From the Chief Medical Officer Dr Michael McBride



HSS(MD)35/2021

FOR ACTION

Chief Executives HSC Trusts (for onward cascade to all staff involved in the COVID-19 vaccination programme)

Chief Executive, Public Health Agency and Health and Social Care Board (for onward cascade as appropriate)

Assistant Director of Integrated Care

Head of General Medical Services, Health and Social Care Board (for onward cascade to all General Practitioners, GP Locums and Practice Staff)

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PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

USE OF THE ASTRAZENECA VACCINE: ADVICE ON UPDATED JCVI STATEMENT

We are writing following today's publication of updated advice from the independent Joint Committee on Vaccination and Immunisation (JCVI) in relation to the use of the AstraZeneca vaccine. The full updated guidance is available here: <u>Use of the AstraZeneca COVID-19</u> (AZD1222) vaccine: updated JCVI statement, 7 May 2021 - GOV.UK (www.gov.uk)

Background

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, with over 2,100 deaths in Northern Ireland. Over 34 million people across the UK, including over 950,000 people in Northern Ireland, 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 the AstraZeneca vaccine. There have been no concerning signals for thrombosis/thrombocytopenia associated with the second dose of the AstraZeneca COVID-



19 vaccine, nor with other COVID-19 vaccines currently approved for use in the UK (Pfizer-BioNTech and Moderna).

The 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 are now more precise. The latest reports on this adverse event are available from the MHRA at: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

Up to 28 April, the MHRA had received Yellow Card reports of 242 cases of major thromboembolic events with concurrent thrombocytopenia in the UK following vaccination with the AstraZeneca vaccine, and of these 31 were in adults aged 30 to 39 years. These events occurred in 141 women and 100 men aged from 18 to 93 years and the overall case fatality rate was 20% with 49 deaths. Six cases have been reported after a second dose.

The estimated number of first doses of the AstraZeneca vaccine administered in the UK by 28 April was 22.6 million and the estimated number of second doses was 5.9 million. The overall incidence of case reports of thromboembolic events with low platelets after first or unknown doses was 10.5 per million doses.

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 COVID-19 vaccine.

Updated JCVI advice

JCVI have today updated their guidance based on a careful consideration of the relative balance of benefits and risks, informed by the latest available data on the current epidemiology, benefit-risk profile by age, modelling predictions on future disease trends and the current forecast on vaccine supply across the UK. It supersedes the previous guidance issued on 7 April 2021, which advised that for adults aged <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 COVID-19 vaccine, if available.

The updated JCVI advice states:

JCVI advises that, in addition to those aged under 30, unvaccinated adults aged 30 - 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 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 >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 18-29 years the precautionary advice for a vaccine preference is stronger, reflecting a gradient in the benefit-risk balance with age.



This updated advice is specific to the current UK context and is contingent upon the current low incidence of COVID-19 disease, availability of alternatives to the AstraZeneca vaccine, and continued pace of vaccine rollout.

Importantly, this updated advice does not mean that JCVI advises against using the AstraZeneca vaccine in the 30 to 39 year cohort, only that an alternative is preferable when this would result in no substantial delay or barrier in access to vaccination would arise. JCVI have recognised that due to its storage and transport requirements, the AstraZeneca vaccine is much more easily delivered in some settings, and in these settings it may be the only vaccine it is practical to offer. In these circumstances JCVI have advised that the benefits of receiving the AstraZeneca vaccine continue to outweigh the risks, and individuals in this event should be offered the AstraZeneca vaccine.

ACTIONS NOW REQUIRED OF ALL VACCINATION PROVIDERS

Second doses

All those who have received a first dose of the AstraZeneca COVID-19 vaccine should continue to be offered a second dose of AstraZeneca COVID-19 vaccine, irrespective of age. The second dose will be important for longer lasting protection against COVID-19.

<u>First doses for unvaccinated adults who are aged 30 to 39 years and are not in a clinical priority group at higher risk of COVID-19 disease</u>

HSC Trusts should ensure that unvaccinated adults aged 30 to 39 years who are not in a clinical priority group at higher risk of COVID-19 disease are offered the Pfizer vaccine, or Moderna when available.

Community pharmacies may offer the AstraZeneca vaccine to individuals in this cohort who have made a fully informed choice to receive the vaccine. Individuals should be informed that it is preferred that an alternative vaccine is used in this cohort and that they can access an alternative vaccine from the HSC Trust vaccination centres, subject to appointment availability.

Individuals may still choose to receive the AstraZeneca vaccine having received clear information on the benefits and risks of vaccination and consenting accordingly, for instance where someone has an appointment booked for vaccination in the coming days and may prefer not to reschedule to receive an alternative vaccine through the HSC Trust vaccination centres.

Individuals should receive clear information on the extremely rare thrombosis/thrombocytopenia adverse events, how to monitor for symptoms that might be related to the adverse event, and what action should be taken by individuals and health professionals in the event of such symptoms arising.

<u>First doses for unvaccinated adults who are aged 30 to 39 years and are in a clinical priority group at higher risk of COVID-19 disease</u>

The advice from JCVI remains that the benefits of prompt vaccination with the AstraZeneca vaccine continue to outweigh the risk of adverse effects in unvaccinated adults who have



underlying health conditions which put them at higher risk of severe COVID-19 disease. No further action is required for this cohort.

First doses for unvaccinated adults who are aged 40 years or over

Community pharmacies and the **SSE Arena vaccination centre** should continue to offer the AstraZeneca vaccine to unvaccinated individuals aged 40 years and over, unless otherwise contraindicated.

We would once again like to take this opportunity to thank you for your continued efforts in delivering this unprecedented programme. It is important to reiterate that the potential risk associated with the first dose of the AstraZeneca vaccine is extremely rare and that the threat from COVID-19 is much higher for the majority of adults. Your efforts in delivering the successes that we have had to date have helped to give hope to our society and allowed us all to start to reclaim our lives from the pandemic, and it is vital that we continue to maintain the momentum of the vaccination rollout to help minimise the health, social and economic impact of any future waves of COVID-19.

Yours sincerely

DR MICHAEL McBRIDE Chief Medical Officer

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Chief Pharmaceutical Officer



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Trade Union Side

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https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-

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