BRITISH ISLAMIC MEDICAL ASSOCIATION

Position Statement on COVID-19 Vaccine AstraZeneca

SUMMARY

The British Islamic Medical Association (BIMA) has consulted various experts in infectious diseases, the pharmaceutical industry, clinical medicine, commissioning, public health, and bioethicists to produce the following statement on the COVID-19 Vaccine AstraZeneca (hereafter referred to as the AZ Covid-19 vaccine) and how it relates to the Muslim community in Britain. This is the second vaccine that the UK Government has procured against Covid-19 to get regulatory approval by the MHRA.

Following consultation with experts, this is a position statement specific to the AZ Covid-19 vaccine and is based on our knowledge at the time of publication. This is a rapidly evolving situation with more vaccines expected to be made available and more clinical trial data pending publication. We may revise our statement should the evidence compel us to do so.

We recommend the COVID-19 Vaccine AstraZeneca for eligible individuals in the Muslim community for protection against Covid-19 when used in accordance with the MHRA authorisation. Prioritised risk groups are outlined in the JCVI guidance.

Individuals should seek the advice of their medical practitioner and make their decision following informed consent.

Despite the availability of vaccines, vigilance with wearing masks, social distancing, adequate ventilation, and good hand hygiene remain paramount and highly effective in managing this pandemic.

At the time of publication there are very high rates of Covid-19 transmission across the UK, with a disproportionate burden on ethnic minorities yet again.

BACKGROUND

We have discussed the pre-existing health and socioeconomic inequalities, as well as the disproportionate impact of Covid-19 in the Muslim community during the first wave, in our earlier statement on the Pfizer/BioNTech Covid-19 vaccine published on 6 December 2020.[1]

Further evidence has since emerged that suggests ethnic minority populations, of which Muslims make up a significant proportion, sadly continue to experience a disproportionate impact in Covid cases and deaths in Britain.[2]

This statement is to help inform Muslim community leaders, scholars, and the Muslim public on how they can make informed decisions about the AZ Covid-19 vaccine. We also provide a brief update on the Pfizer/BioNTech Covid vaccine and issues around equitable access.

EFFICACY & SAFETY

This AZ Covid-19 vaccine uses "a replication deficient chimpanzee adenovirus (ChAd) as a vector to deliver the SARS-CoV-2 spike protein genetic sequence into the host cell."[3] This triggers the body's immune system and there is a natural production of antibodies and stimulation of immune cells to protect against Covid-19 disease. The vaccine is given as 2 injections, the second one within 4 to 12 weeks of the first dose. This method of using a chimpanzee adenovirus vector has been used in vaccines previously, for example, in the vaccine to protect against the MERS virus. It is important to stress that this is a modified virus found in chimpanzees.

Efficacy

The AZ Covid-19 vaccine has been assessed based on an interim analysis of pooled data from four on-going randomised, blinded, controlled trials of 23,745 subjects.[4]

- A Phase I/II Study, COV001, in healthy adults 18 to 55 years of age in the UK
- A Phase II/III Study, COV002, in adults ≥18 years of age (including the elderly) in the UK
- A Phase III Study, COV003, in adults ≥18 years of age (including the elderly) in Brazil
- A Phase I/II study, COV005, in adults aged 18 to 65 years of age in South Africa.

All participants are planned to be followed for up to 12 months, for assessments of safety and efficacy against Covid-19 disease. 11,636 participants (7,548 in the UK and 4,088 in Brazil) were included in the interim primary efficacy analysis which has been published in peer reviewed literature and available on the MHRA data. Of these 5,807 received the AZ Covid-19 vaccine and 5,829 participants received a meningitis ACWY vaccine or saline as a control.[4,5]

"Overall, among the participants who received the vaccine:

- 94.1% of participants were 18 to 64 years old (with 5.9% aged 65 or older)
- 60.7% of subjects were female

- 82.8% were White, 4.6% were Asian, and 4.4% were Black.
- A total of 2,070 (35.6%) participants had at least one pre-existing comorbidity.
- The median follow-up time post-dose 1 and post-dose 2 was 132 days and 63 days, respectively."

The level of protection gained from a single dose of the AZ Covid-19 vaccine was assessed in an exploratory analysis which showed that increased immunogenicity was associated with a longer dose interval. "Efficacy is currently demonstrated with more certainty for dose intervals from 8 to 12 weeks. Data for intervals longer than 12 weeks are limited."

Overall vaccine efficacy against symptomatic disease was 70.42% (95.84% CI: 54.8-80.6). Participants who had one or more comorbidities had a vaccine efficacy of 73.43% [95% CI: 48.49-86.29] which was similar to the vaccine efficacy observed in the overall trial population.

Following vaccination with the AZ Covid-19 vaccine, in participants who were seronegative at baseline, seroconversion (as measured by a ≥4 fold increase from baseline in S-binding antibodies) was demonstrated in ≥98% of participants at 28 days after the first dose and >99% at 28 days after the second. Higher S-binding antibodies were observed with increasing dose intervals. Long term durability of the immune protection is also unknown at this stage. More data is required for the effectiveness of the vaccine in older age groups and regarding the ability of the vaccine to reduce transmission.[5]

These data are reassuring in terms of efficacy, however trial participants were predominantly female and from White ethnic backgrounds, both of which are less likely to contract severe Covid-19 disease compared with ethnic minority populations.

Safety

The most frequently reported adverse reactions were:

- Injection site tenderness (>60%)
- Injection site pain, headache, fatigue (>50%)
- Myalgia, malaise (>40%)
- Pyrexia, chills (>30%)
- Arthralgia, nausea (>20%)

The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination.[4] Of 12,174 participants who received the vaccine, there were 84 participants who experienced a serious adverse event, one of which, transverse myelitis (spinal cord inflammation), was possibly related to the intervention. There were three cases of transverse myelitis in total although two were considered to be unlikely to be related to the intervention. All the participants with this condition have recovered or are recovering.[5] As millions of doses are administered there may be some other rare side effects. Additional data will be provided as the trials complete and data from real world use will give a better idea of the safety profile of this vaccination. This process has been demonstrated by the updated guidance for the Pfizer/BioNTech Covid-19 vaccine mentioned below.

Concerns around the speed of vaccine development and approval have been previously discussed in our Pfizer/BioNTech position statement.[1] As with any new product, there is the Yellow Card scheme – an established reporting mechanism of monitoring adverse reactions. A special reporting site has been created for this: https://coronavirus-yellowcard.mhra.gov.uk. Anyone, including members of the public, can report side effects they may have experienced. Further surveillance data will be undertaken by Public Health England and the MHRA by linking electronic health records in as close to real time as possible.

Excipients

There are no components of animal origin (i.e. no gelatine) in this vaccine.[6] The vaccine has been produced in genetically modified human embryonic kidney (HEK) 293 cells. Cell lines are often required to help the active vaccine ingredients grow. The cell lines used to make some vaccines were originally taken from an aborted foetus many years ago, however it is important to understand that the foetuses were not aborted for this purpose and cells from foetuses have not directly been used in this vaccine. Once grown, these viruses are purified to remove the cell culture material. It is highly unlikely that any human material remains in the final vaccines.[7] The subject of cell lines has been discussed by Muslim scholars for this and other vaccines and has been deemed permissible by a number of renowned scholars.[8,9,10,11]

The vaccine contains alcohol in the form of ethanol which is used as a solvent. There is 0.002mg of alcohol (ethanol) per dose of 0.5ml. This is “not enough to cause any noticeable effects”[12] and has been described as negligible by Muslim scholars.[8,10] It is comparable or less than the amount of ethanol found in natural foods or bread, for example.

COVID-19 VACCINES UPDATE

As of 8 January 2021, more than 17.5 million doses of Covid-19 vaccines have been administered throughout the world.[13] As part of the ongoing surveillance and following reports of anaphylaxis in the Pfizer/BioNTech Covid-19 vaccine, The Commission on Human Medicines has reviewed the data and guidance regarding vaccinating those with allergies has been updated twice so far.[14] This was first done within days following the introduction of the Pfizer/BioNTech vaccine, restricting it for those with any documented severe allergy. Guidance on allergies was then subsequently relaxed as further data and analysis showed this was too cautious.

There has also been updated guidance regarding the administration of the Covid-19 vaccines in pregnant and breastfeeding women. The JCVI have advised consideration of the vaccine in these women where the risk of exposure to the infection is high and cannot be avoided or if a pregnant woman has underlying conditions that put them at high risk of serious complications of Covid-19. The current advice is that with regards to children, only those at very high risk of exposure and serious outcomes should be offered a Covid-19 vaccine where appropriate and after consultation with their specialist clinicians.[15]

There are very few categories of people who cannot receive the Pfizer/BioNTech or AZ Covid-19 Vaccine. The vaccines should not be given to those who have had a previous systemic allergic reaction such as anaphylaxis to a previous dose of the same vaccine or a component of the Covid-19 vaccines.[3]

ONGOING INEQUITY

The JCVI have not as of yet made any changes in their recommendations to include minority communities in their priority framework despite several calls to do so.[16] This remains a concern given the ongoing disproportionate burden these communities face, and the inequity in the response when compared to the decision to prioritise the elderly and those who are shielding. There has also been consistent inaction in collecting or acting on data regarding minorities or occupations that are disproportionately impacted.[17] These are the same people, especially in frontline roles, that will pay the highest price.

Recently the UK Chief Medical Officers and JCVI have advised increasing the gap in the vaccination schedule for the Pfizer/BioNTech Covid vaccine from 3 weeks to within 3 months.[15] In exceptional times pragmatic decisions are necessary. This decision is balancing the provision of effective immunity from Covid-19 to vulnerable populations and workforce, and scaling up vaccination to cover as much of the population as possible by delaying the second dose. Whilst this decision is based on modeling and evidence, it has not been universally welcomed by the medical community - including the BMA, WHO, and Pfizer.[18,19] Good communication is a hallmark of delivering good healthcare. Implementing major changes with little consultation, explanation, or notice tends to cloud even the most legitimate and well-meaning actions.

We reiterate the point made in our earlier Pfizer/BioNTech statement: as trust in public health messaging from Government sources is low, especially amongst minority communities,[20] a failure to undertake effective engagement with these communities will have disastrous consequences.

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