

https://www.phmpt.org/wpcontent/uploads/2022/04/reissue _5.3.6-postmarketingexperience.pdf

Now go back to Pfizer's conclusion, on page 11 of 5.3.6: "None of the 75 cases could be definitively considered as VAED/VAERD." Of course not. Brighton has conceded that a Level 1 diagnosis cannot be reached with current knowledge.

But what about Level 2 or Level 3? To examine VAED and VAERD seriously and responsibly in the BNT162b2-vaccinated population, Pfizer should have begun with Level 2 (probable) or Level 3 (possible) cases. Level 2A and Level 3A require documentation, with a blood test, that an individual has not had prior COVID-19. That information was simply not readily available in early 2021.

Now Level 2B and Level 3B (see Green Box) start with COVID-19 infection in an individual with no prior history of infection. These two levels of certainty do not require a negative antibody test. The next requirement is a positive COVID test. DailyClout Report 90 documents 415 cases with positive SARS-CoV-2 tests. It reports 51 cases of COVID-19 pneumonia. For the cases to be reported as COVID-19 pneumonia, it is reasonable to assume the 51 cases had a positive COVID-19 test. They certainly had severe disease, possibly enough to qualify as VAERD.

LEVEL 2B

A probable case of VAED is defined by the occurrence of disease in a vaccinated individual with no prior history of infection and unknown serostatus, with:

Laboratory confirmed infection with the pathogen targeted by the vaccine

Clinical findings of disease involving one or more organ systems (a case of VAERD if the lung is the primarily affected organ)

Severe disease as evaluated by a clinical severity index/score (systemic in VAED or specific to the lungs in VAERD)

Increased frequency of severe outcomes (including severe disease, hospitalization and mortality) when compared to a non-vaccinated population (control group or background rates)

Evidence of immunopathology in target organs involved by histopathology, if available. [Editorial note from the authors: Specific tests are enumerated, not documented in 5.3.6].

No identified alternative etiology

LEVEL 3B

A possible case of VAED is defined by the occurrence of disease in vaccinated individual with no prior history of infection and unknown serostatus, with:

Laboratory confirmed infection with the pathogen targeted by the vaccine

Clinical findings of disease involving one or more organ systems (a case of VAERD if the lung is the primarily affected organ)

Severe disease as evaluated by a clinical severity index/score (systemic in VAED or specific to the lungs in VAERD)

Increased frequency of severe outcomes (including severe disease, hospitalization and mortality) when compared to a non-vaccinated population (control group or background rates)

No identified alternative etiology

In summary, in Table 5, Pfizer admits to 75 severe cases of COVID-19. These 75 cases fit the Level 3B criteria for possible VAED and should not have been dismissed because they did not fit the nonexistent Level 1 definition of VAED. In addition, there are at least several hundred more cases in Table 7 under the COVID-19 AESIs, reviewed for severity of cases in DailyClout Report 90, which are suspicious of VAED.



The focus of this review, thus, returns to Pfizer's initial statement: "No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time." The discussion and the data presented above bring severe doubt about the veracity of those assertions. Certainly, Pfizer's own data bring into doubt its ability to support its "safe and effective" mantra. Pfizer and the FDA have had a way forward to prove SAFETY but for over two years have failed to do so.

