

From the Expert Haematology Panel and endorsed by Thrombosis UK

We wish to raise our concern with the MHRA regarding wording included in recent changes in MHRA guidance on the use of the AstraZeneca COVID-19 vaccine.

The MHRA Guidance issued 7th April 2021 (<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>)

Indicates:

- I. The MHRA is not recommending age restrictions in COVID-19 Vaccine AstraZeneca use.
- II. As a precaution, administration of COVID-19 Vaccine AstraZeneca in people of any age who are at increased risk of blood clots because of their medical condition should be considered only if benefits from the protection from COVID-19 infection outweighs potential risks.

We wish to draw to the MHRA's attention that there ***is no evidence*** that individuals with a prior history of thrombosis or known risk factors for thrombosis are more at risk of developing the immune complication reported after the AstraZeneca vaccine.

Furthermore, for the majority of individuals, the risk of recurrent thrombosis due to COVID-19 infection is far greater than the risk of this syndrome.

To avoid potential harm arising from unnecessary delay in vaccination for this group, we ask and strongly urge the MHRA to review their statement of 7th April 2021, and amend to be in line with the JCVI statement of the same date which weighed the relative balance of benefit and risk to advise:

- Only individuals under the age of 30 years without underlying health conditions which put them at a higher risk of severe COVID-19 disease, to be offered an alternative COVID-19 vaccine, if available.
- 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.