War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 20:

Vaccine-Associated Enhanced Disease (VAED)* Review of 5.3.6

*including Vaccine-Associated Enhanced Respiratory Disease (VAERD)

SOURCE:
https://www.phmpt.org/wp-content/uploads/2022/04/reissue 5.3.6-postmarketing-experience.pdf

5.3.6 AE REPORTING PERIOD:

"Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021."

5.3.6 AE CASES/EVENTS:

TOTAL AE CASES: 42,086

TOTAL AE EVENTS: 158,893

ABBREVIATIONS:

5.3.6 : Pfizer source document

SOC : System Organ Class

AE : Adverse Event

AESI : Adverse Event of Special Interest

EUA : Emergency Use Authorization by FDA

PM : Post-Marketing

BNT162b2 : Pfizer's mRNA COVID-19 vaccine

SEQUELAE: an abnormal condition resulting from a previous disease, injury, or other trauma

AGE GROUPS defined in 5.3.6 (p. 25 footnote) :

Adult	18 - 64
Elderly	≥ 65
Child	2 - 11
Adolescent	12 - < 18
Infant	1 – 23 months

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Vaccine-Associated Enhanced Disease (VAED), including Vaccine-Associated Enhanced Respiratory Disease (VAERD)	No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time. An expected rate of VAED is difficult to establish so a meaningful observed/expected analysis cannot be conducted at this point based on available data. The feasibility of conducting such an analysis will be re-evaluated on an ongoing basis as data on the virus grows and the vaccine safety data continues to accrue. The search criteria utilised to identify potential cases of VAED for this report includes PTs indicating a lack of effect of the vaccine and PTs potentially indicative of severe or atypical COVID-19[a]. Since the first temporary authorization for emergency supply under Regulation 174 in the UK (01 December 2020) and through 28 February 2021, 138 cases [0.33% of the total PM dataset], reporting 317 potentially relevant events were retrieved: Country of incidence: UK (71), US (25), Germany (14), France, Italy, Mexico, Spain, (4 each), Denmark (3); the remaining 9 cases originated from 9 different countries; Cases Seriousness: 138; Seriousness criteria for the total 138 cases: Medically significant (71, of which 8 also serious for disability), Hospitalization required (non-fatal/non-life threatening) (16, of which 1 also serious for disability), Life threatening (13, of which 7 were also serious for hospitalization), Death (38). Gender: Females (73), Males (57), Unknown (8); Age (n=132) ranged from 21 to 100 years (mean = 57.2 years, median = 59.5); Case outcome: fatal (38), resolved/resolving (26), not resolved (65), resolved with sequelae (1), unknown (8); Of the 317 relevant events, the most frequently reported PTs (≥2%) were: Drug ineffective (135), Dyspnoea (53), Diarrhoea (30), COVID-19 pneumonia (23), Vomiting (20), Respiratory failure (8), and Seizure (7). Conclusion: VAED may present as severe or unusual clinical manifestations of COVID-19. Overall, there were 37 subjects with suspected COVID-19 and 101 subjects with confirmed COVID-19 following one or both doses of the vaccine; 75 of the 101 cases were severe, resulting in hospitalisation, disability, life-threatening consequences or death. None of the 75 cases could be definitively considered as VAED/VAERD. In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue.

https://www.phmpt.org/wpcontent/uploads/2022/04/reissue_5.3.6-postmarketiexperience.pdf

- **Adverse Events were reported to Pfizer during a 90-day period, following the December 1, 2020, public rollout of its COVID-19 experimental "vaccine" product.**
- **In the Pfizer 5.3.6 document, these AEs were categorized by System Organ Classes (SOC) – in other words, by systems in the body.**

VAED refers to a case of post-vaccination COVID-19 that is unusual or more severe than normal. Table 5 of *5.3.6* starts by stating, "No post-authorized AE reports have been identified as cases of VAED/VAERD, therefore, there is no observed data at this time." However, Pfizer reported a long list of illnesses experienced by patients who had had one or both doses of its vaccine and subsequently developed suspected or proven COVID. Thousands of those COVID cases and COVID-related serious adverse events appear to qualify as VAED or VAERD.

In the VAED/VAERD table on page 11, 138 patients had 317 "relevant events,", i.e., conditions or diseases**.** Of the 138 patients from 17 countries, 101 patients had confirmed COVID-19. Thirty-seven had suspected COVID-19. Times from vaccine administration to onset of COVID-19 illness and associated conditions were not reported. There were 130 patients with known gender: 73 females, and 57 males. Ages ranged from 21 years to 100 years with half of the patients over 59.5 years of age. Outcomes included **38 deaths, 65 cases were not resolved**, 26 resolved or resolving, **one resolved with sequelae, and eight unknown.**

All 138 cases, including 38 deaths, were deemed serious. Of the 100 non-fatal cases, 13 were considered life threatening, 16 were hospitalized with non-life-threatening conditions (including one disability), and the remaining **71 patients were "medically significant,"** with eight of those "serious for disability". **These were sick patients.** Specific conditions named more than six times were: vaccine ineffective (135), shortness of breath (53), diarrhea (30), COVID-19 pneumonia (23), vomiting (20), respiratory failure (8), and seizure (7). Another 41 conditions were not stated.

Pfizer stated that, **of the subjects with confirmed COVID-19, "75 of the 101 cases were severe, resulting in hospitalization, disability, life-threatening consequences or death."**

Pfizer concluded:
"None of the 75 cases could be definitively considered as VAED/VAERD. In this review of subjects with COVID-19 following vaccination, based on the current evidence, VAED/VAERD remains a theoretical risk for the vaccine. Surveillance will continue."

Until now, there have been various terms to describe **a vaccine worsening a viral illness when compared to the natural infection in an unvaccinated individual**. Some of these terms are vaccine-mediated enhanced disease, enhanced respiratory disease, and antibody-dependent enhancement. In the Pfizer document *5.3.6*, the term "Vaccine Associated Enhanced Disease" (VAED) is used. **This syndrome is not theoretical** and has been identified since at least the 1960s when it was found with early Respiratory Syncytial Virus (RSV) and measles vaccines, and also later with a trial vaccine for HIV.

In March 2020, the Coalition for Epidemic Preparedness Innovations (CEPI) and the Brighton Collaboration Safety Platform for Emergency Vaccines met to discuss safety and design issues and risk assessment in rapidly developed vaccines. The particular issue arose because "some Middle East respiratory syndrome (MERS) and SARS-CoV-1 vaccines have shown evidence of disease enhancement in some animal models," which raised concerns about SARS-CoV-2 vaccines. Consensus summary report for CEPI/BC March 12–13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines - PMC (nih.gov)