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21 Feb 2022

TITLE OF REPORT:

A COMPARISON OF ADVERSE EVENTS FOR CHILDREN 5-11 YEARS RELATED SPECIFICALLY TO THE COMIRNATY VACCINE PFIZER AND NON-COVID-19 VACCINES FROM 10 JAN 2022 TO 31 JAN 2022

ABOUT THE EXPERT:

I am an internationally experienced director, trusted board advisor, senior executive, leader & business transformation and performance improvement specialist.

In addition to my business and board qualifications, I am a qualified statistician. My abilities have traditionally been used within organisations usually at the highest levels to guide senior executives and boards on the most appropriate course of action.

Please find attached my CV (link to file here).

Please find attached the letter of instruction dated 14 Feb 2022 (link to file here).

ACKNOWLEDGEMENT:

a) I have read and complied with the Federal Court of Australia Expert Evidence Practice Note (GPN-EXPT) and agree to be bound by it; and
b) My opinions are based wholly or substantially on specialised knowledge arising from my training, study or experience.

DEFINITION OF TERMS:

Children: Individuals whose ages are below 18 years.
Deaths: Associated with the Therapeutic Goods Administration (TGA) reporting, this refers to the number of cases where death was a reported outcome from the Database of Adverse Event Notifications (DAEN) website.
Adverse Event: Adverse events are defined by the Australian institute of health and welfare as **incidents in which harm resulted to a person receiving health care**. Adverse Events reported to the TGA are classified by MedDRA classification which includes Organ affected and type of reaction. Refer Appendix 1 - Supplementary Report - MedDRA classifications by Organ. One Adverse Event case can affect many organs and reaction types can include many MedDRA Classifications.

MedDRA Classification: The **Medical Dictionary for Regulatory Activities** (MedDRA) is an internationally used set of terms relating to medical conditions, medicines and medical devices. Refer Appendix 1 - Supplementary Report - MedDRA Classifications by Organ (see first few lines below).

MedDRA System Organ Classes	MedDRA Reaction Terms for selected medicines
Blood and lymphatic system disorders	Abnormal clotting factor
Blood and lymphatic system disorders	Acquired haemophilia
Blood and lymphatic system disorders	Agranulocytosis
Blood and lymphatic system disorders	Anaemia
Blood and lymphatic system disorders	Anaemia macrocytic
Blood and lymphatic system disorders	Antiphospholipid syndrome
Blood and lymphatic system disorders	Aplastic anaemia
Blood and lymphatic system disorders	Autoimmune haemolytic anaemia
Blood and lymphatic system disorders	Bicytopenia
Blood and lymphatic system disorders	Bone marrow oedema
Blood and lymphatic system disorders	Coagulopathy
Blood and lymphatic system disorders	Disseminated intravascular coagulation
Blood and lymphatic system disorders	Eosinophilia
Blood and lymphatic system disorders	Febrile neutropenia
Blood and lymphatic system disorders	Haemolysis
Blood and lymphatic system disorders	Haemolytic anaemia
Blood and lymphatic system disorders	Haemorrhagic diathesis
Blood and lymphatic system disorders	Heparin-induced thrombocytopenia

Date of Report. The report was finalised on 20 February 2022. Data downloads began on 4 February 2022. The most recent data in the DAEN system at that time was up to 24 January 2022. A second data download occurred on 18 Feb 2022 which allowed me to build an analysable data set from 10 Jan 2022 to 31 Jan 2022.

A NOTE ON APPROACH:

Information for Pfizer vaccines only has been provided up to 31 January 2022, PF-64. This was difficult to analyse because of the way the extracted data was presented. (Refer Second Supplementary Affidavit of Peter Halim Fam, with annexures, affirmed 14.02.2022.pdf)

On 18 February a further data download occurred from the DAEN system which included the last week of January from 25 January to 31 January 2022 for all Covid and Non-covid vaccines, to allow my analysable data to extend to 31 Jan 2022. (Refer Appendix 2 - Supplementary Report – Covid and Non-covid Adverse Events children under 18 10 Jan 2022 to 31 Jan 2022.)

To ensure data accuracy the No of Adverse Events for each age range from 5 to 11 from the Second Supplementary Affidavit of Peter Halim Fam, with annexures, affirmed 14.02.2022.pdf which could only be manually tallied were matched with the No of Adverse Events by Age from my newly downloaded analysable database.

The No of Adverse Event cases matched perfectly for every age except for 7 years.

The Second Supplementary Affidavit of Peter Halim Fam, with annexures, affirmed 14.02.2022.pdf showed 54 Adverse Events in children 7 years from 10 Jan 2022 to 31 Jan 2022. The newly downloaded analysable database showed only 53 adverse events in children 7 years from 10 Jan 2022 to 31 Jan2022. The new database was missing one Adverse Event case.

The individual case reference numbers were identified for each of the 54 cases included in the Second Supplementary Affidavit of Peter Halim Fam, with annexures, affirmed 14.02.2022.pdf

These cases were then searched in my data. The missing Adverse Event was identified. Then another search of the DAEN database was done to ensure that the missing case was no longer in the database. This search showed the missing case no was no longer in the DAEN database.

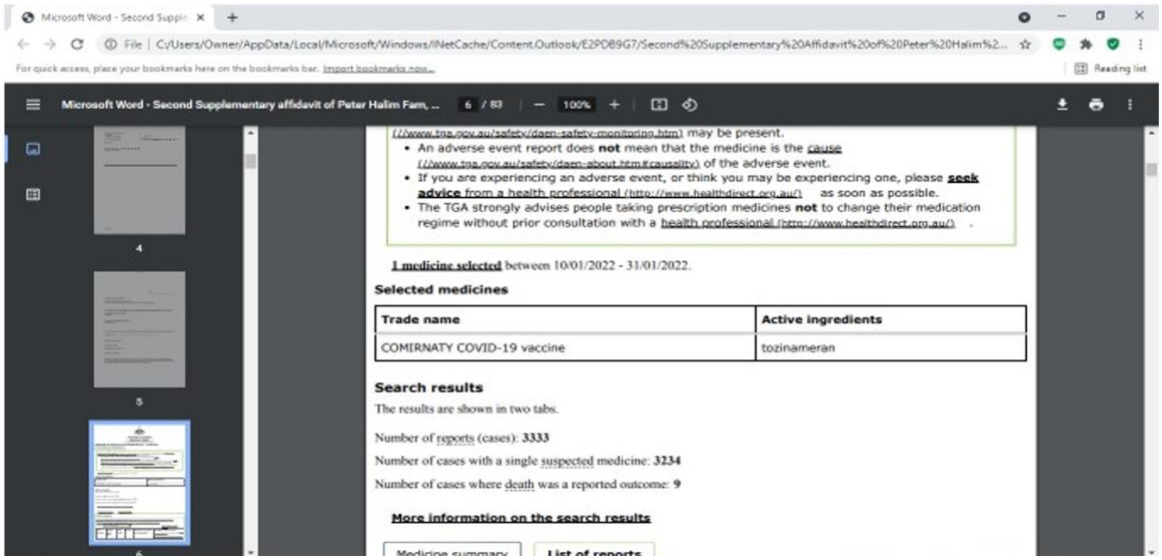
This process revealed a record, Case No 702410 which was in the Second Supplementary Affidavit of Peter Halim Fam, with annexures, affirmed 14.02.2022.pdf and which had been removed from the database some time between the 14 Feb 2022 and 18 Feb 2022.

As a result of this example of missing data, I replicated the process of creating the PF-64 document on 19 Feb 2022. The screenshots of the search results are included below and show significant differences in no of adverse events reported for the same period of time from 10 Jan 2022 to 31 Jan 2022.

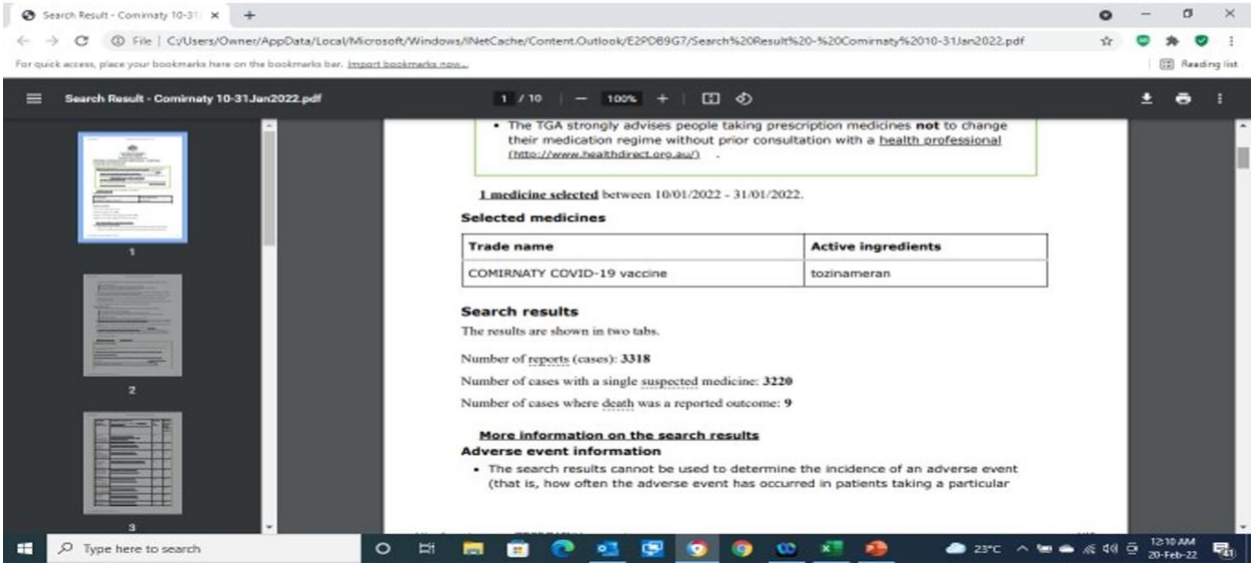
A comparison of the two screenshots from 14 Feb 2022 and 18 Feb 2022 show that:

- the No of Adverse Event Cases reduced by 15 from 3333 to 3318.
- the No of cases with a single suspected medicine also reduced from 3234 to 3220,
- the No of deaths during the period remained the same.

DAEN database search results for Pfizer 10 Jan 2022 to 31 Jan 2022 as at 14 Feb 2022.



DAEN database search results for Pfizer 10 Jan 2022 to 31 Jan 2022 as at 19 Feb 2022



SOURCE OVERVIEW:

The Therapeutic Goods Administration (TGA) receives reports of adverse events associated with medicines and medical devices in Australia. That data it collects is accessible via the Database of Adverse Event Notifications (DAEN) on the TGA website. Using the DAEN data, the following questions are answered, except where otherwise stated.

Question 1:
What does the content of PF-64 (annexed to the affidavit of Peter Halim Fam filed on 14 February 2022) show in terms of reports of Adverse Events for children 5- to 11-years from 10 January 2022 to 31 January 2022? Please explain your reasoning for your answer/s.

My Answer:

There were **394** Adverse Events reported for the Pfizer Vaccine from 10 Jan 2022 to 31 Jan 2022. These Adverse Events were reported in children aged from 0 (unspecified) to 12. Children 5-11 years accounted for **386** of these Adverse Events or around **98%** of the cases included in the PF-64. The process for collating this information is a manual tally. The results from my manual tally are tabled and graphed below.

The PF-64 search screenshot also showed 9 deaths associated with the Pfizer vaccine occurring 10 Jan 2022 to 31 Jan2022.

A visual check of each MedDRA item in PF-64 showed **0** Deaths in children 5-11 years. The analysable data set which was subsequently downloaded from the DAEN database confirmed that the No of Deaths in children from 5-11 from the Pfizer vaccine from 10 Jan 2022 to 31 Jan 2022 was **0**.

As death is included in the MedDRA categories under General Disorders and Administrative Site Conditions, deaths should be able to be searched in the DAEN database.
Refer: Page 18 of Appendix - Supplementary Report – MedDRA classifications.

However, this is not the case. One cannot simply search for deaths in the DAEN database per the above because the option 'death' is not available.

In an effort to confirm that the 9 deaths were all adults, I double checked the DAEN system and produced the table included in the last section of the report which shows that all deaths were outside our age range, one death was a 15 year old male who is technically a child under 18, there were 2 cases which had no age (blanks) and the remaining 6 deaths were all adults.

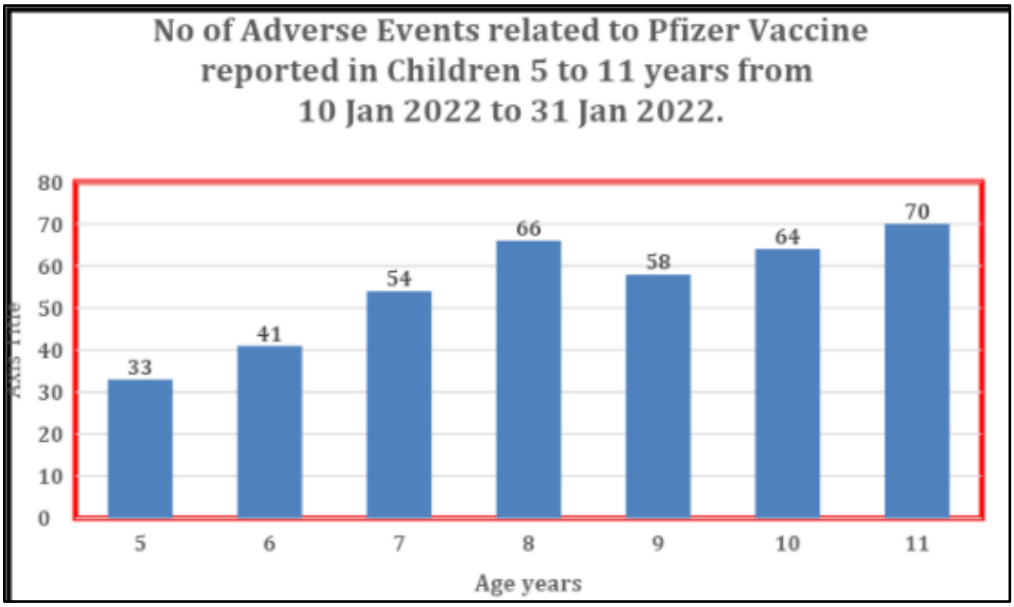
Please see last section of the report.

No of Adverse Events associated with Pfizer Vaccine in Children

Age Years	No of Adverse Events Pfizer 10 Jan 2022 to 31 Jan 2022	% of Adverse Events 5-11 years
0	2	
1	**0**	
2	**0**	
3	**0**	
4	**3**	
5	**33**	**9%**
6	**41**	**11%**
7	**54***	**14%**
8	**66**	**17%**
9	**58**	**15%**
10	**64**	**17%**
11	**70**	**18%**
12	**3**	
Total	**394**	

*includes Case No 702410 which was subsequently removed from the DAEN database some time between 14.02.2022 and 18.02.2022. Refer Appendix 3 – Supplementary Report – Missing data – Pfizer

Case 702410_Not Available. See pages 6-7 for cases data entered on 28.01.2022. Case No 702410 is no longer there. (My data was also checked thoroughly to ensure that the case didn't turn up anywhere else in the data set.)



Susceptibility to an Adverse Event

The Government vaccine roll out plan shows the number of vaccine doses given to children 5-11 years from 10 Jan 2022 to 31 Jan 2022 was 935,020.

The type of Vaccine is not specified, although I know that the Pfizer vaccine was provisionally approved on 10th Jan 2022 for 5-11 years.

Further, the no of vaccines for each specific age is not specified, so I cannot say definitively whether the above reflects a greater susceptibility of children aged 8 years, 9 years, 10 years and 11 years vs 5 years, 6 years and 7 years to Adverse Events from the Pfizer Vaccine or whether this is simply a reflection of the make-up of the population of children 5-11 that have been vaccinated.

Likelihood of an Adverse Event

The likelihood of a child 5-11 having an Adverse Event from a Covid vaccine from 10 Jan 2022 to 31 Jan 2022 was 386 (or 385 less missing case)/935,020 or 4.1 adverse events for every 10,000 doses.

Previous analysis showed that the likelihood of an adverse reaction for a Non-covid vaccine from 2010 to 2020 was of the order of 1 in every 10,000 doses.

So, the likelihood of a child 5-11 having an adverse reaction to a covid vaccine, in this case Pfizer predominantly, is 4 times what I would expect from a traditional non-COVID vaccine.

Sources: Refer page 7 in source documents below:

- https://www.health.gov.au/sites/default/files/documents/2022/02/covid-19-vaccine-rollout-update-1-february-2022.pdf
- https://www.health.gov.au/sites/default/files/documents/2022/01/covid-19-vaccine-rollout-update-10-january-2022.pdf

See My Answer to Q5 in the previous expert report.

"From 2010 to 2020 the likelihood of someone having an Adverse Event as the result of a vaccine was of the order of 1 in every 10,000 doses. It is 1.1 number of doses using the incomplete number of doses data (see Graph 1) and 0.9 using an estimate for total doses (see Graph 2). In 2021 as the result of COVID vaccinations, I can now expect 23 Adverse Events in every 10,000 doses. I set this data out in the below charts"

No. of Adverse Events 10 Jan 2022 to 24 Jan 2022 in children 5-11

The No. of Adverse Events in children from 5-11 from Pfizer from 10 Jan 2022 to 31 Jan 2022 was: 385*cases and 890 Adverse Reactions per the MedDRA classification.
*less missing case

The No. of Adverse Events in children from 5-11 from all COVID vaccines from 10 Jan 2022 to 31 Jan 2022 was:389 and 898 Adverse Reactions per the MedDRA classification.

The No. of Adverse Events in children from 5-11 from all non-COVID vaccines from 10 Jan 2022 to 31 Jan 2022 was: 6 and 22 Adverse Reactions per the MedDRA classification.

The Types of Adverse Reactions Classified by MedDRA Item from 10 Jan 2022 to 31 Jan 2022 in children 5-11.

Reaction Type by MedDRA Classification - Pfizer Vaccine Children 5-11
Sorted highest to Lowest – Top 10 represent 43% of all Reactions Reported

Organ	MedDRA Classification	No of Adverse Reactions	% of Total	Cumulative %
Nervous system disorders	Syncope	58	6.5%	6.5%
General disorders and administration site conditions	Chest pain	52	5.8%	12.4%
Gastrointestinal disorders	Nausea	43	4.8%	17.2%
Gastrointestinal disorders	Vomiting	40	4.5%	21.7%
Vascular disorders	Pallor	37	4.2%	25.8%
General disorders and administration site conditions	Pyrexia	35	3.9%	29.8%

Nervous system disorders	Dizziness	34	3.8%	33.6%
Nervous system disorders	Headache	30	3.4%	37.0%
Skin and subcutaneous tissue disorders	Rash	26	2.9%	39.9%
Skin and subcutaneous tissue disorders	Urticaria	25	2.8%	42.7%
	Dyspnoea	24	2.7%	45.4%
	Abdominal pain	23	2.6%	48.0%
	Presyncope	22	2.5%	50.4%
	Vaccination error	21	2.4%	52.8%
	Malaise	15	1.7%	54.5%
	Lethargy	14	1.6%	56.1%
	Chest discomfort	13	1.5%	57.5%
	Rash pruritic	13	1.5%	59.0%
	Cold sweat	12	1.3%	60.3%
	Hyperhidrosis	12	1.3%	61.7%
	Fatigue	10	1.1%	62.8%
	Palpitations	9	1.0%	63.8%
	Pericarditis	8	0.9%	64.7%
	Pruritus	8	0.9%	65.6%
	Angioedema	7	0.8%	66.4%
	Anxiety	7	0.8%	67.2%
	Cough	7	0.8%	68.0%
	Eye swelling	7	0.8%	68.8%
	Abdominal discomfort	6	0.7%	69.4%
	Diarrhoea	6	0.7%	70.1%
	Injection site pain	6	0.7%	70.8%

Injection site reaction	6	0.7%	71.5%
Lip swelling	6	0.7%	72.1%
Myalgia	6	0.7%	72.8%
Abdominal pain upper	5	0.6%	73.4%
Feeling hot	5	0.6%	73.9%
Oropharyngeal pain	5	0.6%	74.5%
Product administered to patient of inappropriate age	5	0.6%	75.1%
Seizure	5	0.6%	75.6%
Tachycardia	5	0.6%	76.2%
Wrong product administered	5	0.6%	76.7%
Arthralgia	4	0.4%	77.2%
Decreased appetite	4	0.4%	77.6%
Disorientation	4	0.4%	78.1%
Electrocardiogram abnormal	4	0.4%	78.5%
Musculoskeletal chest pain	4	0.4%	79.0%
Myocarditis	4	0.4%	79.4%
Ocular hyperaemia	4	0.4%	79.9%
Rash erythematous	4	0.4%	80.3%
Varicella	4	0.4%	80.8%
Concomitant disease aggravated	3	0.3%	81.1%
Heart rate increased	3	0.3%	81.5%
Hypersensitivity	3	0.3%	81.8%
Hypotension	3	0.3%	82.1%
Incorrect dose administered	3	0.3%	82.5%
Lymphadenopathy	3	0.3%	82.8%

Muscle spasms	3	0.3%	83.1%
Pain	3	0.3%	83.5%
Pain in extremity	3	0.3%	83.8%
Peripheral swelling	3	0.3%	84.2%
Adverse event following immunisation	2	0.2%	84.4%
Arrhythmia	2	0.2%	84.6%
Costochondritis	2	0.2%	84.8%
C-reactive protein increased	2	0.2%	85.1%
Diabetic ketoacidosis	2	0.2%	85.3%
Dysphonia	2	0.2%	85.5%
Electrocardiogram	2	0.2%	85.7%
Epistaxis	2	0.2%	86.0%
Erythema	2	0.2%	86.2%
Eye pruritus	2	0.2%	86.4%
Flushing	2	0.2%	86.6%
Heart rate irregular	2	0.2%	86.9%
Irritability	2	0.2%	87.1%
Musculoskeletal stiffness	2	0.2%	87.3%
Paraesthesia	2	0.2%	87.5%
Photophobia	2	0.2%	87.8%
Respiratory rate increased	2	0.2%	88.0%
Rhinorrhoea	2	0.2%	88.2%
SARS-CoV-2 test negative	2	0.2%	88.4%
Scrotal swelling	2	0.2%	88.7%
Swelling face	2	0.2%	88.9%

Throat irritation	2	0.2%	89.1%
Tongue pruritus	2	0.2%	89.3%
Tremor	2	0.2%	89.6%
Troponin	2	0.2%	89.8%
Vision blurred	2	0.2%	90.0%
Wheezing	2	0.2%	90.2%
Abdominal distension	1	0.1%	90.3%
Administration site irritation	1	0.1%	90.4%
Appendicitis	1	0.1%	90.6%
Asthenia	1	0.1%	90.7%
Attention deficit hyperactivity disorder	1	0.1%	90.8%
Back pain	1	0.1%	90.9%
Basal ganglia haemorrhage	1	0.1%	91.0%
Blood glucose increased	1	0.1%	91.1%
Blood pressure increased	1	0.1%	91.2%
Blood pressure measurement	1	0.1%	91.3%
Bundle branch block right	1	0.1%	91.5%
Carditis	1	0.1%	91.6%
Cerebrovascular accident	1	0.1%	91.7%
Chapped lips	1	0.1%	91.8%
Chills	1	0.1%	91.9%
Confusional state	1	0.1%	92.0%
Conjunctival hyperaemia	1	0.1%	92.1%
Contusion	1	0.1%	92.2%
Croup infectious	1	0.1%	92.4%

Crying	1	0.1%	92.5%
Demyelination	1	0.1%	92.6%
Dizziness postural	1	0.1%	92.7%
Dyspepsia	1	0.1%	92.8%
Dyspnoea exertional	1	0.1%	92.9%
Ear swelling	1	0.1%	93.0%
Eructation	1	0.1%	93.1%
Erythema multiforme	1	0.1%	93.3%
Erythromelalgia	1	0.1%	93.4%
Eye pain	1	0.1%	93.5%
Eyelid oedema	1	0.1%	93.6%
Feeling of body temperature change	1	0.1%	93.7%
Fibrin D dimer increased	1	0.1%	93.8%
Flank pain	1	0.1%	93.9%
Gastrooesophageal reflux disease	1	0.1%	94.0%
Head discomfort	1	0.1%	94.2%
Hypotonia	1	0.1%	94.3%
Inflammatory marker increased	1	0.1%	94.4%
Injection site rash	1	0.1%	94.5%
Lacrimation increased	1	0.1%	94.6%
Lip discolouration	1	0.1%	94.7%
Lipase increased	1	0.1%	94.8%
Listless	1	0.1%	94.9%
Loss of consciousness	1	0.1%	95.1%
Lymphadenopathy mediastinal	1	0.1%	95.2%

Lymphopenia	**1**	**0.1%**	**95.3%**
Menstrual disorder	**1**	**0.1%**	**95.4%**
Migraine	**1**	**0.1%**	**95.5%**
Mouth ulceration	**1**	**0.1%**	**95.6%**
Muscle twitching	**1**	**0.1%**	**95.7%**
Musculoskeletal pain	**1**	**0.1%**	**95.8%**
Nasal congestion	**1**	**0.1%**	**96.0%**
Night sweats	**1**	**0.1%**	**96.1%**
No adverse event	**1**	**0.1%**	**96.2%**
Oesophageal discomfort	**1**	**0.1%**	**96.3%**
Oral disorder	**1**	**0.1%**	**96.4%**
Oral herpes	**1**	**0.1%**	**96.5%**
Oral pruritus	**1**	**0.1%**	**96.6%**
Oropharyngeal discomfort	**1**	**0.1%**	**96.7%**
Painful respiration	**1**	**0.1%**	**96.9%**
Paraesthesia oral	**1**	**0.1%**	**97.0%**
Periorbital oedema	**1**	**0.1%**	**97.1%**
Periorbital swelling	**1**	**0.1%**	**97.2%**
Pharyngeal paraesthesia	**1**	**0.1%**	**97.3%**
Pneumonia	**1**	**0.1%**	**97.4%**
Pollakiuria	**1**	**0.1%**	**97.5%**
Postictal state	**1**	**0.1%**	**97.6%**
Purpura	**1**	**0.1%**	**97.8%**
Rash macular	**1**	**0.1%**	**97.9%**
Red blood cell sedimentation rate increased	**1**	**0.1%**	**98.0%**

SARS-CoV-2 test positive	1	0.1%	98.1%
Scrotal pain	1	0.1%	98.2%
Sensation of foreign body	1	0.1%	98.3%
Serum ferritin increased	1	0.1%	98.4%
Sinus arrhythmia	1	0.1%	98.5%
Sinus rhythm	1	0.1%	98.7%
Sleep disorder	1	0.1%	98.8%
Swelling of eyelid	1	0.1%	98.9%
Swollen tongue	1	0.1%	99.0%
Tachypnoea	1	0.1%	99.1%
Tardive dyskinesia	1	0.1%	99.2%
Taste disorder	1	0.1%	99.3%
Tonic convulsion	1	0.1%	99.4%
Type 1 diabetes mellitus	1	0.1%	99.6%
Urinary incontinence	1	0.1%	99.7%
Vaccination site reaction	1	0.1%	99.8%
Vaginal haemorrhage	1	0.1%	99.9%
Visual impairment	1	0.1%	100.0%
Total	890	100%	100.0%

Reaction Type by MedDRA Classification - Non Covid Vaccines Children 5-11
Sorted Highest to Lowest – Top 10 represent 59% of all Reactions Reported

Organ	MedDRA Classification	No of Adverse Reactions	% of Total	Cumulative %

General disorders and administration site conditions	**Pyrexia**	**4**	**18.2%**	**18.2%**
Psychiatric disorders	**Abnormal behaviour**	**1**	**4.5%**	**22.7%**
General disorders and administration site conditions	**Crying**	**1**	**4.5%**	**27.3%**
General disorders and administration site conditions	**Developmental regression**	**1**	**4.5%**	**31.8%**
Nervous system disorders	**Drooling**	**1**	**4.5%**	**36.4%**
Ear and labyrinth disorders	**Hypoacusis**	**1**	**4.5%**	**40.9%**
Metabolism and nutrition disorders	**Hypophagia**	**1**	**4.5%**	**45.5%**
General disorders and administration site conditions	**Injection site reaction**	**1**	**4.5%**	**50.0%**
Psychiatric disorders	**Irritability**	**1**	**4.5%**	**54.5%**
Nervous system disorders	**Lethargy**	**1**	**4.5%**	**59.1%**
	Rash	**1**	**4.5%**	**63.6%**
	Rash macular	**1**	**4.5%**	**68.2%**
	Salivary gland enlargement	**1**	**4.5%**	**72.7%**
	Tonsillitis	**1**	**4.5%**	**77.3%**
	Urine output decreased	**1**	**4.5%**	**81.8%**
	Urticaria	**1**	**4.5%**	**86.4%**
	Vaccination error	**1**	**4.5%**	**90.9%**
	Vomiting	**1**	**4.5%**	**95.5%**
	Wrong product administered	**1**	**4.5%**	**100.0%**
	Total	**22**	**100.0%**	**100.0%**

No of Adverse Events where Death was a reported Outcome from 10 Jan 2022 to 31 Jan 2022.

The PF-64 search screenshot showed 9 deaths associated with the Pfizer vaccine occurring 10 Jan 2022 to 31 Jan2022.

A visual check of each MedDRA item in PF-64 showed 0 deaths in children 5-11 years. The analysable data set which was subsequently downloaded from the DAEN database confirmed that the No of Deaths in children from 5-11 from the Pfizer vaccine from 10 Jan 2022 to 31 Jan 2022 was 0.

As death is included in the MedDRA categories under General Disorders and Administrative Site Conditions, deaths should be able to be searched in the DAEN database.
Refer: Page 18 of Appendix - Supplementary Report – MedDRA classifications.

However, this is not the case. One cannot simply search for deaths in the DAEN database per the above because the option 'death' is not available.

In an effort to confirm that the 9 deaths were all adults, I double checked the DAEN system and produced the table included below which shows some 22 cases where death was a suspected outcome.

Further, I identified that the 9 deaths that led to the 22 cases were all deaths outside our age range 5-11years, one death was a 15 year old male who is technically a child under 18, there were 2 cases which had no age (blanks), and the remaining 6 were all adults.

Clearly the wording in the table below, which comes directly from the DAEN system is incorrect. There were 22 different MedDRA reactions reported for the 9 deaths, not 22 cases.

Summary Report - Cases where Death was a Reported Outcome 10-31 Jan 2022
Pfizer COMIRNATY COVID-19 Vaccine (Tozinameran)

MedDRA system organ class	MedDRA reaction termClick on a term below to search the MedlinePlus medical dictionary.	Number of cases	Number of cases with a single suspected medicine	Number of cases where death was a reported outcome
Injury, poisoning and procedural complications	Adverse event following immunisation	10	10	3
General disorders and administration site conditions	Vaccination failure	27	17	2
General disorders and administration site conditions	Concomitant disease progression	3	3	2
Respiratory, thoracic and mediastinal disorders	Dyspnoea	358	346	1
Skin and subcutaneous tissue disorders	Hyperhidrosis	95	93	1
Infections and infestations	COVID-19	40	22	1
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	20	19	1
Nervous system disorders	Cerebrovascular accident	16	16	1
Nervous system disorders	Loss of consciousness	13	12	1
Investigations	SARS-CoV-2 test positive	12	12	1
Cardiac disorders	Atrial fibrillation	8	8	1
Cardiac disorders	Myocardial infarction	6	6	1
Injury, poisoning and procedural complications	Fall	5	5	1
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	1	1	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	1	1
Respiratory, thoracic and mediastinal disorders	Respiratory failure	1	1	1
Nervous system disorders	Brain oedema	1	1	1
Psychiatric disorders	Head banging	1	1	1

Source: DAEN database search

The table above is a summary of the PF-64 report which is by individual record. The process to produce this table is the same as the process to replicate the PF-64 document, searching for Pfizer Vaccine, 10 Jan to 31 Jan 2022, and select summary report instead of list of reports. It includes all ages and has not been segmented for 5-11 years. Refer screenshots included above in report in note on approach 19 Feb 2022.

The process for identifying the deaths was complicated. Referring to the table above, I identified the deaths that had only 1 adverse event case, 1 single suspected medicine and 1 case where death was a reported outcome. All searches were for Pfizer within the range 10 Jan 2022 to 31 Jan 2022. First I located the exact day/s of death for the specific organ type and MedDRA reaction. Then I could search again, using the date of death and the MedDRA classification to find the corresponding records.

This allowed me to locate the one record of death which included the case no, the date of data entry, the age, gender, and MedDRA classification relevant to each organ type and MedDRA classification in the summary report above.

The impact of these definite deaths was removed from the other categories. This process led to the table below, and the identification of 8 of the 9 death cases, as follows:

695048,694426,693720,698345,699744,703511,703118,692021.

Cases where Death was a Reported Outcome 10-31 Jan 2022
Pfizer COMIRNATY COVID-19 Vaccine (Tozinameran)

MedDRA system organ class	MedDRA reaction termClick on a term below to search the MedlinePlus medical dictionary.	Number of cases where death was a reported outcome	Case number	Age	Gender	Report Entry Dat	MedDRA reaction term
Injury, poisoning and procedural	Adverse event following immunisation	3	695048	15	M	15/01/2022	Adverse event following immunisationHead banging
			694426	-	M	14/01/2022	Adverse event following immunisation
			693720	-	F	13/01/2022	Adverse event following immunisation
General disorders and administration site conditions	Vaccination failure	2	698345	95	F	21/01/2022	Myocardial infarctionVaccination failure
			699744	75	M	24/01/2022	Concomitant disease progressionCOVID-19Respiratory failureSARS-CoV-2 test positiveVaccination failure
General disorders and administration site conditions	Concomitant disease progression	2	692021	85	F	10-01-2022	Acute pulmonary oedemaConcomitant disease progression
			699744	75	M	24/01/2022	Concomitant disease progressionCOVID-19Respiratory failureSARS-CoV-2 test positiveVaccination failure
Respiratory, thoracic and mediastinal disorders	Dyspnoea	1	703511	75	F	31/01/2022	DyspnoeaFallHyperhidrosisLoss of consciousnessRespiratory arrest
Skin and subcutaneous tissue disorders	Hyperhidrosis	1	703511	75	F	31/01/2022	DyspnoeaFallHyperhidrosisLoss of consciousnessRespiratory arrest
Infections and infestations	COVID-19	1	699744	75	M	24/01/2022	Concomitant disease progressionCOVID-19Respiratory failureSARS-CoV-2 test positiveVaccination failure
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	1	691936	37	F	10-01-2022	Pulmonary embolism
			691965	41	-	10-01-2022	Pulmonary embolism
			692010	53	M	10-01-2022	Pulmonary embolism
Nervous system disorders	Cerebrovascular accident	1	703118	49	F	31/01/2022	Atrial fibrillationBrain oedemaCerebrovascular accident
Nervous system disorders	Loss of consciousness	1	703511	75	F	31/01/2022	DyspnoeaFallHyperhidrosisLoss of consciousnessRespiratory arrest
Investigations	SARS-CoV-2 test positive	1	699744	75	M	24/01/2022	Concomitant disease progressionCOVID-19Respiratory failureSARS-CoV-2 test positiveVaccination failure
Cardiac disorders	Atrial fibrillation	1	703118	49	F	31/01/2022	Atrial fibrillationBrain oedemaCerebrovascular accident
Cardiac disorders	Myocardial infarction	1	698345	95	F	21/01/2022	Myocardial infarctionVaccination failure
Injury, poisoning and procedural complications	Fall	1	703511	75	F	31/01/2022	DyspnoeaFallHyperhidrosisLoss of consciousnessRespiratory arrest
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	1	703511	75	F	31/01/2022	DyspnoeaFallHyperhidrosisLoss of consciousnessRespiratory arrest
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	692021	85	F	10-01-2022	Acute pulmonary oedemaConcomitant disease progression
Respiratory, thoracic and mediastinal disorders	Respiratory failure	1	699744	75	M	24/01/2022	Concomitant disease progressionCOVID-19Respiratory failureSARS-CoV-2 test positiveVaccination failure
Nervous system disorders	Brain oedema	1	703118	49	F	31/01/2022	Atrial fibrillationBrain oedemaCerebrovascular accident
Psychiatric disorders	Head banging	1	695048	15	M	15/01/2022	Adverse event following immunisationHead banging

Source: DAEN database search

The only category for which I could not definitively determine the deaths was Pulmonary Embolism included in Respiratory, Thoracic and Mediastinal Disorders. There were three cases on the one date, 1 of which was a death but it's impossible to identify which one from the DAEN system alone. All 3 were adults.

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END OF REPORT