

Dear NZDSOS

Thank you for providing your list of people dying after receiving Comirnaty vaccine.

In relation to the spread sheet provided I note that more than 10% of the information is not valid as it does not provide information supporting the existence of the individual. Further, more than 10% of the cases have not had Comirnaty vaccine. You will find more information on what constitutes a valid report in this recent Prescriber Update article <https://www.medsafe.govt.nz/profs/PUArticles/June2019/The-fantastic-four-of-adverse-drug-reaction-reporting.htm>.

In addition, I note the comments in your letter about CARM reports and the equivalent reports in the USA to their system called VAERS and a presentation by CDC in October 2020. These comments do not align with the scientific concepts of pharmacovigilance. There are many easily accessible sources of information on pharmacovigilance including the Medsafe website and WHO Covid-19 vaccines safety surveillance manual <https://www.who.int/publications/i/item/10665338400> . I encourage you to develop your knowledge in this area.

The safety monitoring process and CARM reporting have been running in New Zealand for more than 55 years and Medsafe has access to independent advice through the Medicines Adverse Reactions Committee and the COVID-19 Vaccine Independent Safety Monitoring Board. Reports of events of special interest and all those reporting a fatal outcome are followed and presented and discussed with the ISMB.

The mortality web tool for New Zealand (<https://minhealthnz.shinyapps.io/mortality-web-tool/>) shows that there are over 30,000 deaths per year. For the proportion of the population fully vaccinated which is approximately 29% we would have expected there to have been several thousand deaths occurring at some point after vaccination to date.

Therefore, based on the data available we consider there is no safety signal in relation to Comirnaty causing death at this point of time in New Zealand.

Regards

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