



War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 3:

Stroke 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

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

Stroke	Number of cases: 275 (0.6% of the total PM dataset), of which 180 medically confirmed and 95 non-medically confirmed;
Search criteria: HLT Central nervous system haemorrhages and cerebrovascular accidents	Country of incidence: UK (81), US (66), France (32), Germany (21), Norway (14), Netherlands and Spain (11 each), Sweden (9).

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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.

BNT162b2
5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

Table 7. AESIs Evaluation for BNT162b2

AESI ^a Category	Post-Marketing Cases: Evaluation ^b Total Number of Cases (N=42086)
(Primary Path) OR HLT Cerebrovascular venous and sinus thrombosis (Primary Path)	<p>Israel (6), Italy (5), Belgium (3), Denmark, Finland, Poland and Switzerland (2 each); the remaining 8 cases originated from 8 different countries;</p> <ul style="list-style-type: none"> Subjects' gender (n= 273): female (182), male (91); Subjects' age group (n=265): Adult (59), Elderly (205), Child^c (1); Number of relevant events: 300, all serious; Most frequently reported relevant PTs (≥1 occurrence) included: <ul style="list-style-type: none"> PTs indicative of Ischaemic stroke: Cerebrovascular accident (160), Ischaemic stroke (41), Cerebral infarction (15), Cerebral ischaemia, Cerebral thrombosis, Cerebral venous sinus thrombosis, Ischaemic cerebral infarction and Lacunar infarction (3 each) Basal ganglia stroke, Cerebellar infarction and Thrombotic stroke (2 each); PTs indicative of Haemorrhagic stroke: Cerebral haemorrhage (26), Haemorrhagic stroke (11), Haemorrhage intracranial and Subarachnoid haemorrhage (5 each), Cerebral haematoma (4), Basal ganglia haemorrhage and Cerebellar haemorrhage (2 each); Relevant event onset latency (n = 241): Range from <24 hours to 41 days, median 2 days; Relevant event outcome: fatal and resolved/resolving (61 each), resolved with sequelae (10), not resolved (85) and unknown (83). <p>Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.</p>

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This category comprises the diagnoses of strokes attributed to either obstruction of blood flow through arteries to areas of the brain or due to bleeding around or into the brain. Additionally, in this adverse event category, Pfizer included syndromes of diffuse venous clotting in and around the brain and clotting in the venous pools within the skull (cerebral venous sinus thrombosis and cavernous sinus thrombosis). Arterial obstruction blocks oxygen-rich blood delivery, whereas the venous thrombosis prevents drainage of blood from within the head.

The occurrence of these events ranged from within the first 24 hours to 41 days post-vaccination, and 50% were within two days.

Outcomes were listed as "resolved or resolving" in 61 events (20%), though the number "resolved" is not independently reported.

- In the Pfizer 5.3.6 document, these AEs were categorized by System Organ Classes (SOC) – in other words, by systems in the body.
- Within the stroke data set, there are 275 patients with 300 different events reported.
- There were no "non-serious" events. ALL adverse events were categorized as "serious."

95 (32%) did not resolve or "resolved with Sequelae." Thus, those patients were left with health deficits. 83 (28%) unknown outcomes were reported.

The fatal events were 61 (20%). In the 95 events that did not resolve or "resolved with sequelae," how severely disabled were the survivors? Strokes are life-altering events. Even Pfizer categorized all of the reported stroke adverse events as serious.

An additional observation of note involves the unusual diagnosis of cerebral venous sinus thrombosis. There are three cases reported in this data set. This is an extremely rare diagnosis, but it occurred three times in the first 90 days of the Pfizer mRNA COVID-19 "vaccine" rollout.

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"?

