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Australian Medical Professionals Society
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Open letter to, Bette Liu, Sandrine Stepien, Timothy Dobbins, Heather Gidding, David Henry, Rosemary Korda, Lucas Mills, Sallie-Anne Pearson, Nicole Pratt, Claire M. Vajdic, Jennifer Welsh, and Kristine Macartney, authors of:

"Effectiveness of COVID-19 vaccination against COVID-19 specific and all-cause mortality in older Australians: a population based study."

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Dear Associate Professor Bette Lui

## Concerns regarding data integrity and analysis

The retrospective, observational study of 3.8 million Australians of over 65 years, during eleven months of 2022, has reached the following broad conclusion:

> *COVID-19 vaccination is highly effective against COVID-19 mortality among older adults although effectiveness wanes with time since the last dose. Our findings emphasise the importance of continuing to administer booster doses, particularly to those at highest risk.*

This paper and its conclusion have been cited by the Australian Chief Medical Officer in an Australian Senate Estimates inquiry [1] to support government policy of continued vaccination for older adults. The research has been funded by the Australian Government through various government agencies and by pharmaceutical companies.

As it stands, the conclusion of the paper is unclear, if not invalid, because it states that the vaccination is “highly effective”, but “wanes over time”. Can a vaccine be “highly effective” only for

a limited time? How limited? The time limit to effectiveness is one of the key issues to be discussed below.

**Data Integrity Issues**

Most of the paper, consisting of four large tables occupying most of a printed page each, is a presentation of dosage statistics of the Australian population, which, while not irrelevant, are not germane to the main subject of the paper. The space could be better used.

The main subject and conclusion of the paper depend critically on analysis of the data relating dosage to COVID-19 and all-cause mortality shown in Figures 1 to 3. These "death by vaccination status" data, central to the study, are largely absent from the paper.

Importantly, the conclusion quoted above requires analysis of accurate Australian COVID data, but such data are well-known to have serious integrity issues, errors originating from data collected from disparate sources and from flawed data-recording procedures. For example, someone who dies soon after being vaccinated with one dose may be recorded as the death of an unvaccinated person [2].

Also, COVID-19 mortality is intrinsically an unreliable statistic, because attribution of a COVID death may be erroneous. A death (ICD 10 code U07.1) could be *with* COVID (defined by a positive PCR test) rather than *from* COVID (the disease). Sometimes, COVID deaths (ICD 10 code U07.2) have been assigned by judgement without doing any tests.

Raw COVID-19 mortality data by dosage, essential to the paper, have not been disclosed in the paper, even in a summary form. How were COVID-19 mortality data selected and validated? The authors need to discuss the data of Figure 1 and 2 and should publish their compilation of the raw data, so that readers can replicate the results of their paper.

A further deficiency is: that measuring vaccination effectiveness (VE) by survival rates against only COVID-19 mortality is inadequate because it assumes falsely that vaccination does not have lethal side effects. Even the Therapeutic Goods Administration (TGA) has admitted [3] that there were 14 COVID vaccine-induced deaths to March 2023.

With mass vaccination, non-COVID excess deaths have reached about double COVID-19 deaths [4], and this should be investigated for association with vaccination. Yet, with only a brief discussion suggesting how vaccination may reduce all-cause mortality, the authors have inserted "all-cause mortality" in the title of the paper, insinuating vaccination is also effective against all-cause mortality.

**Method and Analysis Issues**

Even ignoring data integrity issues, ignoring non-COVID excess deaths and supposing VE is validly measured against only COVID-19 mortality, the paper still suffers seriously from methodological and analytical defects.

Vaccination, COVID-19 mortality and all-cause mortality data are available from 2021 and well into 2023. Why does the paper select and analyse only eleven months of 2022? There were surges in deaths in 2022 accompanying the rollouts of the first and second boosters, but the paper does not consider that they may be related to vaccinations, rather than only to the COVID disease.

Instead of analysing 2022 data as a whole, COVID and all-cause mortality data are analysed in two separate periods: one five-month period and one six-month period. For different dose groups, vaccine effectiveness (VE) is evaluated by COVID-19 survival effectiveness for three windows: less than three months, three to six months and more than six months.

Such divisions of time periods need to be discussed, because analysing survival over multiple fixed time-periods involves unstated assumptions about the time taken for vaccines to have their effects,

and the delay effects should be discussed. The risk of errors is increased on account of survivorship bias, where a proportion of deaths may fall between the cracks that lie between survival windows.

With two data periods, three dosage groups and three survival windows, there are 18 different vaccine mortality rates to compare to two unvaccinated mortality rates.

As may be expected, there are 18 different VE measures with a wide range of results depending on the various combinations. Importantly, the results appear random with no consistent VE pattern across the two time periods or between the dose groups.

In their main findings, the best and most convenient cases were selected for reporting. For example, from Figure 1 in the first period, the main finding reported was "*VE of a 3rd COVID-19 vaccine dose within 3 months was 93% (95% CI 93–94%) whilst VE of a 2nd dose >6 months since receipt was 34% (26–42%)*".

Among unfavourable findings (see below), the most favourable finding has been cited by the authors to show COVID-19 vaccination is highly effective, but only relatively and "wanes with time". Some of those unfavourable findings are masked by what appear as glaring anomalies, probably serious errors collected in the table below.

From Figure 1 of the paper, the "Dose3>180 days" group has a higher mortality rate (per 100 person-year) than the unvaccinated, yet they have positive vaccine effectiveness of 63.4 percent (COVID-19 VE (%) column below). This and a few other examples are shown in the table below, where a "Relative Risk Reduction (%)" column (should be the same as COVID-19 VE (%)) has been added with shaded cells, simply calculated from the mortality rates given.

| Figure 1-3: Period and Group | Mortality Rate (per 100 PY) | Relative Risk Reduction (%) | COVID-19 VE (%) | All-Cause VE (%) |
|---|---|---|---|---|
| **Jan-May 2022** | | | | |
| Unvaccinated | 0.929 | ref | ref | |
| Dose2>180 days | 0.927 | 0.2 | 34 | -15.8 |
| Dose3>180 days | 1.139 | -22.6 | 63.4 | -2.5 |
| **Jun-Nov 2022** | | | | |
| Unvaccinated | 0.49 | ref | ref | |
| Dose2 8-90 days | 1.218 | -148.6 | 13.9 | -18.8 |
| Dose2 91-180 days | 0.595 | -21.4 | 21.8 | -11.9 |

In the June to November period of Figure 1, the "Dose2 8-90 days" group had 1.218 mortality rate per 100 PY, compared to 0.49 for the unvaccinated. This shows that even in the short-term of less than three months, that vaccinated group (second shaded cell from the bottom) had 2.5 times higher risk of dying from COVID than the unvaccinated. How could the authors claim for that case (second last column in the above table) a positive VE of 13.9 percent in their paper?

The paper needs to disclose the sorts of adjustments used to achieve positive "COVID-19 VE (%)" for those cases where the vaccinated groups had higher mortality rates than the unvaccinated. Those negative relative risk-reduction results calculated here for those cases, if unexplained, would invalidate the main conclusion of the paper that COVID-19 vaccination is highly effective.

Similar criticisms can be raised against the analysis in Figure 2 and Figure 3, where the method of adjustment for obtaining VE results for all-cause mortality is also not transparent, even though the

raw all-cause data would be more accurate than COVID-19 data for reasons explained and discussed above.

On all-cause mortality the authors made unsubstantiated comments such as "COVID-19 vaccines also appeared effective against other specific causes of death…those who are more likely to get multiple vaccine doses, or *to be vaccinated earlier are healthier and less likely to die from any cause*…". Emphasis added. On Pfizer/BioNTech's COMIRNATY vaccines alone, the TGA's DAEN database [5] recorded (subject to underreporting) over 82,000 adverse events associated with many different diseases. Moreover, those comments are contradicted by the authors' own analysis.

Figure 3 of the paper shows clearly that the authors' own calculated VE against all-cause mortality (rates not shown) are all negative for those cases shown in the above table (last column). Therefore, COVID-19 vaccination was ineffective and had increased all-cause mortality among some groups of older adults. Their evidence of ineffectiveness is consistent with Australian macro-data where all-cause mortality has increased substantially for older Australians vaccinated since 2021 [4].

**Summary of Critique**

- The approach of this study depends on official COVID data with integrity issues, which the paper does not acknowledge.
- Only 11 months in 2022 of official data out of possibly more than 24 months have been selected for the study.
- The "death by vaccination status" data which link dosages with mortality data have not been discussed or disclosed. The key data used need to be publicly available for replication of the findings.
- The unseen key data collection has been selectively analysed, by dividing into separate time periods, dose groups and survival durations, producing 18 comparisons. The method of analysis is unsound and has led apparently to random results, without identifiable regularity.
- The vaccination effectiveness results were not simply calculated, but adjusted. The details of the adjustments need to be disclosed.
- The unadjusted results contradict the general conclusion that "COVID-19 vaccination is highly effective against COVID-19 mortality among older adults*"*.
- Out of 18 comparisons of adjusted results, the most favourable and convenient findings have been selected and presented to draw the main conclusion, which is not generally valid.

**Conclusion**

As it stands, the paper has serious deficiencies in data integrity, data selection bias, flawed methods of analysis, undisclosed adjustments of results, selective reporting of findings and the drawing of invalid conclusions. The Australian Government has chosen to take this paper as authoritative evidence to justify its health policy, which has been associated with many excess deaths particularly in older Australians, but those deaths have been brushed off without investigation as coincidental, unrelated to vaccination.

The paper, in its currently published form, has serious methodological and analytical defects, resulting in errors and misleading conclusions. Therefore, the paper needs substantial revision to address the issues raised, or else it should be retracted.

Dr Wilson Sy, Director, PhD, Investment Analytics Research
Dr Christopher Neil, MBBS FRACP PhD, President, Australian Medical Professionals Society

**References**

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