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POSITION STATEMENT ON THE PFIZER/BIONTECH COVID-19 VACCINE

The British Islamic Medical Association (BIMA) has consulted various experts in infectious diseases, the pharmaceutical industry, clinical medicine, commissioning, inequalities research, public health, and bioethicists to produce the following statement on the Pfizer/BioNTech Covid-19 vaccine that is set to be rolled out in the UK, and how it relates to the Muslim community in Britain. This is the first of several vaccines that the UK Government has procured against Covid-19 to get MHRA regulatory approval.

This is a consensus statement specific to the Pfizer/BioNTech vaccine and is based on our knowledge at the time of publication. This is a rapidly evolving situation, with more vaccines due to become authorised, and more trial data pending publication. We may revise our statement should the evidence compel us to do so.

SUMMARY

After discussion with experts, **we recommend the Pfizer/BioNTech Covid-19 vaccine for eligible at-risks individuals in the Muslim community**. These are outlined in the current JCVI guidance.

Individuals should take this Covid-19 vaccine on the advice of their medical practitioner following informed consent. This is to protect these specific groups from a probable and considerable risk of harm from Covid-19 infection, which is likely to be greater than any harm from taking this vaccine. We shall continually review this recommendation as new information becomes available.

A UK-wide population roll out is not available at present and we have therefore **not** considered this.

Despite the development of vaccines, the ongoing vigilance of wearing masks, social distancing, and hand hygiene remain paramount and highly effective in managing this pandemic.

BACKGROUND

The British Muslim community has been disproportionately affected by Covid-19 with excess cases and deaths.[1] One third of those from minority backgrounds in the UK are Muslim,[2] and these communities have had a similarly high burden from Covid-19.[3] Despite being a relatively young population (33% under 15y and 4% over 65y), the self-reported quality of life measures and health outcomes of our communities are poor. Chronic disease is often badly managed,[4] with higher rates of diabetes and cardiovascular disease[5] - which are poor prognostic factors for Covid-19,[6] with poor patient satisfaction and access to health services.[7]

This statement is to help inform Muslim community leaders, scholars, and the Muslim public on how they can make informed decisions about the Pfizer/BioNTech Covid-19 vaccine.

EFFICACY AND SAFETY CONCERNS

This vaccine uses modified RNA technology which is formulated in a lipid nanoparticle.[8] This delivers a section of genetic instruction which, once in the body, starts producing the spike protein found on the SARS-CoV-2 virus and triggers the body's natural production of antibodies and stimulates immune cells to protect against Covid-19 disease. It is given as 2 injections, 21 days apart. This specific method has not been used for approved vaccines

before. However, RNA based treatments and drugs formulated with lipid nanoparticles have been approved by global regulators for other diseases.

Phase I/II data on the safety, tolerability, and immunogenicity for this vaccine has been published in peer review literature.[9] Although Phase III trial data has not yet been published publicly in the scientific literature (efficacy results were announced through press releases), this data has been provided to global regulators, including the MHRA in the UK, and the protocol has been published.[10] The lack of public scrutiny is concerning given the need for transparency and appraisal of the trial data by experts who are independent of industry and regulators.

Human trials of this vaccine involved 42,000 people globally with half receiving the vaccine and the other half given a placebo. 162 people fell ill with Covid-19 in the placebo group as did 8 in the treatment group – resulting in the quoted 95% efficacy figure.[11]

There are legitimate concerns regarding the vaccine. More data is required regarding the ability of the vaccine to improve mortality rates and reduce transmission. Many subgroups of patients were not included in the trials or were in limited numbers. Trial participants had existing stable chronic diseases such as hepatitis, diabetes, and cancer – but none had any serious or unstable conditions. Long term data is understandably not yet available. What has been shared indicates that there has been high efficacy in studied age groups (>16y), including older adults (94% in over 65y, but not tested in over 85y) and ethnic minorities. No serious side effects or adverse events have been reported.

Drug trials and authorisation can take many years due to laborious steps in a process that is fraught with hurdles relating to grants, panel decisions, peer review processes, ethics approval, and other bureaucratic difficulties. In the case of the Covid-19 vaccines, these were optimised and ran in parallel as opposed to in a serial sequence due to the urgent nature of a global pandemic, with unprecedented collaboration with researchers and other bodies, allowing for these trials to be conducted at speed.

Safety concerns from clinical trials are largely down to the nature of the disease, the number and clinical profile of patients studied, the dosages used, and the duration of the study. The approval for this vaccine is based on data relating to over 2,000 person years. All trial participants will be followed for 24 months with data to be provided to regulators on an ongoing basis. Trials in other age groups who were excluded, including pregnant women, are either ongoing or planned. At present the advice is for the vaccination to not be taken by those that are pregnant or breastfeeding, and those intending pregnancy should be delayed for two months following the second vaccination dose.

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 and monitoring electronic health records in as close to real time as possible.

There is no content of animal origin (i.e. no gelatine) and no products are derived from foetal cell lines. The remaining excipients are not of concern.[12]

THE ROLE OF THE MHRA

The Medicines and Healthcare Products Regulatory Authority (MHRA) is the independent agency responsible for ensuring medicines are acceptable and safe. The MHRA approved the Pfizer/BioNTech vaccine for the UK market with a temporary authorisation for emergency use on 2 December 2020, being the first in the world to do so.

As with any regulator, the industry being monitored can play an influential role. However, we have received several reassurances, including from MHRA themselves, that corners have not been cut, processes remain robust in assuring safety, and that they have been regularly reviewing data on a rolling basis. The latter is a novel approach which is how the MHRA have explained their rapid decision process. Regulators have access to more data than is publicly available due to commercial sensitivities.

Processes vary between regulators across the world, but both the European Medicines Agency (EMA) and US Food and Drug Administration (FDA) are expected to also approve the Pfizer/BioNTech Covid-19 vaccine when they make their decision on 29 and 10 December, respectively. The FDA and EMA have raised questions about the speed of the MHRA's decision which may be influenced by political circumstances, particularly considering Brexit. Despite these concerns, and the influence of industry, there is currently have no reason to doubt the decision of the MHRA.

In line with other childhood vaccines in the UK, the Pfizer/BioNTech vaccine has also been added to the Vaccines Damage Payment Scheme which provides financial assistance to anyone suffering a severe disability from taking the vaccine.[13]

THE JCVI – PRIORITISATION & RISK VS BENEFITS

Despite the improvement in mortality rates since the first wave, in part due to better supportive treatment and health system preparedness, Covid-19 remains a serious condition with significant burden on survivors and our society. Research has suggested that 1 in 20 people with Covid-19 are likely to suffer with symptoms for 8 weeks or more,[14] and that psychiatric presentations may be more likely following Covid-19 than other illnesses.[15]

The Joint Committee on Vaccination and Immunisation (JCVI) is an independent UK advisory body of experts who advise on vaccines. Their report on which groups in the UK population should be a priority Covid-19 vaccination outlines several cohorts of the population who should receive the vaccine.[16] They advise that the priority should be to prevent death from Covid-19 and then protect health and social care staff.

Accordingly, a framework has been developed which will see that there is sequential roll down the risk groups, starting with those in care homes, individuals aged 80+, staff in the NHS and care sector, and will currently be going down to those aged 50+. It will also include individuals aged 16+ with underlying conditions that put them at higher risk of serious disease and mortality.

The chances of dying from Covid-19 increase with age: people aged 80y+ have a 20-fold increased risk of dying compared to those aged 50-59.[17] Deaths overall are higher this year compared to previous years.[18] Furthermore, mental health issues have increased with social isolation, working from home, limited services, and the closure of places of worship having negatively affected the wellbeing of the nation.[19]

EQUITABLE ACCESS AND MANDATORY VACCINATIONS

Currently, the Pfizer/BioNTech vaccine is only being rolled out to the at-risk groups as per the JCVI recommendations. Healthy individuals remain at low risk and are currently not being considered, though this may change as more vaccines enter the market and supplies improve. The JCVI guidance does acknowledge minority communities in their recommendations, but in a webinar on 04 December 2020 stated that this is not being prioritised due to the absence of an effective way to target these communities. It is debatable as to the credibility of this line of argument and whether it would be an acceptable excuse for any other at-risk group.

Trust in public health messaging from Government sources is low, especially amongst minority communities.[20] A failure of effective engagement with these communities may mean that there is a lack of confidence in adhering to Government guidelines and messaging in relation to social distancing, wearing of masks, and now uptake of the Covid-19 vaccine. This has seen to be the case with historical low rates of routine immunisations in minority ethnic communities. However, to ensure maximal efficacy, a substantial proportion of the population needs to be vaccinated to achieve herd immunity. This includes those who have previously had Covid-19 and have proven antibodies to it. Thus, it is imperative individuals are given sufficient information regarding vaccination.

There has been some concern that if low levels of the population take up the vaccine this may lead towards mandatory vaccination either through legislation or through exclusion from social or economic activity (e.g. events, travel, education). At present however, there are no concrete plans for this or for "vaccine passports", although this continues to be debated.

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