AstraZeneca / Oxford Covid-19 Vaccine
PATIENT INFORMATION LEAFLET

This leaflet should be used alongside the UKMFA general Covid-19 Vaccines Patient Information Leaflet[i]

The MHRA has provided authorisation for emergency supply of Covid-19 Vaccine AstraZeneca (AZD1222)[ii]. At the time of writing, the safety and efficacy trials are set to conclude in February 2023. Recipients should be aware that this will remain an experimental vaccine at least until this time[iii]. This leaflet provides further information for patients to consider before receiving the vaccine.

OVERVIEW

Vaccine type: Non-replicating, recombinant viral vector vaccine (also termed ChAdOx1 nCoV-19 and AZD1222).

How does it work? This vaccine uses a chimpanzee adenovirus as a vector to deliver a SARS-CoV-2 virus gene into the cells of the recipient's body. The SARS-CoV-2 virus gene (synthetic DNA) that encodes the virus spike protein is inserted into the adenovirus.[iv] Following injection of the vaccine, the adenovirus invades the recipient's cells and the viral gene is expressed by the host cell's machinery which starts to produce spike proteins. These proteins enter the bloodstream and the body mounts an immune response, creating antibodies.

Ingredients: Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS CoV 2 Spike (S) glycoprotein - produced in genetically modified human embryonic kidney (HEK) 293 cells. This product contains genetically modified organisms (GMOs)[v]
Excipients: L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80, ethanol, sucrose, sodium chloride, disodium edetate dihydrate, water[vi]

What do we know about immunity from the vaccine?

- No information is yet available on how long vaccine immunity is likely to last as there is only a few months' worth of data available
- The vaccine is not believed to prevent viral transmission, meaning social distancing will likely still be needed after vaccination
- It is unknown how someone who has already had COVID-19 will react to the vaccine, as anyone with prior exposure was excluded from the trial
- The potential issue of pathogenic priming/antibody-dependent enhancement has not been completely ruled out (see UKMFA general Covid-19 vaccine leaflet for more info)
- "None of the trials currently underway are designed to detect a reduction in any serious outcome such as hospitalisations, intensive care use or deaths." stated Peter Doshi, British Medical Journal [vii]

Doses required: Two separate doses of 0.5ml each. The second dose should be administered between 4 and 12 weeks after the first dose[viii]

ANIMAL TRIALS

In a preliminary trial with six monkeys the vaccine prevented lung damage, but the virus was found to be actively replicating in the nose[ix] which indicated that the vaccine did not prevent infection or potential viral transmission.

Experiments with mice and hamsters were also conducted. In the hamster trial an intranasal vaccine produced a higher immune response than the intramuscular vaccine.[x]

UK Medical Freedom ALLIANCE

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HUMAN TRIALS

PHASE 1 - A trial with 1,077 healthy adults aged 18-55 years, 91% Caucasian, began in the UK in April 2020. The placebo group were given the meningitis (MenACWY) vaccine (not an inert saline placebo). People with known underlying conditions were excluded from this trial.

PHASE 2/3 - In a single-blind, randomised, controlled, phase 2/3 trial, healthy adults > 18 years were enrolled at two UK clinical research facilities. After two doses of vaccine, the following was reported:

- **Local reactions** (**pain, redness, swelling of injection site**) reported in 43/49 (88%) participants in the 18–55 years group, 22/30 (73%) in the 56–69 years group and 30/49 (61%) in the 70+ years group
- **Systemic reactions** (**fever, chills, fatigue, muscle pain, etc**) reported in 42 (86%) participants in the 18–55 years group, 23 (77%) in the 56–69 years group, and 32 (65%) in the 70 + years group
- As of Oct 26, 2020, **13 serious adverse events occurred** during the study period, none of which were considered to be related to the vaccine[xi]
- By 14 days after the second dose, 208 (>99%) of 209 boosted participants had neutralising antibody responses. T-cell responses peaked at day 14 after a single standard dose.[xii]

Further trials took place in the UK, Brazil, South Africa and India, with varied placebos (MenACWY vaccine or saline).

Vaccine effectiveness: Published trial data[xiii] states that between April 23 and Nov 4 2020, 23,848 participants were enrolled in trials. Of these, 11,636 participants (7,548 in the UK, 4,088 in Brazil) were included in the interim primary efficacy analysis. "**Overall vaccine efficacy (effectiveness) across both groups was 70.4%**."

70.4% appears to have been the average of two different dose regimes (accidental half-dose given in UK trial for first dose) – 62% effectiveness in Brazil trial and 90% effectiveness in UK trial.

Vaccine safety: 175 severe adverse events (SAEs) occurred in 168 participants, 84 events in the vaccine group and 91 in the control group. **Three SAEs were classified as possibly related to a vaccine**: one in the Covid-19 vaccine group, one in the control group (MenACWY vaccine) and one in a participant who remains masked to group allocation."[xiv]

Transverse myelitis was mentioned in two SAEs that temporarily stopped trials. One was later reported to have undiagnosed multiple sclerosis. One participant died in Brazil; he is said to have received the placebo (MenACWY). A SAE in India has been reported by a trial participant in the media[xv] and is currently being investigated.

COST/ STORAGE

This vaccine is the lowest in cost of all three contenders for the UK, at £2.23 per dose (based on the EU deal).

Storage is at 2°C, making the logistics easier than the BioNTech/Pfizer vaccine.[xvi]

OTHER INFORMATION

The trials for the Oxford-AstraZeneca trials have come under some criticism e.g. for the mixed dosing regimens used and for combining multiple different studies.

Recent announcements regarding the potential to combine the Oxford-AstraZeneca vaccine with the Russian Sputnik V have not explained how safety standards will be assured[xvii].

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There is conflicting guidance in place on the interchangeability of vaccines (use of alternative if the same vaccine isn't available for the 2nd dose) - both Public Health England[xviii] and the CDC[xix] advise against this.

PLEASE DO YOUR OWN RESEARCH

This vaccine received Emergency Use Authorisation from the MHRA on 30th Dec. 2020. This is defined as authorisation for temporary supply. The vaccine does not have a marketing authorisation.

- It may only be used for individuals aged 18 years and older
- It was not tested on pregnant women
- All trial participants had/have to affirm that they are using "highly effective" contraception 28 days prior to dose 1 through until 60 days after dose 2, because the effects on a foetus are unknown
- A number of provisos relating to this (breastfeeding, etc) apply: please see the Information for UK Recipients[xx]

Further information for UK recipients of the vaccine is available here:

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-uk-recipients-on-covid-19-vaccine-astrazeneca

Package leaflet information for the recipient is here:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948335/Information_for_UK_recipients_COVID-19_Vaccine_AstraZeneca.pdf

Summary of the Public Assessment Report for AstraZeneca COVID-19 vaccine

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/summary-of-the-public-assessment-report-for-astrazeneca-covid-19-vaccine

Patient Group Direction

https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2021/01/C1012-patient-group-direction-for-covid-19-vaccine-astra-zeneca-ChAdOx1-S-6-jan-2021.pdf

Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca

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

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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 https://www.astrazeneca.com/media-centre/press-releases/2020/astrazenecas-covid-19-vaccine-authorised-in-uk.html
iii https://clinicaltrials.gov/ct2/show/NCT04516746#contacts
iv https://www.research.ox.ac.uk/Article/2020-07-19-the-oxford-covid-19-vaccine
v https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca
vi See ref v
vii https://www.bmj.com/content/371/bmj.m4037
viii See ref v
ix https://www.pharmaceutical-technology.com/news/oxford-university-covid-19-vaccine-monkey-data/
x https://www.biorxiv.org/content/10.1101/2020.12.02.408823v1.full.pdf
xi https://www.drugtopics.com/view/oxford-s-covid-19-vaccine-induces-strong-immune-responses-in-early-stage-trial
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xvii https://www.reuters.com/article/health-coronavirus-astrazeneca-russia/astrazeneca-to-test-combining-covid-vaccine-with-russias-sputnik-idUKKBN28L10M
xviii https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/949063/COVID-19_vaccination_programme_guidance_for_healthcare_workers_December_2020_V3.pdf
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xx https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948335/Information_for_UK_recipients_COVID-19_Vaccine_AstraZeneca.pdf