Dear Drs. Nitin Joshi, Thangeswari Rajendran, and Editorial Board

Based on the following peer review, I request the International Society of Pharmacovigilance retract the New Zealand Ministry of Health's (MOH) Comirnaty safety study from its journal ("published study").

Published study: *Walton M, Pletzer V, Teunissen T, Lumley T, Hanlon T. Adverse Events Following the BNT162b2 mRNA COVID-19 Vaccine (Pfizer-BioNTech) in Aotearoa New Zealand. Drug Saf. 2023;46(9):867-879. doi:10.1007/s40264-023-01332-1.*

The published study conclusion that provided "*reassurances around the safety of the vaccine*" is not merited by the data when this is compared with the earlier preprint version ("preprint study") and the officially disclosed Te Whatu Ora data released in February 2023 for the same study population using a 365-day risk period. Compared with the preprint and 365-day risk period data, the published study biasedly concealed a statistically significant number of Comirnaty-related hospitalizing adverse events of special interest (AESI) and at least three AESI risk factors for ill-justified reasons. This published study does not represent reality.

This request and peer review were saved to the Web Archive and will be sent to various Government Ministers and others because of its national importance. Thank you sincerely for publishing this evidence, which I have saved to the Web Archive.[1] Please withdraw this misleading publication. Thank you.

Yours sincerely

Dr. Carlton Brown BVSc (1986, Massey University), MBA (1997, London Business School).
Former CEO and co-innovator at Immune Targeting Systems Ltd (UK), "Vaccines for Mutating Viruses."

PEER REVIEW SUMMARY: The preprint study (day 0-21 risk period, 6,083 AESI) contained 1.6x more AESI than the published study (day 1-21 risk period, 3,921 AESI). Removing day zero from the risk period after the first and second doses was the key version difference, with 1,967 of this difference accounted for by acute kidney injury arising within 24 hours of vaccination. This seemingly small and ill-justified change actually eliminated *acute kidney injury* (AKI), venous *thromboembolism*, and *thrombocytopenia* as statistically significant risk factors. The published and preprint versions of the study also underreported the total AESI events among a list of 12 AESI categories by an average of 6.2x and 4.0x, respectively, compared with a longer 365-day risk period for the same study participants (24,506 AESI, officially disclosed data).

This study was designed with statistical expertise, which concealed hospitalizing AESI cases and risk factors. A biased list of 12 AESI categories out of a potential 39 accounted for 27.7% of the 2019 SAFE Project background AESI. Seven of these AESI categories accounted for a paltry 1.6% of the 2019 background AESI for New Zealand. The published study excluded those AESI cases who had died and

failed to generate hospital discharge information. The 20-day risk period was not empirically defined and was poorly justified. Removing day zero from the post-vaccination risk period was ill-justified, yet it eliminated 42% of all AKI hospitalizations within the first 24 hours following vaccination. Such a large number of acute kidney injuries were not preexisting medical conditions.

NEW ZEALAND GOVERNMENT OFFICIALLY RELEASED DATA: This peer-review of the MOH published study utilized the following publications and data officially disclosed by the government.

1) **MOH publication**: Walton M, Pletzer V, Teunissen T, Lumley T, Hanlon T. Adverse Events Following the BNT162b2 mRNA COVID-19 Vaccine (Pfizer-BioNTech) in Aotearoa New Zealand. Drug Saf. 2023;46(9):867-879. doi:10.1007/s40264-023-01332-1,
2) **MOH preprint version**: a PDF copy of the preprint study (03 February 2023) can be downloaded from the Web Archive. https://web.archive.org/web/20230709023307/https://grandsolarminimum.com/wp-content/uploads/2023/07/SSRN-id4329970.pdf,
3) **Social Science Research Network removal of the preprint (June 2023)**: "Walton, Muireann and Pletzer, Vadim and Teunissen, Thomas and Lumley, Thomas and Hanlon, Timothy, Adverse Events Following the BNT162b2 mRNA COVID-19 Vaccine (Pfizer-BioNTech) in Aotearoa New Zealand. https://web.archive.org/web/20230213202331/https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4329970,
4) **Te Whatu Ora officially disclosed AESI data**: The number of hospital admissions for each AESI following the second dose of BNT162b2 (Comirnaty) in a period of one year between 19 Feb 2021 and 19 Feb 2022 (365-day risk period, n = 24,506), and the 2021 number of public hospital admission for the same diagnostic codes irrespective of their vaccination status (n = 75,249) https://web.archive.org/web/20230324210947/https://fyi.org.nz/request/21710/response/83023/attach/4/HNZ00011430%20OIA%20Reponse.pdf
5) **Statistics New Zealand 2021 population data**: https://infoshare.stats.govt.nz
6) **Global Vaccine Data Network dashboard**: 2014-2019 SAFE Project background AESI case data, https://www.globalvaccinedatanetwork.org/ourwork/safe-project-background-rates-adverse-events-special-interest-aesis-covid-19-vaccination,
7) **MOH data**: https://web.archive.org/web/20220213230159/https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-case-demographics, https://web.archive.org/web/20221231045006/https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-case-demographics (COVID-19 hospitalizations).

CONFLICT OF INTEREST: The four Ministry of Health (MOH) employees and the Chair of

Biostatistics at the University of Auckland, as study authors declared they "*have no conflicts of interest to disclose*" despite four being employed by the MOH in a study funded by the MOH (i.e., the National Immunization Programme budget from the MOH) using highly selected data provided by the MOH. The MOH's Vaccine Safety Surveillance and Research Group undertook the study work, and the project was advised and critically reviewed by the National Immunization Programme, the Clinical Risk Management branch within Medsafe, and the COVID-19 Vaccine Independent Safety Monitoring Board. The New Zealand government funds university professors, and those in key positions do not get there by chance. The fact this MOH study's conclusions were enabled by MOH employees and statistical expertise paid for by the Government means one is justified to question the authors' conflict of interest disclosures.

STRATEGIC CONTEXT TO AESI CONCEALMENT: In New Zealand, we faced a situation where Medsafe declined to approve Comirnaty on 28 January 2021 (Officially disclosed), "*Due to the unresolved concerns and additional quality, safety and efficacy data to be provided at the time of completion of the evaluation, Medsafe is unable to recommend that this product be granted consent*" (Document 7)[2] Furthermore, according to the Medsafe Risk Management Plan conclusion for Comirnaty in January 2021 (Document 17), "It is considered that the safety specification for this product is currently inadequate and does not accurately reflect the important known risks, important potential risks or missing information."[3]

Medsafe's 28 January 2021 decision was then overruled by the Minister of Health's anonymous Medicines Assessment Advisory Committee (MAAC) on 03 February 2021.[4] Medsafe had requested the MAAC focus on whether the "benefit-risk *balance of Comirnaty vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older is positive*" (Documents 7 and 13).[5] The MAAC approval-overrule arose despite Medsafe stating five days previously, "*The benefit-risk balance of Comirnaty (COVID-19 mRNA Vaccine) for active immunization to prevent coronavirus disease 2019 (COVID-19) …, is not clear*."[6]

An independent peer-reviewed **risk-to-benefit analysis** of Comirnaty's interim Phase III clinical study safety data demonstrated there was an excess risk of serious AESI, which exceeded by **4.4x** the risk reduction for COVID-19 hospitalization relative to placebo (Fraiman et al., cited below). This risk-to-benefit analysis predicted the Ministry of Health's 365-day risk period AESI data associated with your Journal's published study. This data yielded **1.1x** (12 AESI categories) and **3.8x** (prorated, 39 AESI categories) more Comirnaty hospitalizing AESI per 100,000 (19 February 2021 to 2022) **than** all COVID-19 hospitalizations per 100,000 in 2022 (i.e., 11 February to 25 December 2022). Thus, the use of statistical bias that conceals AESI and risk factors in the face of a negative benefit-to-risk balance in 2020 and associated with this published Drug Safety study, plus the MAAC's overrule of Medsafe to approve

Comirnaty without a positive benefit-risk balance, intensifies the conveyance of an intent to harm while avoiding detection.

PEER-REVIEW

1.1 Study Design Changes Between Preprint and Published Versions Concealed Adverse Events of Special Interest & Risk Factors

The MOH study involved 4,685,351 New Zealanders aged five years and older, of which 4,277,163 and 4,114,364 received a first and second dose of Comirnaty between 19 February 2021 and 10 February 2022, during a period before widespread community outbreaks of COVID-19 during our quarantine. The published study removed the first 24 hours following vaccination (i.e., days 1-21 risk period, n = 3,921 AESI), whereas the preprint study included day zero within the risk period (i.e., days 0-21 risk period, n = 6,083 AESI). This risk period alteration concealed 2,162 AESI, mainly by removing acute kidney injury AESI cases and concealing three AESI risk factors (i.e., *acute kidney injury, thrombocytopenia, and venous thromboembolism*). The published study's 3,921 AESI after both doses used an ultra-short 20-day risk period post-vaccination compared with 24,506 AESI with a 365-day follow-up after dose two.

PUBLISHED STUDY (TWO RISK FACTORS): The published study disclosed one risk factor linked to one or two doses of Comirnaty (all ages) and one age-restricted risk factor. The published and preprint study versions reported a statistically significant association between Comirnaty and **myo/pericarditis** in the 1-21 days and 0-21 days, respectively, following both vaccine doses. The highest rate difference was in those under 39 years following the second dose. In the published study, no statistically significant increased rates relative to background rates (i.e., age-adjusted standardized incidence ratios) were evident for the other 11 AESI in any specific age group except for **single-organ cutaneous vasculitis** in the 20–39 age group. The authors diminished the significance of this age-specific result because the numbers were small.

PREPRINT STUDY (FIVE RISK FACTORS): In the preprint study, five risk factors were disclosed, yet the front page conclusion diminished the Comirnaty risk, stating, "*BNT162b2 was not found to be associated with most of the AESIs investigated, providing reassurances around the safety of the vaccine*." The authors' interpretation stated, "*Although rare, a statistically significant association between BNT162b2 vaccination and* ***myo/pericarditis*** *and* ***acute kidney injury*** (AKI) *was observed*." There was also a significantly increased incidence relative to background rates, which was not emphasized in the preprint, for **thrombocytopenia** and **venous thromboembolism** (VTE) following the second dose and for **single organ cutaneous vasculitis** in the 20–39-year-olds and for VTE in 40-59-year-olds following the first dose.

In removing the AESI occurring in the first 24 hours following vaccination, 2,162 total AESI were removed from the preprint study version before final publication. Acute kidney injury (AKI) accounted for most of this difference. This data confirms that 1,967, or 42% of all AKI hospitalizations, arose in the first 24 hours after vaccination. This act rendered the AKI rate difference over the background rate **no longer statistically significant**. For context, AKI was the largest AESI category accounting for 20% of SAFE Project background AESI in 2019 (see below), 76% of total preprint AESI, and 68% of published study AESI.

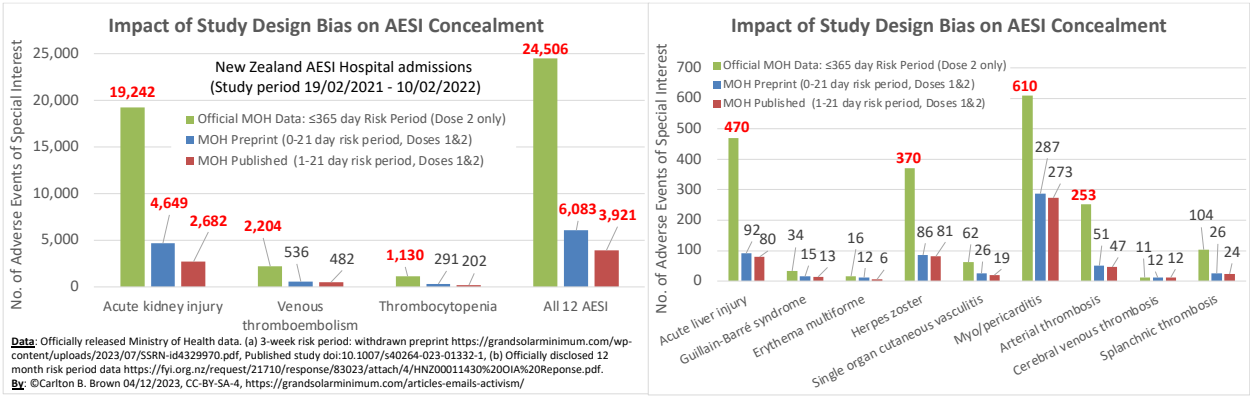


Figure 1: The number of AESI in a 365-day risk period following the second Comirnaty dose between 19 February 2021 and 19 February 2022 (GREEN) is compared with the summed dose one and two AESI cases following Comirnaty for the 0-21 day (preprint study, BLUE) and 1-21 day risk periods (published study, BROWN) during the study period (i.e., 19 February 2021 to 10 February 2022). The 365-day risk period "only counts events that occurred in the study period and in the risk window for each person" and thus does not depict a true 365-day risk period (i.e., *it undercounts*). The 12 AESI were divided into two graphics to help visualize the smaller AESI category data (right graphic). This 365-day risk period data does not include AESI occurring after the first dose. Those AESI categories comprising ≤6 AESI per dose one or two were counted as 6 AESI for the purpose of deriving an AESI category total. This impacted Guillain-Barré syndrome, Erythema multiforme, and Cerebral venous thrombosis. **Summary**: The risk period alteration between the preprint and published versions of the MOH study concealed 2,162 AESI cases. This change mainly removed acute kidney injury AESI cases and concealed three AESI risk factors (i.e., *acute kidney injury, thrombocytopenia, and venous thromboembolism*). The published study's 3,921 AESI cases after both doses used an ultra-short 20-day risk period post-vaccination compared with 24,506 AESI with a 365-day follow-up after dose two. **Conclusion**: The published data concealed Comirnaty AESI cases and risk factors from ready public view. **Data Source**: See the prior cited preprint and published MOH study and 365-day risk period data.

1.1.1 A 20-day Versus a 365-Day Risk Period Assessment Under-reported 12 Hospitalizing Adverse Events of Special Interest by a Mean Factor of 6.2x

The Government **officially disclosed** the number of hospital admissions for each AESI category following the second dose of Comirnaty recorded in a period of one year from 19 Feb 2021 to 19 Feb 2022 (i.e., 365-day risk period, FIGURE 1, n = 24,506 AESI, green bars). This data permitted the quantification of **under-reporting** for the preprint and published versions relative to the MOH's one-year risk period data using the same study subjects whose data was also accessed via the government's electronic health records. Three sets of under-reporting factors were calculated for the 365-day and 3-week risk periods (FIGURE 2).

1) AESI category totals from the 0-21 and 1-21 day risk periods (preprint versus published study versions)

2) AESI category totals from the ≤365-day and 1-21-day risk periods (published study),
3) AESI category totals from the ≤365-day and 0-21-day risk periods (preprint study),

The preprint study contained **1.6x more** AESI than the published study. The published and preprint study versions **underreported** the total AESI events among 12 AESI categories by an average of **6.2x** and **4.0x,** respectively, compared with a longer 365-day risk period (FIGURE 2).

A Chi-square test of independence was used to verify if the data removal and under-reporting were statistically significant. This method compared a 0-21 day (i.e., two doses, preprint) versus 1-21-day risk periods (2 doses, published data) and the officially disclosed 365-day versus 1-21-day risk periods (i.e., two doses, published data). The Chi-square test used the published AESI data in FIGURE 1 and the summed published 4,277,163 first and 4,114,364 second doses of Comirnaty administered to calculate proportions.

1) Published study changes versus the preprint version: The observed preprint AESI proportions were higher than expected, while the observed published AESI proportions were lower than expected, and these differences were highly significant for acute kidney injury (i.e., **p-value < .00001**) and thrombocytopenia (i.e., **p-value < .00006**) and were marginal for venous thromboembolism (i.e., **p-value = 0.09**). By removing the first 24 hours post-vaccination from the risk period assessed, significant and marginal changes were made to *acute kidney injury (AKI), thrombocytopenia, and venous thromboembolism* AESI, which **concealed them as putative Comirnaty risk factors**.

2) The MOH's 2-dose 12 AESI category published data for Comirnaty was compared with the corresponding 365-day risk period data. The published observed AESI proportions were lower than expected, and the 365-day risk period AESI proportions were higher than expected. These differences were highly significant for 9 of 12 AESI (i.e., **p-values < 0.00001**) and significant for 2 of 12 AESI (i.e., **p-values 0.03** and **0.002**). The exception was cerebral venous thrombosis (p-value > 0.83). These results confirm an ultra-short 1-21-day risk period **significantly underreported** the number of hospitalizing AESI compared with a 365-day risk period for **11 of 12 AESI categories**.

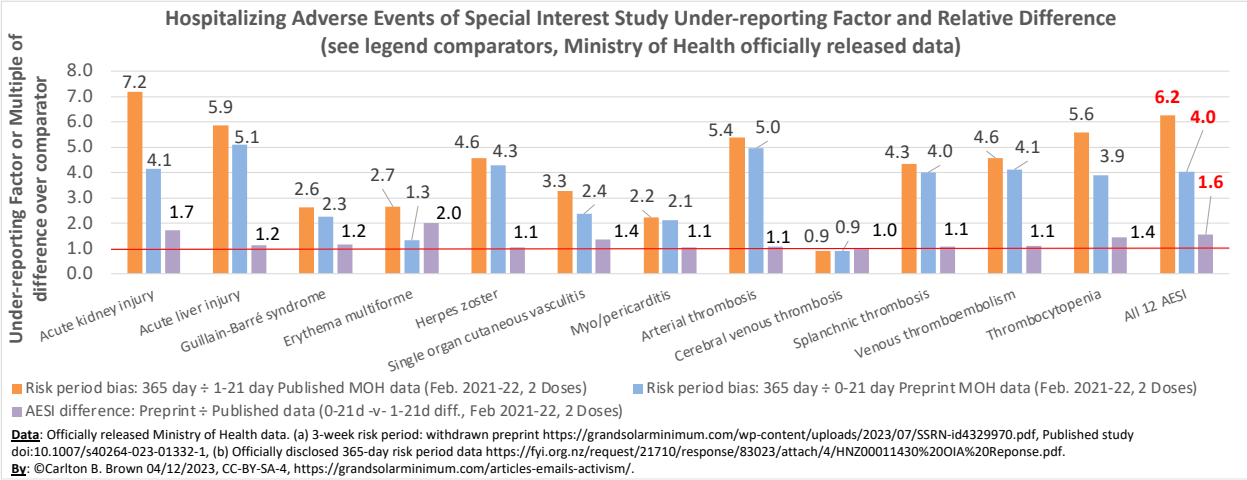


Figure 2: Differences between the preprint and published study versions were depicted by dividing the preprint AESI category cases by the published AESI category cases (0-21 days versus 1-21 days, Feb 2021-22, 2 Doses, PURPLE). **Underreporting** factors for two AESI comparisons were calculated by dividing officially disclosed 365-day AESI category cases by the 1-21 day published study AESI category cases (Febs. 2021-22, 2 Doses, ORANGE) and similarly for the 365-day AESI category cases divided by 0-21 day preprint AESI category cases (Feb. 2021-22, 2 Doses, BLUE). **Summary**: The published and preprint study versions underreported the total AESI cases for the summed 12 AESI categories by an average of **6.2x and 4.0x**, respectively, compared with a longer 365-day risk period. The preprint study contained **1.6x** more AESI cases than the published study. This graphical data collectively demonstrates the impact of statistical and study design **biases** in concealing AESI cases, which impacted the conclusions about Comirnaty safety. **Data**: The published MOH study doi:10.1007/s40264-023-01332-1 (August 2023),[7] a web archived version of the Social Science Research Network (SSRN) posted preprint abstract and a PDF copy of the preprint publication from before both were withdrawn in June 2023 (Web Archived by me),[8] and a Web Archived version of the officially released Te Whatu Ora AESI data were used (i.e., 365-day risk period, and for 2021, OI request HNZ00011430).[9]

1.1.2 How the MOH Study Design Concealed Comirnaty Adverse Events of Special Interest

The four MOH employees and the Chair of Biostatistics at the University of Auckland were provided with a de-identified dataset from the MOH. The MOH study benefited from several statistical-bias-injecting design features that took a minimum potential of **24,506 Comirnaty AESI,** resulting in hospitalization (19 February 2021 – 19 February 2022, 12 AESI categories) officially disclosed by Te Whatu Ora and reduced that raw list to 6,083 AESI (i.e., preprint, 03 February 2023) before it was **whittled** down to **3,921 hospitalizing AESI** for the published study (i.e., 09 August 2023). This sub-section reviews the study design features that enabled the removal of potential raw data before final publication.

1) The study used an **ultra-short 20-day risk period** for monitoring AESI (i.e., 1-21 days) that was **not empirically defined** as the actual risk period. This short risk period was poorly justified by "*the risk period for all events was set as 1–21 days, which is in line with the approved 3-week interval between the two primary doses [25] and other COVID-19 vaccine safety studies [31]*" (citing one study). The study authors unsurprisingly acknowledged the 1-21 day risk period could misrepresent the real risk period. The officially disclosed MOH AESI data, compared with a 21-day and 20-day risk period,

confirms the published study failed to capture the real risk period, which was greater than 20 days.

2) The **day zero post-vaccination AESI exclusion** was justified as "*Events that occurred on the same date as vaccination (day 0) were not included to avoid counting events that occurred prior to vaccination*." **Why** would the Chair in Biostatistics at the University of Auckland and co-author have permitted such an oversight for the preprint study version if that was a bonafide reason? This day zero data exclusion eliminated 2,162 or 36% of the 6,083 preprint AESI data, of which 1,967 or **91%** of the eliminations were **acute** kidney injury (AKI). Three significant **AESI risk factors** were also eliminated with this one key change to the study design prior to publication. AKI is a rapid-onset (i.e., within hours, hence acute) and serious life-threatening condition that would have precluded those same people from receiving Comirnaty in the first place, which undermines the published study's stated reason.

3) The study **excluded those who died** and thereby did not generate hospital discharge information; "*only hospital discharge information was used to identify the outcomes of interest in the vaccinated and historical comparator cohorts*." As such, this study lacked transparency on the mortality status of those entering the hospital system as AESI and leaving via the **morgue**, adding further doubt to the study's conclusion.

4) The study did not include diagnoses made in general practice and private hospitals, only public hospitals.

5) Those who received a COVID-19 vaccine overseas or a different COVID-19 vaccine or second dose within 21 days of their first dose were excluded.

6) A **list of only 12 AESI** from a potential 39 AESI categories was assessed (i.e., see next)

1.1.3 The MOH Study Utilized Only 12 Adverse Events of Special Interest Categories from a Potential SAFE Project Background AESI list of 39 to "Assure" Comirnaty's Safety

In reviewing COVID-19 and its derived mRNA vaccines' multiple mechanisms of pathogenicity (i.e., *thrombosis and thromboembolism, endothelitis and vasculitis, hyperinflammation, immune-mediated disease, autoimmunity, multiple receptor-mediated binding of spike proteins in vital organs, etc.*) that have the potential to target all the body's vital organs, one must reconcile this broad potential for disease and comorbidity **exacerbation** with a focused list of 12 AESI categories that accounted for only 27.7% of 2019 background AESI (i.e., 39 AESI categories). That point is further emphasized when considering seven of those twelve AESI accounted for a paltry 1.6% of 2019 background AESI.

The MOH study only assessed 12 of 39 potential AESI identified by the SAFE Project (Table 2, pg.12-

13),[10] which I term **AESI category selection bias**. The authors described their method of arriving at 12 AESI categories based on an undisclosed **consultation with Medsafe** and via an **undisclosed clinical record assessment** by researchers at the University of Auckland. This university research is said to have validated the accuracy of the ICD-10-AM codes used to identify the AESI. AESIs were omitted from the MOH study if the codes selected to identify the condition had a low positive predictive value of less than 50%. Thus, 39 AESI categories were **whittled down to 12**.

This AESI category selection methodology was suffused with **scientific double standards**. The MOH published study confirmed, "*There is potential for misclassification as clinical record assessments were not conducted to validate the diagnoses or codes used*." In other words, the study authors **secretly verified** the accuracy of diagnostic codes used to whittle the SAFE Project list from 39 AESI categories down to 12 yet **failed to assess the accuracy** of the clinical records for this published study. This undisclosed methodology **concealed 72.3% of potential AESI** on a 2019 background AESI basis (i.e., 27 of 39 AESI categories). This biased list of 12 AESI provide no "*reassurances around the safety of the vaccine*."

Had the MOH prioritized all AESI categories associated with damage to the vascular lining, blood clotting and embolism, and inflammation (i.e., via multiple mechanisms) of the heart, brain, nervous, kidney, respiratory, endocrine, and gastrointestinal systems, as well as anaphylaxis, this would have accounted for **87.2% of background AESI** on a 2019 basis (i.e., 35 AESI categories). This broader focus would have embraced the main mechanisms of pathogenicity associated with COVID-19 vaccination and COVID-19.

1.1.4 A Risk-to-Benefit Analysis of Officially Disclosed Hospitalizing AESI Data Raises Questions about Medsafe's Approval of Comirnaty Under Section 20 of the Medicines Act 1981 (2023)

In prorating the 24,506 Comirnaty AESI resulting in hospitalization for 12 AESI categories associated with the published study (365-day risk period) into 39 categories, there was a potential 88,362 Comirnaty AESI during the MOH study period (19 February 2021 – 19 February 2022). These prorated 88,362 AESI corresponded to **1,729** AESI per 100,000 vaccinated with Comirnaty, while the 24,506 AESI (12 categories) corresponded to **479** AESI per 100,000 vaccinated with Comirnaty. For context, between 11 February and 25 December 2022, during the worst part of the pandemic, there were **455 COVID-19 Hospitalizations per 100,000** among all COVID-19 vaccination statuses and age groups (see Figure 3B for Web Archived MOH case data; COVID-19 hospitalizations 2022, NZStats2021 population 5,111,480).

Thus, there were an estimated **1.1x** (12 AESI categories) and **3.8x** (prorated, 39 AESI categories) more Comirnaty-associated hospitalizing AESI per 100,000 (19 February 2021 – 19 February 2022) **than** all COVID-19 hospitalizations in 2022 (i.e., 11 February to 25 December 2022).

This result suggests the **cure was worse than the disease** and raises **major questions** about Medsafe's full approval of Comirnaty under Section 20 of the Medicines Act 1981 on 07 November 2023.[11] This magnitude of negative benefit-to-risk balance was **anticipated** by the Comirnaty Phase III clinical safety data used to support the FDA's emergency use authorization (i.e., EUA, FDA Advisory Committee Briefing Document Table 23 used in this Fraiman et al. **risk-to-benefit analysis**.[12,13]). This Fraiman et al. risk-to-benefit analysis for Comirnaty demonstrated there was an excess risk of serious AESI (i.e., 10.1 per 10,000 vaccinated), which exceeded by **4.4x** the risk reduction for COVID-19 hospitalization relative to the placebo group (i.e., 2.3 per 10,000 participants).

1.1.5 ANCILLARY ANALYSIS: There was an Estimated 80,000-127,000 Excess Adverse Events of Special Interest and 4.5x Higher Rates of Hospitalization in 2021 than for COVID-19 in 2022

KEY SUMMARY: This section's ancillary analysis is provided because it describes the same risks factors as the preprint publication. This analysis also generated a **risk-to-benefit analysis** outcome comparable to that summarized above for people living in New Zealand during mass vaccination (2021) and the main brunt of the pandemic in 2022. This analysis does not form part of the above published study's peer review but is complementary because it uses alternative Te Whatu Ora/MOH AESI data for the same AESI categories for 10 of the same 12 months (i.e., total population, 2021).

This section's ancillary analysis utilizes officially disclosed Te Whatu Ora data relating to the same 12 AESI categories for the full year 2021, irrespective of vaccination status. There was an estimated **3.5x – 5.5x** more excess hospitalizing AESI per 100,000 in 2021 than there were COVID-19 hospitalizations in 2022 (i.e., FIGURE 3B). This equated to an estimated-prorated **80,722 - 126,904 excess hospitalizing AESI** for 39 AESI categories in 2021 during a period when the MOH administered 8,189,844 COVID-19 vaccine doses.[14] Analysis of the disclosed AESI data revealed statistically significant crude incidence rate ratios (i.e., IRR = observed / expected incidence rates, 12 AESI) for **myo-/pericarditis, acute kidney injury**, **venous thromboembolism**, and **thrombocytopenia**. The latter three AESI categories were the same three AESI categories **concealed by statistical bias** between the preprint and published versions.

ANALYSIS RESULTS: According to officially disclosed data released by Te Whatu Ora on behalf of the MOH (i.e., FIGURE 3 citations), there were 75,249 AESI hospital admissions. These AESI hospital admissions comprised the same 12 AESI categories as utilized in the published study for the period between 01 January 2021 and 31 December 2021, irrespective of vaccination status. Thus, within this officially disclosed 75,249 AESI, there were an estimated **22,387** to **35,195 excess hospitalizing AESI** in 2021 among those 12 AESI categories, largely resulting from AKI. Prediction methods used the SAFE Project background rates to calculate 2021 expected AESI from which excess AESIs were derived (FIGURE 3

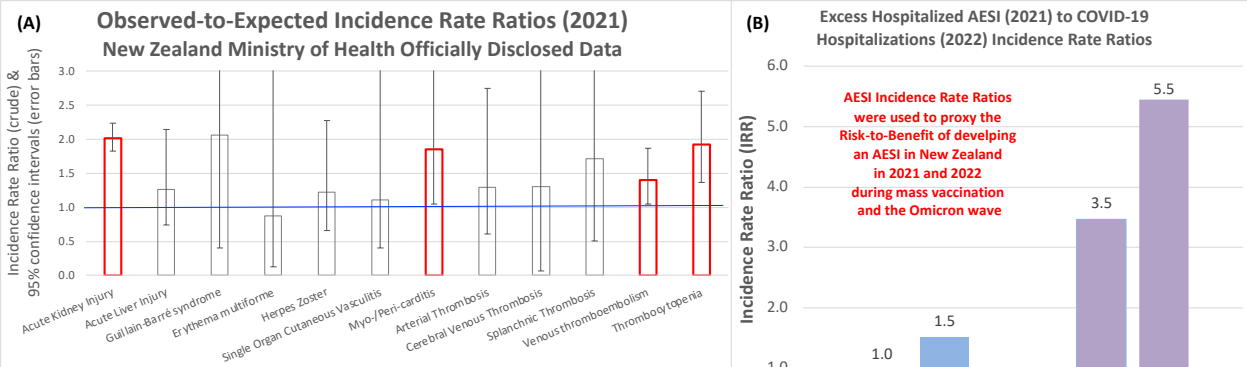
method description).[15,16]

The SAFE Project list of the same 12 AESI categories accounted for 27.7% of New Zealand's background AESI in 2019. This percentage was derived using Table 2 data from the SAFE Project (pgs. 12-13). The two above estimates for excess hospitalizing AESI in 2021 were used to pro-rata an estimated **80,722 - 126,904 excess AESI** in 2021 for 39 AESI categories (i.e., 22,387 - 35,195 excess AESI for 12 categories divided by 0.277 or 27.7% was used to derive-proxy excess AESI for 39 categories).

These excess hospitalizing AESI occurred during a period when 8,189,844 COVID-19 vaccine doses were administered (2021), during Auckland's enforced lockdown (August – December 2021), and when COVID-19 was not in widespread circulation. Furthermore, in also **prorating** the 24,506 Comirnaty AESI resulting in hospitalization for 12 AESI categories, there were an estimated **88,362 hospitalizing AESI** for 39 AESI categories resulting from Comirnaty use. Thus, these two prorated excess AESI and Comirnaty AESI derived using different datasets **converge** and suggest that Comirnaty and the government's vaccination campaign were responsible for an unprecedented level of AESI **concealed from** the mainstream public.

THE CURE WAS WORSE THAN COVID-19: There were 438 - 689 excess hospitalizing AESI per 100,000 population in 2021 for those 12 AESI categories. In pro-rating the 12 AESI into 39 AESI categories (i.e., 80,722 - 126,904 excess AESI cases), there were between **1,579** and **2,483 excess hospitalizing AESI per 100,000** during 2021 when the Government vaccinated most of the population (i.e., StatsNZ2021, n = 5,111,480). See the FIGURE 3 legend for the methodology and data citations.

For context, between 11 February and 25 December 2022, during the worst part of the pandemic in New Zealand, there were **455 COVID-19 Hospitalizations per 100,000** among all vaccination statuses and age groups.[17] Thus, there were an estimated **1.0x - 1.5x** (12 AESI categories) and **3.5x – 5.5x** (39 AESI categories) more excess hospitalizing AESI per 100,000 in 2021 **than** all COVID-19 hospitalizations in 2022 (i.e., see Figure 3.B for the method).



Data: Officially released Ministry of Health data. (a) 12 categories of Adverse Events of Special Interest (01/01/2021 - 31/12/2021), https://fyi.org.nz/request/21710/response/83023/attach/4/HNZ00011430%20OIA%20Reponse.pdf. (b) Expected rates utilized GDVN SAFE Project data (2014-2019) http://www.globalvaccinedatanetwork.org/ourwork/safe-project-background-rates-adverse-events-special-interest-aesis-covid-19-vaccination and StatsNZ2021 population data https://infoshare.stats.govt.nz, (c) COVID-19 cases, https://www.health.govt.nz/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-case-demographics (11/02/2022 - 25/12/2022).

Figure 3: (A) 2021 non-age adjusted observed-to-expected incidence rate ratios and their 95% confidence intervals (i.e., depicted by error bars, derived using the lower expected AESI rate estimates) for the same 12 AESI categories used by the Ministry of Health in its published study. The Global Vaccine Data Network 2014-2019 background AESI rate per 100K trend was checked for each AESI category. In this case, if the AESI rate trend R-squared exceeded 0.50 (i.e., the trend explains more than 50% of the variability across time), then extrapolation of the AESI incidence rate trend to 2021 was used to determine the expected incidence rate per 100,000 (100K) for that 2021 AESI category (i.e., using the R statistical programming language derived linear regression intercept, slope, and number of years). If the R-squared was less than 0.50 (i.e., indicating a random deviation around the 2014-2019 mean rate), then the 2014-2019 mean incidence rate was used to estimate the expected category AESI for 2021. This latter step was used to estimate rates for Guillain-Barré syndrome, erythema multiforme, Herpes Zoster, and arterial thrombosis, which were categories with low AESI rates. Two expected incidence rate estimates were then derived for each AESI category. The **lower expected** AESI rate estimates were derived using 2014-2019 rates extrapolated to 2021 or the mean 2014-2019 rates (i.e., depending on the trend R-squared value being > or < 0.50). The **higher expected** AESI rates per 100K were derived similarly but used the upper 95% confidence interval rates instead. The Observed AESI rates per 100K were calculated using the Te Whatu Ora officially disclosed 2021 AESI data (i.e., 01/01/2021 - 31/12/2021), with each AESI category total divided by the StatsNZ2021 population total (n = 5,111,480) and multiplied by 100,000. Non-age-adjusted incidence rate ratios (IRR) were calculated by dividing the Observed rate by the Expected rate for each AESI category. The 95% confidence intervals for the Incidence Rate Ratios were calculated as described in the following cited text.[18] Age-adjusted IRR could not be calculated due to the limitations of the Te Whatu Ora data disclosed. Figure 3A depicts the lower expected incidence rate data, which was aligned with the MOH published study that used 2014-2019 mean background rates to calculate IRR. **(B)** Excess Hospitalizing AESI (2021) to COVID-19 Hospitalizations (2022) Incidence Rate Ratios were used to proxy the risk-to-benefit of living in New Zealand in 2021-2022: The lower and higher expected AESI incidence rates per 100K were calculated as described in 3(A) for all 12 AESI categories. These expected rates were subtracted from the observed rates to derive the excess AESI rates for 2021. These excess 2021 AESI rates were divided by the COVID-19 hospitalization rates per 100K for 2022 to proxy the **risk-to-benefit ratio**. **NOTE**: The smaller IRR for each bar color represents that derived using the higher expected AESI rates from which these lower excess rates were calculated (by subtraction). COVID-19 hospitalizations for 2022 were obtained from the MOH website (Web Archive) between 11 February 2022 (start of data provision) and 25 December 2022 (i.e., the last 2022 data provision, which was the same as the first in January 2023). COVID-19 hospitalization rates pooled the vaccinated, unvaccinated, and under 12 years old/ineligible COVID-19 hospitalization cases to align with the Te Whatu Ora raw 2021 AESI provided for all vaccination statuses and ages. Rates per 100K were calculated by dividing the total COVID-19 hospitalized cases by the StatsNZ2021 total population and multiplying by 100,000 (Data: 25 December 2022 total "Hospitalizations for COVID-19" = 23,920. 11 February 2022 "Cases who have been hospitalized" = 649. Difference = 23,271 COVID-19 cases in hospital. New Zealand population = 5,111,480. Hospitalized cases per 100K = 455.3). **Conclusion**: **Four statistically significant AESI risk factors** were evident in 2021 (i.e., left graphic, red bars, IRR≥1.0 with the lower bound of the 95% confidence interval also ≥1.0). These significant risk factors (red bars) were **the same as those identified in the preprint study** version before their concealment with statistical bias (i.e., three risk factors). There was a **3.5-5.5x higher risk-to-benefit** in comparing 2021 excess hospitalizing AESI (estimated for 39 AESI categories) with 2022 COVID-19 hospitalizations.

366 **Data**: This analysis was based on data sourced from the Global Vaccine Data Network dashboard,[19] Te Whatu Ora
367 officially disclosed data,[20] Statistics New Zealand 2021 population data,[21] and the Ministry of Health COVID-19
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