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AstraZeneca vaccine: Blood clots are “extremely rare” and benefits outweigh risks, regulators conclude

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Investigations by EU and UK regulators into reports of unusual blood clots after receiving the Oxford-AstraZeneca covid-19 vaccine have concluded that these are a “possible” and “extremely rare” side effect. Neither agency established a causal relation.

However, although both regulators concluded that no age restrictions were necessary for the vaccine, the UK’s vaccine advisory committee has decided that adults under 30 who are healthy and not at risk of developing severe covid-19 should be offered an alternative vaccine where possible.

Wei Shen Lim, chair of the UK’s Joint Committee on Vaccination and Immunisation, said, “We are not advising a stop to any vaccination for any individual in any age group. We are advising a preference for one vaccine over another vaccine for a particular age group, really out of the utmost caution rather than because we have any serious safety concerns.”

Among more than 20 million people who have been vaccinated with the AstraZeneca vaccine in the UK so far, 79 cases of rare blood clots with low platelets have been reported, as well as 19 deaths, said the UK’s Medicines and Healthcare Products Regulatory Agency. This equates to around one case per 250 000 people vaccinated—0.0004%—and one death in a million.

About 100 000 people usually develop blood clots every month in the EU, and 3000 cases a month are thought to occur in the UK.

Other benefits

The preference for offering under 30s an alternative vaccine was determined using a risk-benefit calculation that looked at the intensive care admissions prevented versus potential blood clots. In all age and risk groups except low risk under 30s, the potential benefits far outstripped the potential harms. In people aged 20-29 and low risk—meaning that they have no conditions that make them more at risk of developing severe covid-19 illness—the harms slightly outweighed the benefits.

However, there are important caveats to these data, including that avoiding intensive care is not the only benefit of getting vaccinated. Other potential benefits, such as avoiding being ill and avoiding getting “long covid,” were not considered as part of this calculation.

The UK’s move comes as it begins rolling out its third vaccine—Moderna’s mRNA vaccine—and as it expects other vaccines to be made available soon, including the Novavax and Johnson & Johnson vaccines.

Speaking at a Science Media Centre briefing after the announcement, Adam Finn, professor of paediatrics

at the University of Bristol, said that the recommendation on the AstraZeneca vaccine for under 30s would not have been made if the UK did not have other vaccines lined up.

Anthony Harnden, deputy chair of the Joint Committee on Vaccination and Immunisation, added that “this is very much a UK based decision” and emphasised that both the European Medicines Agency and the UK’s Medicines and Healthcare Products Regulatory Agency had found the AstraZeneca vaccine to be “very safe and effective.”

Harnden added, “This is important for the whole world, really, in that there will be countries in the world where the AstraZeneca vaccine is the only choice, and there would be countries in the world where the life expectancy of the population is very, very low indeed . . . therefore, the risk-benefit equation for the younger age groups in those other countries in the world will be different than in the UK.”

The EMA’s findings

The European Medicines Agency’s investigating committee reviewed 62 cases of cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis reported in the EU’s drug safety database as of 22 March 2021, 18 of which were fatal. At that point around 25 million people in the EU and UK had received the AstraZeneca vaccine. The agency said that most of the cases occurred in women aged under 60 within two weeks of vaccination.

It added that the “benefits outweigh any risks of side effects” in relation to the vaccine and that, while no definite link had been found between the vaccine and clots, a plausible explanation could be a condition similar to heparin induced thrombocytopenia—a reaction to heparin, which is an anticoagulant used for preventing blood clots. In very rare instances the treatment can lead to decreased platelets in the blood (thrombocytopenia) and clots.

Putting the risk in context

- 1 in 250 000 people vaccinated with the AstraZeneca vaccine will develop blood clots with low platelets
- 1 in 2000 women each year will develop a blood clot from taking the combined oral contraceptive pill¹
- 1 in 1000 people a year will develop a blood clot from air travel²

The risk of clots with covid-19

Covid-19 infection also carries a significant risk of developing a blood clot. A study published in the journal *Thorax* found that, in people with covid-19,

the overall prevalence of pulmonary embolism was 7.8% and deep vein thrombosis 11.2%.³ Of those who ended up in intensive care, 23% developed venous thromboembolism.

Covid-19 also led to strokes in around 1.6% of people,³ and an estimated 30% of people with covid-19 will get thrombocytopenia, a lowering of the platelet count.

Munir Pirmohamed, chair of the UK's Commission on Human Medicines, said, "That puts into context [the fact] that the risk of clots and lower platelets is much higher with covid-19 than these extremely rare events which are occurring with the vaccine."

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- 3 Tan BK, Mainbourg S, Friggeri A, et al. Arterial and venous thromboembolism in COVID-19: a study-level meta-analysis. *Thorax* 2021 (published online 23 Feb). doi: 10.1136/thoraxjnl-2020-215383. <https://thorax.bmj.com/content/early/2021/03/24/thoraxjnl-2020-215383>.

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