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To:

- Chief Executives of all NHS Trust and NHS Foundation Trusts
- Accountable Officers of all CCGs
- All PCNs and GP practices
- All Community Pharmacy
- All ICS/STP leaders

Copy to:

- NHS Medical directors
- All Chief Nurses
- Chairs of ICSs and STPs
- Chairs of NHS trusts and foundation trusts
- All Local Government Chief Executives
- All Regional Directors
- NHS Regional Directors of Commissioning

7 April 2021

Dear colleague

MHRA and JCVI announcement regarding AstraZeneca Vaccine and next steps

We are writing to you following today's 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>.

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 aged <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

MHRA and JCVI have made clear the balance of risk is still very much in favour of vaccination. It is therefore critical that we implement their direction in a similarly balanced and operationally robust manner so that we continue to deliver our life-saving programme.

All vaccination sites should therefore take the following actions now:

Second doses

- **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.’**

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.

MHRA are clear that the only individuals who should not have a second dose of AstraZeneca are those set out below:

‘Administration of the COVID-19 Vaccine AstraZeneca in patients with a history of cerebral venous sinus thrombosis, acquired or hereditary thrombophilia, heparin-induced thrombocytopenia or antiphospholipid syndrome should only be considered when the potential benefit outweighs any potential risks. Patients who have experienced major venous and arterial thrombosis occurring with thrombocytopenia following vaccination with any COVID-19 vaccine should not receive a second dose of COVID-19 Vaccine AstraZeneca.’

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

- ***‘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.’***

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

- **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.’**

For these recipients in cohorts 1-9 aged under 30 who have yet to receive a COVID-19 vaccination and are scheduled to receive a first dose of AstraZeneca on or after the 9 April, **the following actions will now need to be taken:**

- For those who have a first dose appointment at a vaccination centre or community pharmacy on or after 9 April, booked through the National Booking Service, these appointments will be cancelled centrally. For those booked via a local booking system, these appointments must be cancelled locally. Individuals will be asked to contact their GP team to discuss the benefit and risks to them of receiving the AstraZeneca or another vaccine.
- If, following a conversation with a clinician, an individual chooses to go ahead with the AstraZeneca vaccination, all vaccination sites should make this option available.
- If an individual chooses to have another vaccine, the NHS will put appropriate arrangements in place:
 - **PCN-led Local Vaccination Services**, working with system partners including Hospital Hubs, should rebook this individual in a clinic offering the Pfizer BioNTech vaccine over the coming four weeks. Guidance on how to access additional Pfizer BioNTech vaccine will follow shortly.
 - For **Hospital Hubs**, any available Pfizer BioNtech doses should be offered as first doses for those in cohort 1-9 aged under 30 or with contraindications.

For those who have contraindications or conditions that require special precautions

For those who have contraindications or conditions that require special precautions for use of the AstraZeneca vaccine (as listed in the updated MHRA information for UK healthcare professionals available at <https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca>), then do as follows:

- 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.
- If, following a conversation with a clinician, an individual chooses to go ahead with the AstraZeneca vaccination, vaccination sites should make this option available.
- If an individual chooses to have another vaccine, the NHS will put appropriate arrangements in place:

- **PCN-led Local Vaccination Services**, working with system partners including Hospital Hubs, should rebook this group at clinics offering Pfizer BioNtech vaccines over the coming four weeks.
 - For **Hospital Hubs**, any available Pfizer BioNtech doses should be offered as first doses for those in cohort 1-9 with the identified risk factor.
- For those in cohorts 1-9 aged under 30 or who have an additional risk factor who have yet to receive a COVID-19 vaccination and are **scheduled to receive a first dose of AstraZeneca on 8 April**, it is not possible to cancel and inform individuals before their appointment.

Therefore, all sites should prepare to have individual conversations about the risks and benefits of receiving the AstraZeneca vaccine should individuals arrive for their appointment. This means all vaccination sites will need to put immediate measures in place to ensure that regulated healthcare professionals are available to support these conversations, using the [materials provided by PHE](#).

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

Yours sincerely



Dr Emily Lawson
NHS Chief Commercial
Officer and SRO



Professor Stephen Powis
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Dr Nikki Kanani
Medical Director for Primary
Care