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LETTER TO THE EDITOR

WILEY

Inaccurate representation of shipped vaccines as administered

Dear Editor,

I am writing in response to your recently published letter https://onlinelibrary.wiley.com/doi/10.1111/eci.13998 by Schmeling et al. The authors have not described the data that they have used correctly. They report that they have received batch-specific information on adverse event reports from the Danish Medicines Agency and administered vaccines from Statens Serum Institut (SSI). This is not correct. The information they have obtained from SSI is on shipped vaccine vials by batch number. From SSI, vaccines were shipped to regional distribution centres (with −90 degree celsius storage capacity). The dates of data retrieval for both sources of data used in the letter are 18 January 2022 (shipment volumes) and 11 January 2022 (adverse event reports). Thus, batches shipped late in 2021 or very early in 2022 will not have any or very few adverse event reports, because they have not been used or only a small proportion have been used. This is also clearly seen in the figure in the letter, where the so-called 'yellow' batches have zero or close to zero reports. Understanding this is critical for the interpretation of these results. This is a particularly serious issue as the crux of the letter hinges on the idea that different vaccine batches have drastically different safety profiles which is not supported at all when you understand that it is not administered vaccines as they claim. There are many other issues with respect to these data. For example, that the very first batches were small, administered during the introduction period where clinical practitioners were instructed to report everything including local reactions, fever, transient headache, etc. These cannot be compared to later only partially used batches, where the authorities urged that mild and transient events should no longer be reported. It is also well-known that in the early part of the vaccination deployment, those vaccinating were urged to attempt to get seven doses out of the vials instead of six due to supply concerns. Again, as the authors do not have data on administered doses but only on shipped vials, the comparisons are further skewed.

I note the statement 'Reporting of the study conforms to broad EQUATOR guidelines'. There are no EQUATOR guidelines. EQUATOR is a network for reporting guidelines and currently houses 573 different reporting guidelines—https://www.equator-network.org/reporting-guidelines/.

Finally, the 'main finding' of three distinct types of safety profiles is based on a so-called non-hierarchical cluster analysis of log-transformed counts. There is no reference to the method, and no further details. Thus, the validity of the method in this context is very difficult to validate.

In summary, the research letter is presenting the study data inaccurately and has a number of reporting inconsistencies that should also be corrected and even so the study data cannot be used to provide any meaningful insights into batch variability with respect to safety.

CONFLICT OF INTEREST STATEMENT

I declare no conflicts of interest.

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