Undisclosed Deaths in the Pfizer mRNA COVID-19 Vaccine Trial: Will There Be Accountability?

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ABSTRACT

The Pfizer/BioNTech and Moderna COVID-19 mRNA vaccines received Emergency Use Authorization (EUA) in December 2020 after only about 20 weeks of testing. Troubling but unacknowledged serious adverse events occurred in the Pfizer/BioNTech clinical trial. Flaws in the FDA's clinical trial review procedures may have contributed to these lapses. Proposed changes could strengthen this critically important evaluation process. The artificially foreshortened Emergency Use Authorization approval process required by the PREP Act likely amplified existing problems in FDA clinical trial procedures regarding evaluation of the COVID-19 vaccines.

Two Undisclosed Deaths

In the 2020 Phase 2/3 clinical trial of the Pfizer mRNA COVID-19 vaccine, a 63-year-old trial participant from Kansas (Subject 11141050), who was enrolled in the treatment arm, died on Oct 19, 2020, 41 days after receiving dose 2 of BNT162b2. That same day, her emergency contact informed the clinical trial site of her death. In the 6-month narrative documentation covering all subject deaths in the trial, it was stated she had had an autopsy, and her cause of death was found to be "sudden cardiac death."[1,2]

Another U.S. participant from Georgia (Subject 11201050), age 58, also enrolled in the active arm of the trial, died in her sleep on Nov 7, 2020. She did not have an autopsy, and the coroner pronounced her cause of death as "cardiac arrest."[1,3]

Neither death was disclosed to regulators when the drug was evaluated for approval.

FDA Approval Process

To understand how this data lapse could have occurred, one needs to understand the FDA's process for vaccine evaluation and approval. The vaccine manufacturer, in this case Pfizer/BioNTech, oversaw the clinical trial, which means subject enrollment, administration of the treatment (vaccine or placebo), monitoring of subject health, and recording/storage of all subject health and testing information as defined in the trial protocol. Typically, at the end of the clinical trial, the accumulated data and documentation is submitted to the FDA's Vaccine and Related Biological Products Advisory Committee (VRBPAC), a committee of 15 voting members with expertise in infectious disease and vaccines, plus other non-voting and ex officio members. The VRBPAC "reviews and evaluates scientific data on the safety and effectiveness of vaccines and provides independent advice on these issues to the FDA Commissioner." The FDA Commissioner decides whether to approve the vaccine. The Commissioner does not have to follow the VRBPAC recommendation.

The Pfizer/BioNTech COVID19 mRNA vaccine clinical trial was far from typical. The trial protocol[4] was part of "Warp Speed" and a "declared health emergency," as defined by the 2005 US PREP (Public Readiness and Emergency Preparedness) Act. VRBPAC evaluation needed to occur while the trial was still ongoing and actively accumulating data! Pfizer was seeking to obtain Emergency Use Authorization (EUA) of its vaccine as a "countermeasure" (in PREP Act terminology). Pfizer's application for EUA of their vaccine only considered data accumulated from the trial start date of Jul 27, 2020, up to the cutoff date of Nov 14, 2020.[5] The EUA application was submitted to the FDA and VRBPAC on Nov 20, 2020. The submission included not only the EUA application[5] but also the accumulated data and documentation on the 44,060 enrolled subjects. VRBPAC met 20 days later, on Dec 10 to hear Pfizer present a summary of the clinical trial findings and discuss issues regarding safety and efficacy of the BNT162b2 vaccine.[6] After only 20 days to independently review and evaluate the clinical trial results, VRBPAC made a positive recommendation to the FDA. The Pfizer/BioNTech mRNA COVID19 vaccine EUA was approved on Dec 11, 2020.

We are part of the team that carried out a forensic review of the 38 subject deaths that occurred in the first 6-month period of the Pfizer COVID19 mRNA vaccine clinical trial.[7] This team reviewed more than half a million pages of Pfizer's original documentation. These are the same documents and data files provided to the FDA that formed the basis of the EUA approval of the vaccine. The FDA intended to delay disclosure of Pfizer's original trial documentation for 75 years. This decision was overruled by court order, and the documents began to be released to the public in January 2022.[8]

Evaluation of the documentation by the VRBPAC must have been an overwhelming task. The clinical trial documentation was submitted on Nov 20, 2020, and the committee met only 20 days later to decide whether to approve Pfizer's EUA. Given this highly compressed timeframe, it is likely that the VRBPAC relied heavily on the information disclosed by Pfizer at the Dec 10 meeting. At this meeting, Pfizer reported that six subjects had died during the first 20 weeks of the clinical trial (Jul 27–Nov 14, 2020), two in the vaccinated arm and four in the placebo.[5] These data were also reported in Polack et al.[9] and in Thomas et al.[10] In the forensic review by Michels et al.[7] the subject ID of each of these six patients was identified. Much to our surprise, the two vaccinated subject deaths highlighted above from Kansas and Georgia were not included in either the VRBPAC presentation or in Polack et al.[9] even though their deaths occurred well within the reporting period Jul 27–Nov 14, 2020. Thus, two subject deaths were "hidden" from the FDA evaluators at a critical point, evaluation of the EUA application.

Of the two deaths in the vaccinated arm that were disclosed to the VRBPAC, one was a 60-year-old man (Subject 11621327) found dead in his house by the police three days after Dose 1 of the BNT162b2 product.[7] The police went to his house to perform a welfare check and found his body cold with visible lividity. The proximity of his death to receiving Dose 1 of the study intervention

was not mentioned in Polack et al.[9] and was only briefly mentioned in the VRBPAC briefing report. According to the medical examiner, the probable cause of death was "progression of atherosclerotic disease". According to the documentation released to date, no autopsy was carried out on this individual to confirm the stated cause of death. Nonetheless, the trial site investigator's opinion was, "...there was no reasonable possibility that the arteriosclerosis was related to the study intervention, concomitant medications, or clinical trial procedures." What was the evidentiary basis that medical regulators such as the FDA and Australia's Therapeutic Goods Administration (TGA) relied upon to accept this conclusion? This question was posed to Professor Lawler of the TGA,[11] but a reply has not been received.

Who is responsible for the very lengthy delay in recording the two "hidden deaths" described above? According to Pfizer's own study protocol, serious adverse events were to be reported to Pfizer within 24 hours.[4] Careful review of the case report forms of these two subjects[2,3] and the 6-month narratives on subject deaths[1] revealed significant delays in recording the date the subject died that may have contributed to the data discrepancies.[7] In fact, based on the 6-month interim report,[12] 11 deaths had occurred in the period up to the Nov 14, 2020, data cutoff (six vaccinated and five placebo), not the six subject deaths publicly disclosed.[5,9] This discrepancy was shown to result from lengthy delays in recording the actual date of death in the subject's records. It should be noted that significant recording delays were not observed in placebo subject deaths.[7]

The forensic analysis of Michels et al.[7] uncovered a multi-layered convoluted series of steps between the trial site and Pfizer that was required to record information on subjects' health events in their records. The process was not transparent to an independent observer. It is likely that the delays originated from this recording process. For the Kansas and Georgia subjects, there was clear documentation that their loved ones had called the clinical trial sites on the day the subjects died to inform them of their deaths.[1] This suggests that, at least in these two cases, the problem lies at a level above that of the trial site.

Equally concerning is the fact that the VRBPAC members failed to ask Pfizer for an update on the number of subject deaths that occurred between Nov 14, the data cutoff date for the EUA application, and Dec 10, the date of the VRBPAC meeting. Had they asked, the VRBPAC would have become aware of an additional six subject deaths that occurred during that interval (two in the vaccinated and four in the placebo arm). A total of 17 subject deaths occurred by the date of the VRBPAC meeting (eight vaccinated and nine 9 placebo).[7] Had these accurate results been presented at the VRBPAC meeting, it would have been clear that the vaccine did not save lives.

By the end of the 6-month interim period of this trial (Mar 13, 2021), there were 21 deaths in the vaccinated arm, and 17 in the placebo. Of the 21 deaths of vaccinated subjects, 10 were found dead or suffered sudden adult death.[7] These were subjects who never woke up from their sleep (subject 11201050); collapsed while walking (subject 11361102); found dead while sitting cross-legged, leaning forward and blue in the face, in the laundry (subject 11271112); found dead in their apartment when neighbours alerted loved ones because of the odor (subject 11291166).[7]

Of those 10 sudden deaths, only two were autopsied, with only one result (the Kansas subject—sudden cardiac death) reported in the publicly available clinical trial documentation. Nonetheless, the investigators repeatedly concluded that although both subjects were in the active arm of a study of a novel therapeutic product, there could be "no reasonable possibility that the death could be due to the study intervention, concomitant medication or clinical trial procedures." In all these cases, Pfizer concurred with the trial site investigator's causality assessment. For Subject 11271112, the conclusion that the death could not be due to the study intervention was made while there was an autopsy report pending, which is still pending to this day.

The 17 placebo subject deaths paint a different picture. Five were sudden deaths, almost half as many as in the vaccinated arm. Of these only two autopsies were performed, with only one result available (aortic rupture as the cause of death). Three of the placebo subject sudden deaths were reportedly due to cardiac events. The primary cause of death of the remaining 12 placebo subjects varied: drug overdose, hemorrhagic stroke, bacterial pneumonia, cancer, diabetes, multi-organ dysfunction syndrome, respiratory failure. COVID-19 is listed as the secondary cause of death in five placebo subject deaths but only one death of a vaccinated subject.

In summary, the clear cardiac event / sudden death signal observed in the vaccinated arm of the trial is not observed in the placebo arm. While there were more COVID19-related deaths of placebo subjects, these might have been avoided had appropriate respiratory virus treatment been provided these subjects earlier.

Other Instances of Clinical Trial Malfeasance

Examples of clinical trial malfeasance are slowly coming to light but are difficult to bring to the public's attention. Rofecoxib (trade name Vioxx™) received FDA approval on May 21, 1999. As stated by Topol,[13] "On September 30, 2004, after more than 80 million patients had taken this medicine and annual sales had topped $2.5 billion, the company withdrew the drug because of an excess risk of myocardial infarctions and strokes. This represents the largest prescription-drug withdrawal in history but had the many warning signs along the way been heeded, such a debacle could have been prevented." Topol asked for a Congressional review, but this never happened.

When examining the clinical trial documents that formed the basis of rofecoxib approval, Psaty and Kronmal[14] found that deaths were underrepresented by the trial sponsor by removing patients who died after they had completed their course of rofecoxib. The trial sponsor for rofecoxib, Merck Sharp Dohme, paid nearly a billion dollars in fines over the course of several judgements.[15]

Another example involves AstraZeneca's heart medication ticagrelor (Brilinta™, Brilique™), which has been discussed in the medical literature in case studies. Analysis of clinical trial results found evidence of serious misreporting and lapses of data integrity.[16,17] Despite this, ticagrelor is still in regular use following the insertion of heart stents instead of the effective and well-tolerated Plavix™ (clopidogrel).

Reporting Delays for Serious Adverse Events and Other Data Discrepancies

Here we are again, more than a decade later, and significant problems in clinical trial oversight persist with yet another example of inaccurate reporting of clinical trial participants' deaths. The Pfizer/BioNTech clinical trial documents reference a

Vaccine Serious Adverse Event Reporting Form.[4] The FDA has yet to publicly release these forms, making it impossible to establish an accurate reporting timeline. Moreover, a far more convoluted process of recording and scrutinizing Serious Adverse Event reports is suggested in the available documents.[7] It is important to note that significantly longer recording delays were found only for subjects in the vaccinated arm of the trial and only before Dec 11, the date the FDA approved Pfizer's EUA application.[7] Recording delays in the placebo arm of the trial were shorter and consistent before and after approval. Once EUA approval was obtained, recording delays in the vaccinated arm were comparable to delays observed in the placebo arm. This finding strongly suggests that the longer delays observed in the vaccinated arm were not merely due to chance or clerical error.

Michels et al.[7] revealed a multitude of data discrepancies including but not limited to delayed reporting of deaths, misrepresentations, and obfuscations that hid a 3.7-fold increase in cardiac events in subjects who received the BNT162b2 vaccine versus the placebo. Whether these findings rise to the level of "willful misconduct" must be decided by the FDA, CDC, or perhaps Congress. The great misfortune is that the treatment under evaluation, mRNA COVID19 vaccine, was ultimately administered to billions of individuals worldwide who are now suffering the consequences.

The increased cardiac events signal revealed by Michels et al.[7] soon became a reality as the mRNA COVID vaccines were rolled out to the world. In spring of 2025, U.S. Senator Ron Johnson, chairman of the Senate Permanent Subcommittee on Investigations, released an interim report entitled "The Corruption of Science and Federal Health Agencies: How Health Officials Downplayed and Hid Myocarditis and Other Adverse Events Associated with the COVID-19 Vaccines."[18] As early as Feb 28, 2021, the U.S. CDC was notified by the Israel Ministry of Health of large numbers of cases of myocarditis following the administration of the Pfizer vaccine, particularly in young people. Throughout April and May 2021, the FDA and CDC discussed whether the public should be alerted to this clear myocarditis/pericarditis signal but did nothing!

In late June 2021 they relented. Published case reports of deaths due to vaccine-associated myocarditis and pericarditis could no longer be ignored.[19-21] Finally, the CDC and FDA reported a "suggested increased risks" of myocarditis and pericarditis from the Moderna and Pfizer COVID-19 vaccines and ordered relevant changes to their safety labels. Shamefully, the danger was minimized by telling parents that the heart damage was "temporary." By this point, the damage had been done. Thousands of teenagers had been needlessly vaccinated. In a 2024 interview made shortly before his death, German pathologist Arne Burkhardt described in detail his demonstration of vaccine-induced inflammation in blood vessels and in all major organs, including myocarditis with associated spike protein expression.[22]

We have already shown that for one of the "hidden deaths," the 63-year-old subject from Kansas, there was a 37-day delay in entering her death in her Case Report Form (CRF).[23] There is evidence in her CRF that her autopsy report of "sudden cardiac death" was available prior to the Dec 10 VRBPAC meeting. On Dec 9, 2020, a clinical researcher was asking whether the cause of death was still unknown, as the safety database had been updated to "sudden cardiac death." This full autopsy report is not part of the publicly available documentation. We wonder whether the VRBPAC reviewers would have hit a pause button on approval if, on Dec 10, 2020, they had reviewed this autopsy report? Why did the VRBPAC reviewers, and ultimately the FDA, accept that a subject with a BMI of 27.2 (weight 74.1 kg, height 165 cm) had risk factors of obesity and hypertension (with no blood pressure readings recorded in her case notes) sufficient to put her at high risk of "sudden cardiac death"?

Reforms Needed to Restore Public Trust

Public trust must be restored in the government's ability to oversee the pharmaceutical industry. Clinical trials are a necessary tool to find new ways to treat disease and ensure that those treatments are safe and effective. We depend on drug regulators to ensure that ethical and safety concerns of the clinical trial participants and the public at large are protected. Participants in these trials often participate to help others and to contribute to moving science forward.[24]

The evidence of "hidden deaths" in the Pfizer/BioNTech mRNA COVID19 vaccine clinical trial raises a serious red flag regarding the integrity of the evidence reporting system, at least for this trial. Investigation into concerns we have raised here should strive to establish accurate timelines as to when adverse event reporting occurred. Improved systems for clinical trial data entry, recording, and storage involving few human intermediaries, will go a long way toward correcting the current flaws in clinical trials procedures.

We applaud recent efforts by President Trump's administration to upgrade clinical trial evaluation methods. Platforms capable of integrating electronic data capture, clinical trial management systems, and analytics tools are in advanced stages of development (TrialAlign, CRIO, Medidata's Intelligent Trials, to name a few). These systems could provide real-time access to trial information clinical trial data. On May 23, 2025, President Trump signed an Executive Order entitled "Restoring Gold Standard Science," which "ensures that agencies practice data transparency, acknowledge relevant scientific uncertainties, be transparent about the assumptions and likelihood of scenarios used, approach scientific findings objectively, and communicate scientific data accurately."[25,26]

Other factors must also be addressed. The structure and function of the FDA advisory committees should be evaluated with particular focus on decreasing the term of membership and strengthening the review of members' conflicts of interest. Additionally, unbiased decision-making would be significantly ensured if independent evaluators (not members of VRBPAC or the FDA) were allowed unfettered access to clinical trial data prior to the advisory committee meeting and allowed to actively contribute to the review process. Post-marketing surveillance methodology to evaluate the safety and efficacy of vaccines and other treatments also must be continually improved and results made available to the public. In the early 2000s, a collaboration between the CDC and several U.S. health maintenance organizations, such as Kaiser Permanente, developed the Vaccine Safety Datalink.[27-30] The method, called rapid cycle analysis (RCA), utilizes these real-time data sources and enhanced analytic approaches to monitor a large patient population for adverse health events. The strengths of this approach are its power to detect rare event signals missed in clinical trials with smaller subject numbers and its rapid response capabilities.

The changes outlined above would significantly strengthen the clinical trial review processes of the FDA but do not fully

address the unique problem encountered in review of the Pfizer/BioNTech or Moderna mRNA COVID19 vaccines. These vaccines were "countermeasures" for a declared health emergency and thus were candidates for Emergency Use. The PREP Act with its artificially foreshortened Emergency Use Authorization approval process was the most significant contributing factor to the flawed review process afforded the mRNA COVID19 vaccine. Many of the flaws presented here are inherent to and an integral part of the Emergency Use Authorization process.

Conclusions

The FDA's clinical review process has many weaknesses. The COVID-19 vaccine emergency "countermeasures" presented a unique problem. Repeal of the PREP Act is the only way to ensure that an inadequately tested treatment of any kind will not be foisted on an unsuspecting population ever again.

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