War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 19 :

COVID-19 AESI Review of 5.3.6

SOURCE:
https://www.phmpt.org/wp-content/uploads/2022/04/reissue5.3.6-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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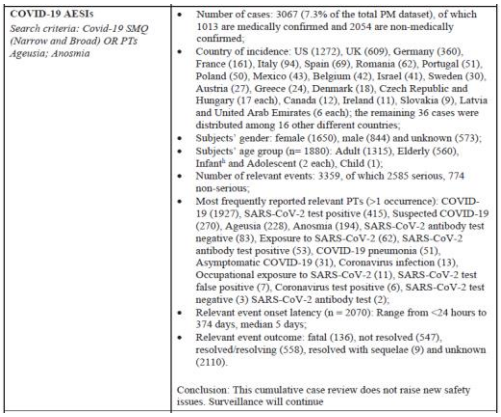

COVID-19 AESIs *Search criteria: Covid-19 SMQ (Narrow and Broad) OR PTs Agenusia; Anosmia*	• Number of cases: 3067 (7.3% of the total PM dataset), of which 1013 are medically confirmed and 2054 are non-medically confirmed; • Country of incidence: US (1272), UK (609), Germany (360), France (161), Italy (94), Spain (69), Romania (62), Portugal (51), Poland (50), Mexico (43), Belgium (42), Israel (41), Sweden (30), Austria (27), Greece (24), Denmark (18), Czech Republic and Hungary (17 each), Canada (12), Ireland (11), Slovakia (9), Latvia and United Arab Emirates (6 each); the remaining 36 cases were distributed among 16 other different countries; • Subjects' gender: female (1650), male (844) and unknown (573); • Subjects' age group (n= 1880): Adult (1315), Elderly (560), Infant[b] and Adolescent (2 each), Child (1); • Number of relevant events: 3359, of which 2585 serious, 774 non-serious; • Most frequently reported relevant PTs (>1 occurrence): COVID-19 (1927), SARS-CoV-2 test positive (415), Suspected COVID-19 (270), Ageusia (228), Anosmia (194), SARS-CoV-2 antibody test negative (83), Exposure to SARS-CoV-2 (62), SARS-CoV-2 antibody test positive (53), COVID-19 pneumonia (51), Asymptomatic COVID-19 (31), Coronavirus infection (13), Occupational exposure to SARS-CoV-2 (11), SARS-CoV-2 test false positive (7), Coronavirus test positive (6), SARS-CoV-2 test negative (3) SARS-CoV-2 antibody test (2); • Relevant event onset latency (n = 2070): Range from <24 hours to 374 days, median 5 days; • Relevant event outcome: fatal (136), not resolved (547), resolved/resolving (558), resolved with sequelae (9) and unknown (2110). Conclusion: This cumulative case review does not raise new safety issues. 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.**
- **Gender: 1,650 females and 844 males, with 573 unknown. Age: adult 1,315, elderly 560, two infant, two adolescent, and one child.** ***(BNT162b2 was not approved for infants and children at the time of this report).***

This AESI category consists of 3,067 cases reported related to COVID-19. It appears likely from the descriptions that **at least 2,391 of the adverse events were, indeed, COVID-19 infection**. The rest of the AEs were an assortment of COVID-19 exposures or COVID-19 test results, but none of these could be considered a serious adverse event (SAE). One must conclude that **all 2,585 serious AEs were related to COVID-19 infections (77% of the 3,359 adverse events)**.

There were 505 adverse events which were positive COVID-19 tests; included in this number are 31 patients who were reported to have "asymptomatic COVID-19." Pfizer did not clarify which test was used, other than 138 who had a SARS-CoV-2 antibody test. (Remember that, early in the pandemic, COVID-19 tests were in very short supply or nonexistent and of variable quality).

> The FDA definition of "serious" means patients died or had a life-threatening injury, were hospitalized, or had a pre-existing hospitalization prolonged, disability or permanent damage, experienced a birth defect, or required medical or surgical intervention to prevent permanent impairment or damage.

Fifty percent of the events began within five days of the injection, with a range from under 24 hours to 374 days. There is no information given as to whether these events occurred within five days of the first shot or the second. Regardless, half of the adverse events occurred before the vaccination was fully protective by Pfizer's definition (starting day 7 after the second shot). The other half, however, occurred after five days; so at least some of them likely occurred after complete vaccination. **It is hard to explain a range out to 374 days**, when the report covered only the first 90 days of the vaccine rollout and was received by the FDA in late April: the maximum range should have been under 150 days.

136 deaths

547 not resolved, 558 resolved/resolving, nine resolved with sequelae.

2,110 unknown (63%)

The number of unknown outcomes is disproportionately large compared to the other categories 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 those patients?**

COVID-19 cases are referenced in three places in 5.3.6: Table 2 reports **1,927** cases (4.6% of the 42,086 cases); Table 6 reports **2,211** cases (1,665 loss of efficacy cases and 546 COVID-19 cases excluded because they occurred so early after the first vaccine dose); and Table 7 with at least **2,391** cases.

Which figure is correct? Or should the three figures be combined? **The numbers don't add up.**

RECALL this unsafe "vaccine."