

**From the Chief Medical Officer
Dr Michael McBride**



Department of
Health

An Roinn Sláinte

Máinnystrie O Poustie

www.health-ni.gov.uk

HSS(MD) 34/2021

FOR ACTION

Chief Executives HSC Trusts
for onward cascade to Medical Directors, Trust Vaccine Leads, Consultant Neurologists, Neurosurgeons, Haematologists, Emergency Medicine Clinicians, Intensivists and Ophthalmologists

Chief Executive, Public Health Agency and Health and Social Care Board/NIAS *for onward cascade as appropriate*

Assistant Director of General Medical Services, Health and Social Care Board *for onward cascade to All General Practitioners, GP Locums and Practice Staff OOHs Medical Managers*

Assistant Director of Pharmacy and Medicines Management, Health and Social Care Board *for onward cascade to Community Pharmacies*

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

**MHRA AND JCVI ANNOUNCEMENT REGARDING ASTRAZENECA VACCINE
UPDATED CONTRAINDICATIONS AND NEXT STEPS**

1. We are writing to you following the recent update from the Medicines and Healthcare product Regulatory Agency (MHRA) and the independent Joint Committee on Vaccination and Immunisation (JCVI) guidance in relation to the use of the AstraZeneca vaccine. The updated guidance has been published and can be found here:

<https://www.gov.uk/government/publications/use-of-the-astrazeneca-covid-19-vaccine-jcvi-statement/jcvi-statement-on-use-of-the-astrazeneca-covid-19-vaccine-7-april-2021>

2. The statement from the JCVI states:

Since the start of the pandemic over 4 million COVID-19 infections have been confirmed in the UK causing more than 120,000 deaths. Over 30 million people have received their first dose of COVID-19 vaccine since the start of the programme, which Public Health England (PHE) estimate has prevented at least 6,000 deaths in the first 3 months of 2021.

There have been reports of an extremely rare adverse event of concurrent thrombosis (blood clots) and thrombocytopenia (low platelet count) following vaccination with the first dose of AstraZeneca CHAdOx1 nCoV-19 vaccine (AZD1222).

JCVI has weighed the relative balance of benefits and risks and advise that the benefits of prompt vaccination with the AstraZeneca COVID-19 vaccine far outweigh the risk of adverse events for individuals 30 years of age and over and those who have underlying health conditions which put them at higher risk of severe COVID-19 disease. JCVI currently advises that it is preferable for adults <30 years without underlying health conditions that put them at higher risk of severe COVID-19 disease, to be offered an alternative COVID-19 vaccine, if available. People may make an informed choice to receive the AstraZeneca COVID-19 vaccine to receive earlier protection.

There are some adults <30 without underlying health conditions who are in phase 1, who were prioritised due to an increased risk of exposure and/or to reduce the risk of passing the infection on to vulnerable individuals. This includes health and social care workers, unpaid carers and household contacts of immunosuppressed individuals. Acting on a precautionary basis, if these persons are still unvaccinated, it is preferable for them to be offered an alternative COVID-19 vaccine, if available.'

ACTIONS NOW REQUIRED

3. MHRA and JCVI have made clear the balance of risk is still very much in favour of vaccination. It is therefore critical that their advice is assimilated in a similarly balanced and operational robust manner so that we continue to deliver our life-saving programme. All vaccination sites should therefore take the following actions now.

Second doses

4. **JCVI state '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'**
5. Therefore, for recipients in cohorts 1-9 who have received a first dose of AstraZeneca and are due to receive their second dose, **no further action is required** and these appointments should continue.

First doses for individuals 30 years of age and over and those who have underlying health conditions which put them at higher risk of severe COVID-19 disease

6. JCVI has weighed the relative balance of benefits and risks and advise that the benefits of prompt vaccination with the AstraZeneca COVID-19 vaccine far outweigh the risk of adverse events for individuals 30 years of age and over and those who have underlying health conditions which put them at higher risk of severe COVID-19 disease.
7. Therefore, for recipients in cohorts 1-9 aged 30 years and above who are scheduled to receive a first dose of AstraZeneca, **vaccination should continue with consent obtained in line with the recommendations set out in the Green Book.**

Adults under 30 without underlying health conditions in Phase 1

8. JCVI guidance states 'There are some adults<30 without underlying health conditions who are in phase 1, who were prioritised due to an increased risk of exposure and/or to reduce the risk of passing the infection on to vulnerable individuals. This includes health and social care workers, unpaid carers and household contacts of immunosuppressed individuals. Acting on a precautionary basis, if these persons are still unvaccinated, it is preferable for them to be offered an alternative COVID-19 vaccine, if available.'
9. For these recipients in cohorts 1-9 aged under 30 who have yet to receive a COVID-19 vaccination Trusts should ensure that these individuals are offered the Pfizer vaccine, or Moderna (when available).

For those who have contraindications or conditions that require special precautions.

In our letter of the 8 April 2021 HSS(MD) 28/2021 <https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-hss-md-28-2021.pdf> we included contraindications to receiving the AstraZeneca COVID-19 vaccine. **That advice has been updated and is detailed in the Chapter 14a of the 'Green Book' Immunisation against Infectious Disease.**

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/978508/Green_book_chapter_16April2021.pdf

Vaccination with the AstraZeneca COVID-19 vaccine is contraindicated in individuals who have a history of a previous episode of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2). These individuals may be offered vaccination with an alternative COVID-19 vaccine.

10. For those who have contraindications or conditions that require special precautions for the use of the AstraZeneca vaccine (as listed in the updated MHRA information for UK health care professionals is available at

<http://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca>) the following actions should be taken.

11. Ensure that everyone who presents for vaccination is asked about additional risk factors, using the materials provided. If they are at increased risk, they should have a discussion about the benefit and risks to them of receiving the AstraZeneca or other vaccine with a clinician.
12. If, following a conversation with a clinician, an individual chooses to go ahead with the AstraZeneca vaccination, vaccination sites should make this option available.
13. If an individual chooses to have another vaccine, the HSC will put appropriate arrangements in place. Further information for health care professionals on blood clotting following COVID-19 vaccination is available at:
<https://www.gov.uk/government/collections/covid-19-vaccination-and-blood-clotting>
14. Further guidance on clinical management for secondary care and emergency departments for the management of thrombosis and thrombocytopenia potentially following vaccination is also available.

<https://www.rcem.ac.uk/docs/Policy/ED-AM%20%20Vaccine%20pathway%20concerns%20-%20RCP%20-%20SAM%20-%20RCEM.pdf>

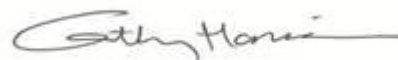
<https://b-s-h.org.uk/about-us/news/guidance-produced-by-the-expert-haematology-panel-ehp-focussed-on-vaccine-induced-thrombosis-and-thrombocytopenia-vitt/>

15. Thank you for your continued efforts and, as ever, we are hugely grateful for everything that you are doing to make the HSC-delivery of this programme the success that it is.

Yours sincerely



DR MICHAEL McBRIDE
Chief Medical Officer



MRS CATHY HARRISON
Chief Pharmaceutical Officer

Circulation List

Director of Public Health/Medical Director, Public Health Agency (*for onward distribution to all relevant health protection staff*)

Director of Nursing, Public Health Agency

Directors of Pharmacy HSC Trusts

Director of Social Care and Children, HSCB

Coronavirus Yellow Card reporting site

Official MHRA side effect and adverse incident reporting site for coronavirus treatments and vaccines | Coronavirus (COVID-19)

Public Health England: Thrombotic events with thrombocytopenia following immunisation to COVID-19

https://cutt.ly/haem_AE

Guidance produced from the Expert Haematology Panel (EHP) focussed on syndrome of Thrombosis and Thrombocytopenia occurring after coronavirus Vaccination **Guidance produced from the Expert Haematology Panel (EHP) focussed on syndrome of Thrombosis and Thrombocytopenia occurring after coronavirus Vaccination | British Society for Haematology (b-s-h.org.uk)**

MHRA issues new advice, concluding a possible link between COVID-19 Vaccine AstraZeneca and extremely rare, unlikely to occur blood clots

<https://www.gov.uk/government/news/mhra-issues-new-advice-concluding-a-possible-link-between-covid-19-vaccine-astrazeneca-and-extremely-rare-unlikely-to-occur-blood-clots>

Use of the AstraZeneca COVID-19 vaccine: JCVI statement

<https://www.gov.uk/government/publications/use-of-the-astrazeneca-covid-19-vaccine-jcvi-statement>

COVID-19 vaccination and blood clotting resources

<https://www.gov.uk/government/collections/covid-19-vaccination-and-blood-clotting>

Blood Clotting following COVID-19 Vaccination - Information for Health Professionals

<https://www.gov.uk/government/collections/covid-19-vac>