Over 3,000 “Health Impact Events” After COVID-19 mRNA Vaccinations

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Between Dec. 11 and 18, 2020, the U.S. Food and Drug Administration (FDA) granted Pfizer/BioNTech and Moderna pharmaceutical companies an Emergency Use Authorization (EUA)[1] to distribute COVID-19 vaccines using messenger RNA (mRNA) technology that to date has not been licensed for use in humans.[2] [3] [4] [5] Although the Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control and Prevention (CDC) held two special Saturday meetings to create national vaccine use recommendations for the two vaccines,[6] [7] legally both vaccines remain experimental until they have been formally licensed by the FDA.[8] As initial supplies of the vaccines roll out into the states and health care workers treating COVID-19 patients in hospitals and medical facilities are the first to be vaccinated, reports of vaccine reactions are emerging.[9]

On Dec. 19, 2020, at a special meeting of the ACIP,[10] the CDC presented information released by the ACIP COVID-19 Vaccines Work Group “Anaphylaxis Following mRNA COVID-19 Vaccine Receipt.”[11] According to the CDC, by Dec. 18 there had been six case reports of anaphylaxis following Pfizer/BioNTech

vaccinations that met the Brighton Collaboration criteria for anaphylaxis, which is a potentially life threatening reaction that occurs when immune cells overreact to a substance that has entered the body and a hyper-inflammatory response is triggered involving sudden release of histamine and other chemicals that may cause:[12] [13]

- skin redness, hives, and itching;
- swelling of the eyes, lips, tongue, throat, hands, feet;
- trouble swallowing and breathing, wheezing;
- diarrhea or vomiting;
- abdominal or chest pain;
- fast or irregular heartbeat;
- dizziness, sudden drop in blood pressure;
- headache;
- confusion, vision and speech problems;
- shock/loss of consciousness;
- cardiac arrest;
- death

Foods are the most common triggers for anaphylactic reactions, followed by drugs/biologicals, insect stings, and idiopathic anaphylaxis (anaphylaxis of unknown cause). A shot of epinephrine is the first-line immediate treatment for anaphylaxis.[14]

Vaccines are known to cause allergic and anaphylactic reactions within minutes to four hours of vaccination, but CDC officials have long considered vaccine-associated anaphylaxis to be rare, stating in a 2018 study that:

> *Vaccine-associated hypersensitivity reactions are not infrequent; however, serious acute-onset, presumably IgE–mediated or IgG and complement-mediated anaphylactic or serious delayed-onset T cell–mediated systemic reactions are considered extremely rare.*

The CDC confirmed that one person, who had an anaphylactic reaction following administration of the Pfizer/BioNTech COVID-19 vaccine, had a previous history of anaphylaxis after a rabies vaccination. The CDC said the reported cases of anaphylaxis are being reviewed by federal health officials.[15]

CDC Reports More Than 3,000 "Health Impact Events" After COVID-19 Shots

At the Dec. 19 ACIP meeting, a chart entitled "V-safe Active Surveillance for COVID-19 Vaccines" was presented indicating that between Dec. 14 and Dec. 18, there were 272,001 doses of the Pfizer/BioNTech vaccine administered and 3,150 "Health Impact Events" recorded, including 514 events in pregnant women after receipt of the Pfizer/BioNTech vaccine. The chart gave no further details about the nature of the more than 3,000 Health Impact Events recorded by the CDC.[16]

The CDC's definition of Health Impact Events is "unable to perform normal daily activities, unable to work, required care from doctor or health care professional."

Great Britain First Reported Anaphylaxis Cases After COVID-19 Shots

Britain was the first country to vaccinate frontline health workers and the elderly with the Pfizer/BioNTech COVID-19 vaccine beginning on Dec. 8. Within 24 hours, *Reuters* reported that there had been two cases anaphylaxis and one possible allergic reaction in health care workers receiving the first doses of the vaccine. Reportedly, both health care workers had a history of allergic reactions and carried an epi-pen. On Dec. 9, the chief executive of Britain's Medicines and Healthcare Products Regulatory Agency (MHRA) stated that, "any person with a history of anaphylaxis to a vaccine, medicine or food should not receive the Pfizer/BioNTech vaccine."[17]

Alaska Health Care Workers Had Allergic Reactions to Covid-19 Vaccine

On Dec. 16, *The New York Times* reported that two health care workers in Alaska who got the Pfizer/BioNTech vaccine suffered allergic reactions. One worker had a reaction serious enough to require hospitalization.[18]

A middle aged woman with no history of allergies experienced shortness of breath, elevated heart rate and a rash covering her face and torso within 10 minutes of receiving the vaccine. She was immediately treated with epinephrine and her reaction subsided but then re-emerged and she was given IV epinephrine and steroids, hospitalized in the intensive care unit for one night and spent a second night in the hospital further recovering. According to *CNN*, the allergic reactions experienced by the two Alaska health care workers after the Pfizer/BioNTech COVID-19 vaccinations were reported to the federal Vaccine Adverse Events Reporting System (VAERS).[19]

History of Anaphylactic Reaction to Previous Dose of COVID-19 Vaccine Only Contraindication

The CDC states there is one contraindication to the Pfizer/BioNTech COVID-19 vaccine: "Severe allergic reaction (e.g. anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 vaccine listed in the prescribing information is a contraindication to vaccination." However, there is one precaution:[20]

> *CDC considers a history of severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy (e.g., intramuscular, intravenous or subcutaneous) as a precaution, but not a contraindication.*

Currently, the government does not consider a history of severe allergic reactions, including anaphylaxis, to foods, drugs, other vaccines or environmental substances to be a

reason to not receive mRNA COVID-19 vaccines.

Dermal Fillers May Be Associated with Facial, Lip Swelling After Moderna COVID-19 Shots

On Dec. 17, there was a report published in *Drug Discovery and Development,* that "temporary facial swelling might be another mild side effect for [Moderna Covid-19] vaccine recipients who have had prior dermal fillers," such as injectable hyaluronic acid (HA) used in certain plastic surgery procedures.

Reportedly, in Moderna's Phase 3 trials, three people developed facial or lip swelling after receiving the vaccine and two of the patients had prior dermal fillers in their cheeks within six months before vaccination. The third patient had received dermal filler in the lip two days after receiving the vaccine and had reported similar swelling in the past after receiving a flu vaccine. Antihistamines and steroids were used to treat the patients.

FDA Recommends Watching for Bell's Palsy After COVID-19 Vaccinations

On Dec. 15, *CNBC* reported that the FDA staff recommends monitoring people who get COVID-19 vaccines manufactured by Pfizer/BioNTech and Moderna for symptoms of Bell's palsy, which involves inflammation and paralysis of the nerve that controls facial muscles.[21] The recommendation came after clinical trial data for both vaccines was analyzed by FDA staff.

In trials of the Moderna vaccine involving about 30,000 participants, there were four reported cases of Bell's palsy and three had received the mRNA COVID-19 vaccine, while one received a placebo. In clinical trials of the Pfizer/BioNTech vaccine involving about 42,000 participants, there were four reported cases of Bell's palsy and all had received the experimental vaccine while no cases of Bell's palsy occurred in the placebo arm of the trial.

FDA staff said there wasn't enough data from the trials to determine causation, but that there should be increased monitoring for cases of Bell's palsy as the mRNA vaccines are given to millions of people.

Bell's palsy can cause facial paralysis (usually one side of face) and drooling, pain around jaw and ear, increased sensitivity to sound, headache, loss of taste and changes in production of tears and saliva.[22] It can develop after a viral infection and has been reported following influenza vaccination.[23] [24]

According to Mayo Clinic, "For most people, Bell's palsy is temporary. Symptoms usually start to improve within a few weeks, with complete recovery in about six months. A small number of people continue to have some Bell's palsy symptoms for life. Rarely, Bell's palsy can recur."[25]

Frequently Reported mRNA COVID-19 Vaccine Reactions

Both the Pfizer/BioNTech and Moderna COVID-19 vaccines require two doses given three to four weeks apart. The CDC states that most common side effects of mRNA COVID-19 vaccines are injection site redness and pain, fever, chills, fatigue (tiredness) and headache.

The CDC warns that, "these side effects may feel like the flu and may even affect your ability to do daily activities, but they should go away in a few days," and instructs people to "get the second shot even if you have side effects after the first one, unless a vaccination provider or your doctor tells you not to get a second shot."[26]

Vaccine Companies, Providers Shielded from Liability for COVID-19 Vaccine Injuries and Deaths

The vaccine manufacturers, doctors and all COVID-19 vaccine providers are completely shielded from civil liability for

vaccine injuries and deaths that occur in the U.S. after COVID-19 vaccinations under the Public Readiness and Emergency Preparedness (PREP) Act passed by Congress in 2005.[27] The Act gives a liability shield to the manufacturer of any vaccine or drug developed in response to a health emergency like a pandemic causes when a vaccine or drug causes the death or permanent injury of an individual who receives it during pre-licensure clinical trials or after it is released for public use.

Individuals who die or suffer serious harm directly caused by the administration of covered countermeasures, such as vaccines, may be eligible to receive compensation through the Countermeasures Injury Compensation Program operated by the U.S. Department of Health and Human Services,[28] whether or not the harm was a result of willful misconduct on the part of the vaccine manufacturer or person administering the vaccine.

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