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Re: Undisclosed Deaths in C4591001 Trial at the Vaccine and Related Biological Products Advisory Committee (VRBPAC) Meeting on December 10, 2020.

Dear Professor Lawler:

I have not yet received a reply to my second letter to you dated 6th April 2024. Once again, I would like to draw the TGA's attention to the undisclosed deaths, especially in the vaccinated arm, in the C4591001 trial at the Vaccine and Related Biological Products Advisory Committee (VRBPAC) on December 10, 2020. I believe my co-authors and I have identified serious safety issues based on our scrutiny of publicly available clinical trial documentation which formed the basis of the emergency use authorisation (EUA) of the Pfizer-BioNTech's COVID-19 vaccine approval in December 2020 in the United States, and subsequently in Australia.

The delayed reporting of vaccinated deaths in the study led to a misrepresentation of the deaths during the trial. Subsequently, Pfizer submitted incorrect death data to the U.S. Food and Drug Administration (FDA) when seeking EUA. In fact, the data through the cut-off date of 14th November 2020 were a gross misrepresentation of the trial results. Instead of the reported six deaths, with more deaths in the placebo arm (four deaths) compared to the vaccinated arm (two deaths), eleven deaths occurred, with six deaths in the vaccinated arm compared to five deaths in the placebo arm. Pfizer's delayed reporting of deaths also obscured the cardiac adverse event signal that was emerging in the vaccinated arm of the study.

In your 27th March 2024 reply to my first letter, you stated, "*It is reassuring to note that, in this case none of the deaths in the trial have been attributed to the vaccine and the initial conclusions remain valid.*".

I would like to further explore this statement and try to ascertain the evidentiary basis upon which the TGA reached this conclusion.

i) Subject 11141050, a 63-year-old female subject from the vaccinated arm of the study died unexpectedly 41 days after receiving Dose 2 of BNT162b2. The autopsy result, which was probably available prior to the December 10th VRBPAC meeting, concluded the cause of death was "sudden cardiac death". The trial investigator expressed, "…there was no reasonable possibility that the sudden cardiac death was related to the study intervention, concomitant medications, or clinical trial procedures". The trial investigators noted that the subject had risk factors of hypertension and obesity, which put her "at high risk for cardiovascular/acute myocardial infarction death". As noted in my previous letter, this subject weighed 74 kg (with a BMI of 27 – overweight) and had no blood pressure readings noted in her clinical records. I find it beyond credible that the TGA would accept that someone with these anthropometric readings is at risk of "sudden cardiac death". Her autopsy results are not publicly available. I implore the TGA to make the autopsy results publicly available for independent experts' scrutiny. https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 71.

ii) Subject 11621327, a 60-year-old male subject from the vaccinated arm of the trial, was found dead in his house by the police three days after Dose 1 of BNT162b2. The police went to his house to perform a welfare check and found his body cold with visible lividity. It is unknown whether an autopsy was done. According to the medical examiner, the probable cause of death was "progression of atherosclerotic disease". The trial investigator's opinion was, "…there was no reasonable possibility that the arteriosclerosis was related to the study intervention, concomitant medications, or clinical trial procedures". In the absence of autopsy results, and with a death that happened in such close temporal proximity to receiving the intervention, what was the evidentiary basis that the TGA relied upon to not include BNT162b2 as a possible cause of death? Please note that there was confusion amongst trial investigators indicated in the patient's medical records as to whether atherosclerosis could be a cause of death as the subject did not have any documented history of it. https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 123.

iii) Subject 10071101, a 56-year-old female subject from the vaccinated arm of the study, suffered cardiac arrest 59 days after receiving Dose 2 of BNT162b2. She may have been a resident at a nursing facility and was brought in intubated. She showed signs of anoxic brain injury, and treatment was aimed at improving neurological outcomes. This proved futile, and she died three days later. It is unknown if an autopsy was performed. In the opinion of the investigator, "…there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures, as the death occurred 2 months after receiving Dose 2." What was the evidentiary basis that the TGA relied upon to concur with this statement?

https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 6.

iv) Subject 11201050, a 58-year-old female from the vaccinated arm of the study was found dead in her sleep by her husband 72 days after receiving Dose 2 of BNT162b2. She had no preceding symptoms or illnesses, so the death was unexpected. She was not seen in hospital, and no autopsy was performed. The death certificate listed cardiac arrest as the cause of death. In the opinion of the investigator, "…there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures." What was the evidentiary basis that the TGA relied upon to concur with that conclusion?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 75.

v) Subject 11401117, a 58-year-old male subject from the vaccinated arm of the study, suffered cardiac arrest 116 days after receiving Dose 2 of BNT162b2. He was obese, weighing 138.7 kg with a BMI of 38. His comorbidities included coronary artery disease, hyperlipidaemia, hyperglycaemia, and hypertension. His was a witnessed cardiac arrest, and he experienced seizure-like activity, collapsed, and received bystander cardiopulmonary resuscitation. Despite resuscitation efforts by the bystander and the emergency department, he died that day. No autopsy was done. In the opinion of the investigator, "…there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures, but rather it was related to underlying comorbidities." I am sure you would appreciate that a significant proportion of the Australian population has similar comorbidities. What was the evidentiary basis that the TGA relied upon to dispositively conclude, in the absence of an autopsy, that this sudden death could not be due to the novel experimental medical intervention but, instead, comorbidities alone?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 105.

vi) Subject 11361102, a 76-year-old male subject from the vaccinated arm of the study, died of cardiac arrest 30 days after receiving Dose 2 of BNT162b2. He had collapsed whilst on a walk, received cardiopulmonary resuscitation, and was found to be in ventricular fibrillation by emergency medical services. Resuscitative efforts proved futile, and he died. It is not known if an autopsy was done. In the opinion of the investigator, "…there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures". What is the evidentiary basis for the TGA to concur with this opinion in the absence of an autopsy?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 101.

vii) Subject 11271112, a 53-year-old male subject from the vaccinated arm of the trial was found sitting, slumped forward and dead by his mother in the laundry 85 days after receiving Dose 2 of BNT162b2. An autopsy was performed, but

results were not available at the time the trial investigator examined his case. His comorbidities included hypoglycaemia, chronic obstructive pulmonary disease, and a myocardial infarction in 2008. The preliminary cause of death was cardiopulmonary arrest. In the opinion of the investigator, "…there was no reasonable possibility that the cardiopulmonary arrest was related to the study intervention, concomitant medications, or clinical trial procedures, but rather to underlying cardiac disease." With an autopsy result still pending, how could this conclusion be reached? What was the evidentiary basis that the TGA relied upon to concur?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 81.

viii) Subject 10391010, an 84-year-old male subject from the vaccinated arm of the study, had a witnessed loss of consciousness 70 days after Dose 2 of BNT162b2. His family attempted resuscitation but it was unsuccessful, and he died. He was not taken to the hospital or the physician's office. No autopsy was performed. His comorbidities included hypertension, hyperlipidaemia, carotid artery stenosis, and coronary artery disease. He had a right carotid stent placed in 2016. He had regular follow-ups with his primary care physician and had no reported events or complications prior to his death. The trial investigators ascribed cause of death to arteriosclerosis and hypertensive heart disease. In the opinion of the investigator, "…there was no reasonable possibility that the arteriosclerosis and hypertensive heart disease was [sic] related to the study intervention, concomitant medications, or clinical trial procedures, but rather they were related to cardiovascular disease." What was the evidentiary basis that the TGA relied upon to concur, especially in the absence of an autopsy result?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 26.

ix) Subject 11311204, an 84-year-old male, was initially in the placebo arm of the trial. When the trial was unblinded, he went on to receive BNT162b2. He died of cardiopulmonary arrest 25 days after receiving Dose 1 of BNT162b2. There was documentation of worsening aortic stenosis 10 days prior to his death, and he required hospitalisation. He had an angiogram, and a stent was recommended; but the cardiologist did not feel it was urgently needed. He was discharged home three days prior to his death. However, at home, he took a nap and was found dead by his wife. No autopsy was done. The death certificate stated the cause of death to be cardiopulmonary arrest secondary to a cerebrovascular event. In the opinion of the investigator, "…there was no reasonable possibility that the worsening aortic stenosis and cardiopulmonary arrest were related to BNT162b2, concomitant medications, or clinical trial procedures". This subject had gone through the trial uneventfully in the placebo arm, had a sudden deterioration 15 days after receiving Dose 1 of BNT162b2, and died 25 days after receiving Dose 1 of the vaccine. What was the evidentiary basis that the TGA relied upon to determine that this sudden deterioration and demise could not be due to the studied intervention (BNT162b2), especially in the absence of an autopsy?

https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf, p. 93.

x) Subject 11291166, a 78-year-old female from the vaccinated arm of the study, was found dead in her apartment by her neighbours, because of the odour, 128 days after receiving Dose 2 of BNT162b2. Her son, who had been alerted by the neighbours, found a large amount of blood and fluids pooled on the floor around her body. Her skin was mottled, bruised, and rigid. Her actual death date is unknown. No autopsy was performed, with the medical examiner reporting her cause of death as myocardial infarct. Her comorbidities were hypercholesterolaemia, peripheral vascular disease, and hypertension. She had been on a cholesterol-lowering drug since 2017. In the opinion of the investigator, "…there was no reasonable possibility that the myocardial infarction was related to the study intervention, concomitant medications, or clinical trial procedures, but related to hyperlipidaemia". Again, in the absence of an autopsy, what was the evidentiary basis for the TGA to accept this conclusion so dispositively?
https://phmpt.org/wp-content/uploads/2023/09/125742_S1_M5_5351_c4591001-interim-mth6-narrative-sensitive.pdf page 89

When one looks at the deaths overall in the trial, the vaccinated arm had 21 deaths, and only three of them (subjects 11141050, 11271112, and 11351033) had autopsies done. One autopsy resulted in a diagnosis of sudden cardiac death (subject 11141050), and the other two reports are still not available. I can understand autopsies not being done for certain patients who had a period of illness prior to dying. However, 10 of the 21 deaths in the vaccinated subjects occurred in those who were found dead or suffered sudden adult death, as highlighted above. Of those 10, only two (subjects 11141050 and 11271112) had reported autopsies done, with only one result (subject 11141050 - sudden cardiac death) made available.

There were 17 deaths in the placebo group, and only four (subjects 11521085, 11561124, 11681083, and 12314987) had autopsies. Of these, two (subjects 11561124 and 11681083) listed a cause of death. The other two results are still not available.

Based on the cases I have highlighted, I find it difficult to accept the statement in your letter dated 27th March 2024, "*It is reassuring to note that, in this case/ none of the deaths in the trial have been attributed to the vaccine and the initial conclusions remain valid."* I hope you can appreciate that I am continuing to highlight the substantial efficacy and safety issues in this trial despite reputational, regulatory, financial, and personal risk to myself. I am doing so because I want to continue to uphold my oath and code of conduct.

I hope to receive a reply from you within 14 days.

Sincerely,

Dr Jeyanthi Kunadhasan
MD (UKM), MMed (AnaesUM), FANZCA MMED (Monash)