

Q&A: AstraZeneca's COVID-19 vaccine and blood clots—what you need to know

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Pharmaceutical giant AstraZeneca admitted in court this week that its COVID-19 vaccine can cause a rare but deadly blood-clotting condition that has become the central focus of a class-action lawsuit worth



potentially \$125 million.

A Northeastern University legal scholar says the admission isn't especially damning, as the rare condition—called thrombosis with thrombocytopenia syndrome, or TTS—was well-studied prior to the ongoing litigation.

"The fact that this had already been listed as a potential side effect reduces its legal impact," says Richard Daynard, university distinguished professor of law and president of the Public Health Advocacy Institute. "After all, the vaccine saved many more lives in Britain than were affected by this side effect, so AstraZeneca's admission—of what had already been listed—would not seem to be a big deal."

There are 51 cases of TTS associated with the AstraZeneca vaccine cited in the U.K.-based class action suit. The Centers for Disease Control and Prevention notes that there are roughly four cases of the blood clot condition reported per 1 million administered doses of the Johnson & Johnson vaccine which, like the AstraZeneca, is an "adenovirus" vaccine.

If you received the AstraZeneca vaccine, should you be concerned about TTS? Northeastern Global News spoke to Mansoor Amiji, Northeastern distinguished professor in the departments of pharmaceutical sciences and chemical engineering, to get a perspective on the link between the shot and the health condition.

Amiji's comments have been edited for brevity and clarity.

What should people know about this blood clot condition that has become the focus of this lawsuit?

There are a couple issues to discuss here. First of all, the AstraZeneca



vaccine is an adenoviral DNA vaccine, so it doesn't use the mRNA molecule delivered through the lipid nanoparticles that Moderna and Pfizer developed.

Through a collaboration with Oxford University, the AstraZeneca vaccine was first approved in the United Kingdom. It uses a modified form of what basically is a cold virus, or an adenoviral vector, and the vaccine delivers a DNA molecule that then gets into the human cell and encodes for the spike protein—very similar, in terms of the final product, to how the mRNA vaccines work.

In the United Kingdom and other places where this particular vaccine was prevalent, we did see a small number of people develop thrombocytopenia, or blood clotting that is initiated by a protein called platelet factor 4. It's a very rare side effect, but it was seen in a number of cases post-approval of this vaccine back in 2021 and the early part of 2022.

The news this week isn't news to the medical community. The reason it is coming to our attention is because AstraZeneca is now saying that this is a side effect of their vaccine. Initially, they was sort of hand-waving about the connection, saying that the development of the blood clots could be due to other factors, like a person's comorbidities, vascular disease or other secondary considerations. It wasn't clear that it was linked directly to the vaccine itself.

However, when you see that the majority of those who developed this condition did so post-vaccination—and it is in a very small percentage of those who received this vaccine, to be clear—the link becomes much more apparent. Now, they're admitting that the vaccine may be responsible.

When the AstraZeneca vaccine was initially suspected



in cases of thrombocytopenia, the causal mechanism wasn't clear. What do we know about how the vaccine might cause this condition?

Like I said before, the adenovirus has a DNA molecule inside it, which is then injected intramuscularly. But when in the bloodstream, this DNA molecule attracts a protein in the blood called platelet factor 4, and in certain individuals—not in all, but in a very small number—platelet factor 4 can exaggerate the body's own immune response.

Typically when you see clot formation in the body, it's a mechanism by which the body is attempting to shield something from everything else in our body. It creates a capsule around the viral particle and recruits more platelets and <u>red blood cells</u> and fibrin, creating a blood clot, and this is referred to as thrombocytopenia.

The U.K., where this lawsuit is ongoing, has a pretty high uptake—about 150 million people—of the COVID-19 vaccine, but the majority of people there have received the Pfizer vaccine. This issue is not prevalent in the mRNA vaccines—at least, we haven't seen that level of clot formation here in the United States, where a majority of individuals have been vaccinated either with Moderna's or Pfizer's mRNA vaccine that is delivered using a lipid nanoparticle formulation.

But in terms of the number of cases of thrombocytopenia and whether this is truly an issue that should worry people, the mechanistic studies have already been conducted, and only a tiny fraction of individuals were affected. Also, we aren't seeing any other serious or new side effects associated with these vaccines.

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