



BRITISH ISLAMIC
MEDICAL ASSOCIATION

Position Statement on COVID-19 Vaccine Moderna

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 Moderna (hereafter referred to as the Moderna vaccine) and how it relates to the Muslim community in Britain. This is the third vaccine to obtain authorisation for temporary supply by the MHRA.

Following consultation with experts, this is a position statement specific to the Moderna 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 Moderna for eligible at-risk 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 writing there are lower rates of Covid-19 transmission across the UK, in part due to the success of the vaccination programme. However, there is some evidence of lower uptake of vaccination in Muslims communities and individuals are encouraged to review this information and continue to follow Government guidance.

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 vaccination 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 Moderna vaccine.

There is emerging evidence that vaccine uptake rates are lower in certain population groups, including Muslim, reflecting a multitude of historical and current inequalities. Muslims are reminded of their duty to seek accurate information and to consider the impact of their decision on their families and communities.

EFFICACY & SAFETY

This Moderna Covid-19 (mRNA-1273) vaccine contains the genetic code (mRNA) for the spike protein of SARS-Cov-2, the virus that causes Covid-19. The genetic code is embedded in lipid nanoparticles. Once injected, cells translate the mRNA sequence to create the spike protein which becomes membrane bound on the expressing cell. The delivered mRNA does not enter the cellular nucleus or interact with the genome, is nonreplicating, and is expressed transiently. The expressed spike protein stimulates the body's immune system (functional antibodies, T-cell and B-cell) and causes the body to produce its own protection against the virus. No ingredients in the vaccine itself can cause Covid-19. It is given as two separate injections into the deltoid (shoulder) muscle of the arm, the second dose is recommended 28 days after the first dose. The recommended interval *may* be extended by the JCVI as they have done for previous vaccines. It has not been studied in children or adolescents under 18 years of age. There is limited experience in pregnant patients during the trials in keeping with normative trial protocols. However, an estimated 90,000 pregnant women have received an mRNA vaccine (either Moderna or Pfizer-BionTech) in the USA and a recent study by the American Journal of Obstetrics and Gynaecology followed up 84 pregnant and breastfeeding women and found them to be effective. 10 of these women have given birth to healthy children without incidence so far.³

Efficacy

The Moderna Covid-19 (mRNA-1273) vaccine has been assessed based on a large, phase 3, randomized 1:1, placebo controlled, observer blinded study in subjects >18 years of age. A total of 30,351 subjects were followed for a median of 92 days for the development of COVID-19. The study started in July 2020 and was conducted in the USA. The efficacy results are from the November 2020 data cut.

At the point of commencing the trial, the UK (B.1.1.7), South African (B.1.351) or Brazilian (P.1) variants had not been reported in the USA. These results are related to Covid-19 triggered by the Wuhan virus (Wuhan-Hu-1).

The predefined study primary endpoint was the efficacy of the Moderna vaccine in preventing a first occurrence of symptomatic Covid-19 with onset at least 14 days after the second injection. Pre-specified cohorts of subjects who were either ≥65 years of age or 18 to < 65 years of age with comorbid medical conditions were included. The study excluded individuals who were immunocompromised or had received immunosuppressants within 6 months.

Summary of primary analysis population:

- 14,143 received Moderna vaccine 14,073 received placebo
- 47.4% of subjects were female
- 19.7% were Hispanic or Latino, 9.7% were African-American
- Median age was 53 years

Overall efficacy results:

- The overall Moderna vaccine efficacy is 94.1% (11 confirmed Covid-19 cases of any severity in the vaccinated population vs. 185 in the placebo population)
- It was 100% effective against severe Covid-19 disease (0 cases vs. 30 in the placebo arm)
- In communities of colour (all non-Whites) efficacy was 97.5% (1 case vs. 41 in placebo arm)
- In high risk groups (including those with pre-existing diabetes or significant cardiac disease), the vaccine efficacy was 90.9% (4 cases vs. 43 in the placebo arm)
- In >65 year olds, the vaccine was 86.4% effective against Covid-19 of any severity

Additional analysis showed the vaccine may provide some level of protection from 14 days after the first dose and before receiving dose 2. For optimal protection, two doses should be administered one month apart. The durability of the Moderna vaccine is currently unknown.

Some early evidence from preliminary in-vitro trials suggest the Moderna vaccine can produce sufficient protection against the UK (B.1.1.7) variant⁶ although less protection versus the South African (B.1.351) variant. Moderna has planned further booster studies.

Safety

The most frequently reported adverse reactions were:

- Injection site pain (92%)
- Fatigue (70%)

- Headache (65%)
- Myalgia (62%)
- Arthralgia (46%)
- Chills (46%)

Adverse reactions were usually mild or moderate in intensity and resolved within a few days after vaccination. Local and systemic adverse reactions were more frequently reported after the second dose than after the first dose.

Anaphylaxis has been reported at a limited rate of 2.5 per million and close monitoring for 15 minutes after vaccination is recommended.⁷

Concerns around the speed of vaccine development and approval have been previously discussed in our Pfizer/BioNTech and Oxford AstraZeneca position statements.^{1,8} 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 is being undertaken by Public Health England and the MHRA by linking electronic health records in as close to real time as possible.

Excipients

The Moderna vaccination has no components of human or animal origin. The lipid nanoparticle contains cholesterol from a plant source. There is no ethanol (alcohol) in the Moderna vaccine.

COVID-19 VACCINES UPDATE

As of 17th April 2021, more than 800 million doses of Covid-19 vaccines have been administered throughout the world.⁹ The Pfizer/BioNTech vaccine was the first to be approved for use in the UK by the MHRA. The Commission on Human Medicines has reviewed the data as it has become available and guidance regarding vaccinating those with allergies has been updated.¹²

There has also been updated guidance regarding the administration of the Covid-19 vaccines in pregnant and breastfeeding women.³

The current advice is that only children with specific conditions 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.¹⁰

There has been a noted possible increase risk of VIITT (Vaccine-induced immune thrombotic thrombocytopenia) after having the Oxford AstraZeneca vaccine. Research is ongoing on mRNA vaccines such as the Moderna vaccine regarding possible increased risk of CVST (Central venous sinus thrombosis), however it is clear that the risk of thrombosis is far more common with Covid infection.¹¹

ONGOING ISSUES

The JCVI have recently started to take on board recommendations to include minority communities in their priority framework after several calls to do so.¹² 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.¹⁶ These are the same people, especially in frontline roles, that will pay the highest price.

The UK Chief Medical Officers and JCVI previously advised increasing the gap in the vaccination schedule for the Pfizer/BioNTech and AstraZeneca/Oxford Covid vaccines from 3 weeks to *within* 3 months.¹³ This approach was controversial.^{14,15} There is some evidence that this strategy has been effective, but there needs to be further research.²⁸

We reiterate the point made in our earlier statement: as trust in public health messaging from Government sources is low, especially amongst minority communities,¹⁷ a failure to undertake effective engagement with these communities will have disastrous consequences, especially as the vaccine programme reaches younger age groups and the Covid virus mutates.

We note how true and authentic partnership can not only bridge inequalities, but empower communities and build trust. The positive effort to use mosques as vaccine hubs, extending vaccination session to twilight hours in Ramadan and the mobilisation of Muslim healthcare professionals, religious scholars and community leaders is evidence of this.

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