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Independent report

Use of the AstraZeneca COVID-19 (AZD1222) vaccine: updated JCVI statement, 7 May 2021

Published 7 May 2021

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Introduction

Since the start of the pandemic over 4.4 million COVID-19 infections have been confirmed in the UK causing more than 127,000 deaths. Over 34 million people have now received their first dose of COVID-19 vaccine, which Public Health England (PHE) estimates has prevented at least 10,000 deaths. Analysis of post-marketing surveillance data in the UK demonstrates that vaccination is highly effective and substantially reduces the risk of infection and severe COVID-19 disease and reduces onward transmission.

There have been reports of extremely rare adverse events of concurrent thrombosis (blood clots) and thrombocytopenia (low platelet count) following vaccination with the first dose of AstraZeneca ChAdOx1 nCoV-19 vaccine (AZD1222). There have been no safety concerns identified for thrombosis/thrombocytopenia associated with the second dose of the AstraZeneca (AZD1222) vaccine, nor with other COVID-19 vaccines currently approved for use in the UK (Pfizer-BioNTech and Moderna).

On 7 April 2021, after considering the relative balance of benefits and risks, the Joint Committee on Vaccination and Immunisation (JCVI) advised that, for adults aged under 30 years without underlying health conditions that put them at higher risk of severe COVID-19 disease, there should be a preference for an alternative to the AstraZeneca (AZD1222) vaccine, if available.

Current situation in the UK

The Medicines and Healthcare products Regulatory Agency (MHRA) has continued to review cases of these extremely rare adverse events, including those reported retrospectively, and data on the frequency of these events by age is now more precise. The latest reports on this adverse event are available from the MHRA's coronavirus vaccine – weekly summary of Yellow Card reporting (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting).

The available data suggests there is a slightly higher incidence (number of cases per million doses of vaccine given) reported in the younger compared to older adult age groups. There are currently no known risk factors for this extremely rare condition, which appears to be an idiosyncratic reaction on first exposure to the AstraZeneca (AZD1222) vaccine.

Consequent on lockdown measures and the ongoing successful deployment of the COVID-19 mass vaccination programme, COVID-19 incidence is currently low, as are COVID-19 associated hospitalisations and deaths. A number of mathematical models have been reviewed on the potential impact of any resurgence of COVID-19 in the UK. These models indicate that as COVID-19 restrictions are lifted across the country, the number of cases is likely to rapidly increase sometime in the second half of 2021. As such, the current high levels of vaccine uptake and high pace of vaccine deployment are critical to maintaining control over COVID-19 in the UK, especially as physical distancing measures are progressively relaxed. Strong and rapid vaccine coverage will help to minimise the health, social and economic impact of any future wave of COVID-19.

The vaccine supply situation for phase 2 of the programme has been carefully examined. Current forecasts indicate that it will be possible to complete phase 2 by offering the Pfizer-BioNTech or Moderna vaccines for individuals under 40 years of age who are yet to receive their first dose, without materially impacting on timelines for delivery of phase 2. However, vaccine supply forecasts are not completely certain, and it should be recognised that these could change at any time.

Updated advice

JCVI's advice is based on the available data on the current epidemiology, benefit-risk profile by age, modelling predictions on future disease trends and the current forecast on vaccine supply. Given the risk (albeit extremely rare) of these adverse events associated with the AstraZeneca (AZD1222) vaccine, the current control of COVID-19 in the UK, model predictions of the potential scale and timing of a future wave, and promising forecasts for the availability of vaccines in the UK, JCVI agreed its advice should be updated.

JCVI advises that, in addition to those aged under 30, unvaccinated adults aged 30 to 39 years who are not in a clinical priority group at higher risk of severe COVID-19 disease, should be preferentially offered an alternative to the AstraZeneca COVID-19 (AZD1222) vaccine, where possible and only where no substantial delay or barrier in access to vaccination would arise.

For those under 40 years who are of older age, male, obese (BMI above 30), from certain ethnic minority backgrounds or experiencing socio-economic deprivation, the risks of acquiring and/or suffering complications of COVID-19 are higher. Every effort should be made to remove barriers to accessing vaccination in those individuals.

For those aged 18 to 29 years the precautionary advice for a vaccine preference is stronger, reflecting a gradient in the benefit-risk balance with age.

This new advice is specific to the current UK context and is based on all of the following remaining favourable:

- the current low incidence of disease
- the availability of alternatives to the Astra-Zeneca (AZD1222) vaccine
- the strength of the whole vaccine programme in terms of maintaining speed and uptake

Should there be a deterioration in any of the above factors, JCVI advises that vaccination of adults aged 30 to 39 years with any of the UK-authorised vaccines is always better than no vaccination, except where there are specific contraindications.

Due to its storage and transport requirements, the AstraZeneca (AZD1222) vaccine is much more easily delivered in some settings, and in these settings may be the only vaccine it is practical to offer. In such circumstances JCVI advises that the benefits of receiving the AstraZeneca (AZD1222) vaccine outweigh the risks, and individuals in this event should be offered the AstraZeneca (AZD1222) vaccine.

JCVI considers that there continues to be no safety concerns for this extremely rare adverse event following receipt of a second dose of AstraZeneca (AZD1222) vaccine. All those who have received a first dose of the AstraZeneca (AZD1222) vaccine should continue to be offered a second dose of AstraZeneca (AZD1222) vaccine, irrespective of age. The second dose will be important for longer lasting protection against COVID-19.

JCVI advises that all individuals offered a COVID-19 vaccine should be fully informed about the benefits and risks of vaccination and consent accordingly. This should include:

- clear information on the extremely rare thrombosis/thrombocytopenia adverse events
- how to monitor for symptoms that might be related to the adverse event

- what action should be taken by individuals and health professionals in the event of such symptoms arising

PHE is preparing updated information for those being offered COVID-19 vaccines, and for health professionals, which will be available through the GOV.UK website.

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