The Guardian

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NHS told not to give Covid vaccine to those with history of allergic reactions

Two health service workers experienced symptoms after receiving Pfizer vaccine

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Wed 9 Dec 2020 13.01 GMT

People with a history of significant allergic reactions should not receive the Covid vaccine, the medicines regulator has said, after two NHS workers experienced symptoms on Wednesday.

Both of the NHS staff carry adrenaline autoinjectors, suggesting they have suffered reactions in the past. These devices, of which the best-known brand is the EpiPen, administer a swift adrenaline boost to counter allergic reactions that occur when some people, for instance, eat nuts.

The patient information leaflet with the Pfizer/BioNTech vaccine says it should not be given to people allergic to any substance in the vaccine.

“Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue,” says the leaflet.

The identities of the NHS workers and hospitals where they were vaccinated have not been disclosed. NHS England confirmed the two incidents and said all trusts had now been advised not to give the jab to people with a history of allergic reaction.

Prof Stephen Powis, the national medical director for the NHS in England, said: “As is common with new vaccines, the MHRA [Medicines and Healthcare products Regulatory Agency] have advised on a precautionary basis that people with a significant history of allergic reactions do not receive this vaccination, after two people with a history of significant allergic reactions responded adversely yesterday. Both are recovering well.”

The MHRA advice states: “Any person with a history of a significant allergic reaction to a vaccine, medicine or food (such as previous history of anaphylactoid reaction or those who have been advised to carry an adrenaline autoinjector) should not receive the Pfizer/BioNtech vaccine. Resuscitation facilities should be available at all times for all vaccinations. Vaccination should only be carried out in facilities where resuscitation measures are available.”

The NHS workers are said to have developed symptoms of “anaphylactoid reaction” shortly after receiving the vaccine, and both have recovered after treatment.

The MHRA recently paid the British firm Genpact (UK) Ltd £1.5m for an artificial intelligence software tool “to process the expected high volume of Covid-19 adverse drug reactions [ADRs] and ensure that no details from the ADRs’ reaction text are missed”.

However, the regulator declined to say whether the technology was already in place and had been monitoring possible adverse reactions when the rollout began on Tuesday or whether it had picked up any other bad reactions since then.

A spokesperson said: “We have a range of resources and technology to support the safety monitoring of any Covid-19 vaccination programme. The use of AI will be one element of that.”

It previously said it expected that between 50,000 and 100,000 people would have an adverse reaction for every 100m doses of Covid vaccine administered over the next six to 12 months.

Peter Openshaw, a professor of experimental medicine at Imperial College London, said: “As with all food and medications, there is a very small chance of an allergic reaction to any vaccine. However, it is important that we put this risk in perspective. The occurrence of any allergic reaction was one of the factors monitored in the phase 3 clinical trial of this Pfizer/BioNTech Covid-19 vaccine, the detailed data from which was released yesterday. In this, they reported a very small number of allergic reactions in both the vaccine and placebo groups (0.63% and 0.51%).

“Similar to the rollout of all new vaccines and medications, this new Covid-19 vaccine is being monitored closely by the Medicines and Healthcare Products Regulatory Agency. They will now investigate these cases in more detail to understand if the allergic reactions were linked to the vaccine or were incidental. The fact that we know so soon about these two allergic reactions and that the regulator has acted on this to issue precautionary advice shows that this monitoring system is working well.”

Pfizer UK said it had been advised by MHRA of the two yellow card reports. “As a precautionary measure, the MHRA has issued temporary guidance to the NHS while it conducts an investigation in order to fully understand each case and its causes. Pfizer and BioNTech are supporting the MHRA in the investigation,” it said.

“In the pivotal phase 3 clinical trial, this vaccine was generally well tolerated with no serious safety concerns reported by the independent data monitoring committee. The trial has enrolled over 44,000 participants to date, over 42,000 of whom have received a second vaccination.”

This article was amended on 10 December 2020 to incorporate a more suitable main photograph.