Danish Bombshell: Three Levels of Pfizer mRNA Vax Batches with Various Association to SAEs, Including Deaths

TSN

trialsitenews Follow

Staff at TrialSite | Quality Journalism

Apr. 12, 2023, 2:00 p.m.

A trio of Danish researchers led by high powered physician-investigator Peter Riis Hansen, Department of Cardiology, Copenhagen University Hospital-Herleve and Gentofe recently had a research letter published in peer reviewed journal European Journal of Clinical Investigation. Titled "Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine," the investigators found three groupings of Pfizer-BioNTech COVID-19 vaccination batches with low, medium and high rates of adverse events. According to TrialSite contributor Dr. David Wiseman, "Is this modRNA degradation or DNA contamination." The findings may correspond to Sasha Latypova contributions to TrialSite concerning various levels of vaccine safety associated with batches.

Background

By November 2022, 701 million doses of the Pfizer-BioNTech vaccine are linked to 971,021 suspected adverse events (SAEs) in the European Union. The authors point out that "vaccine vials with individual doses are supplied in batches with stringent quality control to ensure batch and dose uniformity." They

noted that at the individual vaccine batch level, clinical data was never reported and that a scenario "highly unlikely" would be "batch-dependent variation in clinical efficacy and safety of authorized vaccines." Yet the prospect of investigation into "batch dependent variation" was worthy of investigation, according to the authors. Hence the study, an investigation into SAEs between the different Pfizer-BioNTech batches administered across Denmark and its 5.8 million people from December 2020, to January 11, 2022. This inquiry was possible because all SAE cases are linked with corresponding vaccine batch labels reported to and classified by the Danish Medical Agency according to seriousness of SAE as well as numbers of Pfizer-BioNTech doses in individual vaccine batches registered by the Danish Serum Institute. This data is publicly available if requested.

The study

By linking individual SAES to the batch label(s) of Pfizer-BioNTech dose(s) administered by subject, the authors could report on SAEs at the batch level in Denmark.

They divided total number of SAEs associated by batch by the number of doses in the batch to obtain the rate of SAEs per 1000 doses. They could not apply conventional regression statistics due to the significant heterogenous aspect to the observed relationship between number of SAEs and Pfizer-BioNTech vaccine doses. Rather, the authors employed use of non-hierarchical cluster analysis and general linear model (GLM) test for differences in SAE rates between

batches, with reporting conforming to the EQUATOR guidelines.

So, what did they find?

52 different BNT162b2 batches was associated with 7,835,280 doses administered to 3,748,215 persons (2340-814,320 doses per batch), and 43,496 SAEs were registered in 13,365 persons which came to 3.19 ± 0.03 (mean ± SEM) SAEs per person. "In each person, individual SAEs were associated with vaccine doses from 1.531 ± 0.004 batches resulting in a total of 66,587 SAEs distributed between the 52 batches."

The authors had to further analyze 61,847 batch-identifiable SAEs because batch labels were not fully registered or even missing for a total of 7.11% of all Danish SAEs. Out of this analysis 14,509 (23.5%0 were classified as severe SAEs with 579 (0.9%) involving SAE-related deaths.

Vaccine-related SAEs per 1000 doses varies between batches which was an unexpected find for the Danish authors. They reported "2.32 (0.09–3.59) (median [interquartile range]) SAEs per 1000 doses, and significant heterogeneity ($p < .0001$) was observed in the relationship between numbers of SAEs per 1000 doses and numbers of doses in the individual batches."

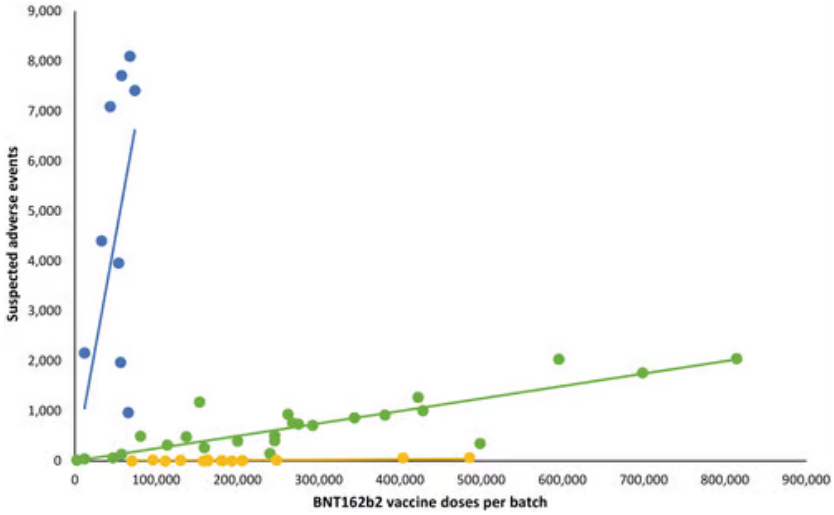
As Wiseman recently noted, the authors found three groupings of Pfizer-BioNTech COVID-19 vaccination batches with low, medium and high rates of adverse events. The authors noted:

"Compared to the rates of all SAEs, serious SAEs and SAE-related deaths per 1.000 doses were much less

frequent and numbers of these SAEs per 1000 doses displayed considerably greater variability between batches, with lesser separation between the three trendlines."

They further identified:

"The observed variation in SAE rates and seriousness between BTN162b2 vaccine batches in this nationwide study was contrary to the expected homogenous rate and distribution of SAEs between batches."



Limitations

The authors identified limitations with this research letter, which include the following:

- Potential for reporting bias given the Danish adverse event reporting system is a passive system, much like Vaccine Adverse Event Reporting System (VAERS) in the USA—potential for both under and over reporting although in USA the CDC and experts in past have suggested underreporting more common.
- Incomplete data associated with inputs
- Data quality variability

- A whole series of questions associated with SAEs not analyzed (specific types, demographics of SAEs, relationship of SAEs with consecutive vaccine doses, temporal trends, etc.

The authors point out that any such signals associated with these reporting systems must be considered hypotheses and not actual causality scenarios.

Riis Hansen and colleagues point out that the "Danish Serum Institute has not issued recalls of BNT162b2 vaccine batches."

Conclusion

The authors point out that their analysis "suggests the existence of a batch-dependent safety signal for the BNT162b2 vaccine" however further investigation is recommended to further explore both A) the preliminary observation and B) consequences.

Peter Riis Hansen, M.D., DMSc, Ph.D., FESC

Lead Research/Investigator

- Peter Riis Hansen, **D., DMSc, Ph.D., FESC** Department of Cardiology, Copenhagen University Hospital-Herleve and Gentofe
- Vibeke Manniche, M.D. LIVA Copenhagen

- Max Schmeling, **Statistician / Economist, MSc (log)**

References

Wiley Online Library

COVID-19 mRNA Pfizer Vaccine Injury

Comments (4)

What do you think?

0/3000

Publish

therealrestoreinc

Apr. 12, 2023, 4:10 p.m.

THE SKETCHY ENDING OF THE SARS-COV-2 PANDEMIC BY THE BIDEN ADMINISTRATION IS NOT QUITE THE END OF THESE EMERGENCY USE AUTHORIZED PFIZER SHOTS! But other nations such as Denmark can do better than the U.S. in taking care of the COVID-19 vaccine-triggered injuries.

The Emergency Use Authorization (EUA) of Pfizer COVID-19 shots was an unconscionable "pseudo"-contract with U.S. citizens ... so how was it for you, citizens of Denmark?
https://www.trialsitenews.com/a/burn-after-reading-ending-unconscionable-contracts-5d8add97

How can these Pfizer products not be recalled yet?

Reply