War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 2:

Thromboembolic System Organ Class (SOC) Review of 5.3.6

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."

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

THROMBUS: clot

EMBOLUS: broken off clot

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BNT162b2
5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

Table 7. AESIs Evaluation for BNT162b2

AESIs[a] Category	Post-Marketing Cases Evaluation[b] Total Number of Cases (N=42086)
(Primary Path) OR Respiratory failures (excl neonatal) (HLT) (Primary Path) OR Viral lower respiratory tract infections (HLT) (Primary Path) OR PTs: Acute respiratory distress syndrome; Endotracheal intubation; Hypoxia; Pulmonary haemorrhage; Respiratory disorder; Severe acute respiratory syndrome	• Countries of incidence: United Kingdom (20), France (18), United States (16), Germany (14), Spain (13), Belgium and Italy (9), Denmark (8), Norway (5), Czech Republic, Iceland (3 each); the remaining 12 cases originated from 8 different countries. • Subjects' gender (n=130): female (72), male (58). • Subjects's age group (n=126): Elderly (78), Adult (47), Adolescent (1). • Number of relevant events: 137, of which 126 serious, 11 non-serious; • Reported relevant PTs: Respiratory failure (44), Hypoxia (42), Respiratory disorder (36), Acute respiratory distress syndrome (10), Chronic respiratory syndrome (3), Severe acute respiratory syndrome (2). • Relevant event onset latency (n=102): range from < 24 hours to 18 days, median 1 day; • Relevant events outcome: fatal (41), Resolved/resolving (47), not recovered (18) and unknown (31). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Thromboembolic Events *Search criteria: Embolism and thrombosis (HLGT) (Primary Path), excluding PTs reviewed as Stroke AESIs, OR PTs Deep vein thrombosis; Disseminated intravascular coagulation; Embolism; Embolism venous; Pulmonary embolism*	• Number of cases: 151 (0.3% of the total PM dataset), of which 111 medically confirmed and 40 non-medically confirmed; • Country of incidence: UK (34), US (31), France (20), Germany (15), Italy and Spain (6 each), Denmark and Sweden (5 each), Austria, Belgium and Israel (3 each), Canada, Cyprus, Netherlands and Portugal (2 each); the remaining 12 cases originated from 12 different countries; • Subjects' gender (n= 144): female (89), male (55); • Subjects' age group (n=136): Adult (66), Elderly (70); • Number of relevant events: 168, of which 165 serious, 3 non-serious; • Most frequently reported relevant PTs (>1 occurrence) included: Pulmonary embolism (60), Thrombosis (39), Deep vein thrombosis (35), Thrombophlebitis superficial (6), Venous thrombosis limb (4), Embolism, Microembolism, Thrombophlebitis and Venous thrombosis (3 each) Blue toe syndrome (2); • Relevant event onset latency (n = 124): Range from <24 hours to 28 days, median 4 days; • Relevant event outcome: fatal (18), resolved/resolving (54), resolved with sequelae (6), not resolved (49) and unknown (42). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.

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- **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.**
- **In these first three months, post-FDA approval of the vaccine, Pfizer reported 151 cases of thromboembolic events.**
- **This made up 0.3% of the total Adverse Events reported, with the vast majority from Europe and North America.**

The Pfizer review of these clinical reports was the compilation of the clotting events reported under diagnoses that include clotting events in arteries and veins. This includes large veins of the limbs, those clots that are carried to the lungs (pulmonary emboli) and other clots carried through the blood stream to other areas of the body.

The thromboembolic category does not include clots that cause strokes. It also does not include most other blood disorders. Both of these are reviewed independently. The thromboembolic category does include general activation of the clotting system, diffuse intravascular coagulation, which results in multi-organ damage throughout the body.

In the 151 patients there were **168 identified conditions with 165 determined to be "serious"**. There were 60 with blood clots to the lung (pulmonary embolus), and 90 events identified as blood vessel clots (primarily in veins).

The adverse events were reported from within the first 24 hours post vaccination to 28 days later, but half were reported as having started in the first four days. There were **18 deaths** with **54 cases reported as "resolved or resolving" but no further follow up to give insight on ultimate outcomes**. Pfizer reports **49 events did not resolve** and six had permanent sequelae." In **42 patients an "unknown" outcome** was reported.

Pfizer's Conclusion: **"This cumulative case review does not raise new safety issues."**

Post-Marketing Team's CONCLUSION:

How many serious **ADVERSE EVENTS, UNRESOLVED and UNKNOWN** outcomes does it take?
How many **DEATHS** does it take to **RECALL PFIZER'S UNSAFE "VACCINE"?**