SOURCE:

https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf

Subsequently, a working group of the Brighton Collaboration reviewed the history of VAED and wrote a series of definitions. Their paper was released on February 23, 2021. "Vaccine-associated enhanced diseases (VAED) are modified presentations of clinical infections affecting individuals exposed to a wild-type pathogen after having received a prior vaccination for the same pathogen." In other words, VAED refers to a case of COVID-19 after vaccination that is unusual or more severe than normal. VAERD was defined as "disease with predominant involvement of the lower respiratory tract." Of note, **one of the authors, Fernando P. Polack, of the Brighton Collaboration report was the primary author of the Pfizer study on BNT162b2 which formed the basis of the emergency use authorization (EUA) by the FDA.** Vaccine-associated enhanced disease: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data - PMC (nih.gov)

The report cites as examples atypical measles and enhanced RSV infection, where "severe disease has been documented resulting from infection in individuals primed with non-protective immune responses against the respective wild-type viruses." Furthermore, the authors state, "**VAED always involves a memory response primed by vaccination** and, in the experiences best characterized until now, targets the same organs as wild-type infections." (Emphasis added.)

The authors go on to say, "As the clinical manifestations of VAED lies (sic) within the spectrum of natural disease – occurring more frequently and/or severely in vaccinated individuals – it is also **difficult to separate vaccine failure (also called breakthrough disease) from VAED in vaccinated individuals. All cases of vaccine failure should be investigated for VAED.**" (Bold added.) (Interestingly, cases of COVID-19 in vaccinated patients were quickly labeled "breakthrough" cases in 2021, without any indication that the Brighton recommendation to investigate for VAED was followed.)

Additionally, they concluded, "The broad spectrum of natural disease manifestations in different populations and age groups makes it **very difficult, if not impossible, to determine how severe COVID-19 infection *would have been* in the absence of vaccination in the individual case."** (Italics in the original, bold added.) Along with this, they state, "Identifying cases of VAED/VAERD might be impossible when assessing individual patients, however, in clinical studies, a control group is helpful to compare the frequency of cases and the severity of illness in vaccinees vs. controls, including the occurrence of specific events of concern such as hospitalization and mortality."

> Pfizer's Phase 2/3 vaccine trial, C4591001, was a randomized controlled trial with a vaccinated group and a placebo (unvaccinated) group. This type of design is considered the gold standard for scientific investigation. The trial was to have two years of follow-up of the vaccinated and placebo groups. However, in December 2020, when the FDA granted Emergency Use Authorization for BNT162b2, Pfizer asked for and received permission from the FDA to unblind the study and offer the vaccine to placebo individuals. Most of them accepted and were vaccinated by March 2021. So a control group no longer exists. This is the only randomized placebo-controlled trial of the Pfizer vaccine. No subsequent trial meets this standard.

Given the above statements, one would assume that Pfizer would have reported as potential VAED the 2,391 COVID-19 cases from Table 7 of *5.3.6*. Recently released DailyClout Report 90 records 2,585 serious adverse events in this group of COVID-19 cases. **That sounds like VAED**. There were **136 fatalities**. Other outcomes were "547 not resolved, 558 resolved/resolving, nine resolved with sequelae, and **2,110 unknown (63%)**." DailyClout Report 90 goes on to say, "The number of unknown outcomes is disproportionately large compared to the other SOCs in Table 7. If one postulated that all the fatalities, and all the 'not resolved,' 'resolved/resolving,' and 'resolved with sequelae' adverse events were serious, that still leaves **over 1,300 *serious* adverse events with unknown outcomes**. **Why were so many outcomes unknown? What happened to these patients?**" Again, these cases are very suggestive of VAED, particularly since most cases of COVID-19 are mild.

The Brighton Collaborative protocols are rigorous and demand testing that was unrealistic for the general population in early 2021. For the average person in the community to document seronegative status for COVID-19 infection prior to contracting COVID would be unrealistic outside of participating in a clinical study. Even finding non-PCR COVID-19 tests in the early months of the pandemic was problematic. At this same time and under these constraints, the Brighton working group concluded:

> **"LEVEL 1 of Diagnostic Certainty (Definitive case)"**
> "The working group considers that a Definitive Case (LOC 1) of VAED cannot be ascertained with current knowledge of the mechanisms of pathogenesis of VAED."

Post Marketing Team