Forensic Analysis of Deaths in Pfizer's mRNA Vaccine Trial Reveals Significant Inconsistencies

A group of researchers are calling Pfizer's and BioNTech's early trial data on its original COVID-19 vaccine into question after a forensic analysis revealed significant inconsistencies between data in the companies' six-month interim report and publications authored by Pfizer/BioNTech trial site administrators.

The preprint, published on Sept. 4, showed trial subjects vaccinated with Pfizer's COVID-19 vaccine experienced a 3.7 times increase in cardiovascular deaths compared to placebo controls—a "significant adverse event signal" not disclosed by Pfizer when the vaccine was authorized for emergency use. In addition, the analysis found numerous instances where Pfizer/BioNTech attributed potential vaccine-associated deaths to other causes and undermined vaccine safety data.

Clinical Trial ‘Cause of Death’ Unsupported by Documentation

Researchers from the DailyClout Pfizer/BioNTech Documents Investigations Team assessed data from Pfizer’s original phase two/three clinical trial involving 44,060 subjects equally divided into two groups. One group received a dose of Pfizer’s COVID-19 vaccine, and the other received a placebo. As part of their analysis, researchers reviewed the cause of death forms (CRFs) of 38 trial subjects who died during the study period from July 27, 2020, to March 13, 2021, the end date of the clinical trial.

They found that 14 of the 38 deaths—more than one-third of deaths—resulted from cardiovascular events, accounting for the difference between the 21 deaths in the vaccination arm compared to the 17 deaths in the placebo arm. In numerous cases, researchers found that documentation did not support the cause of death diagnosis or allow one to rule out the possibility of a cardiovascular event with an autopsy.

“In general, our review of the CRFs found them to be lacking in detail and extremely difficult to interpret and develop a good timeline of events,” researchers wrote. “Often, a subject’s pre-trial clinical history was absent. Absent also were results of the extensive array of medical testing carried out at the pre-trial screening and at other regularly scheduled visits.”

Absent test results included complete blood counts, metabolic tests, pregnancy tests, COVID-19 tests, a comprehensive list of active medications, and other tests that would have provided clarity on a subject’s overall health. Although more detailed clinical data on the trial subjects exists, the researchers said it is being withheld. Given the limitations of what Pfizer provided, the researchers said the information in the CRFs was often insufficient to support the

investigator's conclusions regarding the cause of death.

The researchers also noted frequent communications between Pfizer/BioNTech physicians and trial site medical staff about the CRFs, some of which were over 400 to 900 pages.

Pfizer Used Earlier Data Cutoff and Unblinded Control Group

According to the analysis, Pfizer excluded the 38 deaths from information provided to the U.S. Food and Drug Administration (FDA) during its December 2020 meeting where its vaccine advisory panel was considering whether to authorize the Pfizer/BioNTech vaccine for emergency use.

When Pfizer/BioNTech submitted its application for Emergency Use Authorization (EUA) on Nov. 20, 2020, to the FDA, the application described clinical trial results using a cutoff date of November 14, 2020, even though the end date of the trial was March 13, 2021. Researchers said the earlier cutoff date concealed mortality data from the clinical trial.

"Both Pfizer presenters and the FDA committee failed to ask for and review deaths that occurred in the clinical trial participants after the data cutoff. As a result, they missed a more than three-fold increased risk of cardiovascular death with the Pfizer-BioNTech COVID-19 vaccine," cardiologist Dr. Peter McCullough told The Epoch Times.

"If the FDA presentation with core slides had been presented with accurate, updated data, the Pfizer COVID-19 vaccine should not have been approved because of safety concerns," he added.

Twenty weeks into the clinical trial on Dec. 11, 2020, Pfizer's COVID-19 vaccine received EUA from the FDA, and the agency allowed Pfizer to unblind its control group. Unblinding occurs when study participants are told whether they received

a vaccine or a placebo, and placebo subjects are permitted to get vaccinated. All but a few chose to receive the vaccine.

All subjects continued to be followed for 24 months, and deaths were reported to Pfizer/BioNTech. Pfizer called the period from Dec. 11, 2020, to Jan. 24, 2021, the "open-label follow-up period" without explanation, and the period from Jan. 25, 2021, to the end date of the trial, March 13, 2021, as the cutoff date for the six-month interim report. According to the analysis, this made it easier to conceal deaths potentially linked to the vaccine.

A comparison of the number of deaths during the 33-week study period found no considerable difference between the deaths in the vaccinated versus the placebo groups for the first 20 weeks. After week 20, when participants in the placebo group were unblinded and vaccinated, deaths among the remaining unvaccinated cohort of this group slowed and then plateaued, while deaths in vaccinated subjects continued at the same rate. These inconsistencies were not explained by Pfizer/BioNTech or reported to the FDA, according to the analysis.

Vaccinated Placebo Group Death Cases Used to Obscure Trial Data

Documents obtained through the Freedom of Information Act (FOIA) show that 462 subjects in the placebo group received a dose of Moderna's COVID-19 vaccine, with deaths reported attributed to the unvaccinated control group, and the analysis identified numerous instances where Pfizer/BioNTech undermined potential vaccine-related deaths or used complex terms to obscure trial data.

For example, a 65-year-old male with a medical history of pulmonary fibrosis and hypertension was in the trial's placebo arm. He received doses 1 and 2 of the placebo on Sept. 30,

2020, and Oct. 21, 2020, respectively. After Pfizer/BioNTech unblinded the trial, he received his first dose of Moderna's COVID-19 vaccine on Dec. 23, 2020. Five days later, on Dec. 31, 2021, he reported symptoms of COVID-19 and was admitted to the hospital.

While hospitalized, he became hypoxic and was intubated. Efforts to treat him failed, and he died on Jan. 11, 2021. Pfizer's six-month interim report lists the subject as a "discontinued subject" and classified the death as a placebo death with COVID-19 as the secondary cause of death. The researchers said the subject should have been discontinued from the clinical trial entirely because he received a "non-study COVID-19 vaccine."

Another trial subject, a 53-year-old male with a history of chronic obstructive pulmonary disease and "stress-related myocardial infarction," died suddenly from "cardiopulmonary arrest" less than two months after receiving his second dose of Pfizer's COVID-19 vaccine. According to the analysis, the trial site's medical monitor listed the cause of death as "cardiopulmonary arrest related to myocardial infarction." Days later, Pfizer/BioNTech told the trial site that multiple causes of death could not be entered on the CRF and requested that "related to myocardial infarction" be deleted.

When the medical monitor wouldn't alter the entry's wording, Pfizer/BioNTech overrode the trial site and changed the cause of death to "cardiopulmonary arrest," omitting "myocardial infarction" as a secondary cause of death. Pfizer/BioNTech did not explain why a specific diagnosis of a serious adverse event was later changed to something undefined.

Another vaccine subject died within three days of receiving his first Pfizer vaccine dose. The medical examiner attributed the death to the progression of atherosclerotic disease, and Pfizer listed the cause of death in its six-month interim report as "atherosclerosis."

However, atherosclerosis was not documented in the subject's CRF as a comorbidity of the patient, nor did the subject's CRF include the pre-screening portion of comorbidities that would have shown whether the subject had a history of atherosclerosis. Furthermore, an autopsy would have confirmed whether the subject died from atherosclerosis, but autopsy results were unavailable. The subject's death was attributed to an underlying disease, yet the researchers said there is "no basis for ascribing the subject's death to advanced atherosclerosis or concluding that the death was unrelated to the vaccine" when the subject died "within a day or two" of vaccination.

Another subject died 76 days after receiving the first placebo dose. The primary cause of death was first listed as diabetes mellitus based on the subject's medical history. Yet the diagnosis was revised several times, despite the "presence of very high blood glucose levels," until COVID-19 pneumonia was listed as the secondary cause of death. In addition, the subject was HIV positive with an HIV RNA load over the acceptable limit for inclusion in the trial.

"The FDA should review these data immediately in addition to the mounting safety data and peer-reviewed manuscripts on vaccine injuries, disabilities, and deaths and move swiftly to remove all COVID-19 vaccines from the market," Dr. McCullough said.

FDA and Pfizer Attempted to Hide Health Outcomes of Trial Participants

When Pfizer/BioNTech filed its EUA in November 2020, the FDA didn't make the application containing clinical data available on its website for the general public or the medical community to evaluate until Dec. 11, 2020. Although an article was

published on Dec. 10, 2020, in The New England Journal of Medicine disclosing the interim results of the trial, it was authored by the trial site administrators who were "intimately aware of the trial's findings," researchers said.

The following year, in September 2021—after the Pfizer/BioNTech vaccine had received EUA—the same trial site administrators published another paper in The New England Journal of Medicine on the safety and efficacy of Pfizer's COVID-19 vaccine through six months.

With the "knowledge and approval" of the FDA, the preprint researchers said Pfizer and the FDA had no plans to disclose the clinical trial data that formed the basis of EUA for the Pfizer/BioNTech vaccine for 75 years, including the health outcomes of the 44,060 subjects who participated in the original trial. It wasn't until the Public Health and Medical Professionals for Transparency filed a FOIA lawsuit to obtain the original clinical trial data involved in the licensing of Pfizer/BioNTech's Comirnaty vaccine that data was made available and the problems with the initial clinical trial were revealed.

Release of the data to the Public Health and Medical Professionals for Transparency site began early in June 2022 and was projected to take eight months to complete. They have taken much longer than estimated and documents continue to be downloaded.

"Had it not been for the successful court case brought by the Public Health and Medical Professionals for Transparency, no one outside of the Pfizer and BioNTech corporations would have had the opportunity to investigate the original data generated by this clinical trial and none of the discrepancies reported here would have been revealed," they added.

The researchers said their analysis provides evidence the decision to authorize the Pfizer COVID-19 vaccine as a safe

and effective means of controlling the pandemic was not an “informed decision based on an unbiased, thorough, and transparent evaluation of the evidence.”

Despite early warning signals and other reported adverse events in the post-marketing of mRNA vaccines, the Pfizer vaccine has not been removed from the market and has been approved for the nation’s youngest children. At the very least, the researchers said they hope their analysis will inform physicians and other medical professionals of the dangers of the mRNA vaccines so that they can better advise their patients on the personal risks compared with the benefits of getting vaccinated. “This would return healthcare decisions back to individuals and their medical providers where it belongs.”