaccine_Patient_Information.pdf
[ii] Information for UK recipients on COVID-19 Vaccine Moderna - GOV.UK (www.gov.uk)
[iii] Conditions of Authorisation for COVID-19 Vaccine Moderna - GOV.UK (www.gov.uk)
[iv] Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting
[v] Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Transcript (fda.gov)
[vi] Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Briefing Document-Sponsor (fda.gov)
[vii] Public_Assessment_Report_for_Moderna_COVID-19_vaccine.pdf (publishing.service.gov.uk)
[viii] Vaccines and Related Biological Products Advisory Committee December 17, 2020 Presentation - Emergency Use Authorization (EUA) Application for mRNA-1273 (fda.gov)
[ix] Public_Assessment_Report_for_Moderna_COVID-19_vaccine.pdf (publishing.service.gov.uk)
[x] Information for Healthcare Professionals on COVID-19 Vaccine Moderna - GOV.UK (www.gov.uk)
[xi] Will covid-19 vaccines save lives? Current trials aren't designed to tell us | The BMJ
[xii] Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease - Cardozo - - International Journal of Clinical Practice - Wiley Online Library
[xiii] Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease - PubMed (nih.gov)
[xiv] Structural basis of polyethylene glycol recognition by antibody - PubMed (nih.gov)
xv Suspicions grow that nanoparticles in Pfizer's COVID-19 vaccine trigger rare allergic reactions | Science | AAAS (sciencemag.org)
xvi Analysis of Pre-existing IgG and IgM Antibodies against Polyethylene Glycol (PEG) in the General Population - PubMed (nih.gov)
[xvii] Anti-PEG immunity: emergence, characteristics, and unaddressed questions - PubMed (nih.gov)
[xviii] Information for Healthcare Professionals on COVID-19 Vaccine Moderna - GOV.UK (www.gov.uk)
[xix] COVID-19 Vaccine Moderna, INN-COVID-19 mRNA Vaccine (nucleoside modified) (europa.eu)
[xx] Evaluation of the mRNA-1273 Vaccine against SARS-CoV-2 in Nonhuman Primates | NEJM
[xxi] Coronavirus vaccine clinical trial starting without usual animal data- STAT (statnews.com)
[xxii] Immunization with SARS Coronavirus Vaccines Leads to Pulmonary Immunopathology on Challenge with the SARS Virus (nih.gov)
[xxiii] JCI Insight - Anti–spike IgG causes severe acute lung injury by skewing macrophage responses during acute SARS-CoV infection
[xxiv] nejmoa2022483_protocol.pdf
[xxv] Conditions of Authorisation for COVID-19 Vaccine Moderna - GOV.UK (www.gov.uk)
[xxvi] Safety and Immunogenicity Study of 2019-nCoV Vaccine (mRNA-1273) for Prophylaxis of SARS-CoV-2 Infection (COVID-19) - Full Text View - ClinicalTrials.gov
[xxvii] Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine | NEJM
[xxviii] Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Briefing Document - FDA
[xxix] COVID-19 Vaccine Moderna, INN-COVID-19 mRNA Vaccine (nucleoside modified) (europa.eu)
[xxx] COVID-19 vaccines poised for launch, but impact on pandemic unclear (nature.com)
[xxxi] Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Briefing Document- Sponsor (fda.gov) Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Presentation- FDA Review of Efficacy and Safety of Moderna COVID-19 Vaccine EUA
[xxxiixxxii] Moderna COVID-19 Vaccine EUA FDA review memorandum
[xxxiii] www.nejm.org/doi/full/10.1056/NEJMoa2035389
[xxxiv] Peter Doshi: Pfizer and Moderna's "95% effective" vaccines—we need more details and the raw data - The BMJ
[xxxv] Management of Anaphylaxis at COVID-19 Vaccination Sites | CDC
[xxxvi] Moderna COVID-19 Vaccine Information | CDC
[xxxvii] COVID-19 Greenbook chapter 14a (publishing.service.gov.uk)