



Pharmacovigilance Drug Safety Alert

July 16, 2021

Real-Time Surveillance Detects Four Potential Adverse Events of Interest in Persons Aged 65 years & Older After Pfizer/BioNTech COVID-19 Vaccine

The FDA has routinely been using screening methods to monitor the safety of COVID-19 vaccines and to evaluate potential adverse events of interest (AEI) related to these vaccines.¹

On July 12, 2021 the FDA announced that one of these methods, called near real-time surveillance, detected four potential AEIs in the Medicare healthcare claims database of persons aged 65 years and older who had received the Pfizer/BioNTech COVID-19 vaccine. **The four potential AEI are pulmonary embolism, acute myocardial infarction, immune thrombocytopenia, and disseminated intravascular coagulation.** The screening methods have not identified these AEI after vaccination in persons 65 years and older who received the two other authorized COVID-19 vaccines.

These four events may not be true safety concerns, and the screening method cannot establish that the vaccine caused these AEI. The FDA is sharing the initial findings of this safety study in the spirit of transparency but does not believe there is a cause for concern. There are alternative explanations for the findings, including the fact that the Pfizer/BioNTech vaccine was given to many high-risk individuals who were older and had significant co-morbidities.

These events have not been identified as safety concerns or signals in the [CDC Vaccine Safety Datalink](#) (VSD) or the Veterans Administration (VA) Healthcare data systems screening methods. The Vaccine [Adverse Event Reporting System](#) (VAERS), another government monitoring system, also has not identified any association between any COVID-19 vaccine and these AEI.

The FDA continues to closely monitor the safety of the COVID-19 vaccines and will further investigate these findings by conducting more rigorous epidemiological studies. The FDA will share further updates and information with the public as they become available.

The FDA strongly believes that the known and potential benefits of COVID-19 vaccination greatly outweigh the known and potential risks of COVID-19. There is no need to delay vaccination while the FDA continues its investigation.

****Report all significant or unusual Adverse Vaccine Events (AVE) to the VAERS program as described in the [Indian Health Manual](#). Instructions for submitting an AVE can be found on the [IHS Pharmacovigilance website](#). Please ensure that you document "IHS" in field #26 of the form.**

References:

1. U.S. Food and Drug Administration, 2021 Safety and Availability Communications: [Initial Results of Near Real-Time Safety Monitoring of COVID-10 Vaccine in Persons Aged 65 Years and Older](#). Assess July 15, 2021.