War Room/DailyClout Pfizer Document Analysis

Post-Marketing Team Micro-Report 1:

Hematological 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

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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)
	• Reported relevant PTs: Erythema multiforme (13) and Chillblains (7) • Relevant event onset latency (n = 18): Range from <24 hours to 17 days, median 3 days; • Relevant event outcome: resolved/resolving (7), not resolved (8) and unknown (6). Conclusion: This cumulative case review does not raise new safety issues. Surveillance will continue.
Haematological AESIs *Search criteria: Leukopenias NEC (HLT) (Primary Path) OR Neutropenias (HLT) (Primary Path) OR PTs Immune thrombocytopenia, Thrombocytopenia OR SMQ Haemorrhage terms (excl laboratory terms*	• Number of cases: 932 (2.2 % of the total PM dataset), of which 524 medically confirmed and 408 non-medically confirmed; • Country of incidence: UK (343), US (308), France (50), Germany (43), Italy (37), Spain (27), Mexico and Poland (13 each), Sweden (10), Israel (9), Netherlands (8), Denmark, Finland, Portugal and Ireland (7 each), Austria and Norway (6 each), Croatia (4), Greece, Belgium, Hungary and Switzerland (3 each), Cyprus, Latvia and Serbia (2 each); the remaining 9 cases originated from 9 different countries; • Subjects' gender (n=898): female (676) and male (222); • Subjects' age group (n=837): Adult (543), Elderly (293), Infant (1); • Number of relevant events: 1080, of which 681 serious, 399 non-serious; • Most frequently reported relevant PTs (≥15 occurrences) include: Epistaxis (127), Contusion (112), Vaccination site bruising (96), Vaccination site haemorrhage (51), Petechiae (50), Haemorrhage (42), Haematochezia (34), Thrombocytopenia (33), Vaccination site haematoma (32), Conjunctival haemorrhage and Vaginal haemorrhage (29 each), Haematoma, Haemoptysis and Menorrhagia (27 each), Haematemesis (25), Eye haemorrhage (23), Rectal haemorrhage (22), Immune thrombocytopenia (20), Blood urine present (19), Haematuria, Neutropenia and Purpura (16 each) Diarrhoea haemorrhagic (15); • Relevant event onset latency (n = 787): Range from <24 hours to 33 days, median = 1 day; • Relevant event outcome: fatal (34), resolved/resolving (393), resolved with sequelae (17), not resolved (267) and unknown (371). 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.**
- **Looking at the blood components as a system, those Adverse Events reports made up 2.2% (932 individuals) of the 42,086 total trial participants with AEs identified.**
- **The hematological system includes red cells, white cells, and platelets, as well as clotting proteins.**

Diagnoses included expected and minor issues, such as bruising at the vaccination site and deeper swelling, because it was injected in the muscle. However, more serious diagnoses listed include hematoma, which is suggestive of a significant collection of blood within the deltoid muscle at the site of the injection. Other reports were triggered by vaginal bleeding, coughing up blood, vomiting blood, blood in bowel movements, bloody diarrhea, and blood in the urine.

Blood in the eye was reported, which may be of no consequence if it was only superficial bleeding caused by coughing or sneezing. But, if the bleeding was within the eye, it could cause permanent vision damage. The report does not distinguish which of these scenarios occurred.

Also noted were cases of low white cell counts. These cells protect the body from infections and cancer. Low counts suggest some degree of altered immune response.

Blood also has clotting proteins that circulate. If there is loss or damage to one of the proteins, bleeding can occur due to inadequate clot formation. There were 53 patients reported to have low platelets numbers. Platelets are involved in starting the formation of a clot.

The questions raised by this list are how and to what extent are there disruptions of the clotting system? Are there changes to blood cells that are circulating and/or to those in the bone marrow? Is the presentation of bleeding from so many sources indicative of serious damage and, if so, of what duration? Does the low white blood cell count cause a risk of infection? Is this temporary or long lasting?

Fifty percent of the adverse events reported were noted within 48 hours of Pfizer COVID-19 mRNA vaccination, but there were cases reported as long as 33 days post-injection. In the hematological group of adverse events, **there were 34 deaths and 17 cases of permanent damage.** 393 patients were categorized as "resolved or resolving," but it is unknown whether complete resolution occurred in the "resolving" group. Similarly, a large group of 267 were "not resolved" as of February 28, 2021, and 371 (34%) patients' consequences were categorized as "unknown."

5.3.6 shows a significant collection of serious diagnoses that have no certain explanation and no identification as to either cause and effect or ultimate outcome. However, in the 33 days post injection, and mainly within the first couple of days post injection, there were serious, permanent adverse events including the ultimate serious adverse event: **death**.

Furthermore, the document concludes that these adverse events do not raise new safety issues and says surveillance will continue. Is that adequate in any system devised to assure safety of a pharmaceutical, let alone safety of one based on a novel, experimental technology?

Read Pfizer's STUNNING CONCLUSION:

> 4. DISCUSSION
> Pfizer performs frequent and rigorous signal detection on BNT162b2 cases. The findings of these signal detection analyses are consistent with the known safety profile of the vaccine. This cumulative analysis to support the Biologics License Application for BNT162b2, is an integrated analysis of post-authorization safety data, from U.S. and foreign experience, focused on Important Identified Risks, Important Potential Risks, and areas of Important Missing Information identified in the Pharmacovigilance Plan, as well as adverse events of special interest and vaccine administration errors (whether or not associated with an adverse event). The data do not reveal any novel safety concerns or risks requiring label changes and support a favorable benefit risk profile of to the BNT162b2 vaccine.
>
> 5. SUMMARY AND CONCLUSION
> Review of the available data for this cumulative PM experience, confirms a favorable benefit: risk balance for BNT162b2.
>
> https://www.phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf, pp. 28-29.

Post-Marketing Team's CONCLUSION:

WHAT DOES IT TAKE?

How many serious **ADVERSE EVENTS** does it take?
How many **UNRESOLVED and UNKNOWN** outcomes does it take?
How many **DEATHS** does it take?

What does it take to **RECALL PFIZER'S UNSAFE "VACCINE"?**

Hematological AESIs:

AESI LATENCY:
Relevant event onset latency (n = 787):

Range from <24 hours to 33 days

median = 1 day

AESI OUTCOMES:
Relevant event outcome:
- fatal (34)
- resolved/resolving (393)
- resolved with sequelae (17)
- not resolved (267)
- unknown (371)

PFIZER CONCLUSION:
"This cumulative case review does not raise new safety issues. Surveillance will continue."

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NOTE ON LATENCY:
The interval of time between the time a dose of drug is administered, and an effect is observed.

Post Marketing Team