MAAT'S METHOD

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Opinion

Legal Ramifications for Registered Health Practitioners

And AHPRA Public Officers

Re

The AHPRA and the National Boards joint statement of 9 March 2021

A Note to International readers:

This is an Opinion created in Australia, a member of the Commonwealth. Commonwealth laws are often reflective of one another, as such, this Opinion could prove to provide guidance in other Commonwealth nations.

1. On 9 March 2021 AHPRA released a joint statement with the National Boards (***the March statement***):

   https://www.ahpra.gov.au/News/2021-03-09-vaccination-statement.aspx

2. The statement is an expression by AHPRA and the National Boards of their 'expectations of registered health practitioners', to fully assist with the national vaccination rollout program, while advising that any statements made by practitioners contrary to the government's public health response, and by implication, government messaging, 'may be subject to regulatory action' by AHPRA and the National Boards, with the implied and explicit presumption being, any contrary statements would be deemed 'anti-vaccination messages' or 'anti-vaccination claims'.

3. The statement goes on to say:

   As the national vaccination program gets underway, registered health practitioners and students remain critical to this success by:

   - *being vaccinated against COVID-19 unless medically contraindicated*
   - *being appropriately qualified and trained to administer COVID-19 vaccines if authorised, and*

- ***providing accurate information and advice about COVID-19 vaccination including in social media and advertising.***

And further we find:

> *'.. all registered practitioners have a key role to play* ***by ensuring they provide accurate, evidence-based information to patients about COVID-19 vaccination.***
> ...
>
> *'There is no place* ***for anti-vaccination messages*** *in professional health practice, and any promotion of anti-vaccination claims including on social media, and advertising may be subject to regulatory action.'*
>
> (emphasis added)

4. From the outset it should be clear that the joint statement is about 'expectations' of conduct, in so far as that conduct concerns the national Covid-19 vaccination program which has from the outset been a Federal government campaign the State and Territory governments implemented, and in turn further promoted or indeed mandated.

5. In short, AHPRA and the National Boards had via this joint statement, sought to conscript health practitioners to implement a national Covid-19 vaccination program, which AHPRA and the National Boards 'expected' no health practitioners to question, under threat of reprisals.

6. But the *Health Practitioner Regulation National Law ('the* ***National Law****')* governing registered Health Professionals does not empower AHPRA or National Boards to direct Health Professionals to administer experimental drugs without questioning the need, known safety, or known efficacy of any such drugs; nor does the ***National Law*** empower AHPRA or National Boards to forbid Health Professionals from expressing their expert views with their patients about the need, known safety, or known efficacy of an experimental drug national governments seek to promote in the community. Indeed patients seek out Health Professionals to understand drugs being promoted to

them from any source. When that promotion is coming from government about a new experimental drug, then in an environment bereft of any conclusive clinical or historical data on the actual safety and efficacy and risks associated with such a drug, it becomes incumbent upon Health Professionals to share the best information they possess on any such drugs, with their patients and the community.

7. These duties to share information with patients and the community are in fact found within the ***National Law*** itself.

8. To understand this we must walk through the ***National Law*** to see what powers are available to AHPRA and National Boards, then understand those powers in the context of the duties owed by Health Professionals to their patients and community.

9. For this task I shall use the Queensland version of the ***National Law*** shown here:

> **HEALTH PRACTITIONER REGULATION NATIONAL LAW (QUEENSLAND) - As at 6 December 2021 - Act hprnlq of 2009**

10. From the outset we must note in **Section 3A** that the ***Paramount guiding principle*** of the ***National Law*** is:

> '.. that the health and safety of the public are paramount.'

11. Next, the Ministerial Council under **Section 11** has the power over AHPRA and National Boards to:

> '.. give directions to a National Board about the policies to be applied by the National Board in exercising its functions under this Law.'

12. The Ministerial Council is now called the Health Ministers Meeting (HMM). A search was conducted to locate any policy directive from the HMM to AHPRA and National Boards to prepare and release the March statement. No such directive from the HMM

can be located, therefore it can only be assumed AHPRA and the National Boards are responsible for the March statement.

13. Turning then to **Section 30** we find the power in AHPRA to decide 'policies':

> '**Functions of Agency Management Committee**
>
> (1) The functions of the Agency Management Committee are as follows—
> (a) subject to any directions of the Ministerial Council, to decide the policies of the National Agency'

(Note: the National Agency is the formal title given to AHPRA under the ***National Law***. The Agency Management Committee is the internal management committee within AHPRA.)

14. Nowhere does AHPRA assert the March statement is a 'policy' of AHPRA.

15. AHPRA is required to publish all official Policy Directions and guidance on its website, and record them in its Annual Report. In the 2020-2021 Annual Report covering the period during which the March statement was released, we find that AHPRA made no record seeking to place the March statement forward as an official policy.

16. As such, the March statement at its highest can only be called a 'joint statement' or 'position statement' published by AHPRA and the National Boards.

17. This means the March statement holds no special legal nature or force, nor does it appear possible to call the March statement a 'legislative instrument' or 'subordinate legislation'. Instead, the March statement appears to be nothing more than support for the national Covid-19 vaccination program, where in terms, it seeks to state on behalf of Australian governments 'what is expected' of registered practitioners.

18. However the problem for AHPRA and the National Boards is that the March statement directly conflicts with the ***Codes of Conduct*** for Health Professionals, particularly

where a significant body of peer-reviewed literature and studies inform expert Health Professionals of dangerous outcomes associated with the use of Covid-19 vaccines, while presenting significant data to evidence Covid-19 vaccines do not prevent transmission nor repeated reinfection with SARS-CoV-2.

See for instance the comprehensive report by Dr Phillip Altman: *The Time of Covid*, released in Australia, August 2022, forming **Annexure 1**.

19. Additionally, expert Health Professionals in Australia have been observing historically unprecedented numbers of adverse event reports submitted in relation to the Covid-19 vaccines, where after 18 months of their deployment in Australia, Covid-19 vaccines have recorded more adverse event reports than those collectively submitted during the prior 50 years of adverse event reporting in Australia.

See for instance the comprehensive report by Lisa Mitchell forming Appendix B to the report by Dr Phillip Altman: *A COMPARISON OF ADVERSE EVENTS RELATED SPECIFICALLY TO THE COVID-19 VACCINES AND NON-COVID-19 VACCINES FROM 1 JAN 1971 TO 31 DEC 2021*, being specific to Australia, forming **Annexure 2**.

20. Codes, or more specifically, ***Codes of Conduct*** as they ultimately become named, are a responsibility of National Boards under the ***National Law***, as seen with **Section 39**, which states:

> '**39 Codes and guidelines**
>
> A National Board may develop and approve codes and guidelines—
>
> (a) to provide guidance to the health practitioners it registers'

21. The functional purpose of ***Codes of Conduct*** is again reinforced under **Section 35(1)(c)(iii)** which states:

'**35 Functions of National Boards**

(1) The functions of a National Board established for a health profession are as follows—

(c) to develop or approve standards, codes and guidelines for the health profession, including—

(iii) the development and approval of codes and guidelines that provide guidance to health practitioners registered in the profession'

22. The *Code of Conduct* for Australian doctors contains very clear professional and ethical responsibilities that directly aid to serve the ***Paramount guiding principle*** contained in **Section 3A**, being again: *the health and safety of the public are paramount*.

23. In contradistinction with the March statement by AHPRA, relevant parts of the ***Code of Conduct*** for doctors read (in-part, emphasis added):

1.1 Purpose of the code

Good medical practice **(the code)** describes **what is expected of all doctors registered to practise medicine in Australia**. It sets out the principles that characterise good medical practice and **makes explicit the standards of ethical and professional conduct expected of doctors by their professional peers** and the community.

1.2 Use of the code

Doctors have a professional responsibility to be familiar with Good medical practice and **to apply the guidance it contains**.

This code will be used:

- to assist the Medical Board of Australia in its role of protecting the public, by setting and maintaining standards of medical practice against which a doctor's professional conduct can be evaluated. **If your professional**

conduct varies significantly from this standard, you should be prepared to explain and justify your decisions and actions. Serious or repeated failure to meet these standards may have consequences for your medical registration

2.1 Professional values and qualities of doctors

Doctors have a duty to make the care of patients their first concern and to practise medicine safely and effectively. They must be honest, ethical and trustworthy.

Doctors have a responsibility to protect and promote the health of individuals and the community.

2.2 Public comment and trust in the profession

While there are professional values that underpin good medical practice, **all doctors have a right to have and express their personal views and values.**

3.1 Introduction

In clinical practice, **the care of your patient is your primary concern.**

3.2 Good patient care

Maintaining a high level of medical competence and professional conduct is essential for good patient care. Good medical practice involves:

3.2.4 **Considering the balance of benefit and harm in all clinical-management decisions.**
3.2.6 Providing treatment options **based on the best available information**.
3.2.7 **Only recommending treatments when there is an identified therapeutic nee**d and/or a clinically recognised treatment, **and a reasonable expectation of clinical efficacy and benefit for the patient**.

4.5 Informed consent

Informed consent is a person's voluntary decision about medical care that is made with knowledge and understanding of the benefits and risks involved. Good medical practice involves:

4.5.1 **Providing information to patients in a way they can understand before asking for their consent.**

4.6 Children and young people

Caring for children and young people brings additional responsibilities and challenges for doctors. Good medical practice involves:

4.6.1 **Placing the interests and wellbeing of the child or young person first.**

4.11 Adverse events

When adverse events occur, **you have a responsibility to be open and honest in your communication with your patient, to review what has occurred and to report appropriately.**

8.3 Doctors' performance – you and your colleagues

8.3.3 **Taking steps to protect patients from risk posed by a colleague's conduct, practice** or ill health.
8.3.5 **Complying with any statutory reporting requirements, including mandatory reporting requirements under the National Law as they apply in your jurisdiction**.

9.2 Continuing professional development

9.2.1 **Keeping your knowledge and skills up to date.**

10.12 Conflicts of interest

Patients rely on the independence and trustworthiness of doctors for any advice or treatment. A conflict of interest in medical practice arises when a doctor, entrusted with acting in the interests of a patient, also has

financial, professional or personal interests, or relationships with third parties, which may affect their care of the patient.

10.12.4 **Recognising that pharmaceutical and other medical marketing influences doctors and being aware of ways in which your practice may be being influenced.**

13.2 Research ethics

13.2.6 Ensuring that human participation is voluntary and based on an adequate understanding of sufficient information about the purpose, methods, demands, risks and potential benefits of the research.
13.2.8 Seeking advice when research involves children or adults who are not able to give informed consent, to ensure that there are appropriate safeguards in place.
13.2.10 Monitoring the progress of the research and promptly reporting adverse events or unexpected outcomes.

This code is issued under section 39 of the Health Practitioner Regulation National Law, as in force in each state and territory (the National Law).

24. It is worthy of brief mention at this juncture the *Australian Charter of Healthcare Rights* owed to patients, which relevantly reads (in-part):

Information
Clear information about my condition, the possible benefits and risks of different tests and treatments, so I can give my informed consent

25. ***Codes of Conduct*** created by the various National Boards are required to be published on each National Board's website, pursuant to section 40.

26. Critically, and pursuant to **Section 41**, ***Codes of Conduct*** created and approved under the ***National Law***, are admissible in proceedings under the ***National Law*** against a registered practitioner, *as evidence of what constitutes appropriate professional conduct or practice for the health profession*.

27. The evidential weight afforded to the ***Codes of Conduct*** in turn directly assist National Boards when investigating registered practitioners, pursuant to **Section 35(1)(g)** and **(h)** of the ***National Law***:

> '**35 Functions of National Boards**
>
> (1) The functions of a National Board established for a health profession are as follows—
>
> (g) to oversee the assessment and investigation of matters referred to it by the National Agency about persons who—
>
> (i) are or were registered as health practitioners in the health profession under this Law or a corresponding prior Act;
>
> (h) to establish panels to conduct hearings about—
>
> (i) health and performance and **professional standards matters** in relation to persons who are or were registered in the health profession under this Law or a corresponding prior Act'
>
> (emphasis added)

28. The evidential weight and importance afforded to the Codes of Conduct is further reinforced by their use and reference under the Mandatory notifications sections of the National Law, where the definition of notifiable conduct at **Section 140(d)** reads:

> '**140 Definition of notifiable conduct**
>
> In this Division—
>
> **"notifiable conduct"** , in relation to a registered health practitioner, means—
>
> (d) placing the public at risk of harm by practising the profession in a way that constitutes a significant departure from **accepted professional standards**.'
>
> (emphasis added)

29. Recall, the March statement by AHPRA and the National Boards is not a formally adopted 'policy' of AHPRA, nor did the March statement change any of the ***Codes of Conduct*** for registered practitioners. Furthermore, there are no provisions of the ***National Law*** that state any bare statements such as the March statement, override any ***Codes of Conduct***, just as we find there are no provisions of the ***National Law*** that state any such bare statements are admissible in proceedings against a registered practitioner, *as evidence of what constitutes appropriate professional conduct or practice for the health profession.*

30. To this end the March statement can be broken down into its simplest elements, being:

    a) AHPRA and the National Boards support the national Covid-19 vaccination program;

    b) As such, AHPRA and the National Boards 'expect' health practitioners to also support the Covid-19 vaccination program;

    c) Which expectation was accompanied by a threat: '*There is no place for anti-vaccination messages in professional health practice, and any promotion of anti-vaccination claims including on social media, and advertising may be subject to regulatory action.*';

    d) Which threat was subtly qualified by recognition of the ***Codes of Conduct***: *'all registered practitioners have a key role to play by ensuring they provide accurate, evidence-based information to patients about COVID-19 vaccination.'*

31. Despite the 'expectations' and 'threats' coming from AHPRA and the National Boards, the March statement clearly defaults to give due recognition to the primacy of adherence with ***Codes of Conduct,*** by all health practitioners being, to *provide accurate, evidence-based information to patients about COVID-19 vaccination.*

32. At this point it must be made clear that National Boards and AHPRA owe their existence to the 2008 ***Intergovernmental Agreement for a National Registration and Accreditation Scheme for the Health Professions***. This agreement is between the governments of all Australian States, Territories, and the Commonwealth. As such, no one single Australian government is directly responsible for the existence of National Boards and AHPRA, they are all equally responsible. Therefore AHPRA and each National Board hold a unique status for being a 'Federated Body' created pursuant to a national intergovernmental agreement.

33. Since these Federated Bodies exist due to each Australian State and Territory government enacting essentially identical forms of the ***National Law,*** within their respective jurisdictions, the ***National Law,*** so enacted within each State or Territory, is directly amendable to be referenced and interpreted by each State or Territory's equivalent version of an *Acts Interpretation Act*, or *Interpretation Act*. These Acts assist with providing guidance for better interpreting legislation and for better understanding the importance of certain instruments, standards, or codes, subsequently produced by powers granted under legislation, for 'making rules' in the future, being rules or standards or codes not contained within the original legislation. The ***Codes of Conduct*** subsequently created by National Boards under the ***National Law*** are of this nature. Legally speaking, the *Codes* can also be called subordinate legislation, or statutory rules.

34. In light of the fact ***Codes of Conduct*** are admissible *as evidence of what constitutes appropriate professional conduct or practice for the health profession*, ***Codes of Conduct*** must necessarily be deemed to be statutory rules, in so far as they prescribe minimum levels of conduct and practice to be observed by a health practitioner, in order to be legally deemed an 'appropriately professional' practitioner.

35. In New South Wales there is the *Interpretation Act* of 1987, which sets forth in **Sections 39** through **43** the powers and procedures to be observed when making statutory rules. It does appear that National Boards like the Medical Board of Australia have failed to observe their statutory duties under the *Interpretation Act*, to publish their ***Codes of Conduct*** on the NSW legislation website, and then table a written notice of the making of their ***Codes of Conduct*** before each House of Parliament within 14 sitting days: see

section 40. These failures however do not invalidate the ***Codes of Conduct***: see **Section 40(4)**. Generally speaking, (and not wishing to investigate every State and Territory equivalent of NSW's *Interpretation Act)*, it can be fairly surmised that all National Boards have similarly failed to properly publish on respective government legislation websites their ***Codes of Conduct***, and equally have not laid a 'notice' before relevant Houses of Parliament in each State and Territory.

36. However all the National Boards have published their ***Codes of Conduct*** on their respective websites, where they came into 'effect' on the day they were published:

> Medical: https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx
>
> Psychology: https://www.psychologyboard.gov.au/Standards-and-Guidelines/Code-of-conduct.aspx
>
> Nursing and Midwifery: https://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Professional-standards.aspx
>
> The remaining 12 Boards – ***Shared Code of Conduct***: https://www.ahpra.gov.au/Resources/Code-of-conduct/Shared-Code-of-conduct.aspx

37. As a consequence of the powers, processes, and procedures given to and observed by National Boards in the creation, publication, and enforcement use of ***Codes of Conduct***, it appears to be beyond question that these ***Codes of Conduct*** created and referenced 'as evidence' of what constitutes acceptable professional practice, are properly to be deemed as statutory rules, which gives them paramountcy as subordinate legislation before any Court of law. Although it is a Commonwealth Act, it is worth noting also that the *Legislation Act 2003* (Cth) defines a legislative instrument in **Section 8** as follows:

> '**Definition of legislative instrument**

(1) A ***legislative instrument*** is an instrument to which subsection (2), (3), (4) or (5) applies.

Note: Instruments that can be legislative instruments may be described by their enabling legislation in different ways, for example as regulations, rules, ordinances or determinations.

(4) An instrument is a ***legislative instrument*** if:

(a) the instrument is made under a power delegated by Parliament; and

(b) any provision of the instrument:

…

(ii) has the direct or indirect effect of … **imposing an obligation**, creating a right, or varying or removing an obligation or right.'

(emphasis added)

The *Note* to **Section 8(1)** above can also be read to include *Codes* and ***Codes of Conduct***. **Section 8(4)** 'imposing an obligation' speaks directly to ***Codes of Conduct*** imposing legal obligations upon registered practitioners, particularly when read again in the context of **Section 41** of the ***National Law***, where they are more clearly understood as legal obligations that serve as evidence of what constitutes appropriate professional conduct or practice for the health profession.

38. In light of the foregoing analysis and conclusion, the following statements hold true at law:

a) The legislative status of the ***Codes of Conduct*** have always prevailed over and before the legally hollow March joint statement;

b) Any aspect of the March joint statement that conflicts with any aspect of a ***Code of Conduct*** is invalid and of no effect;

c) To the extent any conduct 'expected' of registered practitioners as directed under the March joint statement, could or would cause a practitioner to conduct

themselves in a manner that would cause them to contravene a ***Code of Conduct***, such 'expectations' were and are invalid and of no effect;

d) The threat of 'regulatory action' against a practitioner for any promotion of claims, including on social media, contrary to the public (government) health response to Covid-19, including Covid-19 vaccination, was always repugnant at law, where such a threat acted as a coercive measure capable of intimidating a practitioner to not fully and completely observe every tenet of their ***Code of Conduct***;

e) While every practitioner has to generally observe public health obligations towards disease control (Medical Code 7.4), those obligations must be read along with all other obligations and responsibilities imposed upon them by their ***Codes of Conduct***, including that they were at all times required to be providing accurate, evidence-based information to patients about COVID-19 vaccination, both before and after the March statement;

f) Every practitioner possessed of evidence-based information capable of reasonably supporting ***claims against any material aspect*** of Covid-19 vaccination, as a possible treatment for SARS-CoV-2 infection, where any such claims ***could materially affect the risk-benefit analysis to be performed by a patient*** prior to their giving Informed Consent to a Covid-19 vaccine, has always remained information a practitioner is required to provide to patients pursuant to their ***Code of Conduct***;

g) Every practitioner possessed of evidence-based information ***capable of reasonably supporting claims against any material aspect*** of Covid-19 vaccination, as a possible treatment for SARS-CoV-2 infection, has always remained entitled to communicate such information via social media or the media, when the presentation of the evidence-based information is done professionally and in accordance with their ***Code of Conduct***.

39. Using again the Medical Board of Australia ***Code of Conduct*** as a point of reference,

and in light of the evidence-based information ('the information') contained in the reports of Dr Phillip Altman and Lisa Mitchell referenced above, every registered practitioner responsible for the provision of a Covid-19 vaccination is required to:

a) Keep their knowledge up to date (Code 9.2.1), which is especially relevant in respect of any provisionally approved Covid-19 vaccine still the subject of Clinical Trials.

b) Be honest and ethical in their appraisal of the information for the protection and promotion of the health of individuals and the community (Code 2.1), in the knowledge all doctors have a right to have and express their personal views and values (Code 2.2). Knowing the care of your patient is your primary concern (Code 3.1) and based upon this best available information (Code 3.2.6), consideration must be given towards the balance of benefit and harm (Code 3.2.4) in respect of Covid-19 vaccination, against whether there is an identified therapeutic need, and a reasonable expectation of clinical efficacy and benefit for the patient (Code 3.2.7).

c) Additionally, a practitioner possessed of the information, is required to provide the information to patients in a way they can understand before asking for their consent (Code 4.5.1) to receive a Covid-19 vaccine, where the information provided enables a patient to understand the benefits and risks involved (Code 4.5). This is so and particularly in respect of children and young people, towards whom a practitioner must place the interests and wellbeing of a child or young person first (Code 4.6.1).

d) When providing the information to patients in a way they can understand before asking for their consent (Code 4.5.1), a practitioner must be careful not to censor or withhold the information due to any conflict of interest they may have, due to their (where relevant) professional relationship with government public health authorities, whose interests could seek to affect a practitioner (Code 10.12), with respect to the information they provide to a patient to enable them to understand the benefits and risks involved (Code 4.5) with Covid-19 vaccination.

e) Should a practitioner be provided fully informed consent to administer a Covid-19 vaccine, after providing all the information needed to properly and reasonably understand the benefits and risks involved, and should after administering the Covid-19 vaccine an Adverse Event occur, the practitioner has the responsibility to be open and honest in their communication with the patient, to review what has occurred and to report appropriately (Code 4.11).

f) Should a practitioner observe another practitioner they know to be aware of the information, fail to properly assess the information, and/or fail to provide the information to a patient in a way they can understand before asking for their consent (Code 4.5.1) to receive a Covid-19 vaccine, where had the information been provided it would have enabled the patient to understand the benefits and risks involved (Code 4.5), then the first practitioner must take steps to protect the patient from the risk posed by the second practitioner's conduct and practice (Code 8.3.3), and the first practitioner must report the second practitioner pursuant to the mandatory reporting requirements under the ***National Law*** (Code 8.3.5 and Section 141 of the ***National Law***).

g) Lastly and perhaps most importantly, the information now available in respect of the Covid-19 vaccines which must be critically evaluated by all registered practitioners, must be considered along with the acknowledged fact that Covid-19 vaccines are only ***provisionally*** approved, meaning they are still globally the subject of Clinical Trials which now incorporate entire national populations, which necessarily requires practitioners to deem the use of these vaccines as '***research involving humans***' (Code 13.1), requiring the observance of research ethics and responsibilities drawn from National Health and Medical Research Council guidelines (Code 13.2).

h) Due to (g) above, a practitioner must ensure their patient is aware they are, by extension, taking part in ***research on humans*** with respect to the Covid-19 vaccine being considered for administration, where the practitioner must establish the patient is taking part in the research on a voluntary basis, based

upon an adequate understanding of sufficient information about the purpose, methods, demands, risks and potential benefits of the research into the Covid-19 vaccine (Code 13.2.6). When imparting and discussing this knowledge and information about the research with their patient, a practitioner must act with honesty and integrity (Code 13.2.2) for respecting and protecting their patient (Code 13.2.1). A practitioner must acknowledge and share with their patient that the practitioner is assisting with recruiting the patient into research involving humans (Code 13.2.7). In the event all of the foregoing considerations and responsibilities have been satisfied and observed, and a patient provides their fully informed consent and is administered a Covid-19 vaccine, a practitioner must continue to monitor the progress of their patient after administering the Covid-19 vaccine, and promptly report any adverse events or unexpected outcomes (Code 13.2.10).

40. It is now August 2022, and still the March statement of 2021 continues to strike fear into Health Professionals, primarily due to AHPRA very publicly and repeatedly subjecting doctors and Health Professionals to the regulatory actions they threatened would occur, should any practitioner seek to present claims or statements at odds with the public health messaging about Covid-19 vaccines. These public health messages issue primarily from Australian governments, politicians, and bureaucrats, many of which politicians and bureaucrats are not registered health practitioners, which places their actions and statements beyond any legal scrutiny under the ***National Law***, by reference to ***National Law*** subordinate legislation, the ***Codes of Conduct***.

41. Instead, and in simple terms, the March statement of 2021 without any legal basis or force of genuine law, managed to silence and 'gag' registered practitioners from speaking out against the wholly one-sided narrative issuing from Australian governments, concerning SARS-CoV-2 and Covid-19 vaccines.

42. This has resulted in a virtual absence of open scientific and medical discussion, debate, or dialogue concerning the medical and scientific literature that has been emerging throughout 2021 and 2022, a now enormous body of peer-reviewed literature and data

specifically focused on SARS-CoV-2 and the Covid-19 vaccines, as seen collected in the reports of Dr Altman and data expert Lisa Mitchell (Annexures 1 & 2).

43. As a consequence:

a) this has led to a ***negligent and gross absence*** of directly relevant information being provided to millions of Australians, for the purpose of their being able to provide fully-informed ***Informed Consent***, prior to the receipt of these acknowledged experimental treatments.

b) this has led to an abundance of misinformation and misunderstanding about SARS-CoV-2 and Covid-19 vaccines.

c) this has led to a denial of directly relevant information being shared and spread throughout the medical and scientific community, which for medical and health professionals, is information needed by them in order to discharge their legal obligations under the ***National Law***, pursuant to their ***Codes of Conduct***.

d) this has led and caused gross breaches of the ***National Law*** by virtually all registered practitioners who have administered, and who continue to administer, Covid-19 vaccines.

e) And as corollary, this has led to failure of ***mandatory notification*** reporting of registered practitioners, being provisions under the ***National Law*** meant to serve as additional protection measure for the Australian public, which has further derogated and magnified the ***gross and negligent*** failings to afford the Australian people directly relevant information registered practitioners are legally obligated to provide, for the purpose of their patients providing fully-informed ***Informed Consent***, prior to the receipt of these acknowledged experimental treatments.

44. Registered health professionals now in possession of the information annexed to this opinion are, in furtherance of the observance of their ***Codes of Conduct***, required to professionally consider the information with scientific objectivity, for the careful

consideration of their legal responsibilities to comply with their ***Codes of Conduct***, as detailed in paragraph 39(a)-(h) above, or potentially face investigation for complaints received from the general public, or mandatory notifications lodged by other registered practitioners calling for their investigation under the ***National Law***, for professional misconduct.

45. When giving due and professional consideration to the information annexed to this opinion, registered practitioners must be mindful of what constitutes *unprofessional conduct*. Unprofessional conduct is intimately associated with a failure to observe ***Codes of Conduct***, where 'a contravention by [a] practitioner of the ***National Law***' does include a contravention of a ***Code of Conduct***, as **Section 41** clearly stipulates (see paragraph 26 above). **Section 5** of the ***National Law*** sets forth the definition of *unprofessional conduct*, and reads (in-part):

> '**"unprofessional conduct"** , of a registered health practitioner, means professional conduct that is of **a lesser standard than that which might reasonably be expected of the health practitioner by the public** or the practitioner's professional peers, and includes—
>
> (a) **a contravention by the practitioner of this Law**, whether or not the practitioner has been prosecuted for, or convicted of, an offence in relation to the contravention; and
>
> (d) **providing a person with health services of a kind that are excessive, unnecessary or otherwise not reasonably required for the person's well-being**'
> (emphasis added)

46. Despite the forgoing legal analysis, it is expected that many registered practitioners will seek to avoid regulatory action from AHPRA. Practitioners possessed of the type of information annexed to this opinion can simply avoid any regulatory action by desisting from the provision of Covid-19 vaccines, where no detailed public explanation is required. Practitioners who choose to publicy share the information with their patients

and community will risk regulatory action from AHPRA. To date AHPRA has ostensibly relied upon **Section 156** which reads:

> '**156 Power to take immediate action**
>
> (1) A National Board may take immediate action in relation to a registered health practitioner or student registered in a health profession for which the Board is established if—
>
> (a) the National Board reasonably believes that—
>
> (i) because of the registered health practitioner's **conduct**, performance or health, the practitioner poses a serious risk to persons; and
>
> (ii) it is necessary to take immediate action to protect public health or safety'

47. Generally speaking, (where this opinion is not the proper place to discuss legal defences to an action brought under **Section 156**), practitioners seeking to resist an *Immediate Action* will need to carefully compile the evidence-based information that supports any public statement or claim made against Covid-19 vaccines, or in respect of SARS-CoV-2. The information annexed to this opinion is amply referenced to adequately assist. While a clear and repeated articulation by a practitioner defending such an action of their legal responsibilities as derived from their ***Code of Conduct***, as contained in this opinion, will serve as a proper legal basis and defence when supported by evidence-based information.

48. Broadly stated, any public office holders and bureaucrats in possession of the information annexed to this opinion, who would seek to withhold such evidence-based information from registered practitioners, will arguably find themselves publicly liable for gross *misfeasance* for acting in 'bad faith'. Generally stated, public officers and their departments are often afforded immunity from civil actions, but immunity is lost to a public officer and their department when they can be shown to have acted in 'bad faith': see for instance **Section 61A** of the *Therapeutics Goods Act* (Cth) and **Section 236** of the ***National Law***. While further still, a public officer can become personally exposed and personally liable to various forms of civil claims by members of the public,

if they can be shown to have acted outside the scope of their employment duties, when seeking to withhold evidence-based information from registered practitioners, and possibly, where shown to have withheld evidence-based information from the public.

Misfeasance in Public Office – Legal Ramifications for AHPRA Public Officers

49. For this section of the opinion much content and analysis will be drawn from the paper by Emeritus Professor Mark Aronson, *Misfeasance in Public Office: A Very Peculiar Tort*.[1]

50. Before proceeding it should be acknowledged that National Boards and in particular AHPRA[2], are enormously well resourced both financially and in terms of staffing, especially in respect of legal services, and particularly for obtaining legal advices in respect of contemplated actions, like the March 2021 joint statement.

51. The elements of the common law *action* of misfeasance are discussed by Aronson in the following paragraphs.

52. In *Farrington v Thomson*,[3] Smith J:

> 'proposed an action for damages for misfeasance in public office where the public officer .. caused damage to the plaintiff by 'an act which, to his knowledge, amounts to an abuse of his office''[4]

53. This 'abuse of office' aspect is often referred to as 'the illegality issue'.

54. Since *Farrington* four later cases added:

[1] Referenced page number will refer to the PDF version: https://law.unimelb.edu.au/__data/assets/pdf_file/0006/1703517/35_1_1.pdf ; web version here: http://classic.austlii.edu.au/au/journals/MelbULawRw/2011/1.html
[2] https://www.ahpra.gov.au/Publications/Annual-reports/Annual-Report-2021/Finance.aspx
[3] [1959] VR 286
[4] Aronson: page 19.

> ‘a third alternative to the mental elements of misfeasance. They reasoned that there was no moral difference between knowing something on the one hand, and being aware of its possibility but not caring whether it might be true or might occur.[5] This third variant is generally referred to as reckless indifference, but it is not to be imputed — the defendant must have consciously adverted to the relevant circumstance or risk and decided not to care about it.’[6]

55. Aronson clarifies the Australian approach to this third element of reckless indifference:[7]

> ‘.. currently, the reckless indifference requirement applies only to the illegality issue, and not to the risk of harm.[8] The harm must have been foreseeable, but the defendant need not have adverted to its risk.[9]’

56. Addressing the further issue of *bad faith* briefly mentioned in paragraph 48 above, Aronson provides clarification with the following:[10]

> ‘In a much-quoted passage, Brennan J said in *Mengel* that the core of misfeasance lay in ‘the absence of an honest attempt to perform the functions of the office’.[11] His Honour said that there was such an absence if the defendant had acted invalidly and with malice, knowledge or reckless indifference, and he may well have intended that list to be exhaustive. There are passages in *Three Rivers* that could be interpreted as requiring

[5] *Mengel* (1995) 185 CLR 307, 347 (Mason CJ, Dawson, Toohey, Gaudron and McHugh JJ), 359 (Brennan J); *Three Rivers* [2003] 2 AC 1, 196 (Lord Steyn), 223 (Lord Hutton), 231 (Lord Hobhouse), 236 (Lord Millett); *Odhavji* [2003] 3 SCR 263, 283 (Iacobucci J for McLachlin CJ, Gonthier, Iacobucci, Major, Bastarache, Binnie, Arbour, LeBel and Deschamps JJ); *Garrett* [1997] 2 NZLR 332, 349 (Blanchard J for Richardson P, Gault, Henry, Keith and Blanchard JJ).
[6] Aronson: page 20.
[7] Aronson: page 22.
[8] *South Australia v Lampard-Trevorrow* (2010) 106 SASR 331, 387–8 [263]–[265] (Doyle CJ, Duggan and White JJ).
[9] Ibid 387–8 [263]–[264].
[10] Aronson: page 22.
[11] *Mengel* (1995) 185 CLR 307, 357.

proof of dishonesty or bad faith as an additional element in all cases.[12] **In Australia, proof that defendants knew that they were acting beyond power is all that is needed to establish bad faith.**[13]'
(emphasis added)

57. The office holders within AHPRA meet the definition of 'public officers' for the tort of misfeasance to be applicable to them. As Aronson states:[14]

> 'Brennan J referred to an old definition of public officers, which in essence contained two elements. First, they must have been appointed to perform a public duty. Secondly, they must be remunerated, although that may come in the form of money or land from the Crown, or fees from the public.[15]'

58. In the case of AHPRA fees come from registered practitioners and are supplemented by government contributions from time to time.

59. With the above commentary and examination of the law of misfeasance by Aronson, we can return now to the AHPRA March statement to make the following observations.

60. Sections within the joint March publication clearly contain statements wholly inconsistent with ***Codes of Conduct***, (statutory rules), being statements coercing and threatening registered practitioners not to follow and closely observe their ***Codes of Conduct***, under threat of regulatory action, where the clear directive was to comply at all costs with the rollout of the Covid-19 national vaccination program, where the wording is beyond any ambivalence:

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[12] [2003] 2 AC 1, 246 [41]–[42] (Lord Hope), 267 [121] (Lord Hutton), 289 [175] (Lord Hobhouse), 290–1 [179]–[182] (Lord Millett).
[13] *Federal Commissioner of Taxation v Futuris Corporation Ltd* (2008) 237 CLR 146, 153 [11] (Gummow, Hayne, Heydon and Crennan JJ).
[14] Page 42.
[15] *Mengel* (1995) 185 CLR 307, 355, referring to *Henly v Lyme* (1828) 5 Bing 91, 107–8; 130 ER 995, 1010 (Best CJ).

> ‘All practitioners, including students on placement, **must comply** with local employer, health service or health department policies, procedures and guidelines on COVID-19 vaccinations.’
> (emphasis added)

61. This coercion coupled with threats is the ‘illegality issue’. At no time were the public officers of AHPRA or the National Boards empowered to lawfully coerce or threaten registered practitioners, let alone threaten registered practitioners to not observe their statutory rules (***Codes of Conduct***). AHPRA and the National Boards coerced and threatened registered practitioners to break the ***National Law*** for which AHPRA and National Boards were created to implement and uphold including, implicitly, the ***Codes of Conduct*** created under the ***National Law***. In consequence the March statement can only be deemed as an illegal act and abuse of power by the public officers of the National Boards, and AHPRA. Using the analysis in paragraphs 54, 55, and 56 above, it can be stated AHPRA and the National Boards were ‘recklessly indifferent’ to this abuse of power. That the March statement does not avert to the risks to Australians from having registered practitioners not observe their ***Codes of Conduct*** does not assist AHPRA or the National Boards, as the risks to Australians were foreseeable.

62. As a consequence, it does appear grounds exist for persons injured by Covid-19 vaccines, or the families of those who died from Covid-19 vaccines, to sue the various public officers within AHPRA and the National Boards responsible for the March statement, in actions of misfeasance in public office.

63. The March statement had the real and consequent effect of intimidating practitioners responsible for the administration of Covid-19 vaccines, to not stringently observe their ***Codes of Conduct*** in similar terms as detailed in paragraph 39 above, resulting generally, in millions of Australians not being fully-informed for the purpose of their being able to provide Informed Consent, where had they been fully-informed many persons (perhaps in the thousands or millions), may have clearly ***chosen to not*** receive an experimental Covid-19 vaccine, for a plethora of reasons, many of which arise from the evidence-based information.

64. The evidence-based information was not being shared by practitioners with patients, nor government health authorities who were in possession of the evidence-based information as it was emerging throughout 2021, commensurate with the rollout of the Covid-19 vaccines. Such evidence-based information has always remained a duty of the ***Therapeutic Goods Administration*** (TGA) to collect as soon as it becomes available, as part of its ongoing Pharmacovigilance duties owed to the Australian public. The departments of health within each State and Territory government have similar ongoing duties to collect and disseminate such evidence-based information. A question arises beyond the scope of this opinion, whether the continued failures by the TGA and relevant departments of health to disseminate to registered practitioners the abundance of evidence-based information merging throughout 2021 and 2022, is not yet another instance of misfeasance in public officers, capable of separate legal actions.

65. A separate though relevant issue when suing public officers for misfeasance also requires mention. Since only AHPRA *as a body* could issue the March statement, then it could be shown no individual within AHPRA can be held accountable for misfeasance, which begs the question whether AHPRA as a body would be directly liable in misfeasance for the harm it caused to Covid-19 vaccine victims.[16] On this issue Aronson observes:

> 'In many misfeasance cases, however, only individual staff members will be directly liable because causal responsibility and the requisite mental states resided only in them. The issue then becomes whether the public bodies for which they worked can be fixed with vicarious liability
>
> .. There have long been difficulties in formulating the basis of vicarious liability for deliberately illegal conduct committed without the employer's de facto authority or ratification. The difficulties increase when the primary tortfeasors act in their own interests and against those of their employers[17]

[16] See Aronson page 44 and supporting case law.
[17] Page 45.

> .. The High Court has not explored the issue, but its analysis in *Mengel* of the tort's structure and principles proceeded on the premise that 'ordinarily', individual misfeasance tortfeasors would receive no indemnity or contribution from their employing authorities.[18]'

66. With respect to the March statement, it can be said the public officers of AHPRA acted in the interests of Federal, State, and Territory governments seeking to implement a national Covid-19 vaccination program. But AHPRA was not created to serve national government's interests and desires to vaccinate the Australian public. The paramount guiding principle for AHPRA has always been and first 'the health and safety of the public', and 'to facilitate the provision of high quality education .. of health practitioners'. Therefore it does appear that AHPRA as a body could be deemed by a Court as not being vicariously liable for the March statement, leaving then liability only with those AHPRA public officers responsible for the March statement, who acted beyond AHPRA's stated statutory objectives and functions, by intimidating, coercing, and threatening registered practitioners with regulatory action, if they did not cease their full and proper observance of their ***Codes of Conduct***, demanding instead they act without comment or criticism while assisting Australian national governments with a vaccination program, using acknowledged experimental drugs.

67. To this end and brief mention should be made of the common law *offence* of misfeasance, discussed by Aronson as follows:[19]

> 'The common law *offence* covers acts or omissions of public officers in the course of or in relation to their public office, which amount to misconduct with a degree of culpability that warrants public condemnation and criminal punishment.[20] Speaking for the Hong Kong Court of Final Appeal,

[18] Page 46
[19] Aronson: page 19.
[20] This is an amalgam drawn from *R v Dytham* [1979] QB 722; *R v Bowden* [1996] 1 WLR 98; *A-G's Reference* (No 3 of 2003) [2005] QB 73; *Sin Kam Wah v Hong Kong Special Administrative Region* [2005] 2 HKLRD 375; *R v Quach* (2010) 201 A Crim R 522; Nicholls et al, above n 89, 66–71.

> Sir Anthony Mason NPJ said that whether the misconduct is sufficiently culpable depends on whether it is serious 'having regard to the responsibilities of the office and the office-holder, the importance of the public objects which they serve and the nature and extent of the departure from those responsibilities.'[21]
> (emphasis added)

68. As mentioned above again in paragraph 66, the paramount guiding principle for AHPRA has always been 'the health and safety of the public', and 'to facilitate the provision of high quality education .. of health practitioners'. The illegal departure from observing that principle as evidenced in the March statement, where the foreseeable risks to Australians included death, illnesses, and injuries arising from the experimental Covid-19 vaccines, given to them with a near absence of relevant evidence-based information for being fully-informed for providing Informed Consent, appears to be *sufficiently culpable* conduct and actions to warrant serious consideration towards bringing actions for the common law ***offence*** of misfeasance, against the public officers of AHPRA and the National Boards responsible for the March statement of 2021.

69. Lastly, and as alluded to in paragraph 43 above, registered practitioners who failed to fully observe their ***Codes of Conduct*** when administering Covid-19 vaccines, now stand grossly exposed to significant liability with respect to patients who subsequently suffered adverse effects or death causally due to these drugs. Should such lawsuits and liability be established in such practitioners, then those practitioners sued by their patients could arguably seek to in turn sue the public officers of AHPRA and the National Boards responsible for the March 2021 statement, with the common law action of misfeasance, for the damages arising from patient lawsuits. The degree of success for such actions in misfeasance Re registered practitioners versus AHPRA public officers, will likely be moderated in terms of the contributory negligence of practitioners in failing to observe foremost their ***Codes of Conduct***, despite the illegalities and threats and coercion contained in the March 2021 statement.

[21] *Sin Kam Wah v Hong Kong Special Administrative Region* [2005] 2 HKLRD 375, 391 [45].

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15 August 2022

The Time of COVID

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9 August 2022

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Appended:
Australian COVID-19 vaccines Adverse Event Summary & Analysis
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Foreword

I am pleased and proud to endorse the attached letter and monograph, meticulously compiled by Dr Phillip Altman and his colleagues. They address some important aspects of COVID19 management and policy, especially in Australia, with a focus on the nature, deployment and effects of “vaccines”. It is abundantly clear that there has been repression and suppression in scientific circles and the media of any views or suggestions that run counter to the government/mainstream narrative. However, many studies now indicate that the Covid19 vaccines, especially the mRNA vaccines, are less than 'safe and effective', and the ramifications are truly confronting. Armed with these facts, the scientific and medical communities can now begin proper discussions of potential solutions that improve the benefit/risk ratios for the public and do not harm careers and livelihoods of professionals seeking the best outcomes for their patients.

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Index

PART A: Background - COVID-19 Gene-Based 'Vaccines'

1. The Nature of the COVID-19 Gene-Based 'Vaccines'

1.1. The nature of the COVID-19 'vaccines' has been largely misrepresented by mainstream media, big pharmaceutical companies, and governments, and is consequently poorly understood by the population at large. Most people consider vaccines to be relatively safe and well researched and readily accept their widespread use.

1.2. However, these COVID-19 'vaccines' are not really vaccines – they are serious gene-based therapies which employ a gene-based technology which has never before been deployed in a fully approved therapeutic product. In this sense they should properly be considered to be experimental, and much safety and efficacy information has been gained since the introduction of these products more than a year ago.

1.3. COVID-19 'vaccines' as a therapeutic fall under the US Food and Drug Administration (**FDA**) Office of Cellular, Tissue, and Gene Therapies' definition of "gene therapy products", in that it involves "introducing a new or modified gene into the body to help treat a disease"[1]. Despite this, the FDA did not evaluate this therapy in relation to the established gene therapy guidelines. Gene therapies have never been widely used in a general population.

2. Regulatory Status of the COVID-19 Gene-Based 'Vaccines'

2.1. On or about the following dates, the TGA granted conditional Provisional Approval of the following gene-based 'vaccines':

- COMIRNATY Pfizer Australia Pty Ltd – a mRNA vaccine (25 January 2021)
- Pfizer paediatric vaccine has been Provisionally Approved (3 December 2021) 5-11 years
- VAXZEVRIA AstraZeneca Pty Ltd – a viral vector vaccine (15 February 2021)
- COVID-19 VACCINE Janssen-Cilag Pty Ltd – a viral vector vaccine (25 June 2021)
- SPIKEVAX Moderna Australia Pty Ltd, - a mRNA vaccine (9 August 2021)
- Moderna paediatric vaccine has been Provisionally Approved (17 February 2022) 6-11 years & 6 month to 5 years (19 July 2022)
- NUVAXOVID Novavax Inc. – a non-gene protein-based vaccine delivering spike protein in a lipid-nanoparticle matrix carrier (19 January 2022)

2.2. The TGA receives technical and policy advice from the Australian Technical Advisory Group on Immunisation (**ATAGI**). Members of ATAGI have both academic and clinical interests in vaccine research. The TGA relies heavily upon the recommendations of ATAGI in relation to the efficacy, safety and use of vaccines. Many government and

[1] *What is Gene Therapy?* (25/7/2018) US-FDA https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy

private corporate entities rely, in many cases exclusively, upon the health policy advice issued by ATAGI. The TGA also receives advice from the Advisory Committee on Vaccines (**ACV**) in relation to safety, quality and efficacy of vaccines supplied in Australia.

2.3. Provisional Approval is a relatively new drug regulatory pathway introduced into the Therapeutic Goods Act in 2018. Under this expedited review system, therapeutic agents (including vaccines) can be made available for use when there is a perceived urgent need to use a drug even though the amount of ordinary safety and efficacy data normally required to approve that drug is not available. The manufacturer is required by the TGA to submit additional safety and efficacy data over a defined period to answer specific important outstanding safety and efficacy issues not completed or concluded before the product is Provisionally Approved. Products released under "Provisional Approval" cannot be considered fully evaluated. Under these circumstances and because there is pending or outstanding safety and efficacy data to be generated and evaluated, it is premature to declare such drugs "safe and effective", and the use of these agents needs to be constantly under review in light of emerging safety data to reassess the risk versus any perceived benefit.

2.4. The new generation COVID-19 'vaccines' have not been fully 'approved' by the Australian drug regulator – all these products have been "Provisionally Approved" due to deficiencies in the normal scope and depth of safety and efficacy data normally required for full approval. This is of particular importance in relation to vaccine mandates in so far as the regulatory status of these products establish without any doubt that important safety and efficacy concerns remain in relation to the use of these products. In such circumstances, forcing individuals on a massive scale to receive such serious medications with potentially unknown and serious adverse consequences, including death, using coercive vaccination mandates, is without precedence in medicine.

2.5. Conventional vaccines usually take about 7 years to develop and test. In a 2018 publication sponsored by the Bill and Melinda Gates Foundation[2], vaccines were divided into three categories: simple, complex and unprecedented.

2.6. The unprecedented category represents those vaccines directed towards a disease that has never before been successfully treated and include vaccines against HIV and malaria. According to authors Seneff and Nigh[3] unprecedented vaccines are expected to take more than 12 years to develop due to the technical difficulties, and they are expected to have a very low chance (about 5%) of proving safety and efficacy in even early Phase II clinical trials involving small numbers of individuals, and a very much lower chance (about 2%) of moving to larger Phase III clinical trials and demonstrating safety and efficacy before being considered for marketing. The gene-based COVID-

[2] Young, R., Bekele, T., Gunn, A., Chapman, N., Chowdhary, V., Corrigan, K., Yamey, G. (2018). *Developing New Health Technologies for Neglected Diseases: A Pipeline Portfolio Review and Cost Model.* Gates Open Res 2:23. https://doi.org/10.12688/gatesopenres.12817.2

[3] Seneff, S and Nigh, G; (10/05/2021) *Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19.* International Journal of Vaccine Theory, practice and Research: 2(1) https://ijvtpr.com/index.php/IJVTPR/article/view/23

19 ‘vaccines’ were developed in less than a year and are supported by abbreviated safety and efficacy clinical data. These gene-based ‘vaccines’ are in the ‘unprecedented’ category.

2.7. Historically, a large number of conventional vaccines have been withdrawn due to safety concerns following widespread use. These include vaccines for Yellow Fever, polio, smallpox, Dengue fever, measles, respiratory syncytial virus, Swine flu, rotavirus, papillomavirus and influenzae.

3. How the Gene-Based COVID-19 ‘Vaccines’ Work

3.1. These ‘vaccines’ use a genetic technology which has not been employed for any fully approved drug and in this sense the use of these products should properly be considered experimental. This technology, due to its inherent safety risks, has previously only been investigated in relatively early clinical research for possible use in certain cancers and rare genetic disorders. These products deliver either RNA in a lipo-nanoparticle (which has never been used previously) or DNA genetic material contained in a viral vector to produce the spike protein, similar to that found on the surface of the coronavirus, in order to provoke an immune response. It is the spike protein which is now known to be the main toxic component of the SARS-CoV-2 coronavirus. It is also the spike protein produced by these ‘vaccines’ which is understood to cause the unprecedented number of serious adverse events and death being reported following vaccination in various international adverse drug reporting systems.

3.2. All COVID-19 ‘vaccines’ employ new generation nanoparticle technology: either non-viral or viral based nanoparticles[4]. The extremely small size of nanomaterials also means that they are much more readily taken up by the human body than larger sized particles. Nanomaterials are able to cross biological membranes and access cells, tissues and organs that larger sized particles normally cannot[5]. Such wide and efficient distribution following administration has significant implications in relation to organ and tissue toxicity as compared to conventional vaccines which largely remain at the site of injection. Specifically, nanoparticles may cross the blood-brain barrier (the membrane protecting the spinal cord and brain) and they may be associated with long term inflammation in various tissues and organs, and they may be associated with cardiovascular adverse effects.[6]

[4] Kisby, T. et al (August 2021) *Reasons for success and lessons learnt from nanoscale vaccines against COVID-19.* Nature Nanotechnology Vol. 16, pp 843-852 https://www.nature.com/articles/s41565-021-00946-9.pdf

[5] Holsapple M, Farland W, Landry T, Monteiro-Riviere N, Carter J, Walker N and Thomas K (2005). *Research strategies for safety evaluation of nanomaterials, Current Challenges and Data needs.* Toxicological Sciences 88(1):12-17 https://academic.oup.com/toxsci/article/88/1/12/1662948

[6] *Nanotechnology and Health Risks* (April, 2008), Health and Environment Alliance https://www.env-health.org/IMG/pdf/17-_NANOTECHNOLOGY_AND_HEALTH_RISKS.pdf

4. Threat Posed by SARS-CoV-2

4.1. The threat posed by SARS-CoV-2 coronavirus in producing the COVID-19 infection to segments of the community has been exaggerated due to the nature of the polymerase chain reaction (**PCR**) test used to detect "cases". The PCR test as used in Australia and elsewhere was set (cycle threshold value: "Ct") to be exquisitely sensitive and could produce a positive result even if no live virus was present or even if a fragment of a single viral particle was present. A survey of the utility of PCR tests reported that positive PCR tests set to a Ct of 35 only correlated with a positive culture in 3% of cases[7]. In Australia and elsewhere, the PCR Ct was normally set at even higher values conferring less reliability. The PCR test was never intended to be diagnostic for COVID-19 due to this attribute. Individuals testing positive for COVID-19 frequently have very low viral loads and are asymptomatic (show no symptoms) and are incapable of transmission of the virus due to their low viral loads. Children, in particular, are at virtually nil threat of serious COVID-19 infection (see below). Some estimates suggest that up to 97% of COVID positive cases" detected by PCR detected no virus on culture and therefore were of questionable value[8]. Indeed, so grave are the many limitations and lack of reliability attributable to PCR tests, that external peer review revealed 10 major scientific[9] flaws that resulted in strong calls for the retraction[10] of the Corman-Drosten paper,[11] published by Eurosurveillance.

4.2. In recognition of the limitations of the PCR testing, these tests are no longer considered generally appropriate by the US Center for Disease Control (**CDC**) in determining the number of COVID-19 cases and their emergency use authorisation has been withdrawn reflecting this fact[12].

4.3. COVID-19 government statistics represent another complicating factor. There is no discrimination between those individuals in hospital or intensive care "dying with" COVID-19 as opposed to 'dying from' COVID-19. Patients in hospital for serious non-COVID-19 related illness are routinely tested for COVID-19 and often return a positive test. These patients are routinely recorded as "COVID cases" and this can be misleading.

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[7] Jaafar, R. et al (2020) Correlation between 3790 Quantitative Polymerase Chain Reaction-Positives Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates Clinical Infectious Diseases, Volume 72, Issue 11, 1 June 2021, page e921. 28 September 2020 https://pubmed.ncbi.nlm.nih.gov/32986798/

[8] Jaafar, R., Aherfi, S., Wurtz, N., et al (2021) Correlation between 3790 Quantitative Polymerase Chain Reaction-Positives Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates Clinical Infectious Diseases, Volume 72, Issue 11, 1 June 2021, Page e921, https://doi.org/10.1093/cid/ciaa1491

[9] Borger, P et al (November 2020) External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results https://cormandrostenreview.com/report/

[10] Borger, P et al (November 2020) *Retraction request letter to Eurosurveillance editorial board* https://cormandrostenreview.com/retraction-request-letter-to-eurosurveillance-editorial-board/

[11] Corman, V et al (January 20202 *Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR*, Eurosurveillance, Volume 25, Issue 3

[12] CDC Laboratory Alert (07/21/2021) *Changes to CDC RT-PCR for SARS-CoV-2 Testing* https://www.cdc.gov/csels/dls/locs/2021/07-21-2021-lab-alert-Changes_CDC_RT-PCR_SARS-CoV-2_Testing_1.html

4.4. According to the Australian Bureau of Statistics up to 15 February 2022[13] "There are 2,639 death registrations that have been received by the ABS where an individual is certified as having died from or with COVID-19 between the start of the pandemic and 31 January 2022". The median age for those who died from COVID-19 was 83.7 years (81.2 years for males, 86.0 years for females) among individuals reasonably assumed to have multiple serious co-morbidities. COVID-19 is an infection principally causing more serious illness in older individuals.

4.5. Australian government Department of Health website: *Coronavirus (COVID-19) case numbers and statistics* (updated 7 May 2022) states there have been a total of 6,165,105 "cases" of COVID-19[14]. This translates to a death rate of COVID-19 of 0.0428% (for those 'dying with' COVID-19). COVID-19 was only the 38th leading cause of death in Australia reported in 2020 statistics. With the delta then Omicron waves since late 2021, deaths with COVID-19 have risen, but data where it is available, as in NSW, indicate that proportions of hospitalisations and deaths are as high or higher among vaccinated than among unvaccinated people (see 13.11 below).

4.6. The NSW Respiratory Surveillance Report ending 23 July 2022 states: *'146 COVID-19 deaths were reported this week, a 3% increase from 142 reported last week. All 146 deaths were eligible for a third dose of COVID-19 vaccine…..*', indicating that there were no deaths reported for unvaccinated individuals[15].

4.7. To place these numbers in perspective, the number of deaths due to influenza reported by the Australian Bureau of Statistics increased steadily from 68 in 2011 to 274 in 2016, and rose sharply to 1,183 in 2017[16]. When grouped, influenza and pneumonia contributed to 4,369 deaths in 2017 and were the ninth leading cause of death for the year. During 2018, influenza and pneumonia were the twelfth leading cause of death (n = 3,102 deaths).

4.8. No statistic is available regarding the number of Australians 'dying from' COVID-19. The total number of Australians 'dying from' COVID-19 would be some fraction of the total deaths reported. Officially reported 'COVID-19 deaths' do not discriminate between those dying "with" COVID-19 and those dying "due to" COVID-19. Some government websites make this clear[17].

4.9. The impact of COVID-19 varies depending on the age group. There is no Australian statistic available to demonstrate that any otherwise healthy child died 'due to' or 'from' COVID-19.

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[13] Australian Bureau of Statistics: *Causes of Death, Australia: Doctor Certified Deaths*, Summary Tables. Reference Period 2019. https://www.abs.gov.au/statistics/health/causes-death/causes-death-australia/latest-release

[14] TGA *COVID-19 vaccine weekly safety report (*23 June 2022) https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-23-06-2022

[15] NSW Respiratory Surveillance Report – ending 23 July 2022.

[16] Australian Government Department of Health (2018) *Communicable Diseases Intelligence. Report of the National Influenza Surveillance Scheme 2011 to 2018*. Year 2022 Volume 46. Communicable Disease Epidemiology and Surveillance Section https://doi.org/10.33321/cdi.2022.46.12

[17] NSW COVID-19 WEEKLY DATA OVERVIEW: www.health.nsw.gov.au/coronavirus

4.10. The lack of information on the actual cause of death in children in these rare instances makes any assessment of the risk of death due to COVID-19 in this age group tenuous. The risk of death due to COVID-19 may range from exceedingly rare to virtually and statistically nil.

4.11. There is emerging evidence that the COVID-19 gene-based 'vaccines' are showing rapid and significant diminished efficacy against the Omicron variant, particularly in children aged 5-11.[18]

4.12. Some useful information regarding COVID-19 ascribed deaths in the UK was obtained by a Freedom of Information Request (FOI/2021/3368), showing the number of deaths where COVID-19 was the only cause mentioned on the death certificate, from 1 February 2020 to 31 December 2021, by sex and age group in England and Wales[19]. This data (presented below as a downloaded Excel table) is important because it is a record where COVID-19 is the only listed possible cause of death, and it covers a period where the most virulent strain of SARS-CoV-2 was circulating in the global population.

Age group	Males	Females
<1	1	0
1-4	0	0
5-9	0	0
10-14	0	1
15-19	1	0
20-24	4	1
25-29	12	3
30-34	24	7
35-39	42	15
40-44	52	24
45-49	87	43
50-54	138	52
55-59	234	92
60-64	254	102
65-69	279	119
70-74	357	204
75-79	395	252
80-84	492	402
85-89	470	533
90+	520	971

4.13. This data supports the view of a virtually or statistically near nil risk of death due to COVID-19 in very young children, adolescents, and adults through to middle-aged.

[18] Dorabawila, V. et al (February 2022) Effectiveness of the BNT162b2 vaccine among children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant. MedRxiv preprint https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1

[19] UK Office of National Statistics FOI/2021/3368. Released 17 January 2022.

4.14. Another study in children and young people (<18 years of age) in the UK covering 12,023,568 individuals, from March 2020 to February 2021, examined the records of 3,105 who died including 61 who were positive for SARS-CoV-2[20].

4.15. This study is instructive, in that it describes in detail an evaluation process which should normally be conducted in evaluating whether or not an individual's death can be ascribed to COVID-19, in light of pre-existing co-morbidities. Many reports of "COVID deaths" do not attempt to discriminate or ascribe causality to this level, and therefore are of limited usefulness. This study was done at a time when the more virulent strain of SARS-CoV-2 was dominant, and it could be assumed to significantly overstate the risk of death due to the current Omicron variant which has been dominant during 2022 worldwide[21].

4.16. Despite the potential for this study to overestimate the risk of death in 2022, the authors conclude:

"…the risk of serious outcomes from SARS-CoV-2 for individuals under 18 years of age remains extremely low" - and even considering child deaths where COVID-19 was not the sole cause, the authors conclude – *"we estimated the infection fatality rate to be five per 100,000 indicating that more than 99.995% of children and young people recover from SARS-CoV-2 infection."*

5. Initial Perceptions of the COVID-19 'Vaccines'

5.1. Initially, despite limited clinical and epidemiological data, a number of community and health professional perceptions were widely held in relation to these new vaccines including:

- the vaccines prevent infection by the SARS-CoV-2 virus and subsequent COVID-19 developing (COVID-19 being the disease caused by the virus)
- the vaccines prevent transmission of the SARS-CoV-2 virus from infected to non-infected individuals
- the vaccines would provide durable immunity
- the vaccines are 95% effective
- the vaccines are safe and effective

5.2. In light of more than a year of widespread COVID-19 vaccination usage all these initial perceptions have been shown to be without foundation. It is undisputed that COVID-

[20] Smith, C et al: Deaths in children and young people in England after SARS-CoV-2 infection during the first pandemic year. Nature Medicine; Vol 28, Jan. 2022, 185-192. https://doi.org/10.1038/s41591-021-01578-1

[21] WANG, L. et al: COVID infection severity in children under 5 years old before and after Omicron emergence in the US. Preprint - doi: https://doi.org/10.1101/2022.01.12.22269179;

19 is commonplace in fully vaccinated individuals and now multiple boosters are being recommended at relatively frequent intervals. The current COVID-19 'vaccines' have lost effectiveness against the emerging variants – to many, they have failed. However, the incidence of serious adverse events from these gene-based 'vaccines' continue to be reported and continue to rise in unprecedented number and severity.[22]

5.3. A good example of the popular misconceptions concerning the gene-based COVID-19 'vaccines' is the claim of 95% efficacy which was repeated and unchallenged in the mainstream media and by health authorities in Australia and elsewhere.

5.4. Approval of the gene-based COVID-19 'vaccines' were based on single clinical trials from each company. These single trials were the sole basis for both the safety and efficacy claims. For example, in the case of the Pfizer gene-based 'vaccine' it was widely stated and generally accepted at the time that the clinical efficacy of the vaccine was determined in a large clinical trial of about 44,000 subjects and the efficacy was 95%.

5.5. Without an understanding of the design, conduct and reporting of clinical trials, the ordinary person might interpret this statement in a number of different ways. For example, this "95%" efficacy might be interpreted to mean that vaccination provides a 95% chance of being protected from being infected following exposure from a person infected with SARS-CoV-2; or it might be interpreted to mean that vaccination reduces the risk of the average healthy person falling seriously ill and needing hospitalisation following SARS-CoV-2 infection; or it might be interpreted as showing the risk of death due to severe COVID-19 illness is reduced by 95%.

5.6. Indeed, none of these interpretations are correct.

5.7. The claimed 95% efficacy was based upon only 170 subjects who contracted COVID-19 during the trial which had a median follow up of two months post-second dose. The claimed clinical efficacy was not based upon 44,000 subjects. Of the 44,000 subjects enrolled and divided roughly equally between receiving active prophylactic vaccination or placebo, only 170 subjects tested positive for COVID-19 AND developed even mild COVID-19 symptoms (similar to the common cold) which was the criterion set for "clinical efficacy"; with eight testing positive in the vaccinated group AND *displaying* a COVID-19 symptom as mild as a sore throat, fever or cough, while 162 tested positive in the placebo group AND *displayed* a COVID-19 symptom as mild as a sore throat, fever or cough. This is where the 95% COVID "vaccine" efficacy claim originated and, based on this pivotal data, it should not be inferred that the Pfizer COVID-19 "vaccine was shown to be 95% effective in preventing serious COVID-19 disease, symptoms, hospitalisation or death"[23].

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[22] US Adverse Event Reporting System (VAERS) – open data – through to 29 April 2022 https://openvaers.com/covid-data RECORDED 27,758 deaths reported as related to the COVID-19 vaccines.

[23] Australian Government – Therapeutic Goods Administration (25 January 2021) *Australian Public Assessment Report for BNT162b2 (mRNA)*, Comirnaty, Pfizer Australia Pty Ltd – PM-2020-05461-1-2 Final https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210125.pdf

5.8. The Pfizer trial (mentioned above) reported 99.07% of unvaccinated individuals did not develop symptoms of COVID-19 while 99.95% the vaccinated group did not report COVID-19 symptoms thus producing an absolute risk reduction of symptoms of 0.88%. This statistic is a realistic measure of protection from COVID-19 (which may only present as mild symptoms) in an uninfected population over the trial surveillance period.

5.9. A subsequent Pfizer COMIRNATY gene-based COVID-19 'vaccine' trial which was pivotal in the approval of this 'vaccine' for children 5-11 relied on the clinical symptoms of only 19 children (3 developed symptoms in the Comirnaty vaccine group and 16 in the placebo group) upon which to base its claimed a relative clinical efficacy of 90.7%.[24] Once again, the claimed clinical efficacy only referred to the chance of preventing the mild symptoms, similar to the common cold, in children who tested positive for COVID-19. The absolute vaccine clinical efficacy to prevent even mild symptoms among the 4500 trial participants can then be calculated to be under 1%.

5.10. A similar approach was adopted by other manufacturers such as Moderna claiming similar "efficacy" which has not been understood by either the media or the lay public.

6. Risk of SARS-CoV-2 Infection in Children

6.1. All therapeutic agents, including vaccines, present a safety risk. Therefore, the risk-benefit analysis of any medication needs to be weighed up.

6.2. Drug regulatory agencies now recognise that most children with COVID-19 have either no symptoms (asymptomatic) or have only mild symptoms.

6.3. I have searched without success for evidence and statistics for the incidence of severe COVID-19 and death due principally to COVID-19 in children aged 5-11 in New Zealand and Australia.

6.4. Some information appears in the Australian TGA AusPAR (Public Assessment Report) Pfizer mRNA Vaccine COMIRNATY dated December 2021, which was used to approve the Pfizer COVID-19 vaccine for children 5-11 years of age. On page 11 of this Australian report, Table 1 (below) includes COVID-19 "cases" in Australia by age

[24] Australian Government – Therapeutic Goods Administration (7 December 2021) Australian Public Assessment Report for Tozinameran (mRNA Covid-19 vaccine), Comirnaty, Pfizer Australia Pty Ltd– PM-2021-05012-1-2 https://www.tga.gov.au/sites/default/files/auspar-tozinameran-mrna-covid-19-vaccine-211207.pdf

group and highest level of illness severity – 1 January 2021 to 10 October 2021 the numbers of children in age group 0-4 and 5-11 are presented. It reports that over more than a nine month period in 2021 (at a time that the more virulent stains of SARS-CoV-2 were prevalent) that one person under 18 years of age died either "with" or "due to" COVID-19.

Table 1: COVID-19 cases in Australia by age group and highest level of illness severity (1 January 2021 to 10 October 2021)

Age group	Count					% of cases		
	Not severe[b]	Hospitalised only (not ICU or died)	ICU (not died)	Died	Total cases	Hospitalised only (not ICU or died)	ICU (not died)	Died
0–4	6,848	386	5	0	7,239	5.3%	0.1%	0.0%
5–11	10,184	279	4	0	10,467	2.7%	0.0%	0.0%
12–15	6,220	235	5	1	6,461	3.6%	0.1%	0.0%
16–17	3,418	132	9	0	3,559	3.7%	0.3%	0.0%
18–29	24,837	1,922	130	7	26,896	7.1%	0.5%	0.0%
30–39	16,500	2,018	222	10	18,750	10.8%	1.2%	0.1%
40–49	11,000	1,790	274	25	13,089	13.7%	2.1%	0.2%
50–59	7,760	1,561	368	74	9,763	16.0%	3.8%	0.8%
60–69	3,763	1,192	299	114	5,368	22.2%	5.6%	2.1%
70–79	1,402	800	141	180	2,523	31.7%	5.6%	7.1%
80–89	493	528	26	207	1,254	42.1%	2.1%	16.5%
90+	125	117	0	71	313	37.4%	0.0%	22.7%
Age unknown	1	0	0	0	1	0.0%	0.0%	0.0%
Total	**92,551**	**10,960**	**1,483**	**689**	**105,683**	**10.4%**	**1.4%**	**0.7%**

Table 1: COVID-19 "cases" in Australia by age group and highest level of illness severity – 1 January 2021 to 10 October 2021

6.5. A search of the Risk Management Plan report released by Pfizer in February 2022 reviewed all available US COVID-19 cases and deaths to 14 August 2021. The incident of death in children who tested positive to COVID-19 in ages 0-4 and 5-11 years was listed as "<0.1%" for each group[25]. This statistic, once again, does not distinguish between those children dying "with" COVID-19 or "due to" COVID-19.

6.6. The above data sets are consistent with studies[26] showing the mortality rate in children hospitalised with COVID-19 of less than 0.18%, which is less than the mortality rate

[25] See European Medicines Agency *COMIRNATY (COVID-19 mRNA VACCINE) RISK MANAGEMENT PLAN* Version number: 5.0, page 21 https://www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf;
Leidman, E (et al) (January 2022) *COVID-19 Trends Among Persons Aged 0-24 Years – United States, March 1-December 12, 2020*, CDC https://www.cdc.gov/mmwr/volumes/70/wr/mm7003e1.htm

[26] Patel, N Paediatric (September-October 2020) *COVID-19: Systematic review of the literature* Am J Otolaryngol. 2020 Sep-Oct;41(5):102573. doi: 10.1016/j.amjoto.2020.102573. Epub 2020 Jun 6. PMID: 32531620; PMCID: PMC7833675. https://pubmed.ncbi.nlm.nih.gov/32531620/;
Ludvigsson, J, (March 2020) *Systematic review of COVID-19 in children shows milder cases and a better prognosis than adults AXTA* https://onlinelibrary.wiley.com/doi/10.1111/apa.15270

seen in children from seasonal influenza.[27] These figures correlate with further findings showing 46.7% of children 0 to 18 years [28] being asymptomatic upon infection.

PART B: Emerging Picture of the Safety and Efficacy of the COVID-19 'Vaccines'

7. Failure to Demonstrate a Favourable Risk/Benefit Case for Vaccinating Children with COVID-19 'Vaccines'

7.1. Table 1 above, shows that no children died and 4 aged 5-11 were admitted to Intensive Care Units (**ICU**), however, as indicated previously in this report, it is important to distinguish between those children admitted to ICU "from COVID-19" or "with COVID-19". It is possible that at least some of these children were admitted for serious co-morbidities (as often is the case), but coincidentally tested positive for COVID-19. Until this reasonable possibility is ruled out, this information should not be relied upon as evidence that children suffer, to any meaningful extent, serious disease caused by COVID-19.

7.2. In reality, the risk of COVID-19 death in an otherwise healthy 5-11 year-old is virtually or statistically nil. Investigations of extremely rare cases have been poorly characterised, and it is unclear to what extent any reported death is directly attributable to COVID-19 as opposed to pre-existing medical conditions. A Johns Hopkins study published in July 2021 monitoring 48,000 children diagnosed with COVID-19 found a mortality rate of zero among children without a pre-existing medical condition.[29]

7.3. As COVID-19 is now known to rarely produce serious disease in children, this should have significant impact upon the risk-benefit analysis of using the gene-based 'vaccines' which have known serious short-term serious adverse effects, including death, and potentially serious unknown longer term adverse effects in this age group.

8. Serious Adverse Effects of the COVID-19 'Vaccines'

8.1. Very limited relatively short-term safety data is available from the individuals involved in the controlled clinical trials submitted to drug regulatory agencies in support of the

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[27] Baht, N et al (December 2005) *Influenza-Associated Deaths among Children in the United States, 2003–2004* N Engl J Med 2005; 353:2559-2567, DOI: 10.1056/NEJMoa051721 https://www.nejm.org/doi/full/10.1056/nejmoa051721;
Tingting, S et al (August 2019) *Mortality risk factors in children with severe influenza virus infection admitted to the paediatric intensive care unit* Medicine: August 2019 - Volume 98 - Issue 35 - p e16861 https://journals.lww.com/md-journal/fulltext/2019/08300/mortality_risk_factors_in_children_with_severe.25.aspx
Fleming, D (July 2005) *Mortality in children from influenza and respiratory syncytial virus* Journal Epidemiol Community Health; 59(7): 586–590 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1757088/ ;
Sachedina, N (November 2010) *Paediatric mortality related to pandemic influenza A H1N1 infection in England: an observational population-based study* The Lancet, VOLUME 376, ISSUE 9755, P1846-1852, NOVEMBER 27, 2010 https://www.thelancet.com/journals/lanonc/article/PIIS0140-6736(10)61195-6/fulltex;
Statista (October 2021) *Influenza mortality rate during the 2019-2020 flu season in the United States, by age group** https://www.statista.com/statistics/1127799/influenza-us-mortality-rate-by-age-group/

[28] Pratha, S (August 2021) *Asymptomatic SARS-CoV-2 infection: A systematic review and meta-analysis* PNAS https://www.pnas.org/doi/abs/10.1073/pnas.2109229118?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub++0pubmed

[29] Makari, M (19/07/21) *The Flimsy Evidence Behind the CDC's Push to Vaccinate Children*, Wall St. J, https://www.wsj.com/articles/cdc-covid-19-coronavirus-vaccine-side-effects-hospitalization-kids-11626706868

emergency authorisations or provisional approvals of the COVID-19 'vaccines'. As such, there is a heavy reliance upon post-marketing adverse drug reaction report (ADR) systems to identify the type and incidence of adverse effects which are caused by the 'vaccines'. There are a number of such systems. Australia has the Drug Adverse Event Reporting system (**DAEN**), and the US has the Vaccine Adverse Events Reporting System (**VAERS**) which reports both US and international adverse events.

8.2. The problem with these systems is that they involve voluntary reporting and most doctors are reluctant to report adverse drug reactions to vaccines due to fear of being accused by health regulators (Australian Health Practitioner Regulatory Agency, AHPRA) of being considered to be "anti-vax".[30] Many doctors both here and overseas and other health professionals fear losing their licence to practice if they even apply for vaccine exemptions, and many investigations are currently underway by AHPRA at the present time. Also, the criteria for assessing a causal relationship between a vaccine and an adverse event can be set so high that only a small percentage of serious adverse events or deaths are officially reported as being caused by a vaccine. These are some of the reasons why it is widely acknowledged all adverse event reporting systems suffer from notorious underreporting[31]. This can result in an underreporting factor of between 10-30 or more, i.e.: one must multiply the official incidence of adverse events by 10-30, to obtain a real-world estimate of the true incidence of the adverse event. For US VAERS reporting in respect of the Covid-19 'vaccines', the underreporting factor (URF) is estimated to be between 40x-49x[32].

8.3. In Australia, it is difficult to obtain statistics regarding details of the number of deaths caused by the gene-based 'vaccines'. A Freedom of Information request (FOI-3586) was made to the TGA for data on the deaths reported as possibly related to the COVID-19 'vaccines' and the 196-page report is available online but is almost completely redacted.[33] In the US the VAERS adverse drug reporting system has recorded 27,758 deaths associated with gene-based "vaccine" administration through to 29 April 2022. The TGA COVID-19 vaccine weekly safety report released 23 June 2022[34] indicates a total of 889 deaths in association with COVID-19 gene-based 'vaccines' of which only 13 have been identified by the TGA as definitely causing death. However, there are no public details available as to the criteria used by the TGA in arriving at this number of 13 deaths. This reported incidence of death does not account for any underreporting factor.

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[30] https://caldronpool.com/the-ahpra-inquisition-against-australian-health-professionals/ ; see point 9 in https://support.mips.com.au/home/12-commandments-to-avoid-ahpra-notifications ; https://www.ahpra.gov.au/News/2021-03-09-vaccination-statement.aspx ; an open letter to the American Board of Medical Specialties and the Federation of State Medical Boards: The destruction of Member Boards' credibility (26 June 2022) http://drelef.org/2022-open-letter-fsmb-abms/pmc-support-letter-final.pdf

[31] https://scholar.google.com.au/scholar?hl=en&as_sdt=0%2C5&as_vis=1&q=EMA+ADR+under-reporting&btnG= ; https://vaers.hhs.gov/data/dataguide.html

[32] https://stevekirsch.substack.com/p/latest-vaers-estimate-388000-americans https://jessicar.substack.com/p/the-true-under-reporting-factor-urf

[33] Response to Australian Freedom of Information request FOI-3586: The age of deceased for all reported adverse events resulting in death for events reported against any of the TGA approved COVID-19 vaccine https://www.tga.gov.au/sites/default/files/foi-3586-01.pdf

[34] https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-23-06-2022

8.4. Further confounding a proper of assessment of reported deaths is the complete lack of guidance or directions from the TGA or State or Territory health departments, with respect to any requirement to conduct autopsies on persons dying at any time post COVID-19 vaccination. This is an unfortunate state of affairs when it is known to the TGA as a consequence of its Pharmacovigilance duties, that by employing new histopathological methods developed in Germany, that identify the mRNA generated spike proteins at the scene of fatal pathological inflammatory reactions, deaths that could be easily attributed to a 'normal' heart attack, or a 'normal' stroke, are now instead being found to have been caused by COVID-19 vaccines. Critically, in the German studies, of the 15 deceased examined, deaths due to the vaccines were found to be 'likely' and 'very likely' in 80% of cases.[35]

8.5. Prior to COVID-19 vaccinations, over the last 10 years there has been an average of about 155 deaths per year reported in relation to all conventional vaccines to the US VAERS. This includes all standard childhood vaccines on vaccine schedules, annual flu vaccines, travel vaccines, hepatitis, human papilloma virus vaccines, tetanus vaccines, meningococcal vaccines and herpes vaccines.

8.6. The website OpenVAERS extracts VAERS data each week specifically in relation to adverse event reports for the Covid-19 ‘vaccines’. An inspection shows the contrast in reported mortality for the gene-based COVID-19 ‘vaccines’ compared to all other vaccines combined since 1990.[36]

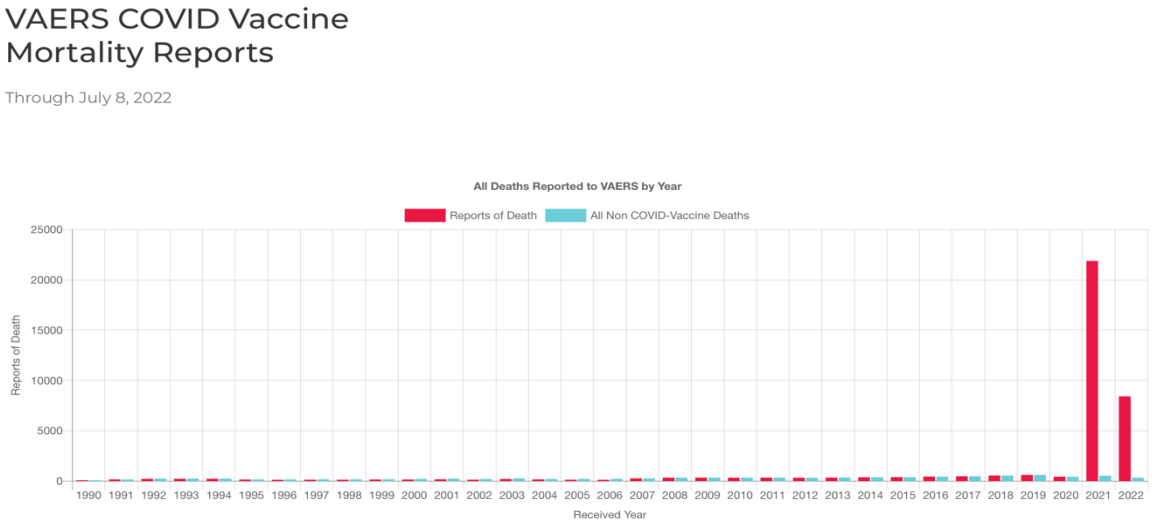


Table 2: All reported potential vaccine deaths to VAERS since 1990 to VAERS

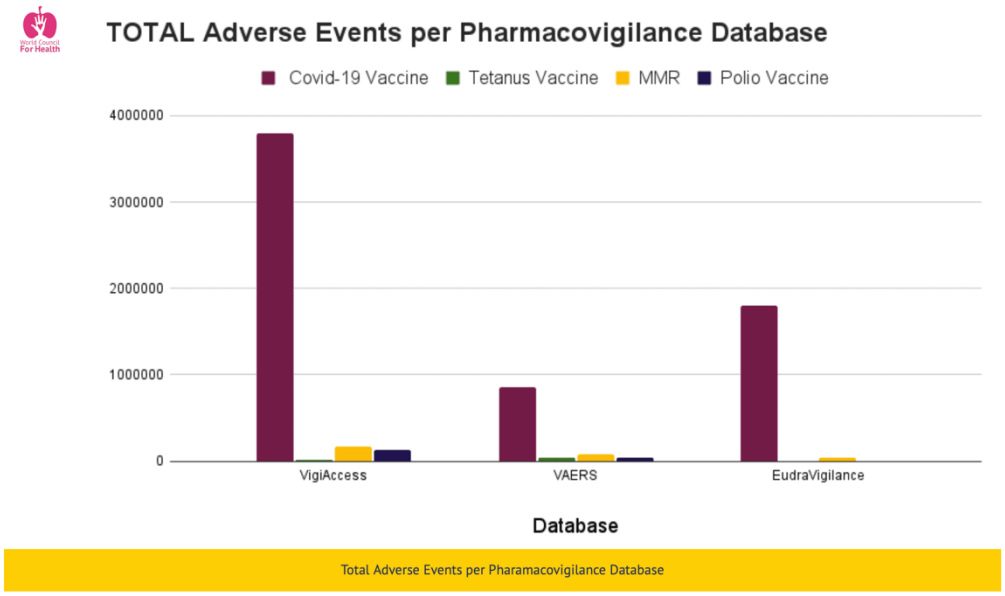
[35] Documents available, but see the recent presentation here: https://odysee.com/@en:a5/Pathology-Conference_Burkhardt_Presentation_EN_20220311:7

[36] US Adverse Event Reporting System (VAERS) – open data- https://openvaers.com/covid-data

8.7. Statistics on the number of flu vaccines administered over many years is provided by the US CDC[37], and range from about 110 million per year to more than 190 million per year since 2008. Similarly, there have been more people who have received measles/mumps/Rubella vaccinations (301,000,000) than COVID-19 vaccinations (255,000,000) since VAERS commenced reporting in 1990[38].

8.8. The relatively high number of adverse reports received by the VAERS (hosted by the US CDC) relative to other commonly used vaccines, is also seen in both of the other two major adverse drug reporting systems: VigiAccess (hosted by WHO) and EudraVigilance (hosted by the European Medicines Agency)[39].

Table 9: Total Adverse Events per Pharmacovigilance Database



Yellow Card data excluded

8.9. Dr. Jessica Rose, specialist data analyst, has focused her attention on the US VAERS data and published on the general ADR data as well as specifically in relation to myocarditis.[40]

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37 Centers for Disease Control and Prevention – Historical Reference of Seasonal influenza Vaccine Doses Distributed. Revised 4 August 2021. https://www.cdc.gov/flu/prevent/vaccine-supply-historical.htm

38 Covid-19 Vaccine Pharmacovigilance Report. World council for Health. Updated 4 August 2022.Worldcouncilforhealth.org: https://worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report

39 Covid-19 Vaccine Pharmacovigilance Report. World council for Health. Updated 4 August 2022.Worldcouncilforhealth.org: https://worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report

40 Rose, J (2021) *A report on US Vaccine Adverse Events Reporting system (VAERS) of the COVID-19 Messenger Ribonucleic Acid (mRNA) Biologicals.* Science, Public Health Policy, and the Law. Volume 2:59-80, May 2021. Clinical and Translational Research. https://www.datascienceassn.org/sites/default/files/VAERS%20Report%20on%20Covid19%20Vaccine%20mRNA%20Biologicals%20-%20May%2C%202021.pdf

8.10. As of 22 April 2022, in the United States alone there had been recorded 5,309 cases of myocarditis, 782,665 adverse events, 151,796 severe adverse events, and 14,613 deaths in VAERS following COVID-19 vaccination.[41] Every adverse drug reaction report needs to be individually assessed to rate the probability of causing any particular adverse reaction – not all reports are assessed as "causal". On the other hand, the underreporting factor can range from 5 to perhaps as high as 31 times[42] or more.

8.11. The confounding assessment factors of underreporting of adverse effects on one hand, and the possible lack of evidence of causation on the other hand in relation to deaths caused by vaccines, can be resolved to a large degree by an examination of the statistics of death temporally associated with vaccine administration.

8.12. Dr. Jessica Rose has analysed the percentage of individuals experiencing adverse effects within 24- and 48-hour periods in relation to COVID-19 vaccine administration.

8.13. Of particular interest is the Rose analysis of VAERS % reported deaths following vaccination with the gene-based vaccines versus the number of days following injection[43]. This analysis included a graphical representation of the temporal relationship between the number of deaths reported in association with COVID-19 vaccine administration and the time of death measured in days following injection.

In relation to the widely accepted Bradford Hill criteria for the assessment of adverse drug reactions, a close temporal relationship between drug administration and the adverse event represents some of the strongest evidence upon which to assign a cause-effect relationship.

The following graphical representation depicts the percent of reported deaths versus the number of days following injection of a COVID-19 "vaccine" (data ending December 2021) showing a clustering of deaths within about 2 days of administration (orange line) compared to an expected background incidence of a hypothetical event which is not related temporally to vaccine administration (yellow line).

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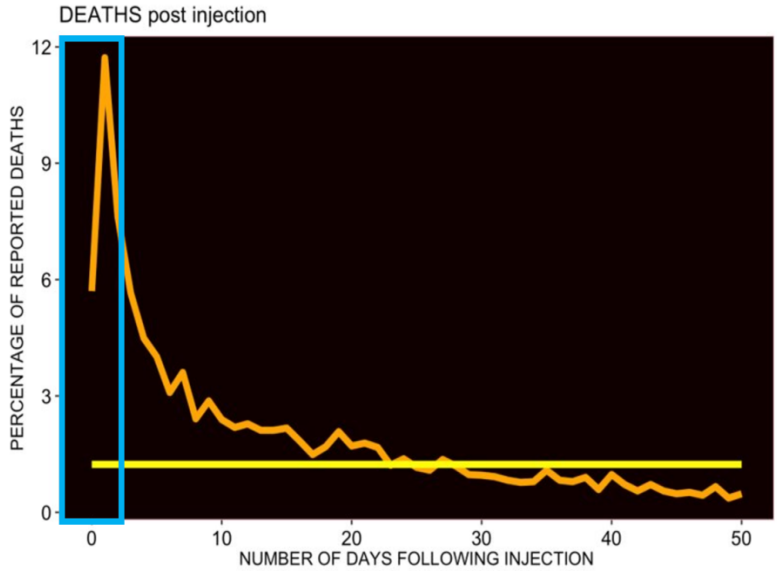
[41] US Adverse Event Reporting System (VAERS) - https://vaers.hhs.gov

[42] Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System? Jessica Rose, The Institute for Pure and Applied Knowledge. Vol 3:100-129, Oct. 2021. https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_0490c898f7514df4b6fbc5935da07322.pdf

[43] Jessica Rose VAERS adverse event data analysis - presentation December 2021 https://maatsmethods-my.sharepoint.com/:p:/g/personal/peter_maatsmethod_com_au/EVmwPI2cfDROiI2ad9z7TWkB9DJUVzvy3t0h8yhbdV41SQ?rtime=mlpjZxh72kg

Evidence of causation remains from previous update…

Clustering of reports around 0 and 1

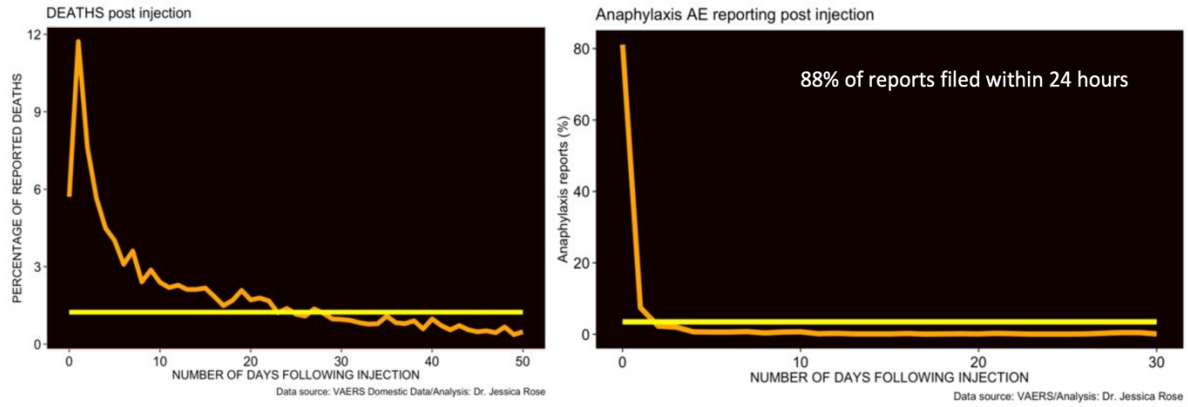


Update as of 12/24/

Data source: VAERS/Analysis: Dr. Jessica Rose

Further evidence to support the cause-effect relationship between death and COVID-19 “vaccine” administration may be seen by comparing the similar characteristic temporal relationship between anaphylaxis and reported deaths. In this respect, anaphylaxis is used as a positive control to assist the interpretation of the data.

Evidence of causation remains from previous update…

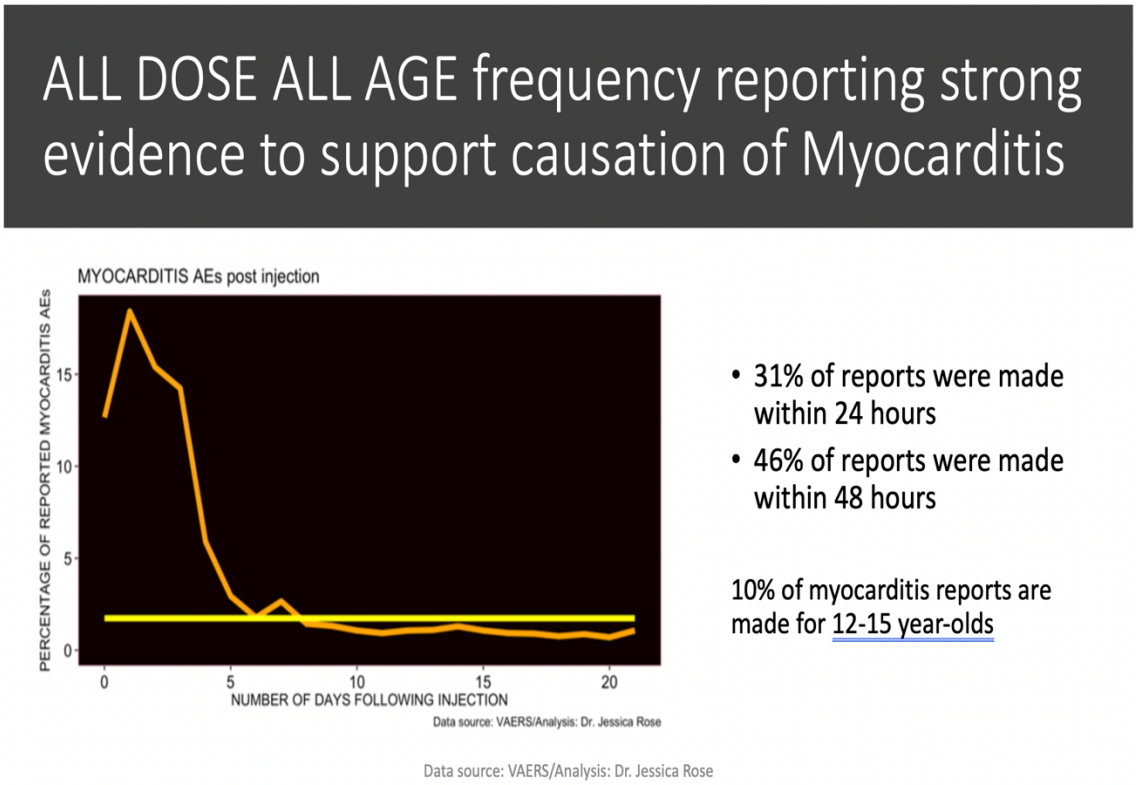


Anaphylaxis as a positive control…

Update as of 12/24/21

Data source: VAERS/Analysis: Dr. Jessica Rose

Another important temporal relationship extracted from the VAERS data is shown below between the incidence of myocarditis and COVID-19 “vaccine” administration.



8.14. The abovementioned analyses are short-term analyses, i.e. observations within days, weeks or months of vaccination. No long-term safety data is available for the COVID-19 gene-based vaccines. The long-term safety of the gene-based vaccines is completely unknown and there are potentially serious concerns which will only be resolved many years into the future. These concerns are based on the identification of pathogenic attributes of the spike protein and include profound disturbances in regulatory control of protein synthesis and natural cancer surveillance protective mechanisms, a potentially causal link to neurodegenerative disease, immune thrombocytopenia, Bell’s palsy, liver disease, impaired adaptive immunity, impaired DNA damage response and tumorigenesis.

8.15. It has been suggested that the increase in deaths temporally associated with the introduction of the gene-based ‘vaccines’ is not due to these new ‘vaccines’ but rather due to increased numbers of injections overall. However, this explanation does not appear valid as the COVID-19 vaccines represent a small proportion of all vaccines given in the US since 1990. For example, just considering flu vaccines, it has been reported that since the 08/09 flu season a total of 1,720,400,000 flu vaccines were administered while only 557,637,223 doses of the COVID-19 vaccines were administered in the USA. Many other types of vaccines are routinely used.

8.16. A detailed summary and analysis of the adverse drug reactions reported in association with the COVID-19 gene-based "vaccines" is presented as an addendum to this Report[44]

Focus on Myocarditis and Pericarditis

8.17. Of all the serious more short-term adverse events receiving attention in relation to the gene-based COVID-19 vaccines, myocarditis has probably received the most attention due to the seriousness of the condition (can cause permanent heart damage and be fatal) and its potential to affect longevity especially in the younger age groups with a predominance among younger males.

8.18. In analysing the possible incidence of myocarditis associated with the gene-based vaccines, it is useful to compare the historical rates of myocarditis prior to the introduction of these vaccines with the rate associated with the vaccine rollouts (Pfizer, Moderna and Janssen) during 2021[45].

8.19. It appears that there is a risk of myocarditis from both COVID-19 infection (especially in the elderly population) and from gene-based COVID-19 vaccines – both considered to be related to the toxic spike protein. The US Center for Disease Control (CDC) has attempted to discriminate between the two causal factors in order to arrive at a risk of myocarditis caused by the vaccines. If there is a risk of people contracting myocarditis from SARS-CoV-2 then this would appear to be negligible, as no health authority has produced a report or meaningful evidence that SARS-CoV-2 significantly elevates the risk of myocarditis.

8.20. The risk of myocarditis, pericarditis and cardiac arrhythmias associated with several gene-based COVID-19 'vaccines' or SARS-CoV-2 infection itself was studied in a large case series study of people aged 16 or older in England between 1 December 2020 and 24 August 2021.[46]

8.21. In this large study the temporal relationship between the gene-based vaccines and myocarditis was seen in the subgroup analysis by age showing an increased risk of myocarditis associated with the two mRNA vaccines in those younger than 40 years of age. Subgroup analysis was only performed for myocarditis. While those under 16 years of age were not studied it is widely recognised and accepted that younger males are most at risk of myocarditis. In addition, the authors state:

'Our findings are relevant to the public, clinicians and policy makers. First, there was an increase in the risk of myocarditis within a week of receiving the first dose of both

[44] Mitchell, Lisa: Summary and analysis on adverse drug reactions regarding COVID-19 vaccines submitted to the Australian Drug Adverse Event Notification (DAEN) system (5 August 2022)

[45] Rose, J and McCullough P (September 2021) A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting system (VAERS) in Association with COVID-19 injectable Biological Products. Current Problems in Cardiology https://drtrozzi.org/wp-content/uploads/2021/12/Rose-J-McCullough-PA-Myocarditis-in-VAERS-Curr-Prob-Cardiol-2021.pdf

[46] Patone, M et al, (December 2021) Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection Nature Medicine, 28, pages410–422 (2022) https://pubmed.ncbi.nlm.nih.gov/34907393/

adenovirus and mRNA vaccines, and a higher increased risk after the second dose of both mRNA vaccines.'

'Myocarditis is underdiagnosed in practice, with clinical bias being directed towards myocardial ischemia or infarction.'

8.22. In a nationwide study in France involving 32 million people aged 12-50 years of age and receiving 46 million doses of mRNA vaccines, 1,612 cases of myocarditis and 1,613 cases of pericarditis occurred in France between 12 May 2021 and 31 October 2021.[47] The risk of myocarditis and pericarditis for both the Pfizer and Moderna mRNA COVID-19 vaccines was found to be increased both after the first and second doses. The risk of this association was statistically significant and particularly evident for the Moderna COVID-19 'vaccine' where the risk of myocarditis/pericarditis was increased 30 times suggesting a dose-response relationship, given Moderna has 100 micrograms of mRNA and COMIRNATY has 30 micrograms of mRNA per dose. The risk was increased in younger age groups. The incidence of both myocarditis and pericarditis reported in this study was consistent with the incidence reported in other countries.

8.23. Another study from Israel investigated the incidence of myocarditis and pericarditis in post COVID-19 unvaccinated patients.[48] This is an important study because some have argued that the myocarditis and pericarditis incidence observed in populations may be due to COVID-19 and not due to COVID-19 'vaccines'. This retrospective cohort study of 196,992 adults following COVID-19 infection and 590,976 control adults who tested negative for COVID-19 concluded:

'Post COVID-19 infection was not associated with either myocarditis or pericarditis. We did not observe an increased incidence of either pericarditis nor myocarditis in adult patients recovering from COVID-19 infection.'

8.24. Aside from being under-diagnosed in practice, it is generally known that many doctors avoid reporting myocarditis and other serious possible adverse events in relation to the gene-based vaccines for fear of being seen as critical of the national health COVID-19 vaccination policies, and possible health regulator intimidation and retribution. This, combined with the inherent underreporting of adverse events in general, suggest the true incidence of adverse effects such as myocarditis may be much higher than officially reported. This needs to be considered in the calculation of the risk-benefit analysis.

8.25. This is most recently outlined in an Australian Government report on *Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines* dated 29 April 2022 –

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[47] Le Vu, S. (2022) Age and sex-specific risks of myocarditis and pericarditis following Covid-19 messenger RNA vaccines. NATURE COMMUNICATIONS (2022) https://www.nature.com/articles/s41467-022-31401-5

[48] Tuvali, O et al: (2022) *The Incidence of Myocarditis and Pericarditis in Post COVID-19 Unvaccinated Patients – a Large Population-Based Study.* J. Clin. Med. 2022, 11, 2219. https://doi.org/10.3390/jcm11082219

rates of myocarditis per million doses by age cohort and sex (see Table 1 below reproduced image from the report).[49]

Table 1: Rates of myocarditis per million doses by age cohort and sex following dose two of Comirnaty (Pfizer) and Spikevax (Moderna) adapted from the rates reported by the Therapeutic Goods Administration (TGA) in Australia[13]

	Pfizer		Moderna	
	Dose 2		Dose 2	
Age Cohort	**Males**	**Females**	**Males**	**Females**
5-11*	Not available	Not available	Not available	Not available
12-17	**107**	24	**159**	26
18-29	67	20	142	12
30-39	19	6	52	0
40-49	12	9	0	0
50-59	1	4	0	26
60-69	0	0	0	0
≥70	0	4	0	0
All ages	**37**	**12**	**75**	**11**

**Up to 27 February 2022 approximately 1.2 million doses had been administered to children aged 5-11 years, and no cases of myocarditis had been reported, noting that majority of these would have been first doses.*

Up-to-date data on cases and rates of myocarditis and pericarditis reported to the Australian Therapeutic Goods Administration is available at https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report.

Table 1 - rates of myocarditis per million doses by age cohort and sex in Australia Government report on Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines dated 29 April 2022

8.26. As of 10 July 2022, since inoculating 5-11 year-olds in Australia began on 10 January 2022, five (5) children were previously reported to have died following receiving a COVID-19 'vaccine', as recorded by the TGA's DAEN website *Australian Government Therapeutic Goods Administration, Database of Adverse Event Notifications*,[50] specifically:

- Case no. 719838 11 Mar 7-year-old male – cardiac arrest, generalised tonic-clonic seizure.
- Case no. 724023 25 Mar 9-year-old female – cardiac arrest.
- Case no. 724925 28 Mar 6-year-old male – adverse event following immunisation (which has since been removed).
- Case no. 733723 6 May 10-year-old male – adverse event following immunisation (which has since been reclassified).

[49] Australian Government report (Updated 28 April 2022) *Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines* https://www.health.gov.au/sites/default/files/documents/2022/04/covid-19-vaccination-guidance-on-myocarditis-and-pericarditis-after-mrna-covid-19-vaccines.docx

[50] Australian Database of Adverse Event Notifications (DAEN) https://www.tga.gov.au/database-adverse-event-notifications-daen

- Case no. 734187 10 May 5-year-old male – abdominal pain, cardiac arrest.

8.27. Myocarditis and pericarditis are serious medical conditions which may have life-long consequences and may be life threatening and may affect 5-11 year-old children. As of 28-7-2022, despite possibly significant underreporting, there have been 37 suspected cases of chest pain (indicative of myocarditis and pericarditis) have been reported to the DAEN system in this age group[51].

8.28. The paediatric COVID-19 gene-based 'vaccines' have only been available for a limited time as compared to the vaccines for the older age groups. But the safety record of the 'vaccines' used in the older age groups is an indicator of the adverse events one might expect in the younger age groups.

8.29. In this regard, the following information should be taken into consideration:

a. The VAERS database reports that as of 22 April 2022, in the US alone there were 5,309 cases of myocarditis, 782,665 adverse events, 151,796 severe adverse events, and 14,613 deaths recorded following COVID-19 vaccination in the US.[52]

b. After introduction of the gene-based COVID-19 vaccines in the US, VAERS quickly accumulated an unusually large number of adverse events. Between November 3 and December 19, 2021, VAERS received an overwhelming 4,249 adverse reaction reports for children aged five through eleven years who received the Pfizer COVID-19 COMIRNATY 'vaccine'.[53]

8.30. Further, in the documents related to a recent FOIA request, in the Pfizer informed consent document[54] it was revealed that the company recognised the risk of myocarditis to be as high as 1 in 1,000. Myocarditis is overwhelmingly found in younger people.

Other Safety Factors and Issues to Consider

8.31. Another factor which needs to be considered is the delay in assessing and reporting adverse drug events due to the unprecedented number of such events being reported. Pfizer itself has acknowledged this issue in its cumulative analysis of post-authorisation adverse event report 5.3.6 of pf-07302048 (bnt162b2), dated 30 April 2021 (**Pfizer's Adverse Events Report**) (released in or about November 2021

[51] Australian Government Therapeutic Goods Administration COVID-19 Vaccine Safety Report 28-0702022. https://www.tga.gov.au/periodic/covid-19-vaccine-safety-report-28-07-2022

[52] U.S. Adverse Event Reporting System (VAERS) - https://vaers.hhs.gov

[53] Hause, A et al (December 2021) *COVID-19 Vaccine Safety in Children Aged 5-11 Years – United States US November 3- December 19, 2021* CDC Report https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a1.htm

[54] Pfizer Clinical Trial Informed Consent Document. Cincinnati Children's Hospital Medical Center (Sub Study C). Study title: A Study to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated with BNT162b2. CCH IRB Approval Date 4 Jan. 2022. IRB Number: 2021-0430 (page 23)

pursuant to court ordered disclosure expedited under the Freedom of Information Act):[55]

"Pfizer has also taken multiple actions to help alleviate the large increase of adverse event reports. This includes significant technology enhancements, and process and workflow solutions, as well as increasing the number of data entry and case processing colleagues. To date, Pfizer has onboarded approximately 600 additional fulltime employees (FTEs). More are joining each month with an expected total of more than 1,800 additional resources by the end of June 2021."[56]

8.32. During phase III clinical trials for the mRNA COVID-19 vaccine products, safety was assessed based on a maximum observation period of 6 months. This is not adequate to assess long-term safety outcomes. A typical timeline of up to 10 years would be considered appropriate for long-term follow up. There are many examples where biological products have been recalled (let alone gene-based products) such as the rotavirus vaccines in 2010, the H1N1 influenza vaccine in 2009 and a meningococcal vaccine in 2005-2008.

8.33. Data from pivotal clinical trials used to support the gene-based 'vaccines' of Moderna, Pfizer and Janssen were re-analysed by Classen[57] to determine '*all cause severe morbidity" defined as "severe infections with COVID-19 and all other severe adverse events between the treatment arms and control arms respectively*'. This type of analysis avoids any bias within the adverse drug reporting system where a cause-effect assessment might be arbitrarily discounted due to the overly strict criteria required to establish such a relationship. This analysis found a statistically significant increase in all cause severe morbidity in the vaccinated group compared to the placebo group. When all types of severe events were considered, the vaccinated group suffered more severe adverse events; this suggests the gene-based vaccines are doing more harm than good.

8.34. In a published paper by a world-expert analyst of the VAERS database for all age groups, Dr. Jessica Rose[58] found that, based on the ratio of expected severe adverse events to observed adverse events in VAERS for a number of conditions, the 'underreporting factor (**URF**)' for COVID vaccine-associated deaths was 31. Using this URF for all VAERS-classified severe adverse events, as of October 2021, COVID-19 'vaccines' were associated with 205,809 deaths, 818,462 hospitalizations, 1,830,891

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[55] FDA released document: *Pfizer 5.3.6 Cumulative analysis of post-authorization adverse event reports* of pf-07302048 (bnt162b2) received through 28-feb-2021 – page 6

[56] The Vault Project: Pfizer Secretly Hired 600+ Employees to Process Flood of COVID Vaccine Adverse Events. April 7, 2022. Taken from unredacted Pfizer documents. https://thevaultproject.org/pfizer-secretly-hired-600-employees-to-process-flood-of-covid-vaccine-adverse-events/

[57] Classen, J.B: Classen B. (2021) US COVID-19 Vaccines Proven to Cause More Harm than Good Based on Pivotal Clinical Trial Data Analyzed Using the Proper Scientific Endpoint, "All Cause Severe Morbidity". Trends Int Med. 2021; 1(1): 1-6. https://www.semanticscholar.org/paper/US-COVID-19-Vaccines-Proven-to-Cause-More-Harm-than-Classen/141e12167e43917c679988bc91c91f7b8a6b9671

[58] Rose, J (October 2021) Critical Appraisal of VAERS Pharmacovigilance: Is the U.S. Vaccine Adverse Events Reporting System (VAERS) a Functioning Pharmacovigilance System? The Institute for Pure and Applied Knowledge. Vol 3:100-129, Oct. 2021 https://cf5e727d-d02d-4d71-89ff-9fe2d3ad957f.filesusr.com/ugd/adf864_0490c898f7514df4b6fbc5935da07322.pdf

emergency room visits, 230,113 life-threatening events, 212,691 disabled and 7,998 birth defects."

8.35. Further relevant background information is provided by life insurance industry data for adults. These data suggest historic increases in death claims coinciding with gene-based 'vaccine' rollouts. A publicly available quarterly report by the Group Life Insurance Industry, covering roughly 90% of the employer-based policies in the US, reported that younger age groups were suddenly dying at historically unprecedented rates beginning in Q3 of 2021.[59]

8.36. Other evidence of the damage caused by the gene-based 'vaccines' comes from the number of ambulance calls in response to cardiac arrests and acute coronary syndromes (heart attacks) for young people in the 16–39 age group during the COVID-19 vaccination rollout in Israel (January–May, 2021) compared with the same period of time in prior years 2019 and 2020.[60]

8.37. There is also an alarming and massive rise in deaths among healthy, young professional athletes from around the world since the COVID-19 vaccination campaign was initiated. As of 4 June 2022, approximately 1,090 athletes[61] suffered a cardiac arrest, with 715 of them dying as a result. The majority of arrests occurred in competition or training. The frequency of these events in comparison to historical data is of great concern. In a 2009 review of professional athletes' deaths[62], published in a prominent European Cardiology journal, they found that from 1966 to 2004, there was an average of only 29 sudden athlete deaths per year worldwide. Compare this number to just the month of January 2022 alone where 127 collapses and 87 deaths among professional athletes were reported. Overall, these athlete deaths reflect an approximately 22-fold increase in the year after the introduction of COVID vaccines, to date unexplained by other identifiable causes.

8.38. Australian Bureau of Statistics data also reflect a similar surge in Excess Deaths commensurate with the rollout of the 'vaccines', where Excess (non-COVID) Deaths for 2022 already are 17.5% above baseline, as the following graph[63] vividly depicts.

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[59] SOA Research Institute (January 2022) *Group Life COVID-19 Mortality Survey Report* (page 23) https://www.soa.org/48ff80/globalassets/assets/files/resources/research-report/2022/group-life-covid-19-mortality.pdf

[60] Sun, C.L.F et al (2022) *Increased emergency cardiovascular events among under-40 population in Israel during vaccine rollout and third COVID-19 wave* Scientific Reports 12:6978. https://doi.org/10.1038/s41598-022-10928-z

[61] 1111 Athlete Cardiac Arrests, Serious Issues, 732 Dead, After COVID Injection. Real Science. https://goodsciencing.com/covid/athletes-suffer-cardiac-arrest-die-after-covid-shot/

[62] Bille, K et al (2006) *Sudden cardiac death in athletes* The Lausanne Recommendations. Eur J Cardiovasc Prev Rehabil 2006 Dec;13(6):859-75. doi: 10.1097/01.hjr.0000238397.50341.4a https://pubmed.ncbi.nlm.nih.gov/17143117/

[63] Australian Bureau of Statistics *Provisional Mortality Statistics* - COVID-19 new infections have been excluded due to the aforementioned unreliability of PCR testing https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/latest-release

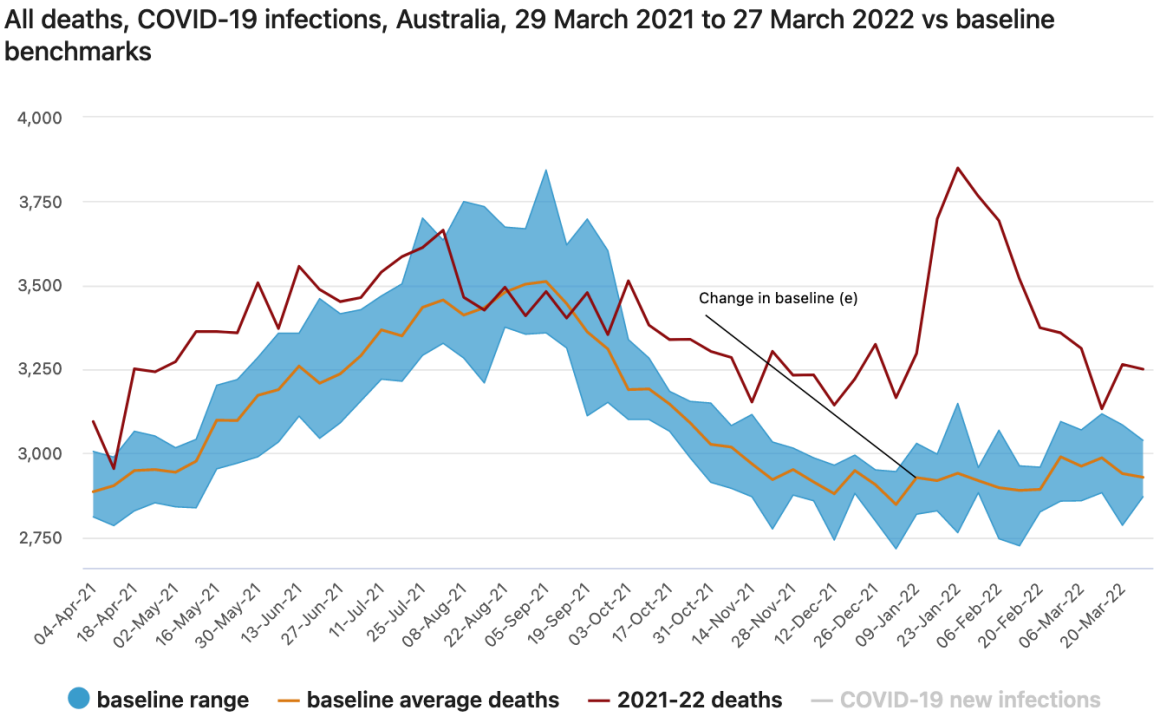

Table 7 - Australian Bureau of Statistics data reflecting surge in Excess Deaths commensurate with the rollout of the COVID-19 'vaccines'

8.39. New South Wales COVID-19 data for hospital admissions, ICU admissions and deaths in the 14 days up to 23 July 2022[64] is shown below. The data shows 693 people with known vaccination status were admitted to hospital; of these, one person was reported as unvaccinated. In interpreting this data it is noted that this is at a time when it is estimated that about 95% of individuals over 16 years of age are reported to be vaccinated. Also, unvaccinated individuals entering hospital for any reason may be more likely to be tested for COVID-19 as compared to those individuals who declare they are vaccinated. Taking these factors into account, the data suggests that Covid-19 vaccinated individuals are placing relatively higher demands on hospital resources as compared to the unvaccinated, a trend that has been occurring in 2022.

[64] https://www.health.nsw.gov.au/Infectious/covid-19/Documents/weekly-covid-overview-20220723.pdf

NSW COVID-19 WEEKLY DATA OVERVIEW

Epidemiological week 29, ending 23 July 2022

www.health.nsw.gov.au/coronavirus

Table 1. People with a COVID-19 diagnosis in the previous 14 days who were admitted to hospital, admitted to ICU or reported as having died in the week ending 23 July 2022

	Admitted to hospital (but not to ICU)	Admitted to ICU	Deaths
Gender			
Female	447	32	65
Male	470	45	81
Not stated / inadequately described	1	0	0
Age group (years)			
0-9	68	1	0
10-19	19	1	0
20-29	56	3	0
30-39	68	6	0
40-49	42	4	0
50-59	54	9	1
60-69	109	16	10
70-79	169	25	30
80-89	218	12	63
90+	115	0	42
Local Health District of residence*			
Central Coast	37	2	4
Illawarra Shoalhaven	58	5	14
Nepean Blue Mountains	20	0	3
Northern Sydney	109	12	18
South Eastern Sydney	108	8	15
South Western Sydney	131	6	17
Sydney	72	6	7
Western Sydney	104	8	12
Far West	8	0	2
Hunter New England	97	7	15
Mid North Coast	19	2	13
Murrumbidgee	31	8	7
Northern NSW	44	1	12
Southern NSW	19	3	3
Western NSW	47	7	4
Vaccination status^			
Four or more doses	221	12	45
Three doses	292	28	55
Two doses	165	10	22
One dose	14	3	5
No dose	1	1	15
Unknown	225	23	4
Total	**918**	**77**	**146**

*Excludes cases in correctional settings

^Vaccination status is determined by matching to Australian Immunisation Register (AIR) data. Name and date of birth need to be an exact match to that recorded in AIR. People with unknown vaccination status were unable to be found in AIR, though may have vaccination details recorded in AIR under a shortened name or different spelling.

Fertility, Birth Rates, miscarriages, stillbirths and neonatal deaths

8.40. One category of death not normally accounted for in Excess Deaths figures are stillbirths. After the deployment of COVID-19 'vaccines' in Germany and Scotland, statistically significant increases in stillbirths, perinatal, and neonatal deaths are now apparent from late 2021 leading into 2022[65].

[65] Guetzkow, J (July 2022) Springtime for Stillbirths in Germany Winter for women and babies, Substack https://jackanapes.substack.com/p/springtime-for-stillbirths-in-germany

8.41. Correspondingly, extraordinarily high drops in birth rates are now apparent in Germany and Taiwan, with an over 10% decline[66] in the former, and an over 25% decline[67] in the latter. Similar declines in birth rates are now also being seen across US states[68], Sweden[69], Canada[70], and highly COVID-19 vaccinated Hungary.[71]

8.42. These declines appear to correlate with data released by Pfizer to regulators on or shortly after 28 February 2021[72], where Pfizer reported on outcomes in 270 pregnant women who received the Pfizer 'vaccine'. No outcome or follow-up by Pfizer was provided for 238 of the pregnancies thus undermining any claims of safety in pregnancy. Of the remaining pregnancies 28 out of 29 babies died, a death rate of 97% in those pregnancies Pfizer did follow-up. Though this Pfizer pregnancy data is grossly lacking, it nonetheless begs critical questions which regulators have to date not asked. Regulators should begin asking questions or considering the continued use of these 'vaccines', particularly now when further studies are confirming relatively high impacts on women's menstrual cycles[73]. Furthermore, data[74]procured from Pfizer under Court order show that the Lipid Nanoparticles (**LNPs**) used as the delivery vehicle for the synthetic mRNA, extensively bio-distributes throughout the human body and accumulates in various organs including the kidney, spleen, adrenal glands, testes and ovaries although 'vaccine' recipients were initially informed the 'vaccines' would remain in the deltoid muscle at the site of injection. Although the effects of the delivered synthetic mRNA upon the various organs studied is currently unknown, many studies[75] show toxic effects of LNPs.

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[66] Syed, A (July 2022) *Children of Men* Substack https://arkmedic.substack.com/p/children-of-men/comments?utm_source=substack&utm_medium=email

[67] Chudov, I (July 2022) *Taiwan: Birth Rate Dropped -27.66% in June 2022!!!* https://igorchudov.substack.com/p/taiwan-birth-rate-cratered-2766-in

[68] Bizuobo (June 2022) *Preview: A US state-focused variant on Jikkyleaks birthrate decline thread* Substack https://baizuobu.substack.com/p/preview-a-us-state-focused-variant/comments

[69] El Gato Malo (July 2022) *Swedish birth rate data: what does it really show us?* Substack https://boriquagato.substack.com/p/swedish-birth-rate-data-what-does

[70] Jestre (July 2022) *Birth rate declines come to Canada* Substack https://jestre.substack.com/p/birth-rate-declines-come-to-canada

[71] Chudov, I (July 2022) Hungary: Highest Vaccinated Counties Have Worst Birth Rate Drops! https://igorchudov.substack.com/p/hungary-most-vaccinated-counties

[72] FDA released document: *Pfizer 5.3.6 Cumulative analysis of post-authorization adverse event reports* of pf-07302048 (bnt162b2) received through 28-feb-2021 – see 'Missing Information' pages 9 & 12: https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf; and commentary
Bridle, B (April 2022) A Moratorium on mRNA 'Vaccines' is Needed
Substack https://mail.google.com/mail/u/0/#inbox/FMfcgzGpHHKDKvZPqGLrFJVQLcZTBpdB

[73] Lessans, N et al (July 2022) *The effect of BNT162b2 SARS-CoV-2 mRNA vaccine on menstrual cycle symptoms in healthy women* International Journal of Obstetrics and Gynaecology https://doi.org/10.1002/ijgo.14356

[74] FDA released document: Acuitas Therapeutics Inc / Pfizer A Tissue Distribution Study of a [3 H]-Labelled Lipid Nanoparticle-mRNA Formulation Containing ALC-0315 and ALC-0159 Following Intramuscular Administration in Wistar Han Rats https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M4_4223_185350.pdf; and commentary
Bridle, B (April 2022) A Moratorium on mRNA 'Vaccines' is Needed
Substack https://mail.google.com/mail/u/0/#inbox/FMfcgzGpHHKDKvZPqGLrFJVQLcZTBpdB

[75] Dokka, S et al (2000) *Oxygen Radical-Mediated Pulmonary Toxicity Induced by Some Cationic Liposomes* Pharm Res 17, 521–525 https://doi.org/10.1023/A:1007504613351; Hongtao Lv, Shubiao Zhang, Bing Wang, Shaohui Cui, Yan, J (2006) T*oxicity of cationic lipids and cationic polymers in gene delivery,* Journal of Controlled Release, Volume 114, Issue 1, Pages 100-109, ISSN 0168-3659, https://doi.org/10.1016/j.jconrel.2006.04.014; Ranit Kedmi, Ben-Arie, N.; Peer, D. (20210) *The systemic toxicity of positively charged lipid nanoparticles and the role of Toll-like receptor 4 in immune activation*, Biomaterials, Volume 31, Issue 26, 2010, Pages 6867-6875, ISSN 0142-9612, https://doi.org/10.1016/j.biomaterials.2010.05.027;
Filion, M., Phillips, N (1997) *Toxicity and immunomodulatory activity of liposomal vectors formulated with cationic lipids toward immune effector cells*, Biochemical et Biophysica Acta (BBA) – Biomembranes, Volume 1329, Issue 2, 1997, Pages 345-356, ISSN 0005-2736, https://doi.org/10.1016/S0005-2736(97)00126-0

8.43. Collectively, the available peer-reviewed literature points to a number of serious safety concerns regarding COVID-19 'vaccines'. Already by December 2021, in excess of 1,000 peer-reviewed articles and studies focussing upon post-vaccination deaths and injuries had been published[76].

8.44. The long-term potential for the Spike Protein (produced by the COVID-19 'vaccines') to induce a range of autoimmune diseases has been commented upon by several authors. Because there is no long-term safety data available at the moment, the chance of induced autoimmune disease cannot be determined[77].

9. Potential Toxicity of the Spike Protein Produced by Gene-Based 'Vaccines'

9.1. The Spike Protein contained on the surface of the SARS-CoV-2 virus facilitates the binding of the viral particle to human cells, allowing infection of those cells, and has inherent toxicity in its own right.[78] However, the Spike Proteins produced by the COVID-19 'vaccines' are not identical to the Spike Protein on the natural SARS-CoV-2 virus[79] in that some uracil nucleotide bases (there are 4 different nucleotide bases in RNA: uridine, cytosine, guanine and adenine) are replaced with pseudouridine (a methylated derivative). This seemingly small change imparts profound pharmacological characteristics to the mRNA molecule produced by the COVID-19 'vaccines' including the ability to evade natural degradation as happens to natural mRNA. Further, the synthetic mRNA Spike Proteins interfere with the body's natural immune system (including Toll Like Receptors) which explains why these mRNA particles can provoke latent viral eruptions of Herpes Zoster and Epstein-Barr viruses as reported in adverse drug reaction reporting systems.

9.2. Reactivation of the dormant virus Herpes Zoster, which is responsible for shingles, has been reported in relation to COVID-19 vaccination but at the moment no cause-and-effect relationship has been acknowledged. In order to investigate a possible cause-effect relationship, a systematic review of the literature was undertaken[80]. A total of 54 cases reported in the literature were found and reviewed. Thirty-six patients out of 45 (80%) developed herpes zoster following the priming dose of mRNA COVID-19 vaccine. Furthermore, 96% of patients developed it within a temporal timeframe defined by WHO as indicative of a causal relationship. The authors even suggested possible use of prophylactic herpes zoster anti-viral medication prior to vaccination to herpes prone individuals.

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[76] Peer Reviewed Medical Papers for Adverse Events in COVID-19 Vaccine Recipients - AVN https://avn.org.au/peer-reviewed-medical-papers-for-adverse-events-in-covid-19-vaccine-recipients/

[77] Seneff, S and Nigh, G; (May 021) W*orse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19.* International Journal of Vaccine Theory, practice and Research: 2(1) https://ijvtpr.com/index.php/IJVTPR/article/view/23

[78] Seneff, S and Nigh, G; (May 2021) *Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19.* International Journal of Vaccine Theory, practice and Research: 2(1) https://ijvtpr.com/index.php/IJVTPR/article/view/23

[79] McKernan, K. et al (2021) *Differences in Vaccine and SARS-CoV-2 Replication Derived mRNA: Implications for Cell Biology and Future Disease* (Version 4). DOI: 10.31219/osf.io/bcsa6

[80] Desai, H.D. et al (2021) *Can SARS-CoV-2 vaccine increase the risk of reactivation of Varicella zoster? A systematic review.* Journal of Cosmetic Dermatology Volume 20, Issue 11, Pages 3350-3361 https://doi.org/10.1111/jocd.14521

9.3. Multiple modes of Spike Protein toxicity have been reported including those related to blood clotting and mitochondrial damage[81].

9.4. It has been a widespread belief that the Spike Protein produced by the gene-based 'vaccines' is the same as the Spike Protein on the surface of the SARS-CoV-2 virus, therefore, the effects of both will be similar. Furthermore, it has been assumed that exposing an individual to just the Spike Protein of the 'vaccines' is safer than exposure to the natural virus. However, these reasonings are now being questioned. It is now understood that the mRNA produced by the gene-based 'vaccines' contains pseudo-uridine instead of uridine as a nucleotide base and remains in circulation for much longer.

10. mRNA Does Not Remain at the Injection Site and Is Not Rapidly Destroyed

10.1. The normal biochemical protective mechanisms ensure that mRNA molecules are normally rapidly destroyed outside cells. Initially, it was thought that mRNA produced from COVID-19 'vaccines' would be rapidly destroyed. However, evidence now shows that the mRNA from these 'vaccines' may linger for 15 days or more post-vaccination[82]. The persistence of this mRNA has implications for continued production of Spike Protein and associated possible toxicity associated with the Spike Protein. Another study suggests mRNA produced following COVID-19 vaccination may remain in lymph nodes for up to 60 days[83].

10.2. These nucleotide manipulations of the 'vaccine' mRNAs to reduce its rate of degradation and therefore to enhance its capacity to drive Spike Protein production per molecule of mRNA, may produce concentrations much higher than those observed with natural infection in some individuals. Gene-based 'vaccines' appear to drive production of incredibly high numbers of Spike Protein mRNA molecules (13 trillion to 40 trillion) almost instantaneously as compared to natural infection. This may account for the serious adverse effects and deaths reported following administration of gene-based COVID-19 'vaccines' in adverse drug reporting systems, and further research is needed with regard to this important observation.

10.3. The immediate injection of literally trillions of Spike Protein producing mRNA molecules, as distinct from the slower accumulation of Spike Protein by natural infection, could be responsible for the numbers of deaths reported within 48 hours of COVID-19 'vaccine' injection, although this is yet to be proven. This is why COVID-19

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[81] Lei Y, Zhang J, Schiavon CR, et al (2021) *SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE 2.* Circulation Research 2021, April 30, 2021 Vol 128, Issue 9 https://www.ahajournals.org/doi/full/10.1161/CIRCRESAHA.121.318902

[82] Fertig, T.E. et al (2022) *Vaccine mRNA Can Be Detected in Blood at 15 Days Post-Vaccination* Biomedicines 2022, 10, 1538. https://doi.org/10.3390/biomedicines10071538

[83] Röltgen, K. et al (March 2022) *Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination.* Cell - Volume 185, Issue 6, 17 March 2022, Pages 1025-1040.e14. https://doi.org/10.1016/j.cell.2022.01.018

'vaccine' related deaths need to be thoroughly investigated, with autopsies that include determination of tissue levels of Spike Protein.

10.4. These authors also reflect upon the lack of transparency regarding lot-to-lot gene sequencing for vaccine quality control which might explain why some batches/lots of gene-based COVID-19 'vaccines' are associated with much high incidences of severe adverse effects[84].

10.5. A biopsy study provided direct evidence linking Spike Protein concentrations produced following vaccination in heart tissue to the development of myocarditis.[85]

11. Long-Term Potential Genetic Damage and Cancer Potential of COVID-19 'Vaccines'

11.1. In considering the safety of any new therapeutic, potential for both genotoxicity (damage to genes) and mutagenicity (potential to cause cancer) are among the highest priorities. This should especially apply to genetic therapeutics such as the COVID-19 'vaccines', and more so when administration of these products to healthy individuals of all ages worldwide was envisioned.

11.2. Evidence shows the spike protein produced by the Pfizer mRNA vaccine can enter into the nucleus of cells and disrupt fundamental cellular processes involved in DNA repair. This adds to concerns and raises serious potential safety issues regarding a diminished ability of the body to prevent the rise of cancers[86]. Neither of these observed genetic type molecular effects are expected in relation to conventional vaccines.

11.3. The gene-based COVID-19 'vaccine' manufacturers presented their products as 'vaccines' to drug regulators even though, by their very nature, they were a new class of gene-based therapies. This had significant impact on reducing the usual safety testing requirements which were normally applied to gene-based therapies. It should be noted that in order to assist and accommodate the introduction of these experimental drugs, the CDC and other organisations began applying recently reduced safety data requirements applicable to conventional vaccines to these gene-based 'vaccines' and the definition of 'vaccine' was amended to accommodate these new gene-based therapies[87].

The World Health Organisation (WHO) Technical Report Series, no. 927m 2005 Annex *1, WHO Guidelines on nonclinical evaluation of vaccine*[88] page 50 section 4.2.3 states:

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72 Batch toxicity analysis by Craig-Paardekooper: https://www.bitchute.com/video/6xlYPZBkydsu/ ; https://www.bitchute.com/video/keoCmPh3vuiG/

85 Baumeier, C. et al: (2022) *Intramyocardial Inflammation after COVID-19 Vaccination: An Endomyocardial Biopsy-Proven Case Series* International Journal Molecular Science 2022, 23, 6940. https://doi.org/10.3390/ijms23136940

86 Jiang, H., Mei. Y.-F. (2021) *SARS–CoV–2 Spike Impairs DNA Damage Repair and Inhibits V(D)J Recombination In Vitro.* Viruses 13:2056 https://doi.org/10.3390/v13102056

87 https://deathship.wordpress.com/2021/09/25/cdc-changes-the-definition-of-vaccines/

88 Jaafar, R. et al (June 2021) Correlation between 3790 Quantitative Polymerase Chain Reaction-Positives Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates

'Genotoxicity studies are normally not needed for the final vaccine formulation'. But these guidelines were drafted well before the invention of the gene-based COVID 'vaccines'.

11.4. Drug regulators around the world have accepted official product information statements which acknowledge the omission of this important pre-clinical (in-vitro and/or animal) genotoxicity and mutagenicity safety data.

11.5. Provisional Approval for the new gene-based COVID-19 'vaccines' began early 2021. However, since then important laboratory genetic data has been published which raises the theoretical possibility that the mRNA contained in these gene-based 'vaccines' may be reverse transcribed (that is, incorporated) into one's DNA around the body (including a wide variety of tissues and organs including eggs in the ovary) which is contrary to the assumptions of the drug regulators such as the TGA. This research, according to established protocols, was done on an in-vitro human liver cell line. The potential safety implications for current and future generations are of great relevance and significance and drug regulators should be demanding immediate further investigations[89]. These findings raise the possibility that these gene-based COVID-19 'vaccines' might induce cancers and that these effects may be inherited into future generations. Until this and other questions are addressed it is not prudent nor reasonable to claim these products are "safe".

11.6. Following an extensive critical review of the immunological and metabolic consequences associated with the mRNA based COVID-19 'vaccines', some expert molecular biologists have concluded these 'vaccines' should be withdrawn due to their potentially devastating and wide ranging short-term and long-term adverse effects[90].

11.7. Furthermore, in relation to risk-benefit, it has been reported that "based on publicly available official UK and US data, all age groups under 50 years old are at greater risk of death after receiving a COVID-19 inoculation than an unvaccinated person is at risk of a COVID-19 death[91]. In such circumstances, it is extremely difficult to justify mandatory vaccination.

11.8. It is also unknown if the Danish drug regulator's recent decision to cease its gene-based vaccination program is related to concerns regarding genotoxicity[92]. The

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Clinical Infectious Diseases, Volume 72, Issue 11, 1 June 2021, page e921. 28 September 2020. https://doi.org/10.1093/cid/ciaa1491

89 Aldén, M. et al (2022) I*ntracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line.* Current Issues in Molecular Biology 44: 1115–1126 https://doi.org/10.3390/cimb44030073

90 Seneff, S and Nigh, G; (10/05/2021) *Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19.* International Journal of Vaccine Theory, practice and Research: 2(1) https://ijvtpr.com/index.php/IJVTPR/article/view/23

91 Dopp, K and Seneff, S. (February 2022) COVID-19 and All-Cause Mortality Data by Age Group Reveals Risk of COVID Vaccine-Induced Fatality is Equal to or Greater than the Risk of a COVID death for all Age Groups Under 80 Years Old as of 6 February 2022 https://www.skirsch.com/covid/Seneff_costBenefit.pdf

92 *COVID-19: Denmark suspends COVID vaccination programme with health chiefs saying virus under control* (28 April 2022) Sky News https://news.sky.com/story/covid-19-denmark-suspends-covid-vaccination-programme-with-health-chiefs-saying-virus-under-control-12600593?fbclid=IwAR2xIYS6Dil45imXz0Flp7JB19JaVNovUgeN8VmYG0mhP5hiE6GJ4zHNnXM

Danish drug regulatory agency has long been considered to rank among the most competent regulatory agencies in the world and is highly regarded.

11.9. The issue of potential mutagenicity and genotoxicity is of high importance and received attention at Australian Senate Estimates on 1 June 2021 (Community Affairs Legislation Committee)[93].

11.10. In that hearing, Prof. Skerritt (head of the Australian TGA) by Senator Malcolm Roberts on the potential for the mRNA to enter the nucleus of cells and cause potentially serious genetic adverse events which could affect future generations:

> "Senator ROBERTS: *How long before we know the intergenerational effects?*
>
> Dr Skerritt: *There is no evidence at all from animal or human studies that the RNA vaccines, if you're talking about them, incorporate into the genetic material of human beings. They wouldn't have received regulatory approval, and that includes by much bigger regulators such as the FDA, if these bits of mRNA incorporated into the human genetic material. In fact, medicines that incorporate into human genetic material and are inherited are currently not permitted in most major countries, including Australia.*"

11.11. The statement by Prof. Skerritt was made prior to the publications referred to above. These events provide compelling evidence to reject the indiscriminate general use of these gene-based COVID-19 'vaccines' and to prevent mandatory vaccination on safety grounds.

12. COVID-19 'Vaccines' Do Not Prevent Infection or Transmission

12.1. The COVID-19 'vaccines' neither prevent infection nor do they prevent transmission of the infection. SARS-CoV-2 infection is via airborne infection of viral particles entering via the mucosa (surface lining) of the nose. COVID-19 'vaccines' do not induce mucosal immunity: instead they induce blood-borne immunity, which is not effective in countering organisms entering and multiplying in the mucosal tract. This is why, despite population vaccination rates approaching 90%, COVID-19 cases remain stubbornly high in many countries.

12.2. 'Dr Anthony Fauci, head of the National Institute of Allergy and Infectious Disease (NIAID) said the viral load of Delta variant in the nasal passages of vaccinated people was "almost identical" to that in noses of unvaccinated people.[94] It is an accepted principle that the viral load or amount of virus present is directly proportional to both

[93] https://parlinfo.aph.gov.au/parlInfo/download/committees/estimate/074f811f-4fa9-49b2-a2d5-f8dc2b74d47d/toc_pdf/Community%20Affairs%20Legislation%20Committee_2021_0601_8809_Official.pdf;fileType=application%2Fpdf#search=%22committees/estimate/074f811f-4fa9-49b2-a2d5-f8dc2b74d47d/0000%22 page 53

[94] https://thehill.com/homenews/sunday-talk-shows/565831-fauci-amount-of-virus-in-breakthrough-Delta-cases-almost-identical

the development of symptoms of infection and the ability to transmit the infection to others.

12.3. Dr Rochelle Walensky, director of the Center for Disease Control (CDC) said publicly that the COVID-19 vaccines "can't prevent transmission" [of SARS-CoV-2][95]. This is basically because the COVID-19 vaccines do not prevent infection in an individual i.e. the COVID-19 'vaccines' are not "sterilizing".

12.4. In addition, three articles in The Lancet report that the current COVID-19 gene-based vaccines do not prevent transmission of SARS-CoV-2[96].

12.5. Contrary to initial popular belief and in light of recent evidence, mandatory COVID-19 vaccination will neither significantly or effectively prevent SARS-CoV-2 infection or prevention of transmission of infection to others. According to Gunter Kampf, fully vaccinated individuals can carry similar viral loads to unvaccinated individuals and spread the virus just as easily[97].

12.6. Gunter Kampf, stated:

> *"There is increasing evidence that vaccinated individuals continue to have a relevant role in transmission. In Massachusetts, USA, a total of 469 new COVID-19 cases were detected during various events in July, 2021, and 346 (74%) of these cases were in people who were fully or partly vaccinated, 274 (79%) of whom were symptomatic. Cycle threshold values were similarly low between people who were fully vaccinated (median 22.8) and people who were unvaccinated, not fully vaccinated, or whose vaccination status was unknown (median 21.5), indicating a high viral load even among people who were fully vaccinated."*

12.7. The author concludes: *"It is therefore wrong and dangerous to speak of a pandemic of the unvaccinated"*.

12.8. A Wisconsin, USA, study in June/July 2021 (when the Delta variant was prominent) found no difference for SARS-CoV-2 infected individuals in viral load measurements by PCR test cycle threshold (Ct) data between 310 fully vaccinated and 389 unvaccinated individuals: Testing found high viral load in 68% of the fully vaccinated

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[95] Jaafar, R. et al (2020) Correlation between 3790 Quantitative Polymerase Chain Reaction-Positives Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates Clinical Infectious Diseases, Volume 72, Issue 11, 1 June 2021, page e921. 28 September 2020 https://pubmed.ncbi.nlm.nih.gov/32986798/

[96] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02243-1/fulltext , https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00090-3/fulltext#sec1 & https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00768-4/fulltext

[97] Kampf, G. (2021) *COVID-19: stigmatising the unvaccinated is not justified* The Lancet VOLUME 398, ISSUE 10314, P1871, NOVEMBER 20, 2021 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02243-1/fulltext
Brown CM, et al (July 2021) Outbreak of SARS-CoV-2 infections, including COVID-19 vaccine breakthrough infections, associated with large public gatherings— Barnstable County, Massachusetts, July 2021 CDC MMWR Morb Mortal Wkly Rep 2021;70: 1059–62 https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm

and 63% of the unvaccinated. This data suggests that vaccinated are just as likely to be spreaders of SARS-CoV-2[98].

12.9. The risk of infection leading to COVID-19 varies depending on age and clinical status (including the presence of natural immunity) and must be weighed against the accumulating evidence of serious adverse effects including death, as well as the waning efficacy of the vaccines in protecting against infection.

13. Diminished 'Vaccine' Efficacy and Potential Negative 'Vaccine' Efficacy

13.1. In the first part of 2022 a number of public health sources in the US, Australia, Denmark, Israel and the UK have suggested the protective efficacy of the COVID 'vaccines' is waning or possibly even resulting in "negative efficacy", i.e. those vaccinated are at a higher risk of infection. This was in the context of the later subvariants of Omicron as reported in an observational study of 22,072,550 SARS-CoV-2 cases[99].

13.2. The authors state:

> *"The vaccine effectiveness (VE) for the third dose was in negative since December 20, 2021, with a significantly increased proportion of SARS-CoV2 cases hospitalizations and deaths among the vaccinated; and a decreased proportion of cases, hospitalizations, and deaths among the unvaccinated."*

13.3. In is acknowledged that epidemiological data interpretation is both challenging and complicated because there are confounding variables to consider such as age, gender, vaccination status and co-morbidities. There is also the added complexity of consideration of the definition of "fully vaccinated" as this varies depending on vaccine schedules. There remains the lack of distinction between someone hospitalised or dying "with" COVID versus someone hospitalised or dying "due to" COVID and often those dying within 14 days of vaccination are often considered as "unvaccinated". Overall, however, this large study suggests a negative vaccine efficacy, which is of great concern.

13.4. The main reason for this negative vaccine efficacy has been mainly ascribed to the fact that the Omicron strain of viruses which we are experiencing now are considerably different to the original Wuhan strain and subsequent Delta strain. Those individuals vaccinated with the gene-based 'vaccines' based on the Wuhan strain of virus are paradoxically more susceptible to Omicron infection.

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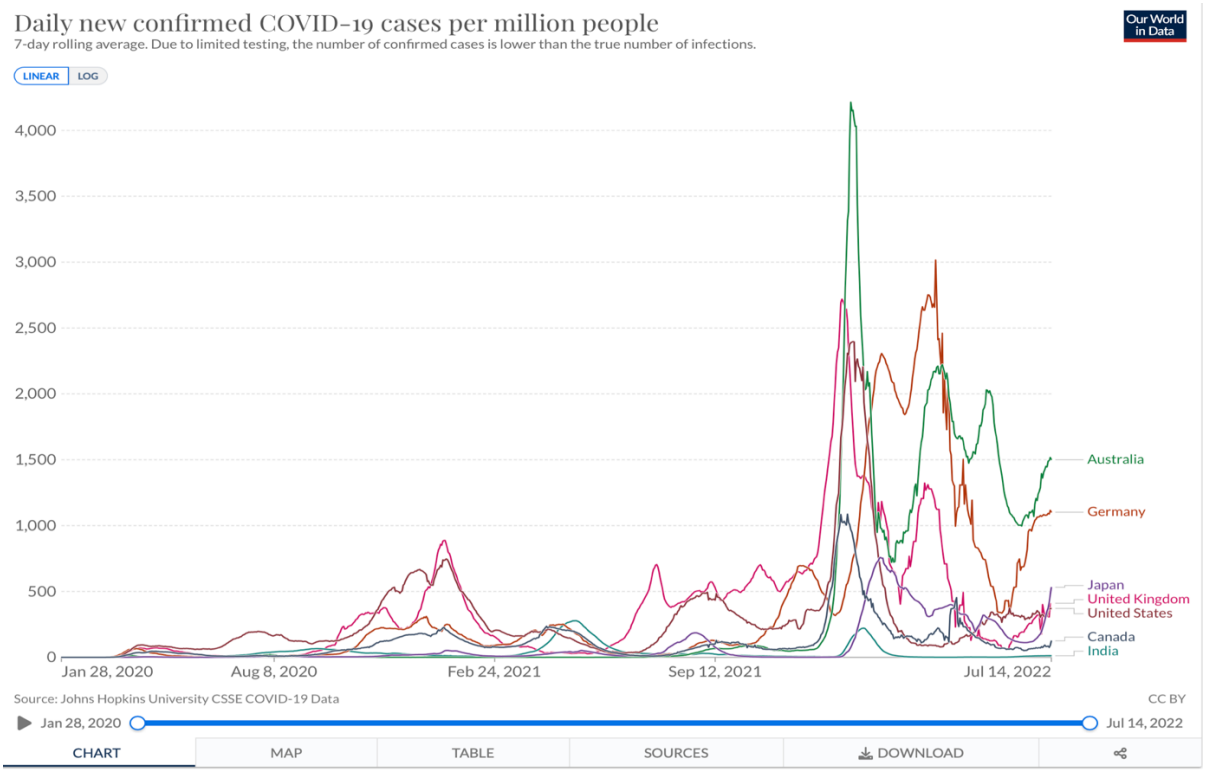
[98] Riemersma, K.K. et al. Shedding of Infectious SARS-CoV-2 Despite Vaccination: Preprint. https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v6.full-text

[99] Emani, V et al (June 2022) Increasing SARS-CoV-2 cases, hospitalizations and deaths among the vaccinated elderly populations during the Omicron (B.1.1.529) variant surge in UK medRixiV preprint https://www.medrxiv.org/content/10.1101/2022.06.28.22276926v2

13.5. Stanford University researchers[100] found that "prior vaccination with Wuhan-Hu-1-like antigens followed by infection with Alpha or Delta variants gives rise to plasma antibody responses with apparent Wuhan-Hu-1-specific imprinting manifesting as relatively decreased responses to the variant virus epitopes compared with unvaccinated patients infected with those variant viruses." Basically, these researchers are saying that vaccination with the current COVID-19 'vaccines' will lead to a diminished ability to protect from infection by the newer variants.

13.6. Pivotal epidemiological data which is useful in determining vaccine effectiveness versus time is published by "Our World in Data", a non-profit organisation based in the United Kingdom.[101] This organisation uses data sourced from Johns Hopkins University Center for Systems Science and Engineering (CSSE).

13.7. The data below plots the rate (cases per million) of confirmed COVID-19 cases by selected country versus time (and is updated regularly).

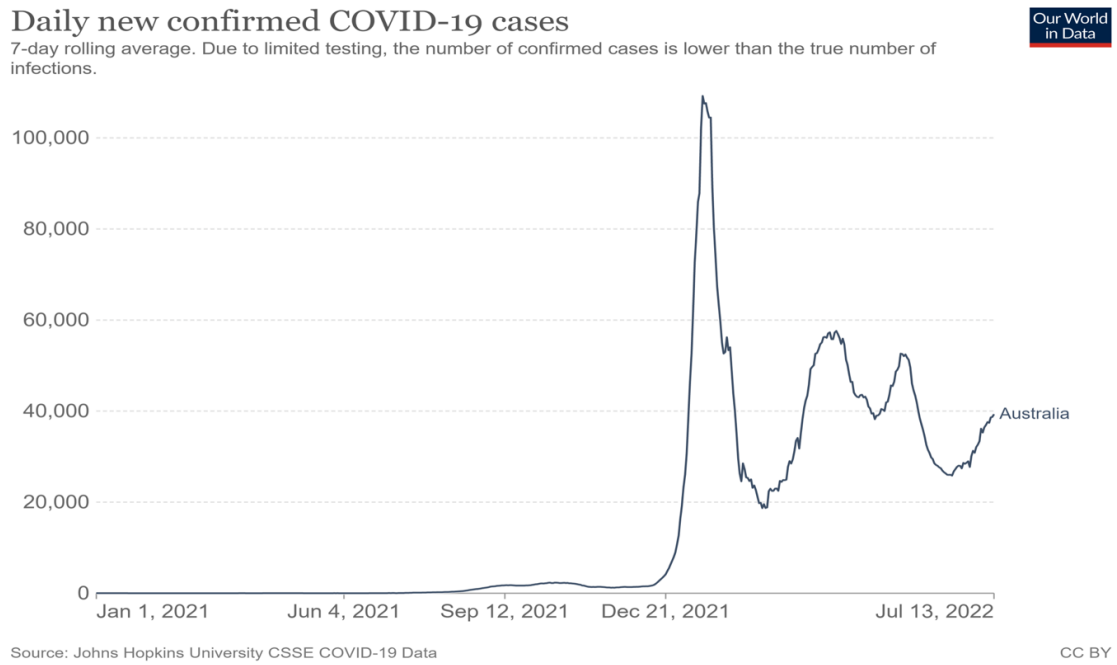


COVID-19 cases by selected country versus time

13.8. This same data can be used to represent the 7-day rolling average of confirmed COVID-19 cases in Australia.

[100] Roltgen, K et al (March 2022) *Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination*. Cell 185,1025-1040, March 17, 2022 https://doi.org/10.1016/j.cell.2022.01.018 https://www.cell.com/action/showPdf?pii=S0092-8674%2822%2900076-9

[101] https://ourworldindata.org/coronavirus#explore-the-global-situation



7-day rolling average of confirmed COVID-19 cases in Australia

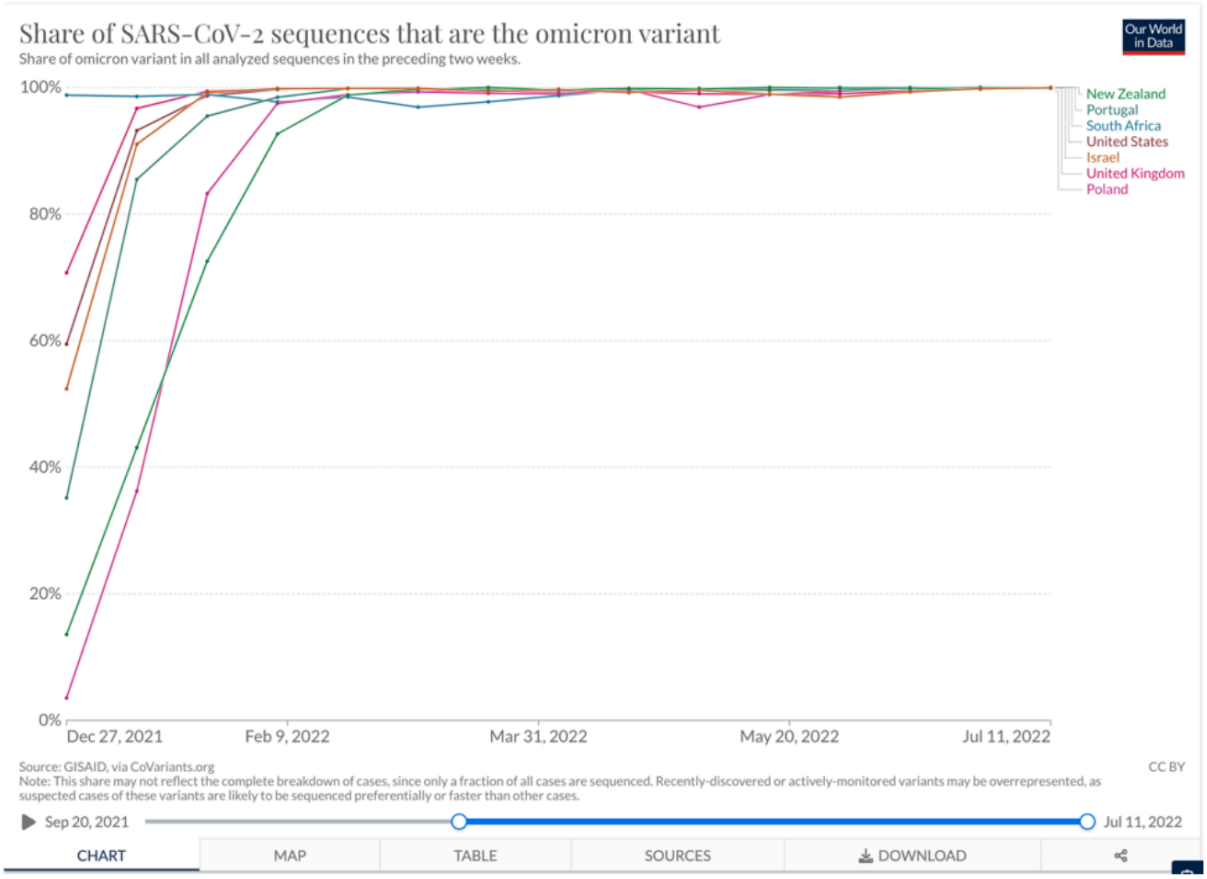
13.9. COVID-19 vaccination commenced in Australia early in 2021. While the both absolute number and percent of the population COVID vaccinated increased rapidly for countries during 2021 and into 2022, the data shows both the rate and absolute number of confirmed COVID-19 cases markedly increased towards the end of 2021. This worldwide data demonstrates a failure of the COVID-19 'vaccines' to prevent infection and transmission of the disease.

13.10. This data strongly suggests that commencing in 2022 the COVID-19 vaccines have substantially lost the ability to prevent infection and transmission of the virus, despite high rates of vaccine uptake in the population. This provides evidence of the futility of vaccine mandates.

13.11. All epidemiological and health statistical data requires careful interpretation as definitions may vary from jurisdiction to jurisdiction and health protocols can impact the interpretation of the data. However, without evidence to the contrary, the above data appears to provide a compelling evidence of a negative vaccine efficacy. In other words, COVID-19 vaccinated individuals are more likely to be infected with the current strain of the COVID-19 virus and be admitted to hospital than compared to non-vaccinated individuals. Similar observations have been made in other countries.

13.12. As mentioned earlier, a major contributing factor to this phenomenon may be due to the fact that since early 2022, the dominant variant of the SARS-CoV-2 virus is

Omicron[102] (see graph below) whereas the current COVID-19 'vaccines' are constructed to produce antibodies towards the original Wuhan strain.



Share of SARS-CoV-2 sequences that is the Omicron variant by country

14. The COVID-19 'Vaccines' Do Not Provide a Similar and Acceptable Risk/Benefit Across All Age Groups irrespective of individual Clinical Status including Natural Immunity

14.1. Mandatory vaccination by its very nature assumes that a therapeutic agent produces a similar risk and a similar benefit for all individuals. However, this is never the case. Therapeutics should always be prescribed with a consideration of the particular clinical status of the individual, which is why prescribing information always contains specific warnings and contraindications of use in relation to age, health status etc. Drugs are never prescribed on a "one size fits all" basis. Prescribing a drug and ignoring the particular clinical circumstances of an individual is not good medical practice.

14.2. Natural immunity plays an important role in COVID-19. There is no evidence to suggest that COVID-19 gene-based 'vaccination' offers superior protection from COVID-19 as compared to natural immunity. Indeed, many believe the reverse is true.

[102] Source: GISAID, via CoVariants.org as presented by Our World in Data up to 11 July 2022 https://ourworldindata.org/covid-cases

14.3. In acknowledgement of the important role of natural immunity, even Bill Gates, perhaps the most prominent vaccine proponent, speaking at the Munich Security Conference reported 23 February 2022[103], admitted that *"the virus itself, particularly the variant called Omicron, is a type of vaccine"*.

14.4. The important role of natural immunity from both a personal and societal point of view needs to be recognised. This societal natural immunity was commonly referred to as 'herd immunity' and was initially widely considered important to limit the impact of the virus.

14.5. Conventional wisdom suggests that natural immunity following COVID-19 infection provides a high level of durable protection from re-infection in many ways superior to "vaccination" because natural immune response is a multifaceted immune response directed against a number of components including the envelope, the membrane, the nucleocapsid and the spike within the virus – unlike the immune response produced by gene-based 'vaccines' which only direct the production of specific antibodies only towards the virus Spike Protein.

14.6. It has been likely that hundreds of millions of people have recovered from COVID-19. Numerous scientists have found that natural immunity offers a decreased risk of re-infection and extremely low rates of hospitalisation in relation to repeat infection[104].

14.7. A study in Qatar found that *'natural infection appears to elicit strong protection against reinfection with an efficacy ~95% for at least seven months'*[105].

14.8. The UK study by Hall et al, with funding from the UK Government, reported a similar level of protection due to natural immunity[106].

14.9. A study in Austria found that the frequency of re-infection from COVID-19 caused hospitalisation in only five out of 14,840 (0.03%) people and death in one out of 14,840 (0.01%)[107].

14.10. In many ways, natural immunity protection will be superior to the protection afforded by gene-based COVID-19 'vaccines'. In such circumstances, voluntary or mandatory

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[103] Published in Locke (johnlocke.org)– Mitch Kokai, (23 February 2022): Bill Gates Gives Omicron More Credit Than Vaccines in Battling COVID. https://www.johnlocke.org/bill- gates-gives-omicron-more-credit-than-vaccines-in-battling-covid/

[104] Klausner, J., Kojima, N. (May 2021) Op-Ed: Quit Ignoring Natural COVID Immunity — Antibody testing and proof of prior infection can allow more people to return to normal Medpage Today, 28 May 2021. www.medpagetoday.com/infectiousdisease/covid19/92836 ;
150 Plus Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/

[105] Abu-Raddad, L. et al (May 2021) *SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy.* eClinicalMedicine, Part of The Lancet Discovery Science, Vol 35, May 2021, 100861 https://doi.org/10.1016/j.eclinm.2021.100861

[106] Hall, V. J (2021) SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study (SIREN) VOLUME 397, ISSUE 10283, P1459-1469, APRIL 17, 2021 https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00675-9/fulltext

[107] Pilz S et al (2021) *SARS-CoV-2 re-infection risk in Austria.* European Journal of Clinical Investigation Volume 51, Issue 4 e13520 https://doi.org/10.1111/eci.13520

vaccination with gene-based COVID-19 'vaccines' do not offer any additional protection. There is no scientific theoretical basis or reliable evidence to suggest that a person with natural immunity might benefit from administration of a Provisionally Approved gene-based COVID-19 'vaccine' while the 'vaccine' itself has significant adverse effects and no long-term safety data to support its use.

14.11. A retrospective observational study of 124,500 individuals, conducted during the Delta wave of SARS-CoV-2 compared two groups: people who had not been previously infected with SARS-CoV-2 and received a 2-dose regimen of the Pfizer COVID-19 "vaccine" and previously infected individuals who had not been vaccinated[108]. Individuals who had been vaccinated had a 13-fold greater chance of breakthrough infection compared to re-infection in the non-vaccinated group.

14.12. The conclusion of the authors was: *'Naturally acquired immunity confers stronger protection against infection and symptomatic disease caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2-2 [Pfizer COVID-19 'vaccine'] dose vaccine-induced immunity'*.

14.13. While the current SARS-CoV-2 variant is Omicron, in the absence of data to the contrary, these data provide a compelling case to support the importance of natural immunity in protecting against SARS-CoV-2 infection.

14.14. The Swedish drug regulator is regarded as one of the most respected regulatory agencies and they have recently reversed its recommendation on the administration of COVID-19 'vaccines' to adolescent children as they do not see any clear benefit in COVID-19 vaccination. According to a Reuters news release in Stockholm on 27 January 2022, Sweden decided against recommending COVID-19 'vaccines' for children aged 5-11, the Swedish Health Agency said that the benefits did not outweigh the risks: 'With the knowledge we have today, with a low risk for serious disease for kids, we don't see any clear benefit with vaccinating them'[109].

14.15. It is reported that children in the population are at a substantially lower risk of developing COVID-19.[110]

14.16. In addition, it has been suggested that a high proportion of children in the population have acquired natural immunity which offers better protection from infection as compared to vaccination. As above, a large study during the Delta wave found vaccinated individuals had a 13-fold greater chance of breakthrough infection than unvaccinated individuals had of being re-infected.

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[108] Gazit, S et al (2022) Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Naturally Acquired Immunity versus Vaccine-induced Immunity, Reinfections versus Breakthrough Infections: A Retrospective Cohort Study. Clinical Diseases Major Article https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9047157/pdf/ciac262.pdf

[109] *Sweden decides against recommending COVID vaccines for kids aged 5-11 (*27 January 2022) Reuters - Stockholm https://www.reuters.com/world/europe/sweden-decides-against-recommending-covid-vaccines-kids-aged-5-12-2022-01-27/

[110] Loske, J. et al (March 2022) *Pre-activated antiviral innate immunity in the upper airways controls early SARS-CoV-2 infection in children.* Nature Biotechnology: Vol 40, March 2022, 319-324 s://doi.org/10

Conclusion

The introduction and worldwide use of COVID-19 gene-based 'vaccines' has been associated, in the short term, with far more deaths, illnesses, injuries, and disabilities than any other therapeutic agent in the history of medicine. Due to the total lack of any long-term safety data, the potential future iatrogenic effects (including neurological, immunological and carcinogenic effects) may be even more devasting.

Despite initial claims, the COVID-19 gene-based 'vaccines' have now been shown to possess disappointing clinical efficacy - they neither prevent SARS-CoV-2 infection nor do they prevent transmission of the virus; any immunological protection wanes rapidly and, coincident with the emergence of the Omicron variant, evidence of negative vaccine efficacy is being reported in many countries including Australia.

In light of widely reported emerging and compelling evidence, there appears to be little scientific or clinical justification to support vaccine mandates as a health policy.

The latest hospital admission statistics do not support the claim that unvaccinated individuals are more at risk of serious COVID-19 disease, hospitalisation or death. Excess non-COVID-19 related deaths coincident with the introduction of the gene-based 'vaccines' are now being reported by many countries, and suggest a surge in heart attack and stroke among both the young, adolescents and middle age individuals (especially males).

Advocating the worldwide use of a new class of serious COVID-19 gene-based 'vaccines' never before deployed, and advocated for use in healthy individuals of all ages regardless of clinical status (eg. natural immunity, pregnancy etc), with relatively little short-term safety data and no long-term safety data, is neither prudent or necessary and defies the Precautionary Principle.

The knowledge that the synthetic mRNA in both the Pfizer and Moderna vaccines can enter the nucleus of human liver cells in culture, raises the serious questions about genotoxicity and carcinogenicity, and adverse impact on future generations. Disturbing safety signals regarding fertility and miscarriages are emerging.

Given the statistically or virtually nil risk of serious COVID-19 in general affecting children aged 6 months to 11 or 12 years of age and the clear and significant risk of serious adverse effects including myocarditis, pericarditis and death in this age group – there seems to be little benefit to be gained by vaccinating these children.

Considerable scientific, clinical and statistical epidemiological data and understanding has been acquired since the introduction (on a provisional basis only) of the investigational COVID-19 gene-based "vaccines". Many of the initial ambitious claims and assumed perceptions regarding the safety and efficacy of these serious therapeutics have now been invalidated and it is now time to review and reconsider the utility of these products in light of the known unprecedented level of serious adverse reactions and death attributed to their use.

The urgency for this review cannot be overestimated given the current and potential future impact on the health and wellbeing of all Australians.

Phillip M. Altman

Appendix A

Abbreviated Curriculum Vitae – Dr Phillip Altman

Dr Phillip Altman has expertise in the areas of clinical medical research and pharmaceutical drug regulatory affairs in Australia.

Holding the degrees Bachelor of Pharmacy (Hons), and Master of Science and Doctor of Philosophy, Phillip's doctorate concerned the development new of cardiotonic drugs with lower intrinsic toxicity, compared to existing drugs including their chemical synthesis and testing in various animal models.

Phillip has worked primarily within the Australian pharmaceutical industry since 1974 in relation to clinical trial design, management, and reporting in relation to obtaining new drug approvals, dealing with the Secretary of the Department of Health, and the Therapeutic Goods Administration (**TGA**). After many years working within multinational pharmaceutical companies, Phillip later became a senior industry pharmaceutical consultant through his contract research company, Pharmaco Pty Ltd., which provided both clinical trial and regulatory consultant services to the Australian pharmaceutical industry, which focussed his experience in critically evaluating clinical trial safety and efficacy data, as submitted in complex new drug dossiers for international regulatory purposes. This work saw Phillip consulted by more than half of the multinational pharmaceutical companies in Australia, in various capacities, with a focus on drug regulatory affairs.

Phillip founded the Association of Regulatory and Clinical Scientists (ARCS), which includes more than 2,000 scientists, clinicians, and associated health professionals involved in both clinical trial and regulatory affairs, in Australia and New Zealand, where ARCS continues to be the foremost educational forum for both industry and government (including the TGA) personnel, involved in clinical trials and regulatory affairs.

Phillip's experience involves more than 100 clinical trials (covering Phases I,II, III and IV, i.e. from first administration to animals, then man, to post-approval trials), and a similar number of new drug applications, TGA appeals, and applications to modify existing approvals. In collaboration with the TGA and on behalf of pharmaceutical companies, Phillip also directed 2 major drug withdrawals in relation to public safety. More recently Phillip has been a senior clinical trial and regulatory affairs advisor to an Australian company which has developed a live virus for the treatment of melanoma.

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05 AUG 2022

TITLE OF REPORT:

SECTION 1: A COMPARISON OF ADVERSE EVENTS RELATED SPECIFICALLY TO THE COVID-19 VACCINES AND NON-COVID-19 VACCINES FROM 1 JAN 1971 TO 31 DEC 2021.

SECTION 2: ADVERSE EVENTS AND DEATHS REPORTED TO TGA DAENS, AUSTRALIA FOLLOWING COVID-19 VACCINES BETWEEN 1 FEBRUARY 2021 TO 8 JUNE 2022 HIGHLIGHTING DEATHS AND ADVERSE EVENTS IN CHILDREN 5-11 YRS OLD.

1 EXECUTIVE SUMMARY

1.1 I have conducted a number of reviews of the Therapeutic Goods Administration's (**TGA**) published adverse events as recorded in the Database of Adverse Event Notifications (**DAENs**) database to 8 June 2022, specifically following the COVID-19 Vaccines entries in that database and I confirm that:

a since 10 January 2022, there were 1,390 Adverse Events and 5 Deaths reported for the 5-11 year age group since the roll out of the Pfizer Vaccine commenced.

b since 1 February 2021, there have been at least 108,542 Adverse Events and 723 Deaths reported in adolescents and adults since the roll out of the Covid-19 Vaccines.

c since 1 February 2021, that together, there have been at least 131,991 Adverse Events following Covid-19 Vaccines reported in all ages.

d since 1 February 2021, together there have been at least 884 total Deaths as the reported outcome following immunisation in all ages. and including unspecified ages,

1.2 By comparison, I have also reviewed the TGA weekly safety reports to 5 June 2022. The TGA reports record that there were:

a 1,470 Adverse Events in 5-11 year olds following 2.2M doses of Pfizer Vaccine.
Source: The TGA weekly safety report https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-09-06-2022

b 129,995 Adverse Events in all ages following 59,431,403 doses of Covid-19 Vaccines.
Source: The TGA weekly safety report https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-09-06-2022

2 DEFINITION OF TERMS:

2.1 Throughout this report I have used a number of definitions:

Adverse Events:

a) Adverse Events are defined by the TGA as unintended and sometimes harmful occurrences associated with the use of a medicine, vaccine or medical device (collectively known as therapeutic goods). Adverse events include side effects to medicines and vaccines, and problems or incidents involving medical devices.

b) Examples of adverse events are any unfavourable and unintended sign, symptom or disease associated with the use of a therapeutic good.

c) All Adverse events referred to in this document relate to vaccines.

d) Adverse Events reported to the TGA have been classified by MedDRA classification which includes Organ affected and type of reaction. One Adverse Event case can affect many organs and reaction types can include many MedDRA Classifications.

e) Adverse events are defined by the Australian institute of Health and Welfare as '*incidents in which harm resulted to a person receiving health care'*. There is no definition included on the TGA web site.

f) Importantly, an adverse event is not always caused by the therapeutic good itself. The occurrence of an adverse event does not necessarily mean that there is something wrong with the therapeutic good.

Ages:

- **Children:** Individuals whose ages are 5-11 years.
- **Babies/infants:** 0-4years
- **Unspecified:** Age is left blank or marked with a hyphen –
- **Adolescents:** 12-18
- **Adults 19 years and over**

Covid-19 Vaccines: There are 4 vaccines that are being administered in Australia. They include:

- Pfizer Comirnaty Covid-19 vaccine (**Pfizer Vaccine**)
- Covid-19 vaccine Astra Zeneca
- *Nuvaxovid (Nuvavax) Covid-19 Vaccine
- Spikevax (Moderna) Covid-19 Vaccine
- TNS DAENs database record for Covid-19 Vaccine Type Not Specified.

*In searches up to 31 Dec 2021, I have searched for 4 vaccines only, because Novavax, or Nuvaxovid has only been approved for use in Australia from 20 Jan 2022 for people 18 years and over. On 25 July the provisional approval was extended to 12-17year olds.

Database of Adverse Event Notifications (DAEN): **"**The TGA receives Adverse Event reports associated with medicines and medical devices. These reports come from a wide range of sources, including members of the public, general practitioners, nurses, other health professionals and the therapeutic goods industry and are" stored in an online database.

Source: https://www.tga.gov.au/database-adverse-event-notifications-daen

Deaths: Associated with the TGA reporting, this refers to the number of cases where death was a reported outcome following immunisation from the DAEN website. It should be noted that this does not necessarily imply causality. Also, to determine deaths in TGA DAENs website is quite a convoluted process because the death MedDRA item category has been removed and so one cannot simply search for deaths.

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 to some items below for reference:

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

Please find a complete listing of MedDRA items using the following link**.** **https://1drv.ms/b/s!Al71AGIGLVVzgUj3L1lBYHafccTF?e=sKvJS2**

Pfizer Vaccine: is the Comirnaty Covid-19 Vaccine as described in DAENs for all age groups. The Pfizer Vaccine was provisionally approved Covid-19 Vaccine for 5-11 year olds. It was approved by the TGA on 5 December 2021. Roll out of the Pfizer Vaccine for 5-11 year olds commenced on or about 10 January 2022.

Spikevax (Moderna) Covid-19 Vaccine: on 17 February 2022 the Spikevax Vaccine was provisionally approved for 6-11 year olds.
Source: https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/who-can-get-vaccinated/children?gclid=CjwKCAjwzeqVBhAoEiwAOrEmzWO2iNsMIeqs1wsBQ0kVEeqpu0m4lo59czwpmIjoPCdeU-ZT4yl1jxoCFJoQAvD_BwE&gclsrc=aw.ds

3. KEY POINTS TO NOTE

3.1 In SECTION 1, all the questions relating to the COVID-19 vaccines ask for figures for each COVID vaccine type from date of approval to the report date.

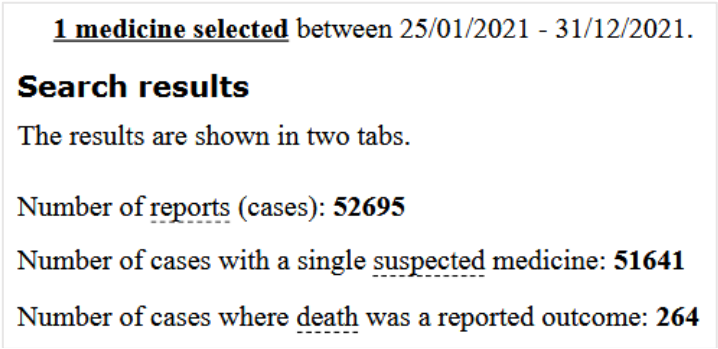
While the work underlying this report was begun by me around 6 January 2022, the data I collected was for 2021, and as such, I have a hard end to the year 2021 (31 Dec 2021).

Further, it appears that when the database is searched for each vaccine type from date of approval to end of 2021, and then when one adds the results, I do not get the same answer as I do when I search the entire database, all at once, using all 4 vaccines and the dates 1 Jan 2021 and 31 Dec 2021.

For simplicity, I have used this search as my master data search. All the COVID results will balance to that master data (I cannot explain why this phenomenon exists but suffice it to say, it goes to data integrity). I will demonstrate this in the following report.

A search for Pfizer, AstraZeneca, Moderna and unspecified, reveals the following information:

- Pfizer 25/01/2021 to 31/12/2021
  - No. of cases 52,695
  - No. of cases with a single suspected medicine 51,641
  - No. of cases where death was a reported outcome 264


1 medicine selected between 25/01/2021 - 31/12/2021.

Search results

The results are shown in two tabs.

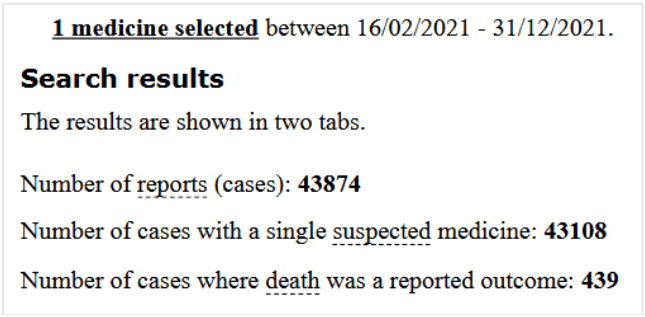
Number of reports (cases): **52695**

Number of cases with a single suspected medicine: **51641**

Number of cases where death was a reported outcome: **264**

Source: Appendix 2.2 - DAEN Results for Individual COVID Vaccines (Including Unspecified Type) with Index, page 2-10

- AstraZeneca 16/02/201 to 31/12/2021
  - No. of cases 43,874
  - No. of cases with a single suspected medicine 43,108
  - No. of cases where death was a reported outcome 439



1 medicine selected between 16/02/2021 - 31/12/2021.

Search results

The results are shown in two tabs.

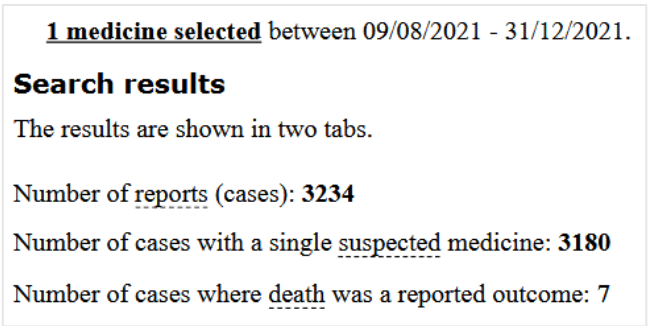
Number of reports (cases): **43874**

Number of cases with a single suspected medicine: **43108**

Number of cases where death was a reported outcome: **439**

Source: Appendix 2.2 - DAEN Results for Individual COVID Vaccines (Including Unspecified Type) with Index, page 11-19

- Moderna (Spikevax) 09/08/2021 to 31/12/2021
  - No. of cases 3,234
  - No. of cases with a single suspected medicine 3,180
  - No. of cases where death was a reported outcome 7



1 medicine selected between 09/08/2021 - 31/12/2021.

Search results

The results are shown in two tabs.

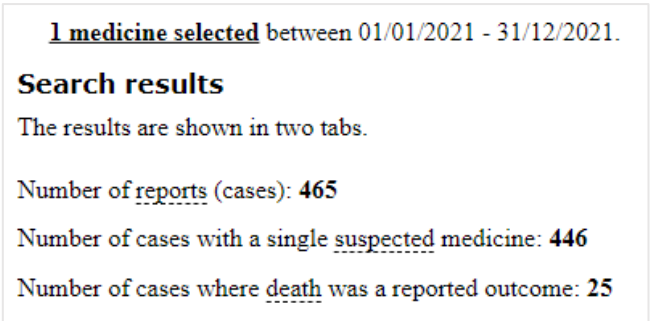
Number of reports (cases): **3234**

Number of cases with a single suspected medicine: **3180**

Number of cases where death was a reported outcome: **7**

Source: Appendix 2.2 - DAEN Results for Individual COVID Vaccines (Including Unspecified Type) with Index, page 20-28

- Unspecified COVID vaccines 01/01/2021 to 31/12/2021
  - No. of cases 465
  - No. of cases with a single suspected medicine 446
  - No. of cases where death was a reported outcome 25



1 medicine selected between 01/01/2021 - 31/12/2021.

Search results

The results are shown in two tabs.

Number of reports (cases): **465**

Number of cases with a single suspected medicine: **446**

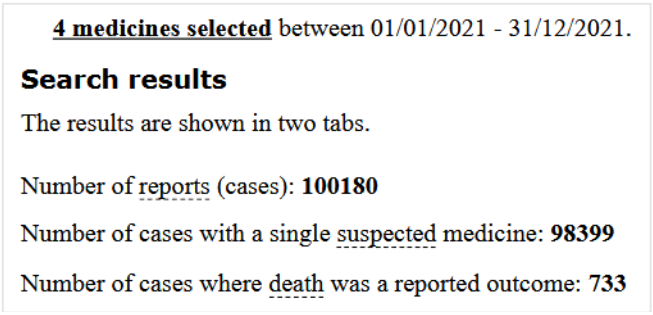
Number of cases where death was a reported outcome: **25**

Source: Appendix 2.2 - DAEN Results for Individual COVID Vaccines (Including Unspecified Type) with Index, page 29-37

- Total for all COVID vaccines plus unspecified COVID vaccines is:
  - No. of cases 100,268
  - No. of cases with a single suspected medicine 98,375
  - No. of cases where death was a reported outcome 735

It is important to note that when I search for all COVID vaccines including unspecified for the period 01/01/2021 to 31/12/2021 I get:

- ***No. of cases: 100,180***
- ***No. of cases with a single suspected medicine 98,399***
- ***No. of cases where death was a reported outcome 733***



4 medicines selected between 01/01/2021 - 31/12/2021.

Search results

The results are shown in two tabs.

Number of reports (cases): **100180**

Number of cases with a single suspected medicine: **98399**

Number of cases where death was a reported outcome: **733**

Source: Appendix 2.1 - DAEN Results for COVID Vaccine (Including Unspecified Type), page 1

So, I have elected to use this as our master COVID data.

3.2 In the entirety of this report, whenever I refer to deaths associated with the Therapeutic Goods Administration (TGA) reporting, I am referring to the number of cases where death was a reported outcome from the Database of Adverse Event Notifications (DAEN) website.

3.3 In Section 2 of this report:

a The data in this report is dated from 1 February 2021 when the Covid-19 Vaccines became available until to 8 June 2022, being the last date the DEANs data was updated and when I was briefed to provide this further report.

b The data was extracted by me from the TGA DAENs system over three days: Wednesday 22 June 2022; Thursday 23 June 2022; and Friday 24 June 2022.

c Despite the TGA website stating that its numbers are up to date as at 8 June 2022, which is 2 weeks before 22 June (first day of data extraction), and 9 June (second day of data extraction), the same search of the data on Wednesday 22 June and then Thursday 23 June produces different numbers. This is an issue I have identified in my previous reports.

d The TGA safety reports contain further information than the DAENs database, such as vaccine doses. I also used the TGA safety reports to cross check the results obtained from DAENs.

e The TGA safety report as at 9 June 2022 includes data predominantly up to the 5 June 2022. The numbers in DAENs and those in the TGA safety report for Adverse Events are comparable, I summarise the TGA safety report Adverse Events by vaccine doses further in my response under Item 5 below.

3.4 All questions that I have answered have been advised by a letter of instruction from the instructing legal experts. The questions are integrated into the document.

3.5 Underreporting.

a) As reporting to the TGA Daen's database is voluntary there is a question regarding data coverage.

b) It is globally accepted that there is significant underreporting of adverse events to all voluntary and spontaneous reporting systems. However, the true extent of underreporting is not known.

c) Whilst not perfect, the suspected underreporting to the DAEN system can be approximately validated by referring to the Ausvax website and then using their publicly available information on the number of adverse events that they are reporting within 3-7 days of vaccines being administered. *Source:* ***Ausvax - https://ausvaxsafety.org.au*** *(Monitors adverse events that occur within 3-7 days after vaccination)*

d) The comparison above suggests that underreporting to the DAEN website is at least 90%: that is, they are reporting a maximum of 10% of adverse events and not reporting some 90% of adverse events (as a minimum).

3.6 Appendices. Throughout this document you will see many references to appendices. These appendices amount to many hundreds of pages and as such are not included with this document. If there is a need for specific appendices to be accessed, please advise and I can make links available.

<u>SECTION 1</u>: A COMPARISON OF ADVERSE EVENTS RELATED SPECIFICALLY TO THE COVID-19 VACCINES AND NON-COVID-19 VACCINES FROM 1 JAN 1971 TO 31 DEC 2021. Pages 4-19 of original document.

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. Please use the DAEN data, and only that data, to answer the following questions, except where otherwise stated. In answering the below questions, please indicate the relevant pages of the DAEN data which you have used in order to answer each question:

1. For all of the vaccines in the DAEN combined, except for;
    a. Comirnaty Covid-19 Vaccine (Pfizer);
    b. Covid-19 Vaccine (TNS) (Janssen);
    c. Covid-19 Vaccine AstraZeneca (AstraZeneca); and
    d. Spikevax Covid-19 vaccine (Moderna);
        i) How many reports of adverse events were made between 1971 and the date of your report? Please set out the process by which you have come to your view.

My Answer:

*The number of adverse events from 1 Jan 1971 until 31 Dec 2021 is **19,330**. On the DAEN search engine, type "vaccine" on the first field. Next, select all vaccines, and then deselect the following COVID-19 vaccines so as to exclude them from the search:*

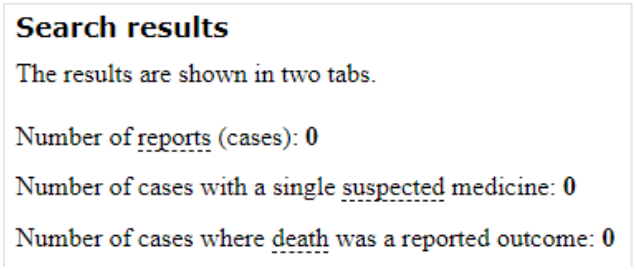
- *COMIRNATY COVID-19 vaccine*
- *COVID-19 Vaccine (TNS)*
- *COVID-19 Vaccine AstraZeneca*
- *Spikevax COVID-19 vaccine*

There should be a total of 76 medicines, but this may change depending on the year. The search process was undertaken by year starting 1971 until 2021. Below is the search result for the entire year of 1971. The search results for the other years until 2021 can be found in Appendix 1.

<u>76 medicines selected</u> between 01/01/1971 - 31/12/1971.

Selected medicines

Trade name	Active ingredients
BCG Vaccine	Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain)
Cholerae Vaccine (TNS)	Vibrio cholerae
Coryza Vaccine	Haemophilus influenzae; Klebsiella pneumoniae ssp pneumoniae; Moraxella catarrhalis; Staphylococcus species; Streptococcus pneumoniae; Streptococcus species
Diphtheria And Tetanus Vaccine CDT	dried aluminium phosphate; Tetanus toxoid; Diphtheria toxoid
Diphtheria-tetanus-pertussis Vaccine	Bordetella pertussis; Diphtheria toxoid; dried aluminium phosphate; Tetanus toxoid



Search results

The results are shown in two tabs.

Number of reports (cases): **0**

Number of cases with a single suspected medicine: **0**

Number of cases where death was a reported outcome: **0**

Sources:

- ***DAEN Search Engine:*** *https://apps.tga.gov.au/PROD/DAEN/daen-report.aspx*
- ***Appendix 1 - DAEN Bundle (System Organ Class) with Index 20.01.22****, pages 672-1382: adding the data from individual years from 1971 to 2021 totals 19,330 adverse events.*
- ***Appendix 3 – Annual Tally of Non-COVID Adverse Events and Deaths 1971-2021****, pages 1-3: this is a manual tally in reference to the individual searches per year in Appendix 1.*

ii) How many reports of death were made between 1971 and the date of your report? Please set out the process by which you have come to your view.

My Answer:

*There were **59** reported deaths from 1971 to 2021. The same search process as the number of adverse events yields results for the number of deaths in the said period. Please refer to the search results shown above.*

Sources:

- ***DAEN Search Engine:*** *https://apps.tga.gov.au/PROD/DAEN/daen-report.aspx*
- ***Appendix 1 - DAEN Bundle (System Organ Class) with Index 20.01.22****, pages 672-1382: adding the data from individual years from 1971 to 2021 totals 59 deaths.*
- ***Appendix 3 – Annual Tally of Non-COVID Adverse Events and Deaths 1971-2021****, pages 1-3: this is a manual tally in reference to the individual searches per year in Appendix 1.*

2. For the three following vaccines which have been provisionally approved by the TGA in relation to Covid-19, being;

a. Pfizer;
b. AstraZeneca; and
c. Moderna;

i) How many reports of adverse events were made between the date each vaccine was provisionally approved and the date of your report? Please set out the process by which you have come to your view.

My Answer:

Initially, I started searching by COVID vaccine type, however, I soon realized that searching by individual COVID vaccine type from date of provisional approval, to the end of 2021, and adding them up did not give the same result as the search if all were done together and I used the blanket dates 1 Jan 2021 to 31 Dec 2021. I determined to go with the 4 vaccine types and the blanket dates as our master data (as per intro to report). The number of adverse events in total for the 4 vaccines from 1 Jan 2021 to 31 Dec 2021 was 100,180 cases, no of cases with a single suspected medicine were 98,399 and no of deaths were 733. (You can see that the information from each vaccine type is incomplete. It is also inconsistent with the 4-vaccine approach). See search results below:

4 medicines selected between 01/01/2021 - 31/12/2021.

Search results

The results are shown in two tabs.

Number of reports (cases): **100180**

Number of cases with a single suspected medicine: **98399**

Number of cases where death was a reported outcome: **733**

Source: Appendix 2.1 - DAEN Results for COVID Vaccine (Including Unspecified Type)

- *COMIRNATY COVID-19 vaccine (Pfizer): **52,934** reports of adverse events*

1 medicine selected between 25/01/2021 - 06/01/2022.

Selected medicines

Trade name	Active ingredients
COMIRNATY COVID-19 vaccine	tozinameran

Search results

The results are shown in two tabs.

Number of reports (cases): **52934**

Number of cases with a single suspected medicine: **51869**

Number of cases where death was a reported outcome: **265**

- *COVID-19 Vaccine AstraZeneca: **43,912** reports of adverse events*

1 medicine selected between 16/02/2021 - 06/01/2022.

Selected medicines

Trade name	Active ingredients
COVID-19 Vaccine AstraZeneca	ChAdOx1-S (Viral vector)

Search results

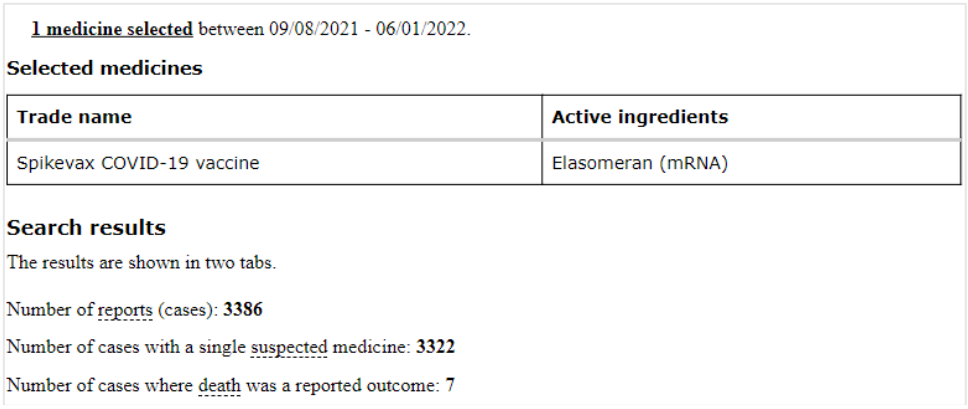
The results are shown in two tabs.

Number of reports (cases): **43912**

Number of cases with a single suspected medicine: **43134**

Number of cases where death was a reported outcome: **439**

- *Spikevax COVID-19 vaccine (Moderna): **3,386** reports of adverse events*



1 medicine selected between 09/08/2021 - 06/01/2022.

Selected medicines

Trade name	Active ingredients
Spikevax COVID-19 vaccine	Elasomeran (mRNA)

Search results

The results are shown in two tabs.

Number of reports (cases): **3386**

Number of cases with a single suspected medicine: **3322**

Number of cases where death was a reported outcome: 7

Sources:

- ***DAEN Search Engine:*** *https://apps.tga.gov.au/PROD/DAEN/daen-report.aspx*
- ***Appendix 1 - DAEN Bundle (System Organ Class) with Index 20.01.22***

On the DAEN search engine, select the vaccine on the "medicine" field. Adjust the date range accordingly. Here, I am using the 31st of December 2021 as the end date and the start date is the date of provisional approval for the Covid-19 vaccine in question.

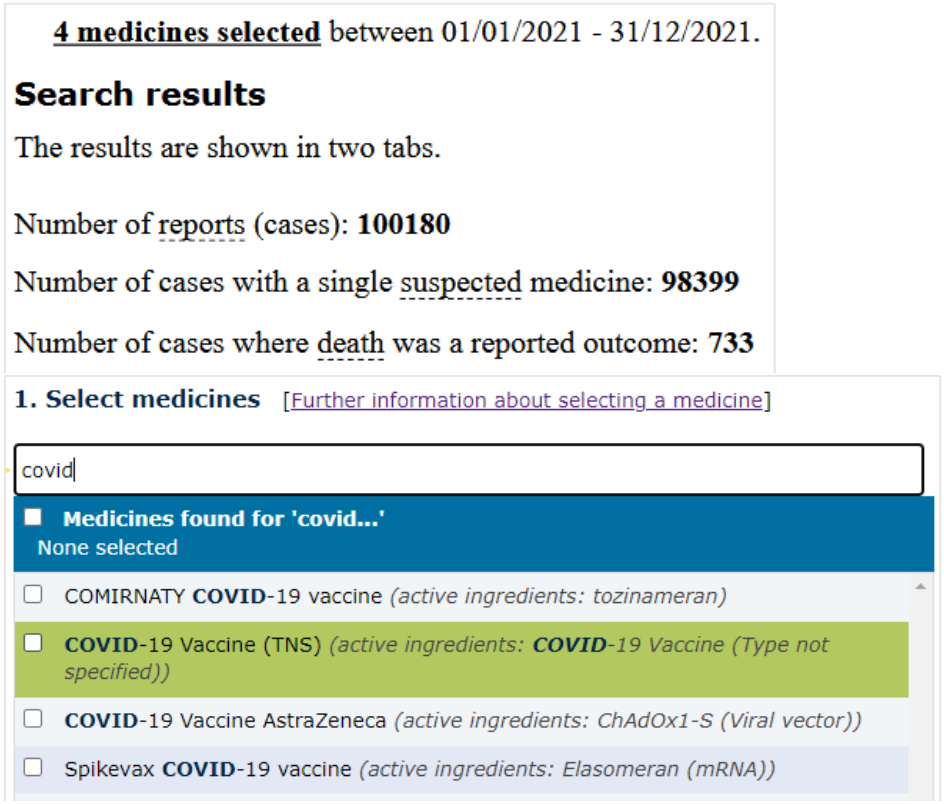
ii) How many reports of death were made between the date each vaccine was provisionally approved and the date of your report? Please set out the process by which you have come to your view.

My Answer:

- *COMIRNATY COVID-19 vaccine (Pfizer):* ***265*** *cases where death was a reported outcome*
- *COVID-19 Vaccine AstraZeneca:* ***439*** *cases where death was a reported outcome*
- *Spikevax COVID-19 vaccine (Moderna):* ***7*** *cases where death was a reported outcome*

The data was taken from Appendix 1 and totals ***711*** *cases where death was a reported outcome. Note that this is for the three (3) aforementioned vaccines only.*

However, as per the DAEN search engine, there is a fourth type of COVID vaccine, medicine name: ***COVID-19 Vaccine (TNS)****.This stands for Type Not Specified. I included this upon pulling out information and found a total of* ***733*** *cases where death was a reported outcome, as opposed to the total of 711 which is the sum of only three (3) COVID vaccines. Actually, I also ran the unspecified vaccine by itself and I found that when I added that to the above individual vaccines I reported 735 deaths, and not 733. I have elected to use the 733 as our master data.*



Source: Appendix 2.1 - DAEN results for COVID Vaccine (including Unspecified type)

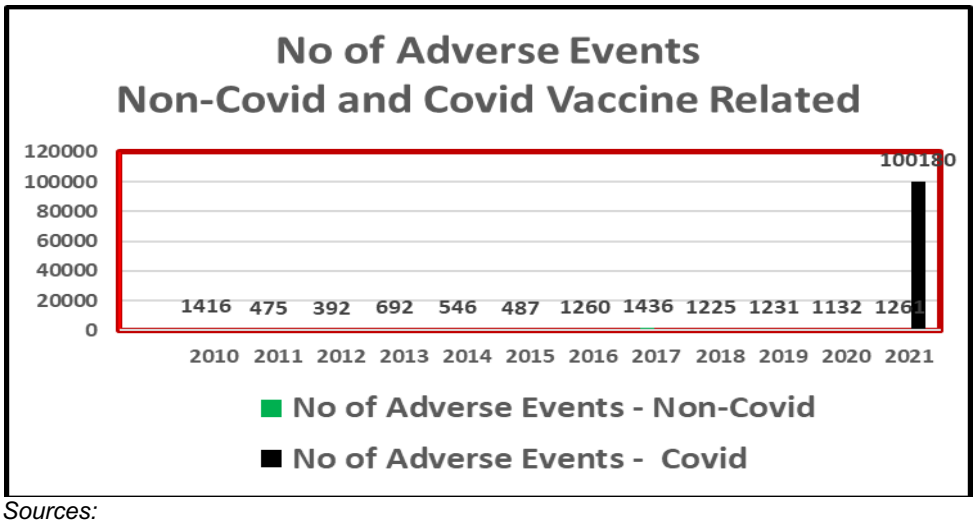
The same search process as the number of adverse events yields results for the deaths related to COVID-19 vaccines. Please refer to the search results shown above.

Note – Pfizer was provisionally approved on 25 January 2021; AstraZeneca was provisionally approved on 16 February 2021; Moderna was provisionally approved on 9 August 2021.

3. Has there been a significant increase in adverse event reports when comparing all other vaccines in the DAEN to Pfizer, AstraZeneca and Moderna? Please set out the process by which you have come to your view.

My Answer:

*Yes, there has been a significant increase in adverse events. Comparing the search results on DAEN, the non-COVID vaccines are at **19,330** adverse events from 1971 until 2021 (50-year range), whereas the COVID-vaccines in the year 2021 alone already had a total of **100,180** reported adverse events. Refer to Appendix 2 - DAEN results for COVID Vaccine (including Unspecified type). Refer to search results presented in questions 1 and 2.*



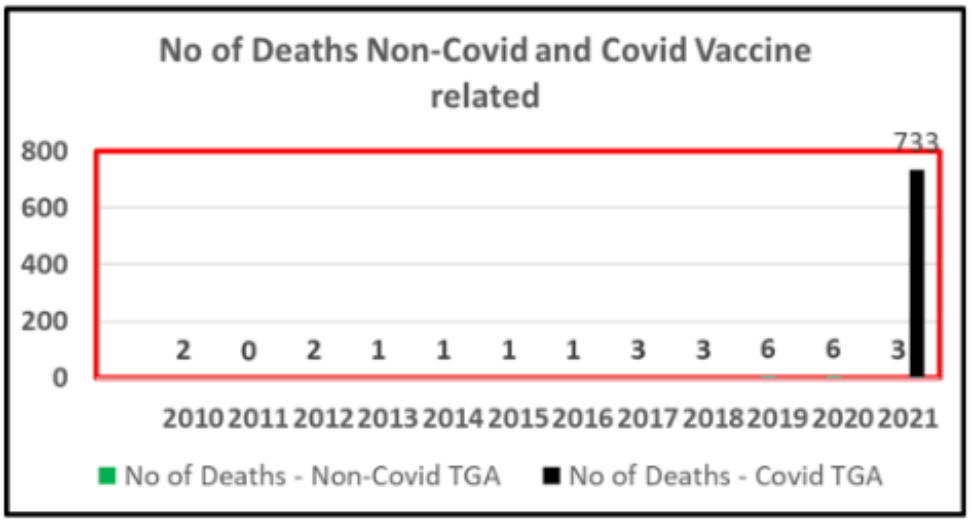
Sources:

- *Appendix 1 – DAEN Bundle (System Organ Class) with Index 20.01.22*
- *Appendix 2.1 – DAEN results for COVID Vaccine (including Unspecified type)*
- *Appendix 3 – Annual Tally of Non-COVID Adverse Events and Deaths 1971-2021*

4. Has there been a significant increase in reports of death when comparing all other vaccines in the DAEN to Pfizer, AstraZeneca and Moderna? Please set out the process by which you have come to your view.

My Answer:

*Yes, there has been a significant increase in cases where death was a reported outcome. Comparing the search results on DAEN, the non-COVID vaccines are at 59 cases where death was a reported outcome from 1971 until 2021 (50-year range), whereas the COVID-vaccines in the calendar year 2021 alone already had a total of **733** cases where death was a reported outcome. Refer to search results presented in questions 1 and 2. I present this data in the following chart from 2010:*



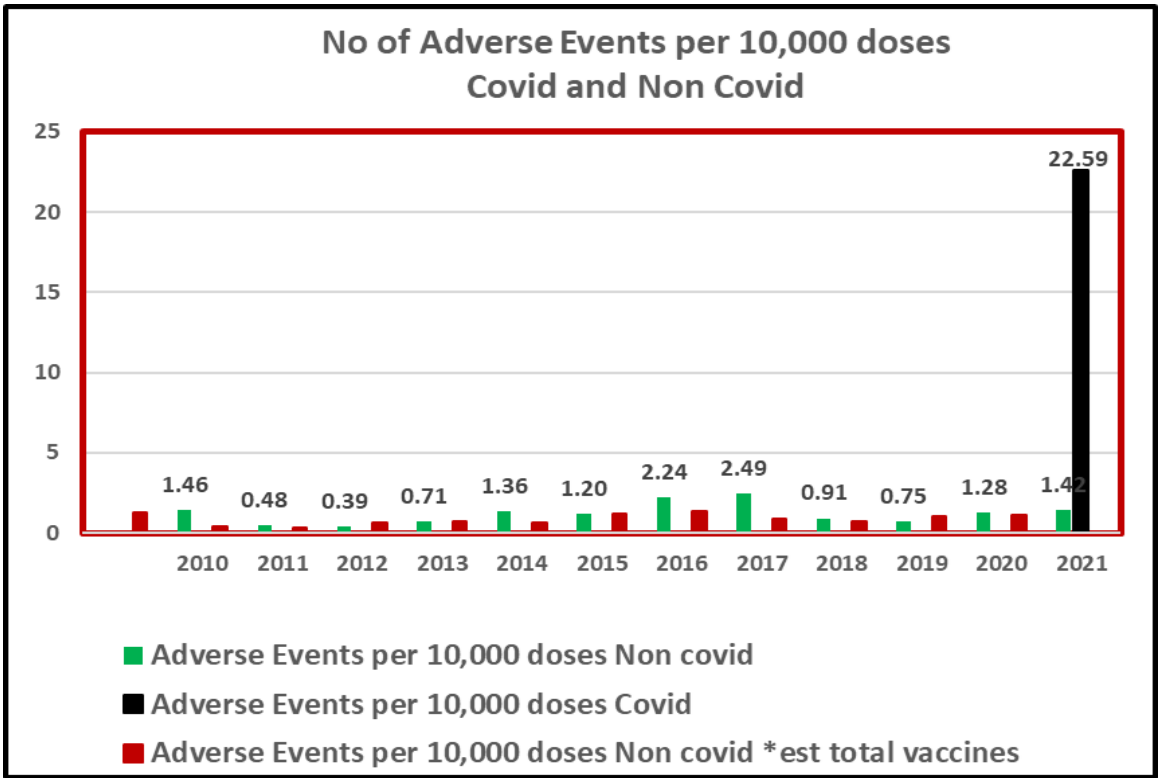
Sources:

- *Appendix 1 – DAEN Bundle (System Organ Class) with Index 20.01.22*
- *Appendix 2.1 – DAEN results for COVID Vaccine (including Unspecified type)*
- *Appendix 3 – Annual Tally of Non-COVID Adverse Events and Deaths 1971-2021*

5. How much more likely is it for an adverse event to be reported to the TGA from Pfizer, AstraZeneca and/or Moderna than it is from all other vaccines in the DAEN combined? Please set out the process by which you have come to your view.

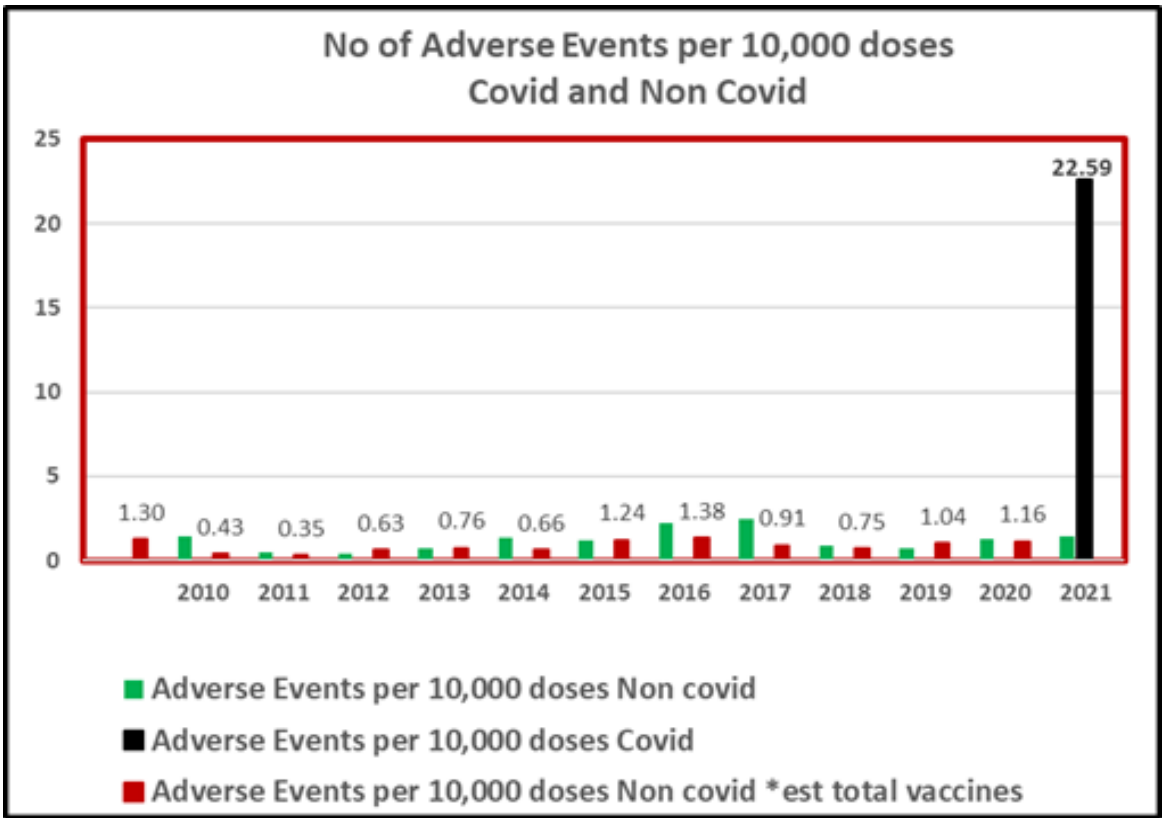
My Answer:

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:



Graph 1 – Labelled data is based on incomplete data for total non-COVID cases
Sources:

- *No. of adverse events: Appendix 3 - Annual Tally of Non-COVID Adverse Events and Deaths 1971-2021*
- *No of COVID vaccine doses: Appendix 6 – No. of COVID Doses by Vaccine*
- *No of non-COVID vaccine doses: Surveillance of Adverse Events following immunization, annual reports for 2010 to 2019*



Graph 2 – Labelled data uses an estimate for total non-COVID doses
Sources:

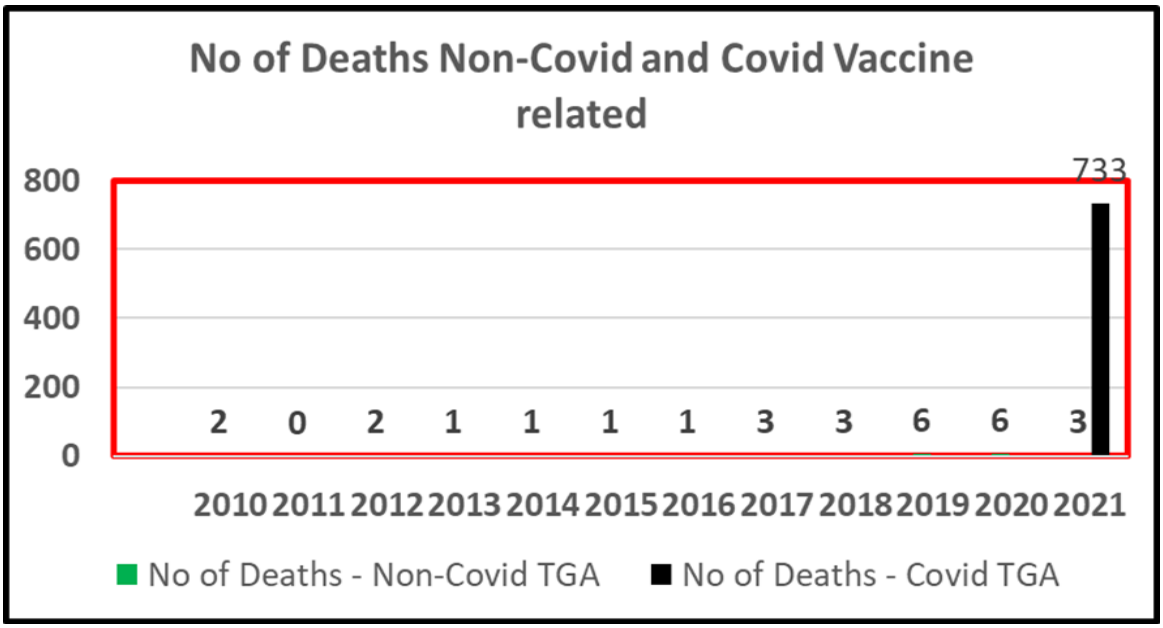
- *No. of adverse events: Appendix 3 - Annual Tally of Non-COVID Adverse Events and Deaths 1971-2021*
- *No of COVID vaccine doses: Appendix 6 – No. of COVID Doses by Vaccine*
- *No of non-COVID vaccine doses: Appendix 5 - Surveillance of Adverse Events following immunization, annual reports for 2010 to 2019*

Refer to search results presented in questions 1 and 2. Note that the non-COVID vaccine adverse events are from 1971 to 2021, while COVID vaccine adverse events are for the year 2021 only.

6. How much more likely is it for a death to be reported to the TGA from Pfizer, AstraZeneca and/or Moderna than it is from all other vaccines in the DAEN combined? Please set out the process by which you have come to your view.

My Answer:

The number of cases where death was a reported outcome to the TGA, associated with a non-COVID vaccine from 2010 to 2021 was 29, or an average of 2.4 deaths per annum vs 733 in 2021 associated with COVID vaccines. This is an increase of 30,442%. It is represented by the below chart.

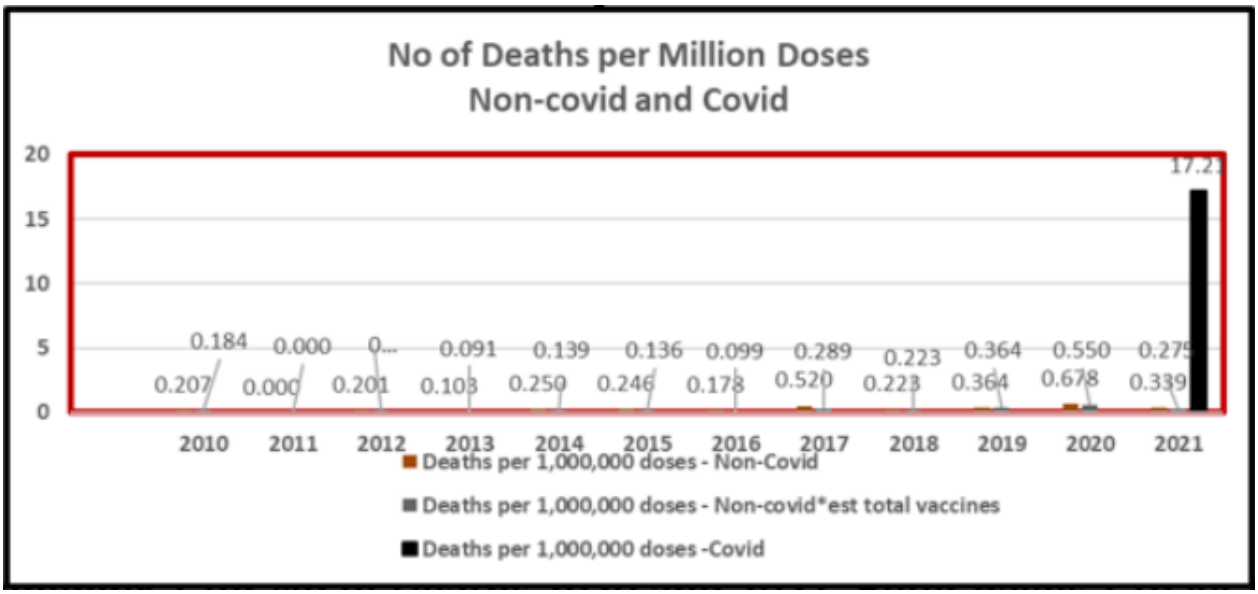


Sources:

- *No. of deaths: Appendix 3 - Annual Tally of Non-COVID Adverse Events and Deaths 1971-2021*

Given the size of the increase reported above, another source of deaths associated with vaccines has been located. The Surveillance of Adverse Events following Immunisation in Australia, Annual Reports from 2010 to 2019, report 31 deaths associated with vaccines over 10 years which is an average of 3.1 deaths per annum. (Author: The Department of Health, Australian Federal Government) It would appear that the TGA reports of death and the annual report referred to above are inconsistent in the no. of deaths that they report. (Both are, however, reporting on the deaths as a result of adverse events and claim to use the DAEN TGA website as their source of information.)

From 2010 to 2021, the likelihood of death from an adverse reaction to a vaccine was 0.22 to 0.27 per million doses (approx. 1 death every 4 million doses). As a result of COVID doses in 2021, I have had 17 deaths per million doses. As a consequence, COVID vaccines are 69 times more likely to result in death as a reported outcome than traditional vaccines. (If I use the death figures from the Surveillance of Adverse Events after immunisation in Australia, annual reports from 2010 to 2019, referred to previously, this shows around 0.463 deaths per million doses or 1 death every 2 million doses. This makes the covid vaccines 36 times more likely to result in deaths as aa reported outcome than traditional vaccines).



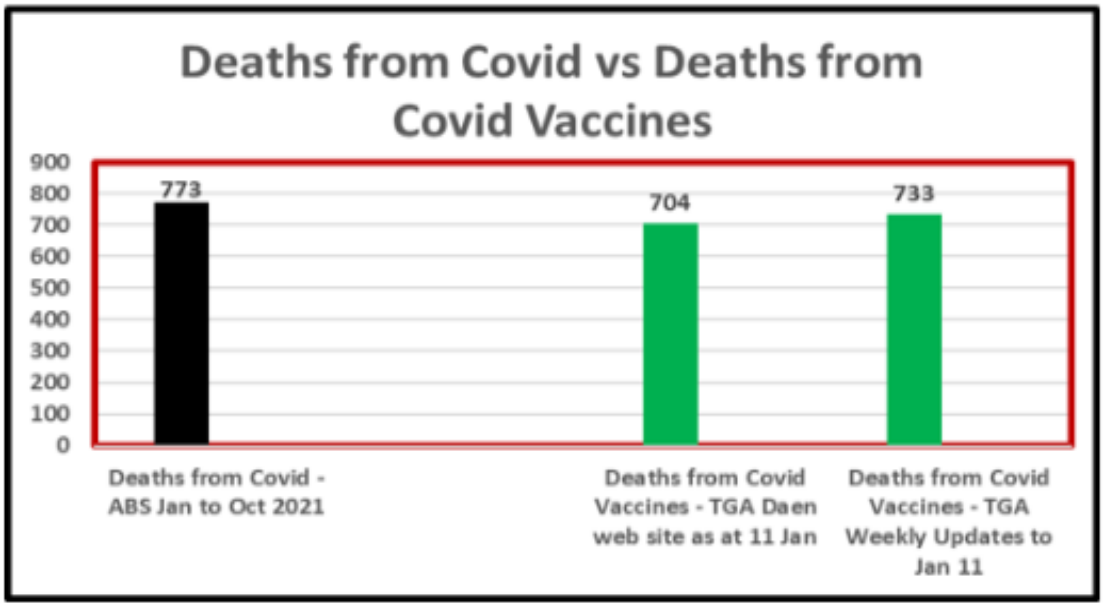
Sources:

- *No. of Deaths: Appendix 3 - Annual Tally of Non-COVID Adverse Events and Deaths 1971-2021*
- *No. of COVID vaccine doses: Appendix 6 – No. of COVID Doses by Vaccine*
- *No. of non-COVID vaccine doses: Appendix 5 – Surveillance of Adverse Events following immunization, annual reports for 2010 to 2019*

7. How do deaths reported to the TGA from Pfizer, AstraZeneca and Moderna compare to deaths recorded in association with Covid-19 itself? You may also refer to data from the Australian Bureau of Statistics to answer this question. Please set out the process by which you have come to your view.

My Answer:

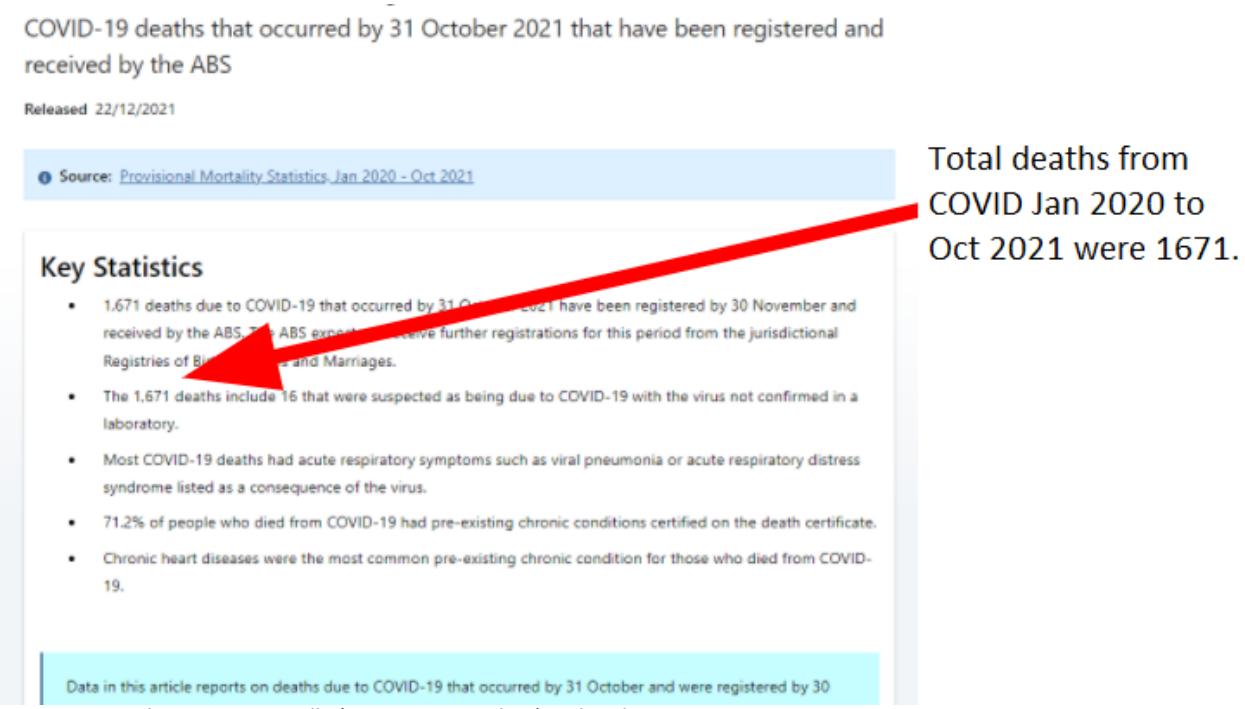
The Australian Bureau of Statistics (ABS) reports 773 deaths from COVID from January to October 2021 albeit 2 months short of the entire year. In the last 2 weeks of January 2022,when this report was being written, the number of cases where death was a reported outcome, associated with a COVID vaccine in 2021 have increased from 704 to 733. This is reported in the below chart:



Sources:

- *Appendix 1 - DAEN Bundle (System Organ Class) with Index 20.01.22. See page 1400 which indicates that 1671 people died from covid Jan 202 to 31 Oct 2021.Refer below to ABS source*
- *Appendix 2.1 - DAEN Results for COVID Vaccine (Including Unspecified Type)*

The ABS reports that the total deaths from COVID Jan 2020 to Oct 2021 were 1671. They also report that the total deaths from COVID in 2020 were 832. Therefore, the total deaths from COVID Jan 2021 to Oct 2021 were 773.



Source: Appendix 1 - DAEN Bundle (System Organ Class) with Index 20.01.22

https://www.abs.gov.au/statistics/health/causes-death/provisional-mortality-statistics/jan-dec-2020

All causes											
2020	141116	11196	10799	11789	11678	12242	11535	12538	12906	11973	11
2015-19 average	140892	10906	9975	11078	11008	12058	12258	13241	13560	12579	12
2015-19 minimum	137278	11408	10399	11467	11352	12482	12904	13971	14606	13603	12
2015-19 maximum	144104	10444	9601	10727	10766	11608	11786	[illegible]	13047	11948	11
COVID-19											
2020	832	0	0	21	63	9	2	133	445	139	15
Respiratory diseases											
2020	12022	1025	949	1107	1009	1027	987	1020	1048	1046	91
2015-19 average	14350	971	849	945	985	1177	1248	1491	1723	1583	13
Influenza and pneumonia											
2020	2131	179	183	237	232	189	186	192	186	152	12
2015-19 average	3332	189	165	178	208	249	280	358	491	466	32
Pneumonia											
2020	2089	169	175	219	228	189	185	191	186	152	12
2015-19 average	2723	177	156	166	187	222	245	296	330	294	25
Chronic lower											

Total deaths from COVID Jan 2020 to Dec 2020 were 832.

Sources:

- *Appendix 1 - DAEN Bundle (System Organ Class) with Index 20.01.22*

Measuring 'excess' deaths

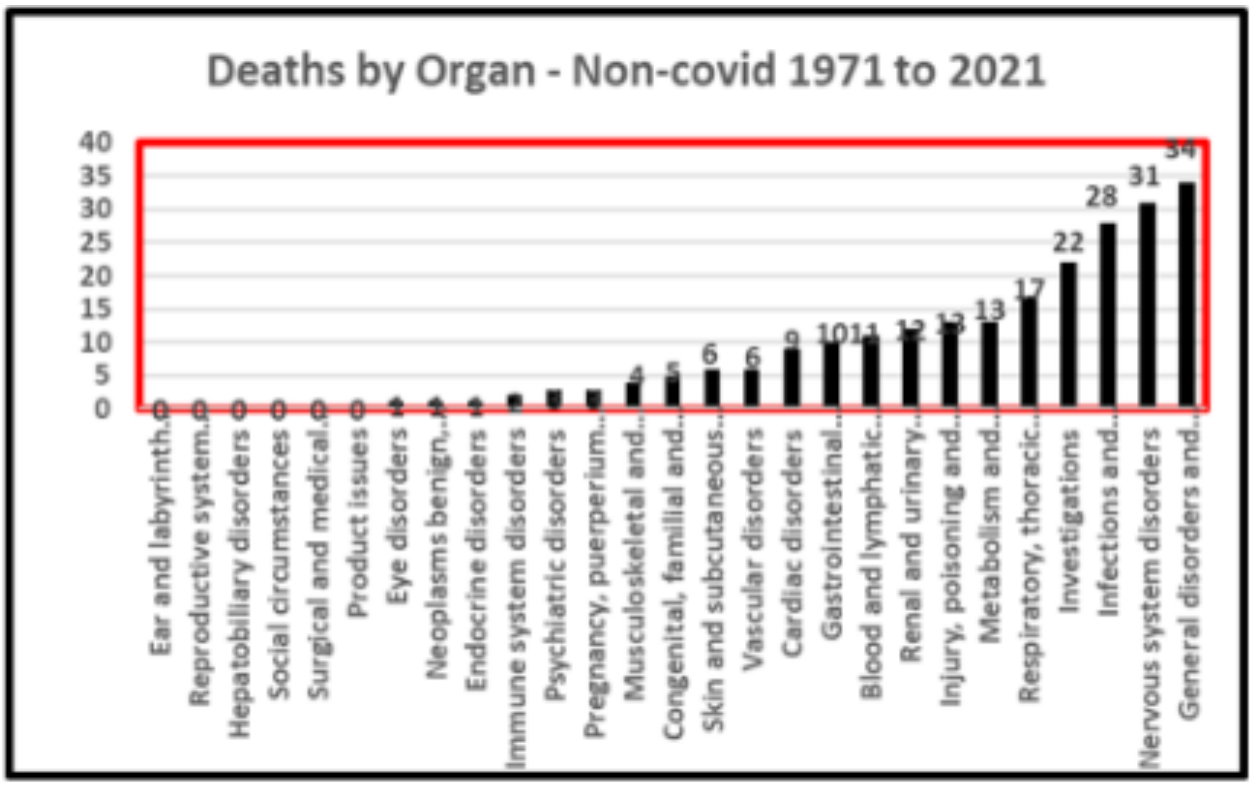
> An article on COVID-19 mortality (https://www.abs.gov.au/articles/covid-19-mortality-2) is available via the Articles link. This article (https://www.abs.gov.au/articles/covid-19-mortality-2) outlines key demographics of the 1,671 people who died due to COVID-19 up until 31 October 2021.

Source: Appendix 1, page 1400

8. What are the most significant categories, or types, of adverse events reported to the TGA for all vaccines except for Pfizer, AstraZeneca and Moderna from 1971 to the date of this report? Please set out the process by which you have come to your view.

My Answer:

The top 5 Categories of Deaths by Organ reported to the TGA from 1971 to 2021 non-COVID were General Disorders and Administrative Site Conditions, Nervous System Disorders, Infections and Infestations, Investigations (undefined by TGA), Respiratory Thoracic and Mediastinal. The top 5 represent 57% of all Deaths by Organ reports. This is represented in the chart below:



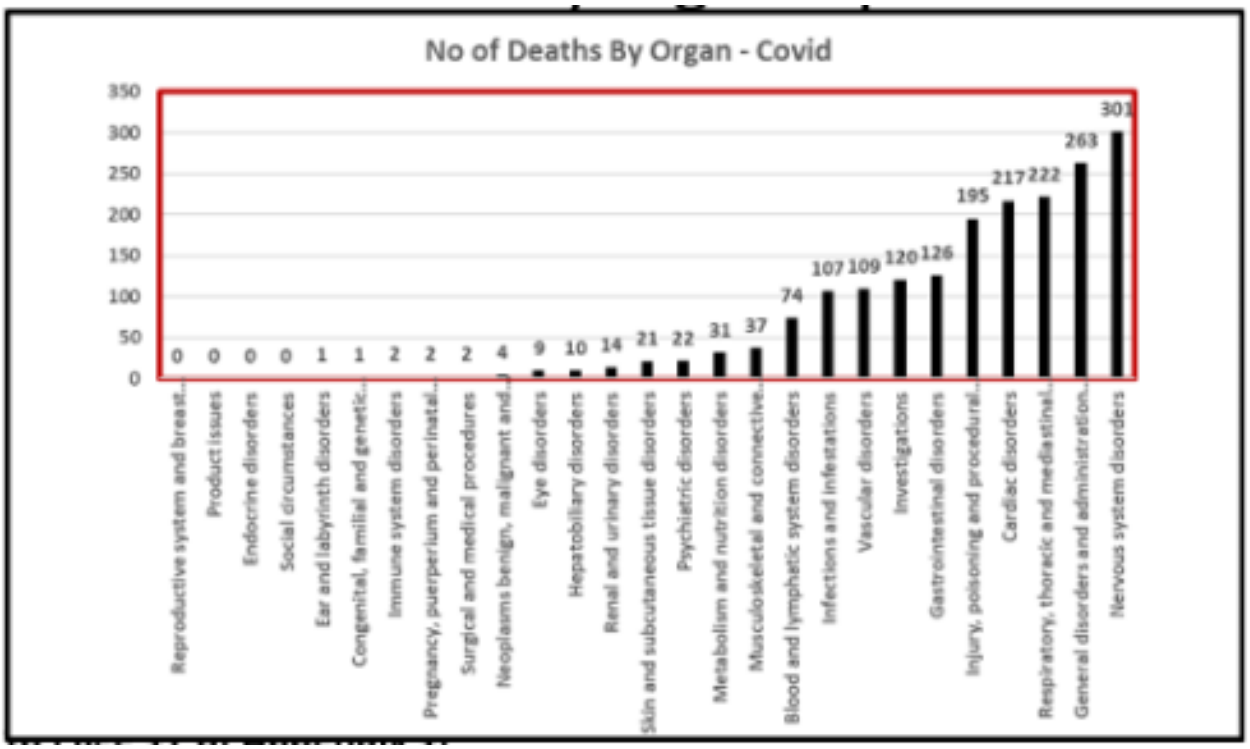
Source:

- *Appendix 4 - Instructions_TGA DAEN Download (*note: to create the above chart, I had to work out how to download the data into a format that allowed us to analyse it; the steps I took are in Appendix 4; the data was sourced from DAEN TGA website on Tue, 25th of Jan 2022)*

9. What are the most significant categories, or types, of adverse events reported to the TGA for Pfizer, AstraZeneca and Moderna? How many more categories, or types, of adverse event reports have been reported to the TGA in relation to Pfizer, AstraZeneca and Moderna than have been reported for all other vaccines combined? Please set out the process by which you have come to your view.

My Answer:

The Top 5 Categories of Deaths by Organ reported to the TGA for 2021 related to Covid vaccines were Nervous System Disorders, General Disorders and Administrative Site Conditions, Respiratory Thoracic and Mediastinal Disorders, Cardiac Disorders and Injury Poisoning and Procedural complications. These categories account for 58.8% of all Death by organ reports. This is represented in the chart below:



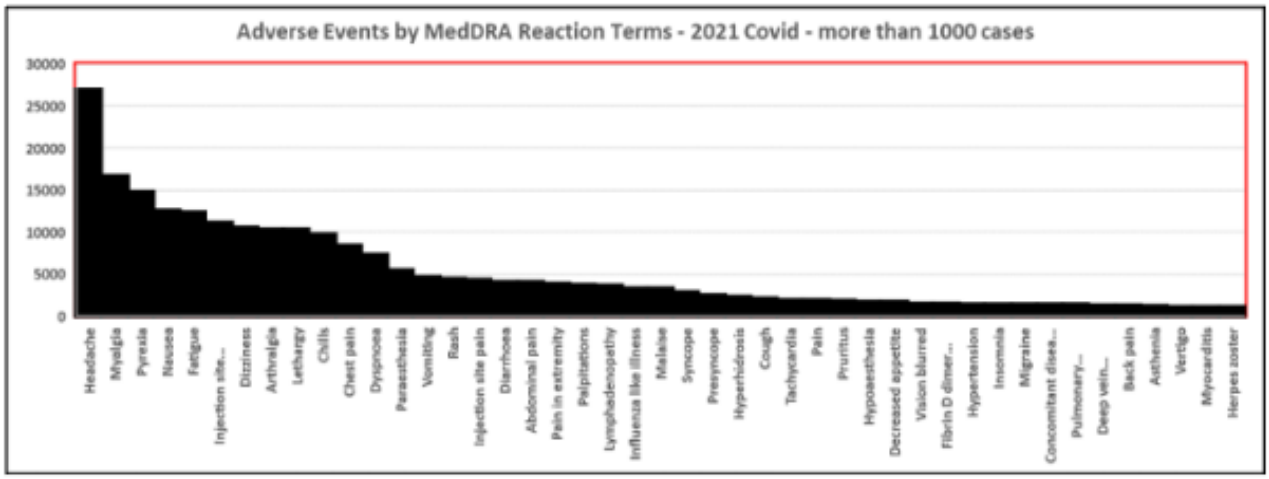
Source:

- *Appendix 4 - Instructions_TGA DAEN Download (*note: to create the above chart, I had to work out how to download the data into a format that allowed us to analyse it; the steps I took are in Appendix 4; the data was sourced from DAEN TGA website on Tue, 25th of Jan 2022)*

10. Have there been any significant increases in categories, or types, of adverse event reports to the TGA since the provisional approval of Pfizer, AstraZeneca and Moderna?

My Answer:

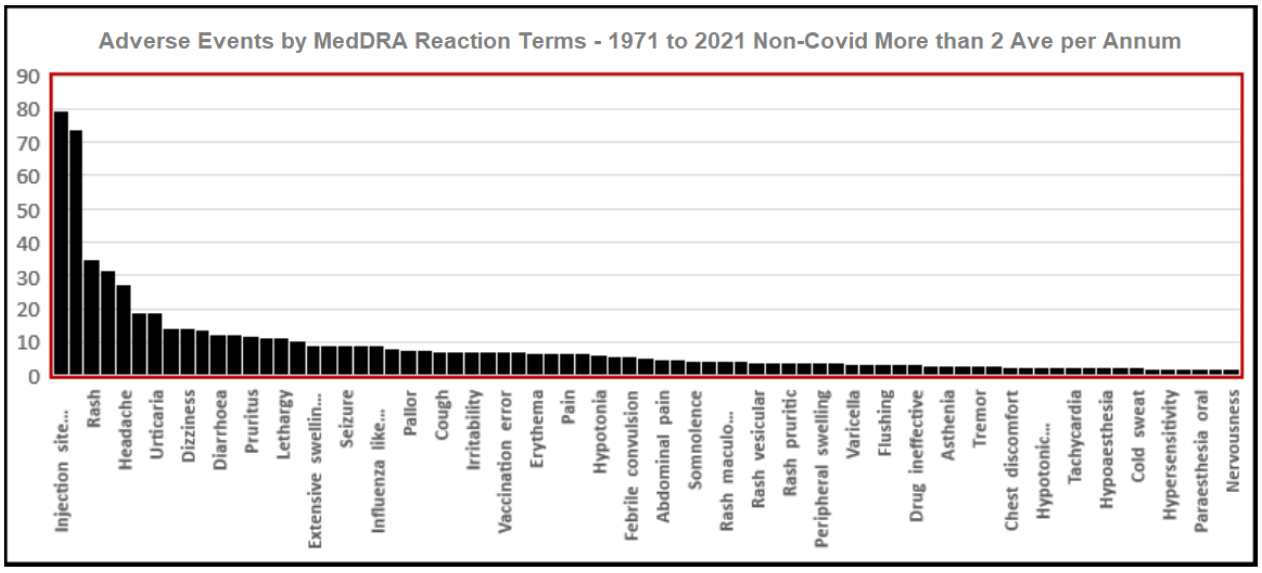
The number of adverse events reported to the TGA in 2021 is 100,180 relating to COVID vaccines. In summarizing these adverse events by disease type, one event can be reported as many diseases/conditions. I now have a list of 3,122 disease types, more than double the number of different conditions that were reported prior to COVID vaccines. See table below:



Source:

- *Appendix 4 - Instructions_TGA DAEN Download (*note: to create the above chart, I had to work out how to download the data into a format that allowed us to analyse it; the steps I took are in Appendix 4; the data was sourced from DAEN TGA website on Tue, 25th of Jan 2022)*

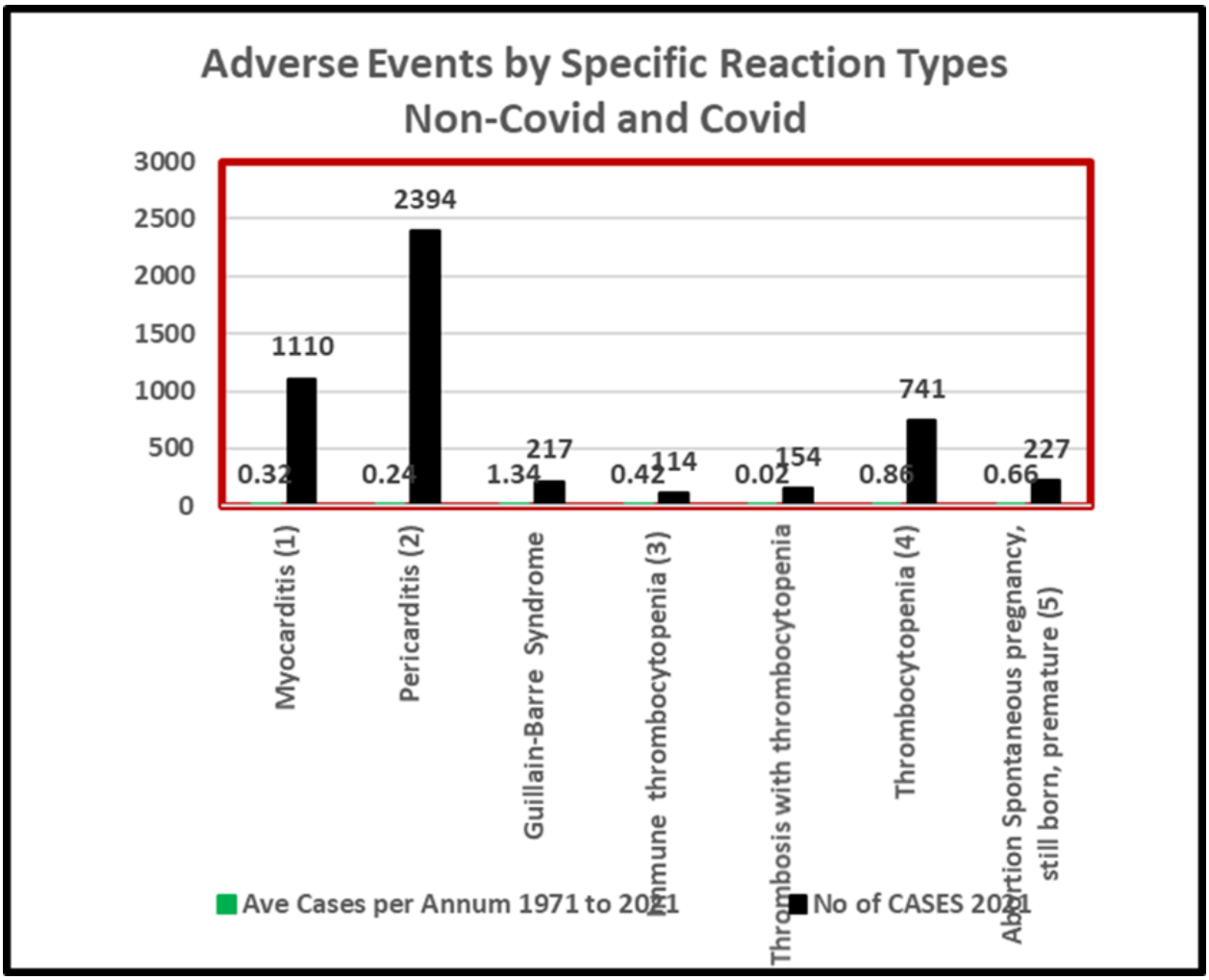
The number of non-COVID adverse events reported to the TGA from 1971 to 2021 was 19,330. In summarizing these adverse events by disease type, one event can be reported as many diseases/conditions. For the last 20 years, I have been able to incorporate all conditions in a list of 1,492 different conditions. See table below:



Source:

- *Appendix 4 - Instructions_TGA DAEN Download (*note: to create the above chart, I had to work out how to download the data into a format that allowed us to analyse it; the steps I took are in Appendix 4; the data was sourced from DAEN TGA website on Tue, 25th of Jan 2022)*

The Specific Reaction types associated with Adverse Events of Myocarditis, Pericarditis, Guillain-Barre Syndrome, Immune Thrombocytopenia, Thrombosis with Thrombocytopenia Syndrome, and Abortions and Spontaneous miscarriages have been analysed to compare their frequency for non-COVID 1971 to 2021 and Covid 2021 vaccines. All categories increased significantly.



Source:

- *Appendix 4 - Instructions_TGA DAEN Download (*note: to create the above chart, I had to work out how to download the data into a format that allowed us to analyse it; the steps I took are in Appendix 4; the data was sourced from DAEN TGA website on Tue, 25th of Jan 2022)*

ADVERSE EVENTS		NON-COVID		COVID 2021	COMPARISON
ORGAN CLASS	ADVERSE EVENT REACTIONS	No of Cases 1971 to 2021	Ave Cases per Annum 1971 to 2021	No of CASES 2021	% Increase Non-Covid to Covid
Cardiac Disorders	Myocarditis (1)	16	0.32	1110	346775%
	Pericarditis (2)	12	0.24	2394	997400%
Nervous System Disorders	Guillain-Barre Syndrome	67	1.34	217	16094%
Blood and ILmphatic System Disorders	Immune thrombocytopenia (3)	21	0.42	114	27043%
	Thrombosis with thrombocytopenia	1	0.02	154	769900%
	Thrombocytopenia (4)	43	0.86	741	86063%
Pregnancy, Puerperium and Perinatal Conditions	Abortion Spontaneous pregnancy, still born, premature (5)	33	0.66	227	34294%
	Subtotal	193	3.86	4957	128320%
	Total reactions reported	43878	878	327015	37145%
	Specific Categories as a% of total	0.44%	0.44%	1.52%	

(1) includes myocarditial infarction, acute myocardial infarction,myocardial ischaema
(2) pericarditis includes pericardial effusion
(3) Immunie thrombocytopenia includes immune thrombocytopenia purpera
(4) Thrombocytopenia includesthrombotic thrombocytopenia purpera and thrombotic cytopenia purpera
(5) Pregnancy, Puerperium and perinatal includes the entire category

Source:

- *Appendix 4 - Instructions_TGA DAEN Download (*note: to create the above chart, I had to work out how to download the data into a format that allowed us to analyse it; the steps I took are in Appendix 4; the data was sourced from DAEN TGA website on Tue, 25th of Jan 2022)*

11. Do you have any final observations on comments to make as the result of undertaking this analysis.

As a final remark, I note that in addition to generating more adverse events and generating more disease types, COVID vaccines are generating more Reaction Reports than seen before by traditional vaccines.

In fact, the TGA is seeing more Adverse Event Reaction reports in 2021, than they have seen in the entire 50 years since 1971.

(This is separate and different to Adverse Event Cases. It says that each Non-Covid 1971 to 2021 Adverse Event Case would have included on average of 2.27 MedDRA reactions per event. Covid Vaccines 2021 include an average of 3.26 reactions per event. Refer table above for examples of Major Organ classes and Adverse Event Reaction Types.)

- *No of Adverse Events Non-covid – 1971 to 2021 – 19330*
- *No of Disease Types Non-covid – 1971 to 2021 - 1492*
- *No of Adverse Event Reactions – Death by Organ Report non-covid 1971 to 2021 – 43878*
- *Adverse Reactions reported per Adverse Event 1971 to 2021 – 2.27 Reactions per Event*

- *No of Adverse Events Covid 2021 – 100,180*
- *No of Disease Types Covid 2021 - 3122*
- *No of Adverse Event Reactions – Death by Organ Report Covid 2021 – 327015*
- *Adverse Reactions reported per Adverse Event 2021 – 3.26 Reactions per Event*

Sources:

- *See DAEN website for no. of adverse events non-COVID and COVID*
- *See DAEN website for Deaths by Organ – no of disease types non-COVID and COVID*
- *See DAEN website for Deaths by Organ – total no of reports using medDRA reaction items, 43,878 non-COVID and 327,015 COVID*
- *Adverse Reactions Reported per Adverse Event = reactions divided by adverse events*

<u>SECTION 2</u>: ADVERSE EVENTS AND DEATHS REPORTED TO TGA DAENS, AUSTRALIA FOLLOWING COVID-19 VACCINES BETWEEN 1 FEBRUARY 2021 TO 8 JUNE 2022 HIGHLIGHTING DEATHS AND ADVERSE EVENTS IN CHILDREN 5-11 YRS OLD. Section 6 onwards.

6.0 ITEM 1

Since 10 January 2022, how many Deaths are reported in DAENs in 5-11 year olds following Covid-19 Vaccines?

6.1 Since 10 January 2022, 135 deaths following Covid-19 Vaccines are recorded on the DAENs database for all ages.

6.2 Since 10 January 2022, 5 Deaths were reported in children 5-11 in DAENs since the roll-out of Covid-19 Vaccines began for this age group.

6.3 Details of these Deaths are set out in Table 1 below. Five screenshots are included in Schedule B to this report. These screenshots are from the DAENs website for each death reported in the 5-11 age cohort since the roll out of the Pfizer Vaccine began. Each screenshot (on the left hand side) confirms "death as a reported outcome" from "a single medicine", namely a Covid-19 Vaccine.

Date	Case Number	Gender	Age	Adverse Event	Result
11 March 2021	719838	M	7	Cardiac Arrest Generalised tonic-clonic seizure	Death as reported Outcome
25 March 2021	724023	F	9	Cardiac Arrest	Death as reported Outcome
28 March 2021	724925	M	6	Adverse Event Following Immunisation	Death as reported Outcome
6 May 2021	733723	M	10	Adverse Event Following Immunisation	Death as reported Outcome
10 May 2021	734187	M	5	Abdominal Pain Cardiac arrest	Death as reported Outcome

Table 1: Summary of deaths reported to DAENs following Covid-19 Vaccine in 5-11 year olds since the roll out to this age group began on 10 January 2022

6.5 The DAENs website also routinely reports Deaths where no age is specified. At the time of producing this report, 90 of the 135 Deaths sampled (14 or 15.6%) had no age specified. It is possible that some of these Deaths where the age is not specified may also fall within the age cohort 5-11 years. I have included a further discussion of these Deaths in my response to Item 3 (below).

7.0 ITEM 2
Since 10 January 2022, how many Adverse Events were reported in the DAENs associated with 5-11 year olds following Covid-19 Vaccines?

7.1 Since 10 January 2022, 27,742 Adverse Events were reported following Covid-19 Vaccines in all ages. This number includes the 135 Death reports reported in Item 1 (6.1) above (in all ages).

7.2 In 5-11 year olds, 1,390 Adverse Events have been reported by DAENs following Covid-19 Vaccines.

7.3 Table 2 below shows breakdown of Adverse Events from 10 January 2022 to 8 June 2022 by Covid-19 Vaccine type for 5-11 year olds (and includes Deaths). The Pfizer and Spikevax (Maderna) Vaccine are the only provisionally approved Covid-19 Vaccines for the 5-11 and 6-11 year old group, respectively. I am not able to explain why there are 5-11 year olds that received Covid-19 Vaccines not provisionally approved for their age.

Vaccine Type	Number of Reports (Cases) Adverse Events	Number of cases with a single suspected medicine	Number of cases where Death was a reported outcome
Pfizer Comirnaty	1371	N/A	5
Astra Zeneca	3	N/A	0
Covid-19 TNS	6	N/A	0
Spikevax	10	N/A	0
Nuvaxovid	-		0
Total	**1390**	**N/A**	**5**

Table 2: number reports of Adverse Events in 5-11 year olds following Covid-19 Vaccines since 10 January 2022

7.4 DAENs also records 28 Adverse Events in 5-11 year olds prior to 10 January 2022, when the Covid-19 Vaccines were rolled out to this age group. I have included details about these 28 reports in Schedule C to this report. These reports begin at 29 September 2021. I cannot explain why children received the Covid-19 Vaccines before they were provisionally approved and rolled out to this age group. Nor can I explain why they received Covid-19 Vaccines not provisionally approved for this age group.

7.5 Note, since 10 January 2022 there are 5,221 Adverse Events in DAENs where no age range is specified. Absent that detail from the DAENs database, it is not possible for me to say whether there are more Adverse Events in the 5-11 year old age cohort. I have dealt with this further under Item 4 below.
Source: DAENs 10 January 2022 to 8 June 2022 https://1drv.ms/x/s!Al71AGIGLVVzgk90LkH0sKUeqH9b?e=0Y6AZ0

7.6 These 1,390 Adverse Events resulted in 3,635 reactions all classified as per the MedDRA reaction types. At Schedule D to this report, I have listed out the types of Adverse Events being reported by DAENs by frequency from highest to lowest.

7.7 Table 3 below shows the top 10 Adverse Events reaction types being reported in 5-11 year olds following Covid-19 Vaccines. These top 10 Adverse Events represent 1,327 reactions or 37% (1,327/3,635) of Total Adverse Event reactions being reported in children aged 5-11 years of age.

MedDRA reaction	Number of Adverse Events Reactions	Potentially Serious	% of Total
Chest pain	211		5.80%
Vomiting	163		4.48%
Pyrexia	159	x	4.37%
Headache	131		3.60%
Abdominal pain	127		3.49%
Dyspnoea	118		3.25%
Vaccination error	111		3.05%
Nausea	110		3.03%
Lethargy	99		2.72%

Table 3: Top 10 Adverse Events Reaction types reported in children 5-11 years since 10 January 2022

7.8 Table 4 below shows the number of Adverse Events reactions by the organ affected. The top 10 organs affected (down to cardiac disorders) represent 89% of all reactions reported by DAENs in 5-11 year olds following Covid-19 Vaccine.

Organ Class	Number of Reactions	% of Total
General disorders and administration site conditions	750	21%
Nervous system disorders	544	15%
Gastrointestinal disorders	534	15%
Skin and subcutaneous tissue disorders	336	9%
Respiratory, thoracic and mediastinal disorders	287	8%
Injury, poisoning and procedural complications	221	6%
Musculoskeletal and connective tissue disorders	163	4%
Investigations	137	4%
Infections and infestations	131	4%
Cardiac disorders	127	3%
Vascular disorders	107	3%
Blood and lymphatic system disorders	63	2%
Eye disorders	52	1%

Organ Class	Number of Reactions	% of Total
Psychiatric disorders	43	1%
Metabolism and nutrition disorders	37	1%
Other (Non-aligned)	33	1%
Immune system disorders	20	1%
Renal and urinary disorders	19	1%
Reproductive system and breast disorders	17	0%
Ear and labyrinth disorders	8	0%
Endocrine disorders	3	0%
Hepatobiliary disorders	2	0%
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	0%
Total	**3635**	100%

Table 4: Top 10 Adverse Events Reaction Types reported in children 5-11 years since 10 January 2022

7.9 Following is Table 5, that lists Potentially Serious Adverse Events in children 5-11 years. The DAENs Adverse Event Database does not advise which events are serious. The TGA does report on serious adverse events in their weekly reports. The specific adverse events which are considered serious are not specifically identified. As such, in absence of information from the TGA, I have assessed and interpret the following reaction types to be potentially serious. This is my assessment as this detail is not information provided in DAENs or by the TGA.

MedDRA reaction	Number of Adverse Events	Potentially Serious	% of Total Adverse Event Reactions
Pyrexia	159	x	4.37%
Syncope	98	x	2.70%
Tachycardia	27	x	0.74%
Pericarditis	23	x	0.63%
Seizure	21	x	0.58%
Expired product administered	17	x	0.47%
Product administered to patient of inappropriate age	16	x	0.44%
Appendicitis	12	x	0.33%
Myocarditis	9	x	0.25%
Adverse event following immunisation	7	x	0.19%
Hypotension	6	x	0.17%
Kawasaki's disease	6	x	0.17%
Loss of consciousness	6	x	0.17%

MedDRA reaction	Number of Adverse Events	Potentially Serious	% of Total Adverse Event Reactions
Pneumonia	4	x	0.11%
Urinary incontinence	4	x	0.11%
Cardiac arrest	3	x	0.08%
Myocarditis/pericarditis	3	x	0.08%
Carditis	2	x	0.06%
Product administered at inappropriate site	2	x	0.06%
Vaginal haemorrhage	2	x	0.06%
Demyelination	1	x	0.03%
Myocardial infarction	1	x	0.03%
Pleurisy	1	x	0.03%
Total Potentially Serious Adverse Events	**430**	**x**	**11.8%**
Total Adverse Event Reactions	**3635**		**100%**

Table 5: Potentially serious adverse events.

8.0 ITEM 3
Since 1 February 2021, how many Deaths were reported in the DAENs in adolescents and adults following Covid-19 Vaccines?

8.1 Since 1 February 2021, 884 Deaths have been reported in the DAENs database following Covid- 19 Vaccines (all ages).

8.2 After removal of the Deaths in 5-11 year olds, that leaves 879 Deaths reported in DAENs.

8.3 As mentioned, in Item 1 above, there are a number of reports of Death in DAENs where no age is specified. I have reviewed in excess of 90% of these deaths and 147 of them had no age detailed against them. That is 17.6% of the Deaths did not have an age specified, so I have extrapolated that to be 156 Deaths out of the total 884 Deaths (all ages) where no age is specified.
Source: Death Sample link https://1drv.ms/x/s!Al71AGlGLVVzgkwl1C85ztAq5BTW?e=nz49ZT

8.4 Therefore, from the DAENs data, there are 723 deaths that have been reported in adolescents and adults following Covid-19 Vaccines (after removal of the unspecified age Deaths and Deaths in 5-11 year olds).

8.5 Table 6 below sets out the Deaths reported on the DAENs website following Covid-19 Vaccines per age cohort is set out as follows:

	Deaths 1 February 2021 to 8 June 2022
Infant deaths (one foetal death) not counted	0
Deaths in 5-11 years	5
Deaths in adolescents and adults	723
Unspecified Age Deaths	156
Total Deaths	884

Table 6: Adolescent and adult deaths from 1 February 2021 to 8 June 2022

9.0 ITEM 4
Since 1 February 2021, how many adverse events were reported in DAENs associated with adolescents and adults following Covid-19 Vaccines?

9.1 Since 1 February 2021, there were 131,991 Adverse Events reported in DAENs following Covid-19 Vaccines (all ages), as per the "Number of reports (cases)" in the screenshot from the DAENs website below:

Screenshot 1: Adverse Events reported in DAENs following Covid-19 Vaccines (all ages)

9.2 Of those Adverse Events reported, the DAENs database states 129,244 are "with a single medicine". That is the Adverse Event was following a single medication, ie Covid-19 Vaccine. I do not use this number for my analysis.

9.3 Separately, I have reviewed the Adverse Events by Covid-19 Vaccine and have set these figures out in Table 7 below.

Vaccine Type	Adverse Events	Suspected Single Medication	Deaths as a Reported Outcome
Pfizer Comirnaty	76,938	75,110	370
Astra Zeneca	47,567	46,553	464
Nuvaxovid	753	721	1
Spikevax	6,506	6,283	25
Type Not Specified	620	577	25
Total	**132,384***	**129,244**	**885***

Table 7: Total of Adverse Events reported by Covid-19 Vaccine type since 1 February 2021 – see screenshot in Schedule E

9.4 The number of Adverse Event "report (cases)" on the DAENs website is 131,991 (screenshot 1 above). This number is different to the number of Adverse Events I tallied up by each Covid-19 Vaccine type by 393 events. From the data, I am not able to explain this difference.

9.5 The number of Deaths I tallied up by Covid-19 Vaccine type is 885 and is also different to the number of Deaths reported on the DAENs website (884) (screenshot 1 above). From the data, I am not able to explain this difference.

9.6 Of the 132,384 Adverse Events reported since 1 February 2021 in DAENs, there were 22,007 Adverse Events that were unspecified in terms of age. I have set these out in Table 8.

Vaccine Type	Unspecified Adverse Events 1 February 2021 to 9 January 2022	Unspecified Adverse Events 10 January 2022 to 8 June 2022	Total Unspecified Adverse Events 1 February 2021 to 8 June 2022
Pfizer Comirnaty	9,345	4,082	13,427
Astra Zeneca	6,923	616	7,539
Nuvaxovid (Nuvavax)	0	65	65
Spikevax (Moderna)	341	409	750
Covid-19 TNS	177	49	226
Total	16,786	5,221	22,007

Table 8: Unspecified Adverse Events from 1 February 2021 to 8 June 2022

9.7 As explained under Item 3 above, unspecified means that the age range was left blank or noted with hyphens. These Adverse Events therefore could cover any age.

9.8 Links to the original source data set to derive unspecified Adverse Events follows. This data set also provided adverse events in infants 0-4 and children 5-11.
Source: DAENs1 February 2021 to 9 January 2022 https://1drv.ms/x/s!Al71AGIGLVVzglBTiDtJYJ_v-JqM?e=Zgz2bD
*Source: DAENs 10 January 2022 to 8 June 2022*https://1drv.ms/x/s!Al71AGIGLVVzgk90LkH0sKUeqH9b?e=0Y6AZ0

9.9 Table 9 below shows the calculation for the Number of Adverse Events for adolescents and adults from 1 February 2021 to 8 June 2022.

Vaccine Type	Number of Reports (Cases) Adverse Events All Ages 1 February 2021 to 8 June 2022	Number of Reports(Cases) Adverse Events Unspecified ages 1 February 2021 to 8 June 2022	Number of Reports (Cases) Adverse Events 5-11 Years 10 January 2022 to 8 June 2022	Number of Reports (Cases) Adverse Events 0-4 years 10 January 2022 to 8 June 2022	Number of Reports (Cases) Adverse Events Adolescents and Adults 1 February 2021 to 8 June 2022
Pfizer Comirnaty	76,938	13,427	1371	22	62,118
Astra Zeneca	47,567	7,539	3	1	40,024
Nuvaxovid (Nuvavax)	753	65	0	0	688
Spikevax	6,506	750	6	1	5749
Type Not Specified	620	226	10	0	384
Total (by ind Covid vaccine type)	**132,384**	**22,007**	**1390**	**24**	**108,963**
Total (all Covid vaccines)	**131,991**	**22,007**	**1390**	**24**	**108,570**

Table 9: Number of adverse events in adolescents and adults by Covid-19 Vaccine type since 1 February 2021

9.10 There are somewhere between 108,570 and 108,963 Adverse Events from 1 February 2021 to 8 June 2022 which have been reported by the TGA as relating to adolescents and adults following Covid-19 Vaccine. This includes the 28 Adverse Events in 5-11 year olds which occurred prior to 10 January 2022 (as detailed in Schedule C to this report). Removing the Adverse Events in 5-11 year olds prior to roll out of Covid-19 Vaccines to this age group, leaves 108,542 and 108,935 Adverse Events in adolescents and adults.

9.11 There are no COVID-19 Vaccines that have been provisionally approved or otherwise for children <5, therefore I am unable to explain why there are a number of Adverse Events reported in 0-4 year olds.

10.0 ITEM 5

Where the TGA safety report numbers differ from DAENs, I have also been asked to comment on the reporting in the TGA safety reports for Adverse Events following Covid-19 Vaccines with respect children 5-11 and all ages.

10.1 In my previous reports, I have compared reporting of Adverse Events in NON-covid Vaccines to Covid-19 Vaccines. On 31 January 2022, the likelihood of someone having an Adverse Event as the result of a NON-Covid Vaccine (between 2010-2020) was 1 in every 10,000 doses. With Covid-19 Vaccines the likelihood of someone having an Adverse Events as the result of the vaccine was 23 Adverse Events per 10,000 doses as at 31 January 2022. This is highlighted in Table 10 below.

10.2 Using the TGA's more up to date data, the likelihood now of someone having an adverse event as the result of a Covid-19 vaccine as at 5 June 2022 is 21.87 Adverse Events per 10,000 doses. This is 20 times worse than Non-covid times and is reasonably consistent with the Adverse Events I was reporting on at the end of January 2022.

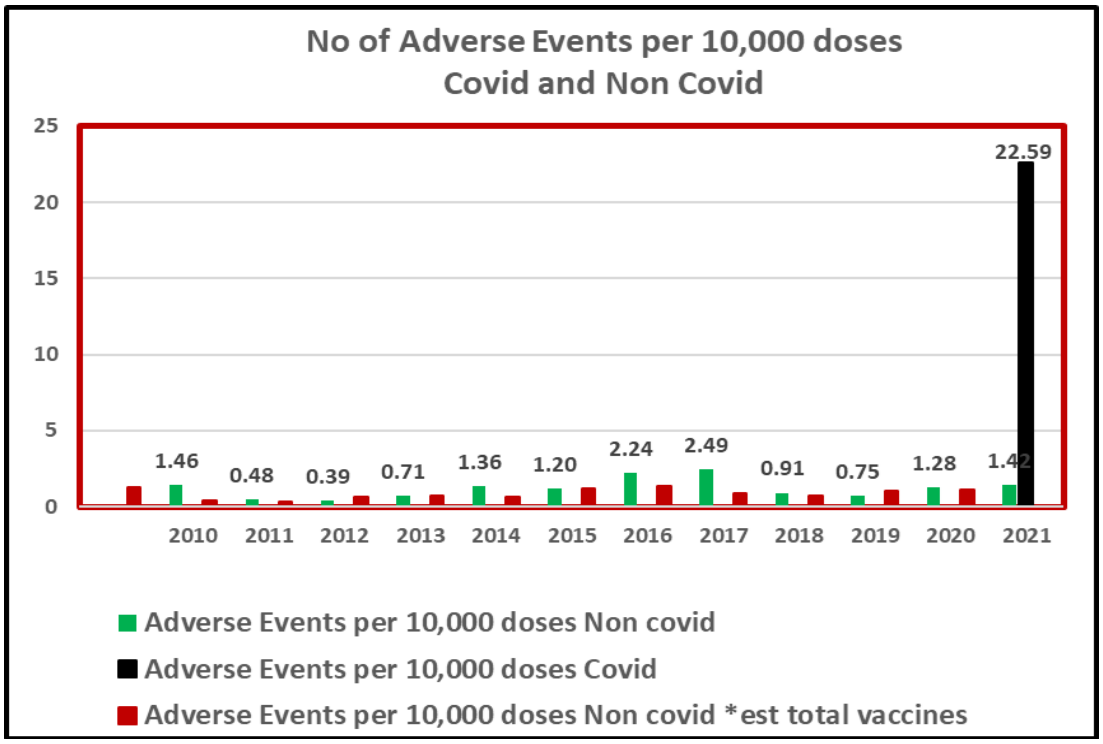


Table 10: – number of Adverse Events reported per 10,000 doses between Non-Covid (2010-2020) and Covid-19 (2021) Vaccines

Prepared by:

Lisa Mitchell B.Sc, M.App.Stats, MBA, FAICD
Corporate Transformation Services Pty Ltd

END OF REPORT

Schedule A includes CV.

"A"

Lisa Mitchell B.Sc, M.App.Stats, M.B.A, F.A.I.C.D
Director, Corporate Transformation Services Pty Ltd

Resume

Home: 02-9460-4417
Address: 3 Wilona Ave, Lavender Bay, NSW 2060
Mobile: 0408028326
Disc profile: Director
E-mail: Lisam000@tpg.com.au
Myers Briggs: INTJ

Personal Profile

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

I have deep experience and knowledge of strategic problem solving and frameworks, delivering large scale projects and am a qualified and licensed change and transformation leader, statistician, facilitator and management practitioner.

I have extensive commercial expertise & operate across the end to end value chain of the organisation.
I lead large scale high value creation, high corporate priority initiatives to generate long term sustainable results using advanced tools and optimisation techniques in complex organisations through holistic leveraging of people, process, technology and capital. The value that I bring to corporations is in increased revenue through improved customer service levels, reduced costs driving improved ROI through improved purchasing, and operational performance, improved cash flow, through reduced lead times and improved product velocity through supply chain. All of this on a sound base of optimised operational performance linked to the corporations' goals and objectives using sound change management models and practices.

I have 12 years solid blue-chip corporate experience working at the highest levels in E.I. Du Pont de Nemours Pty Ltd and Coca Cola Amatil as well as 10 years consulting with firms such as Partners in Performance, Maxx implementation and Momentum Partners as well as directly to clients.

My work has been in the areas of sustainable and timely value creation through strategy, business planning, business portfolio optimisation, capital value maximisation, business and supply chain management, planning and optimisation, procurement and strategic sourcing and all aspects of achieving and sustaining operational excellence.

I am an executive, advisor, consultant, and contractor, seeking roles which will allow me to use my broad and deep expertise for the long term benefit for a selection of specially selected businesses.

Career Highlights so far…..

E. I. Du Pont de Nemours Pty Ltd: With Chad Holliday, the CEO and Chairman of the entire Du Pont co and the 34 Strategic Business Unit leaders of Du Pont globally, I developed the Asia Pacific Strategic planning process and then the Strategic plan for Du Pont in Asia Pacific. I have in depth detailed knowledge of every one of Du Pont's strategic portfolios. I also developed the Global Strategic Business unit pre-profit objective process, which was required to align the global business unit profit objectives with the board expectations which delivered billions in revenue to the global Du Pont business. Developed Du Pont global supply chain approach in Printing and Publishing and Medical x-ray film businesses in preparation for their eventual sale.

CCA: With Mark Clark director of CCA, and reporting to the board, responsible for the optimisation of the entire end to end value chain including development of planning systems and processes such as D&OP across Asia Pacific which delivered coke to within an arms' reach of desire at the desired cost adding many hundreds of millions in value across AP.

BlueScope Steel: With Len Blackmore VP of Procurement, established and ran the PMO within BlueScope Steel (second most critical initiative in corporation after safety.) Developed PMO rules, governance and operating procedures. PMO included several thousand projects occurring across the organisation, accounting for more than $Billion in cost and many hundreds of millions in savings potential.

QR: With Paul Sonego VP, Lead capital value maximisation team within QR prior to listing and name change to Aurizon. Delivered millions in savings to the corporation in below and above rail areas. Employed specifically to work with McKinsey.

Mondelez: With Hunter Burke VP, Led major global transformation initiative for EEMEA establishing the basis for profitable growth and sustainability into the future.

Executive director (CTS) where I consult to multinational corporations. My business is a channel partner of IBM which ensures that I am in the best position to introduce the most advanced technology into corporations to transform their operations.

Core Competencies

- **Leadership -** Personal and Professional Development Focus.
- **People Skills -** Proven and demonstrated ability to partner, influence and inspire
- **Demonstrated superior supply chain and value chain leadership capability -** Demonstrated capability to work with and 'transform' value chains and organisations in a way that engages positively all stakeholders and results in sustainable outcomes.
- **Results focused strategic planning capability -** Developed and tested in several top 100 multinationals.
- **Extensive strategic marketing capability -** Demonstrated capability in reviewing products and services and how they align with markets, growth industries and key drivers of growth, (completed for most AP countries, including Australia, Europe and US) and the implications for the business.
- **Internationally developed and results focused organizational problem solving skills** as well as demonstrated capability in benchmarking profitability.(globally) Demonstrated capability in most basic organizational problem solving to high level development of complex models and systems to optimize performance.
- **Superior Quantitative capability and disciplined business approach** – Optimised the planning and operations of the entire end to end value chain across APAC for CCA. Qualified statistician using advanced techniques and technology.
- **Sound knowledge of Asia Pacific countries, economies and cultures -** I have lived, worked and been required to deliver results on every continent and as such have internationally developed business skills and highly developed cultural sensitivity.
- **Superior ability to influence-** I have proven and demonstrated ability to partner, influence and inspire at all levels in an organisation, from very senior management through to operations.
- **P&L Accountability –** I have been accountable for financial outcomes, budgets and direct reports across global regions such as LA & APAC.

Experience

- I have worked in many areas including: Global Value/Supply Chain strategy, planning & operational improvement (S&OP), Business Strategy, development, implementation, & benefits realisation (suppliers, competitors, customers, market conditions, risk assessment and mitigation, Portfolio Optimisation, transforming businesses into money making powerhouses including innovation and commercialisation ,Leading Business transformation & cross functional Change Program Delivery, Restructuring & rationalisation, Outsourcing, divestment or acquisition, Strategic partnerships - Realising the business case, Procurement, Strategic Sourcing, including commercial negotiation, Capital Value Maximisation (CVM) improving capital, resource utilisation & productivity , pre and post merger separation and integration and the analysis of all of the above.
- I have worked with more than 40 Multinationals & many medium sized businesses. Every assignment that I have ever had, has involved problem solving (of some kind) and as such has needed my analytic skills, to measure the current state and indeed work out what needs to be done, to deliver the appropriate output, then measure the impact of initiatives implemented.
- Demonstrated capability in **broad range of industries**: FMCG, Pharmaceuticals, Healthcare, Printing and Publishing, Chemicals, Services, Industrial products, heavy industrial including steel manufacturing, rail infrastructure and Mining. I have worked in industrial, consumer and service industries.

- I have consulted independently; both directly to my clients and to a variety of tier 1strategy and operational consulting firms. I am an organizational strategic and operational improvement specialist and my focus is on all aspects of making the organization work better, and then delivering profitable growth faster. I work on the organization as well as in it. I work from the top down
- My skills apply to large and small organizations although my primary experience is in multinational corporations. I have consulted to 10 major multinationals and 1 GOC since 2003 as well as several national, and privately held companies. I have fulfilled interim **senior executive roles including CEO and General Manager.**
- Prior to 2005 I worked in line management roles and internal consulting roles, at the very highest levels of E.I. Du Pont. De Nemours and Coca Cola Amatil. **With Chad Holliday, the CEO and Chairman of the entire Du Pont company and subsequently with the 34 Strategic Business Unit leaders of Du Pont globally**.
- As a Business and supply chain strategist for **Coca Cola (Amatil), responsible for the optimisation of the entire end to end value chain across Asia Pacific.**
- **My line of reporting for the last 15 years has been to directors, chairman, boards and global VP's.**
- I have lived, worked and been required to deliver results on every continent (short and long term assignments) in Japan, 11 other Asian countries, US, Europe and the UK as well as Australia and has as such well developed international business skills along with highly developed cultural sensitivity.

Career Summary

January 2005 to present	**Director, CTS (Corporate Transformation Services) Pty Ltd** **Panellist and Thought leader, Current and Convetit Advisor, Start-ups** **Engagement Manager and Consultant – Direct to client and to various tier 1 strategy and operational consulting firms including Partners in Performance reporting to Director Level**
September 1998 to January 2005	**Manager, Asia Pacific Customer Consumer Services Systems** **Coca Cola Amatil (Asia Pacific) - Reporting to Director level**
September 1996 to August 1998	**Business Manager P&P AP (Asia Pacific), P&L responsibility** **E.I. Du Pont de Nemours Pty Ltd - Reporting to Regional Director P&P– AP**
September 1994 to August 1996	**Regional Manager LAAP (Latin America Asia Pacific), P&L responsibility** **E.I. Du Pont de Nemours Pty Ltd - Reporting to VP of finance and Global VP Printing and Publishing – plus special assignments for CEO and Chairman**
September 1993 to August 1994	**Manager, Marketing services and export – Supply Chain (Asia Pacific), Du Pont in Asia Pacific** **Reporting to General Manager P&P, Australia**
September 1991 to August 1993	**Strategic Planning Consultant** **Du Pont in Asia Pacific - Reporting to Director of Finance in Asia Pacific and Chairman of Asia Pacific**
October 1990 to August 1991	**Strategic Planning Consultant – Du Pont (Australia)** **Reporting to Country Manager Du Pont (Australia)**

Education

B. Sc (Majors Statistics and Psychology) Sydney University
M. App. Stats (Masters in Applied Statistics) Macquarie University
M.B.A (Business Strategy, Management and Leadership) University of Technology, Sydney

Company director training and FAICD qualification received
Completed International Company directors qualification

Key Training Courses

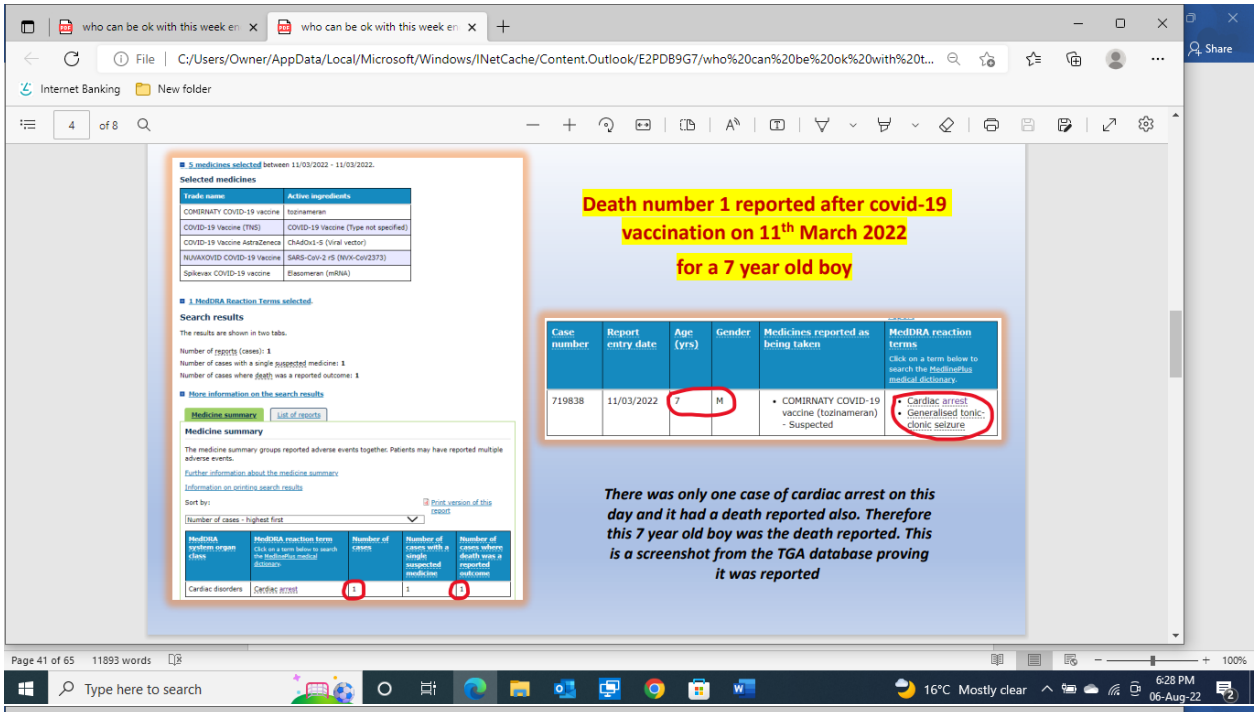
- Extensive and continuous responsibility for my own personal and professional development has meant that I have attended numerous training courses, extending from technical application training to human resource training.

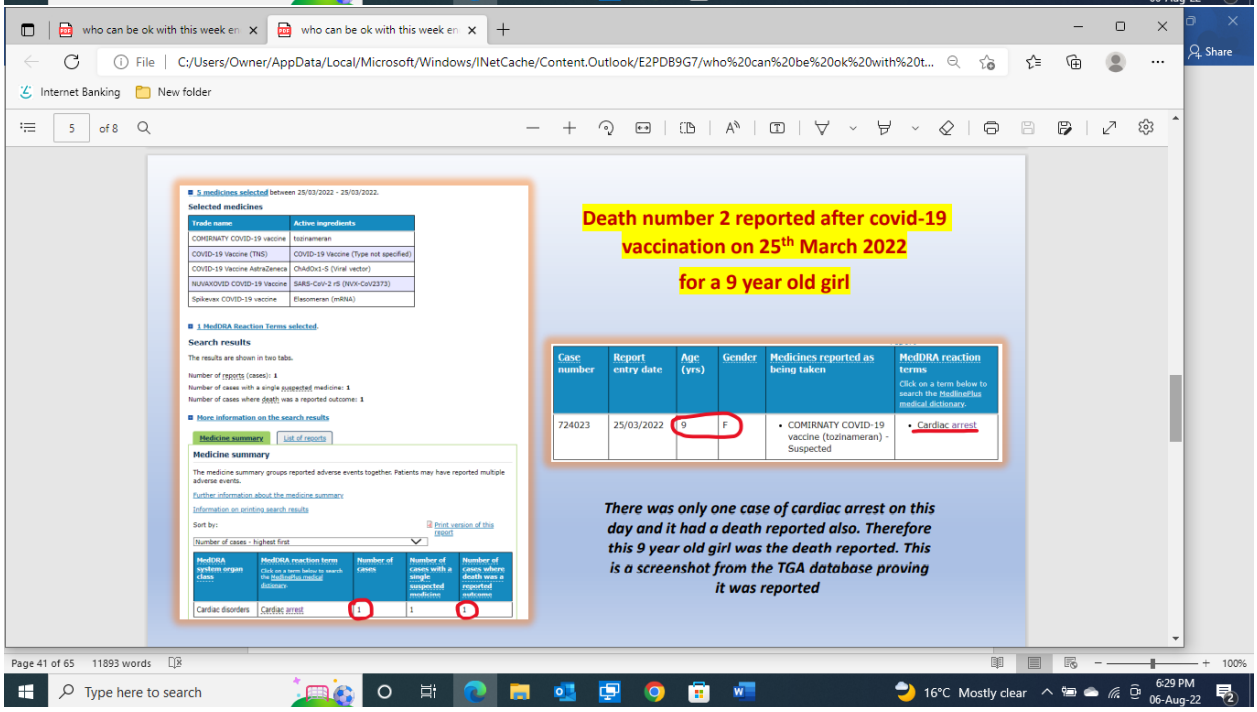
1990	**E.I.Du Pont de Nemours Business Strategy and Planning – Gary Hamel**
1990	**E.I Du Pont de Nemours Safety training**
1990	**E.I.Du Pont de Nemours – Organisational Effectiveness Training**
1992	**Envisioning the future – Ram Charam – Ed Woollard then CEO and chairman of Du Pont and senior Du Pont SBU leaders**
1992 to 1996	**Various organisational effectiveness training and change management programmes, various strategy development training sessions, interpersonal behaviour training, relationship mastery, negotiation training, physical mastery, emotional mastery, emotional intelligence training**.
1996 to 2003	**Strategic selling, leadership development, Value Chain planning, D&OP training, CSS training, MGSM Strategic management programme,**

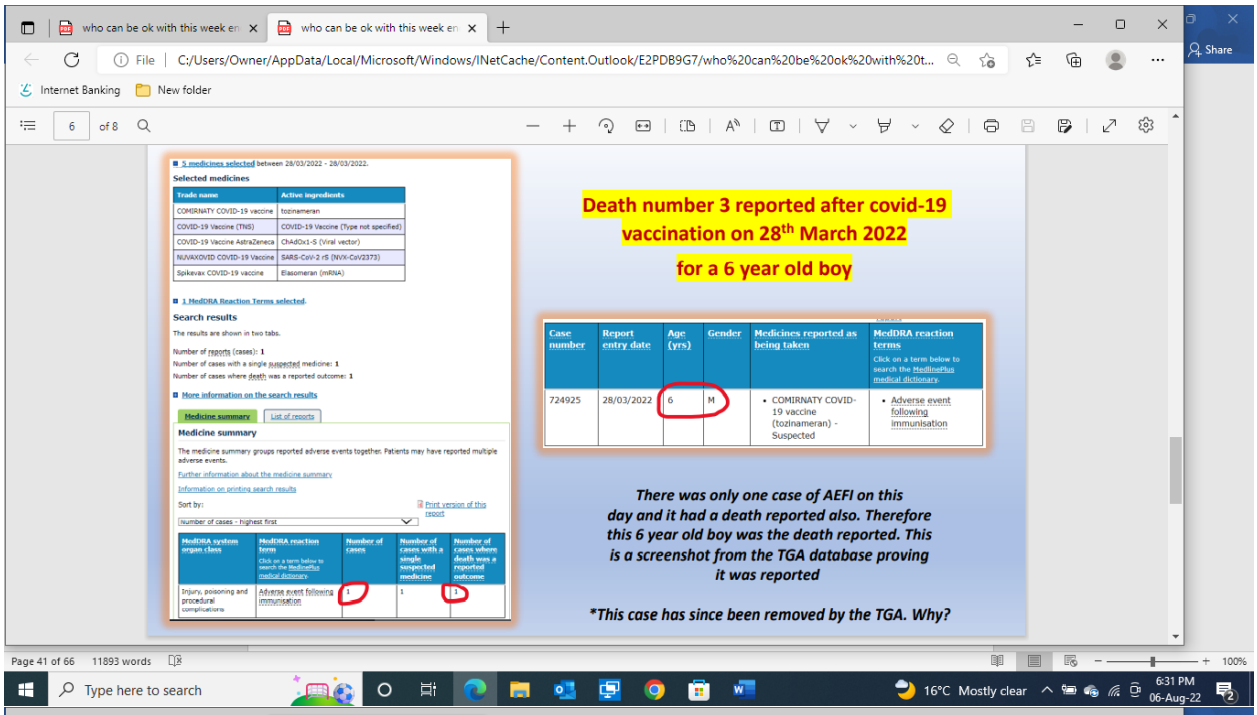
Personal Details

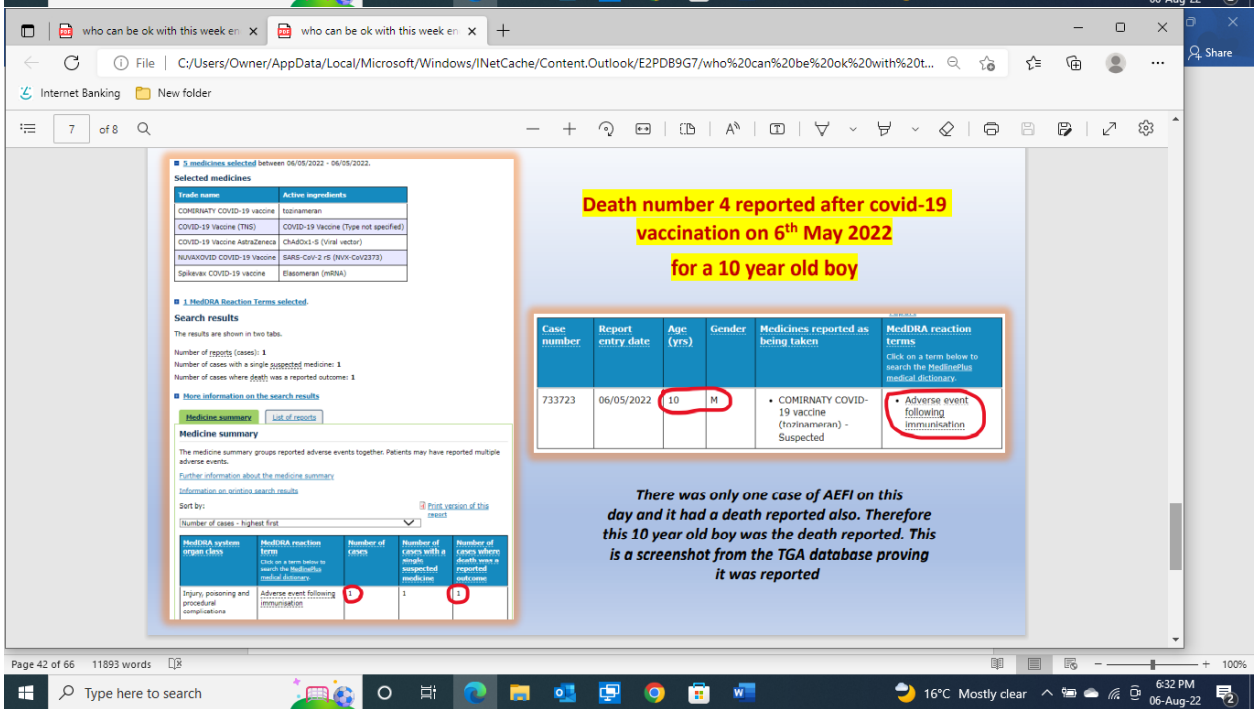
- Fellow of Australian Institute of Company directors (youngest ever)
- Interests are in human group psychology and organisational behaviour, Business strategy and value chain.
- Keen collector of antique furniture from Europe and the Orient.
- Enjoys keeping fit, Ashtanga yoga and walking

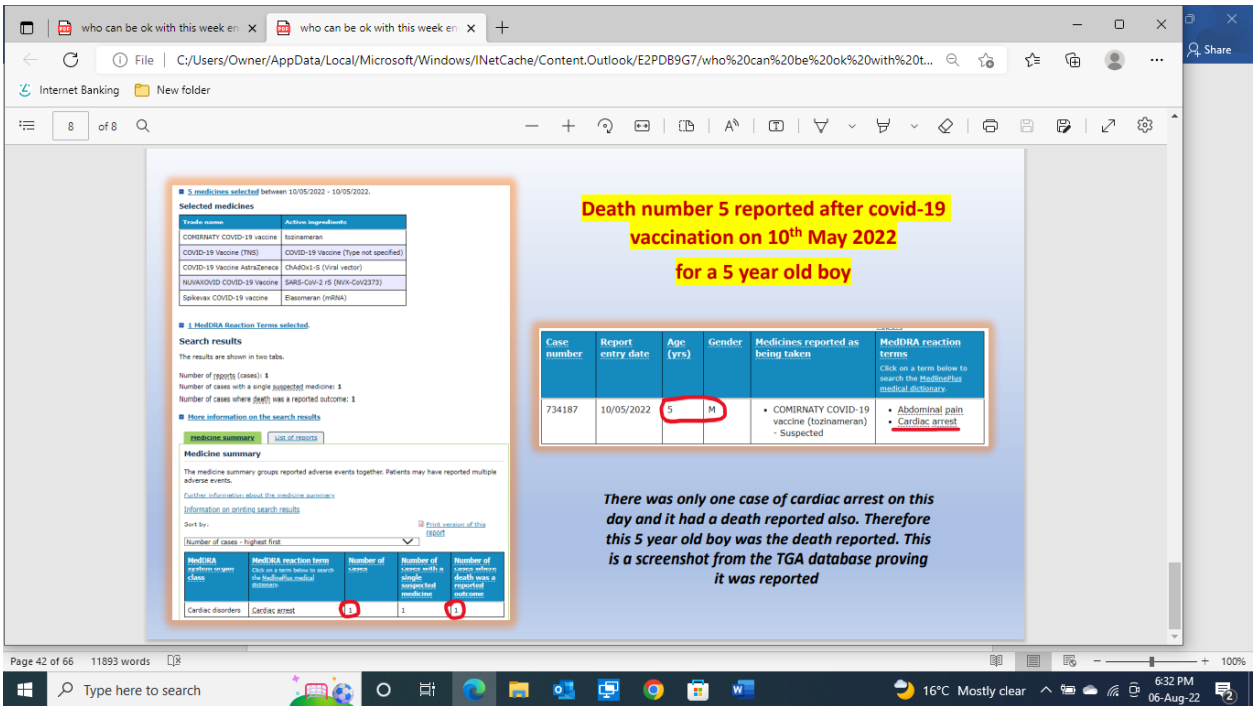
SCHEDULE B – from Item 1 - screenshots of DAENs database of 5-11 year olds where Death was the reported outcome






who can be ok with this week en
who can be ok with this week en
File C:/Users/Owner/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/E2PDB9G7/who%20can%20be%20ok%20with%20t...
Share
Internet Banking
New folder
6 of 8
5 medicines selected between 28/03/2022 - 28/03/2022.
Selected medicines
Trade name
Active ingredients
COMIRNATY COVID-19 vaccine
tozinameran
COVID-19 Vaccine (TN5)
COVID-19 Vaccine (Type not specified)
COVID-19 Vaccine AstraZeneca
ChAdOx1-S (Viral vector)
NUVAXOVID COVID-19 Vaccine
SARS-CoV-2 rS (NVX-CoV2373)
Spikevax COVID-19 vaccine
Elasomeran (mRNA)
1 MedDRA Reaction Terms selected.
Search results
The results are shown in two tabs.
Number of reports (cases): 1
Number of cases with a single suspected medicine: 1
Number of cases where death was a reported outcome: 1
More information on the search results
Medicine summary
List of reports
Medicine summary
The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.
Further information about the medicine summary
Information on printing search results
Sort by:
Print version of this report
Number of cases - highest first
MedDRA system organ class
MedDRA reaction term
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
1
1
1
Death number 3 reported after covid-19 vaccination on 28th March 2022
for a 6 year old boy
Case number
Report entry date
Age (yrs)
Gender
Medicines reported as being taken
MedDRA reaction terms
Click on a term below to search the MedlinePlus medical dictionary.
724925
28/03/2022
6
M
• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected
• Adverse event following immunisation
There was only one case of AEFI on this day and it had a death reported also. Therefore this 6 year old boy was the death reported. This is a screenshot from the TGA database proving it was reported
*This case has since been removed by the TGA. Why?
Page 41 of 66
11893 words
100%
Type here to search
16°C Mostly clear
6:31 PM
06-Aug-22


who can be ok with this week en
who can be ok with this week en
File C:/Users/Owner/AppData/Local/Microsoft/Windows/INetCache/Content.Outlook/E2PDB9G7/who%20can%20be%20ok%20with%20t...
Share
Internet Banking
New folder
7 of 8
5 medicines selected between 06/05/2022 - 06/05/2022.
Selected medicines
Trade name
Active ingredients
COMIRNATY COVID-19 vaccine
tozinameran
COVID-19 Vaccine (TN5)
COVID-19 Vaccine (Type not specified)
COVID-19 Vaccine AstraZeneca
ChAdOx1-S (Viral vector)
NUVAXOVID COVID-19 Vaccine
SARS-CoV-2 rS (NVX-CoV2373)
Spikevax COVID-19 vaccine
Elasomeran (mRNA)
1 MedDRA Reaction Terms selected.
Search results
The results are shown in two tabs.
Number of reports (cases): 1
Number of cases with a single suspected medicine: 1
Number of cases where death was a reported outcome: 1
More information on the search results
Medicine summary
List of reports
Medicine summary
The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.
Further information about the medicine summary
Information on printing search results
Sort by:
Print version of this report
Number of cases - highest first
MedDRA system organ class
MedDRA reaction term
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
1
1
1
Death number 4 reported after covid-19 vaccination on 6th May 2022
for a 10 year old boy
Case number
Report entry date
Age (yrs)
Gender
Medicines reported as being taken
MedDRA reaction terms
Click on a term below to search the MedlinePlus medical dictionary.
733723
06/05/2022
10
M
• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected
• Adverse event following immunisation
There was only one case of AEFI on this day and it had a death reported also. Therefore this 10 year old boy was the death reported. This is a screenshot from the TGA database proving it was reported
Page 42 of 66
11893 words
100%
Type here to search
16°C Mostly clear
6:32 PM
06-Aug-22


Death number 5 reported after covid-19 vaccination on 10th May 2022
for a 5 year old boy
Case number
Report entry date
Age (yrs)
Gender
Medicines reported as being taken
MedDRA reaction terms
734187
10/05/2022
5
M
COMIRNATY COVID-19 vaccine (tozinameran) - Suspected
Abdominal pain
Cardiac arrest
There was only one case of cardiac arrest on this day and it had a death reported also. Therefore this 5 year old boy was the death reported. This is a screenshot from the TGA database proving it was reported

SCHEDULE C – Adverse Events reported in 5-11 year olds prior to 10 January 2022 following Covid-19 Vaccine

Case number	Report entry date	Age (years)	Gender	Medicines reported as being taken	MedDRA reaction terms
633664	29/09/2021	10	Male	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
635551	1/10/2021	10	Male	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
650124	25/10/2021	10	Male	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
658593	5/11/2021	10	Female	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
685756	21/12/2021	10	Male	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Vaccination error • Wrong product administered
651053	26/10/2021	11	Female	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Injection site reaction • Product administered to patient of inappropriate age • Vaccination error
651064	26/10/2021	11	Female	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Injection site reaction • Product administered to patient of inappropriate age • Vaccination error
653735	1/11/2021	11	Male	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
655365	3/11/2021	11	Female	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Injection site reaction • Product administered to patient of inappropriate age
658365	4/11/2021	11	Male	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Product administered to patient of inappropriate age • Vaccination error

Case number	Report entry date	Age (years)	Gender	Medicines reported as being taken	MedDRA reaction terms
664723	15/11/2021	11	Female	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
666052	17/11/2021	11	Not Specified	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
670461	23/11/2021	11	Female	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Product administered to patient of inappropriate age
669960	23/11/2021	11	Not Specified	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
678287	7/12/2021	11	Male	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
679963	9/12/2021	11	Female	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Incorrect dose administered • Product administered to patient of inappropriate age • Vaccination error
680889	12/12/2021	11	Female	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
681491	14/12/2021	11	Female	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
683931	17/12/2021	11	Female	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
684667	20/12/2021	11	Female	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Product administered to patient of inappropriate age • Vaccination error

Case number	Report entry date	Age (years)	Gender	Medicines reported as being taken	MedDRA reaction terms
688859	31/12/2021	11	Female	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
689991	5/01/2022	11	Male	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
690115	5/01/2022	11	Male	• Spikevax COVID-19 vaccine (Elasomeran (mRNA)) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
690395	6/01/2022	11	Male	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Incorrect dose administered • Product administered to patient of inappropriate age • Vaccination error
580704	6/07/2021	8	Male	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Product administered to patient of inappropriate age • Vaccination error
635726	1/10/2021	8	Female	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Fatigue • Pain in extremity • Product administered to patient of inappropriate age • Vaccination error
526666	25/03/2021	9	Female	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Headache • Myalgia • Product administered to patient of inappropriate age
580197	5/07/2021	9	Male	• COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected	• Product administered to patient of inappropriate age

SCHEDULE D – Total Adverse events reported by DAENs in children 5-11 from 10 January 2022 to 8 June 2022 being 1,390 Adverse Events, which resulted in 3,635 reactions - classified as per the MedDRA reaction types. Types listed by frequency from highest to lowest.

MedDRA reaction	Count	Potentially Serious	% of Total
Chest pain	211		5.80%
Vomiting	163		4.48%
Pyrexia	159	x	4.37%
Headache	131		3.60%
Abdominal pain	127		3.49%
Dyspnoea	118		3.25%
Vaccination error	111		3.05%
Nausea	110		3.03%
Lethargy	99		2.72%
Syncope	98	x	2.70%
Rash	90		2.48%
Dizziness	84		2.31%
Pallor	82		2.26%
Urticaria	76		2.09%
Injection site reaction	66		1.82%
Fatigue	57		1.57%
Myalgia	52		1.43%
Diarrhoea	50		1.38%
Malaise	45		1.24%
Palpitations	44		1.21%
Presyncope	41		1.13%
Chest discomfort	39		1.07%
Lymphadenopathy	39		1.07%
Arthralgia	33		0.91%
Injection site pain	31		0.85%
Cough	30		0.83%
Oropharyngeal pain	30		0.83%

MedDRA reaction	Count	Potentially Serious	% of Total
Pain in extremity	29		0.80%
Tachycardia	27	x	0.74%
Rash pruritic	26		0.72%
Concomitant disease aggravated	25		0.69%
Pruritus	25		0.69%
Decreased appetite	24		0.66%
Abdominal pain upper	23		0.63%
Incorrect dose administered	23		0.63%
Pericarditis	23	x	0.63%
Hyperhidrosis	22		0.61%
Cold sweat	21		0.58%
Seizure	21	x	0.58%
Covid-19	20		0.55%
Asthma	19		0.52%
SARS-CoV-2 test positive	18		0.50%
Expired product administered	17	x	0.47%
Rhinorrhoea	17		0.47%
Chills	16		0.44%
Electrocardiogram abnormal	16		0.44%
Product administered to patient of inappropriate age	16	x	0.44%
Influenza like illness	15		0.41%
Swelling face	14		0.39%
Epistaxis	13		0.36%
Lymphadenitis	13		0.36%
Anxiety	12		0.33%
Appendicitis	12	x	0.33%
Eye swelling	12		0.33%
Wrong product administered	12		0.33%
Abdominal discomfort	11		0.30%
Feeling hot	11		0.30%

MedDRA reaction	Count	Potentially Serious	% of Total
Influenza	11		0.30%
Hypersensitivity	10		0.28%
Paraesthesia	10		0.28%
Rash erythematous	10		0.28%
Angioedema	9		0.25%
Croup infectious	9		0.25%
Lip swelling	9		0.25%
Myocarditis	9	x	0.25%
Pain	9		0.25%
Troponin	9		0.25%
Musculoskeletal chest pain	8		0.22%
Ocular hyperaemia	8		0.22%
Throat tightness	8		0.22%
Tremor	8		0.22%
Wheezing	8		0.22%
Adverse event following immunisation	7	x	0.19%
C-reactive protein increased	7		0.19%
Electrocardiogram	7		0.19%
Erythema	7		0.19%
Gastroenteritis	7		0.19%
Herpes zoster	7		0.19%
Neck pain	7		0.19%
Rash maculo-papular	7		0.19%
Troponin increased	7		0.19%
Asthenia	6		0.17%
Cyanosis	6		0.17%
Disorientation	6		0.17%
Generalised tonic-clonic seizure	6		0.17%
Heart rate increased	6		0.17%
Hypotension	6	x	0.17%

MedDRA reaction	Count	Potentially Serious	% of Total
Inappropriate schedule of product administration	6		0.17%
Kawasaki's disease	6	x	0.17%
Loss of consciousness	6	x	0.17%
Muscle spasms	6		0.17%
Product preparation issue	6		0.17%
SARS-CoV-2 antibody test positive	6		0.17%
Sneezing	6		0.17%
Tonsillitis	6		0.17%
Underdose	6		0.17%
Vaccine breakthrough infection	6		0.17%
Varicella	6		0.17%
Arrhythmia	5		0.14%
Axillary pain	5		0.14%
Conjunctivitis	5		0.14%
Flushing	5		0.14%
Incorrect dosage administered	5		0.14%
Migraine	5		0.14%
Peripheral swelling	5		0.14%
Rash macular	5		0.14%
Rash papular	5		0.14%
Sleep disorder	5		0.14%
Throat irritation	5		0.14%
Abdominal lymphadenopathy	4		0.11%
Breakthrough Covid-19	4		0.11%
Dehydration	4		0.11%
Dysphonia	4		0.11%
Haematuria	4		0.11%
Heart rate irregular	4		0.11%
Injection site rash	4		0.11%
Irritability	4		0.11%

MedDRA reaction	Count	Potentially Serious	% of Total
Menstrual disorder	4		0.11%
Multisystem inflammatory syndrome in children	4		0.11%
Oropharyngeal discomfort	4		0.11%
Oxygen saturation decreased	4		0.11%
Periorbital swelling	4		0.11%
Photophobia	4		0.11%
Pneumonia	4	x	0.11%
Thrombocytopenia	4		0.11%
Urinary incontinence	4	x	0.11%
Vision blurred	4		0.11%
Visual impairment	4		0.11%
Anaphylactic reaction	3		0.08%
Cardiac arrest	3	x	0.08%
Contusion	3		0.08%
Costochondritis	3		0.08%
Diabetic ketoacidosis	3		0.08%
Dyspnoea exertional	3		0.08%
Dysuria	3		0.08%
Ear infection	3		0.08%
Electrocardiogram ST segment elevation	3		0.08%
Henoch-Schonlein purpura	3		0.08%
Infection	3		0.08%
Musculoskeletal stiffness	3		0.08%
Myopericarditis	3	x	0.08%
Nasal congestion	3		0.08%
Oral pruritus	3		0.08%
Painful respiration	3		0.08%
Pleuritic pain	3		0.08%
Pollakiuria	3		0.08%
Rash vesicular	3		0.08%

MedDRA reaction	Count	Potentially Serious	% of Total
Respiratory rate increased	3		0.08%
Somnolence	3		0.08%
Swollen tongue	3		0.08%
Tachypnoea	3		0.08%
Thirst	3		0.08%
Troponin I	3		0.08%
Troponin I increased	3		0.08%
Urinary tract infection	3		0.08%
Vertigo	3		0.08%
Viral infection	3		0.08%
Abdominal pain lower	2		0.06%
Acne	2		0.06%
Alopecia	2		0.06%
Bacterial infection	2		0.06%
Bell's palsy	2		0.06%
Cardiac murmur	2		0.06%
Carditis	2	x	0.06%
Confusional state	2		0.06%
Conjunctival hyperaemia	2		0.06%
Crying	2		0.06%
Delirium	2		0.06%
Dyspepsia	2		0.06%
Dysphagia	2		0.06%
Echocardiogram normal	2		0.06%
Electrocardiogram normal	2		0.06%
Erythema multiforme	2		0.06%
Exercise tolerance decreased	2		0.06%
Eye pain	2		0.06%
Eye pruritus	2		0.06%
Feeling abnormal	2		0.06%

MedDRA reaction	Count	Potentially Serious	% of Total
Feeling cold	2		0.06%
Fibrin D dimer increased	2		0.06%
Flank pain	2		0.06%
Fracture	2		0.06%
Haematemesis	2		0.06%
Hepatitis	2		0.06%
Hypoaesthesia	2		0.06%
Hypotonia	2		0.06%
IgA nephropathy	2		0.06%
Inflammation	2		0.06%
Inflammatory marker increased	2		0.06%
Joint swelling	2		0.06%
Lymph node pain	2		0.06%
Lymphopenia	2		0.06%
Mouth ulceration	2		0.06%
No adverse event	2		0.06%
Oligomenorrhoea	2		0.06%
Oral herpes	2		0.06%
Osteomyelitis	2		0.06%
Pain in jaw	2		0.06%
Pharyngeal swelling	2		0.06%
Pharyngitis	2		0.06%
Pityriasis rosea	2		0.06%
Postictal state	2		0.06%
Product administered at inappropriate site	2	x	0.06%
Psoriasis	2		0.06%
Purpura	2		0.06%
Red blood cell sedimentation rate increased	2		0.06%
Renal impairment	2		0.06%
Respiratory tract infection	2		0.06%

MedDRA reaction	Count	Potentially Serious	% of Total
Retching	2		0.06%
SARS-CoV-2 test	2		0.06%
SARS-CoV-2 test negative	2		0.06%
Scrotal swelling	2		0.06%
Secretion discharge	2		0.06%
Sensation of foreign body	2		0.06%
Sinus arrhythmia	2		0.06%
Sinus tachycardia	2		0.06%
Skin discolouration	2		0.06%
Skin exfoliation	2		0.06%
Swelling	2		0.06%
Synovitis	2		0.06%
Taste disorder	2		0.06%
Testicular swelling	2		0.06%
Tinnitus	2		0.06%
Tongue discomfort	2		0.06%
Tongue pruritus	2		0.06%
Type 1 diabetes mellitus	2		0.06%
Unresponsive to stimuli	2		0.06%
Upper respiratory tract infection	2		0.06%
Vaginal haemorrhage	2	x	0.06%
Abdominal distension	1		0.03%
Abnormal faeces	1		0.03%
Administration site irritation	1		0.03%
Allergy to arthropod sting	1		0.03%
Ankle fracture	1		0.03%
Appendicitis perforated	1		0.03%
Arthritis	1		0.03%
Aspartate aminotransferase increased	1		0.03%
Atrial tachycardia	1		0.03%

MedDRA reaction	Count	Potentially Serious	% of Total
Attention deficit hyperactivity disorder	1		0.03%
Autonomic nervous system imbalance	1		0.03%
Axillary mass	1		0.03%
Back pain	1		0.03%
Basal ganglia haemorrhage	1		0.03%
Basedow's disease	1		0.03%
Blood blister	1		0.03%
Blood creatine increased	1		0.03%
Blood creatine phosphokinase increased	1		0.03%
Blood glucose abnormal	1		0.03%
Blood glucose increased	1		0.03%
Blood pressure increased	1		0.03%
Blood pressure measurement	1		0.03%
Blood urea increased	1		0.03%
Bradycardia	1		0.03%
Breath holding	1		0.03%
Bundle branch block right	1		0.03%
Cardiac discomfort	1		0.03%
Cardiac disorder	1		0.03%
Cardiomegaly	1		0.03%
Cellulitis	1		0.03%
Cerebrovascular accident	1		0.03%
Chapped lips	1		0.03%
Cheilitis	1		0.03%
Chest wall mass	1		0.03%
Chest X-ray	1		0.03%
Chest X-ray abnormal	1		0.03%
Chest X-ray normal	1		0.03%
Chillblains	1		0.03%
Clonic convulsion	1		0.03%

MedDRA reaction	Count	Potentially Serious	% of Total
Coma scale abnormal	1		0.03%
Conjunctival haemorrhage	1		0.03%
Constipation	1		0.03%
Corneal reflex decreased	1		0.03%
Coronary artery aneurysm	1		0.03%
C-reactive protein	1		0.03%
Cutaneous vasculitis	1		0.03%
Deafness	1		0.03%
Demyelination	1	x	0.03%
Dermatitis	1		0.03%
Diabetes mellitus	1		0.03%
Dizziness postural	1		0.03%
Drug ineffective	1		0.03%
Dyskinesia	1		0.03%
Dyspareunia	1		0.03%
Dysphemia	1		0.03%
Ear pain	1		0.03%
Ear swelling	1		0.03%
Echocardiogram	1		0.03%
Eczema	1		0.03%
Electrocardiogram QRS complex prolonged	1		0.03%
Electroencephalogram abnormal	1		0.03%
Empyema	1		0.03%
Encephalopathy	1		0.03%
Endocarditis	1		0.03%
Enterocolitis	1		0.03%
Epidemic polyarthritis	1		0.03%
Epigastric discomfort	1		0.03%
Eructation	1		0.03%
Erythromelalgia	1		0.03%

MedDRA reaction	Count	Potentially Serious	% of Total
Excessive eye blinking	1		0.03%
Extensive swelling of vaccinated limb	1		0.03%
Extrasystoles	1		0.03%
Eye inflammation	1		0.03%
Eye irritation	1		0.03%
Eye movement disorder	1		0.03%
Eyelid oedema	1		0.03%
Febrile convulsion	1		0.03%
Feeling of body temperature change	1		0.03%
Foaming at mouth	1		0.03%
Food allergy	1		0.03%
Frequent bowel movements	1		0.03%
Gait disturbance	1		0.03%
Gastrointestinal infection	1		0.03%
Gastrooesophageal reflux disease	1		0.03%
Gianotti-Crosti syndrome	1		0.03%
Gingival blister	1		0.03%
Gingivitis	1		0.03%
Glassy eyes	1		0.03%
Goitre	1		0.03%
Haemoglobin decreased	1		0.03%
Haemoglobin increased	1		0.03%
Hallucination	1		0.03%
Hallucination, visual	1		0.03%
Hand fracture	1		0.03%
Head discomfort	1		0.03%
Heart rate decreased	1		0.03%
Heavy menstrual bleeding	1		0.03%
Hypertensive encephalopathy	1		0.03%
Hypoglycaemia	1		0.03%

MedDRA reaction	Count	Potentially Serious	% of Total
Hypothyroidism	1		0.03%
Increased appetite	1		0.03%
Influenza A virus test positive	1		0.03%
Influenza virus test positive	1		0.03%
Injection site erythema	1		0.03%
Injection site swelling	1		0.03%
Insomnia	1		0.03%
Intestinal obstruction	1		0.03%
Intracranial pressure increased	1		0.03%
Joint instability	1		0.03%
Kidney infection	1		0.03%
Lacrimation increased	1		0.03%
Limb discomfort	1		0.03%
Limb injury	1		0.03%
Lip discolouration	1		0.03%
Lip dry	1		0.03%
Lip ulceration	1		0.03%
Lipase increased	1		0.03%
Listless	1		0.03%
Lower respiratory tract infection	1		0.03%
Lymphadenopathy mediastinal	1		0.03%
Lymphocyte count decreased	1		0.03%
Lymphoedema	1		0.03%
Lymphoma	1		0.03%
Molluscum contagiosum	1		0.03%
Mood altered	1		0.03%
Multiple use of single-use product	1		0.03%
Muscle fatigue	1		0.03%
Muscle rigidity	1		0.03%
Muscle twitching	1		0.03%

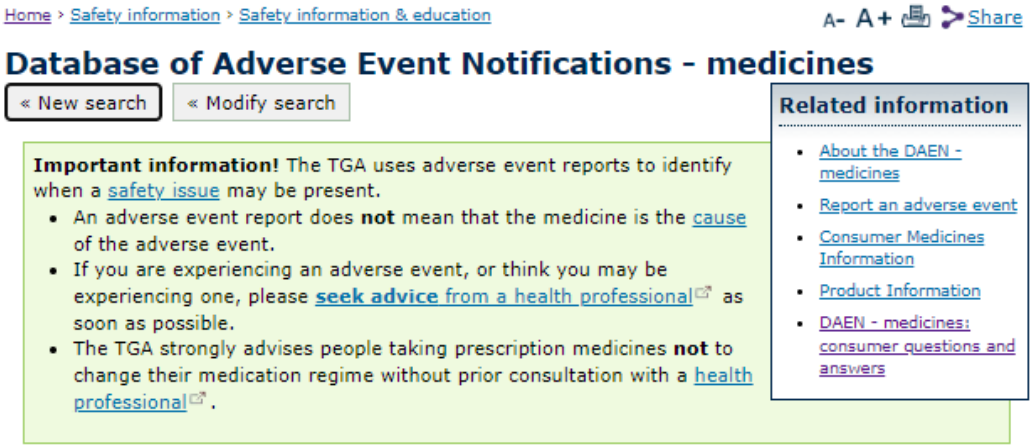
MedDRA reaction	Count	Potentially Serious	% of Total
Muscular weakness	1		0.03%
Musculoskeletal discomfort	1		0.03%
Musculoskeletal pain	1		0.03%
Mydriasis	1		0.03%
Myelitis transverse	1		0.03%
Myocardial infarction	1	x	0.03%
Nasal discomfort	1		0.03%
Nasopharyngitis	1		0.03%
Neutrophilia	1		0.03%
Night sweats	1		0.03%
Nightmare	1		0.03%
Nystagmus	1		0.03%
Obstructive airways disorder	1		0.03%
Oesophageal discomfort	1		0.03%
Oral candidiasis	1		0.03%
Oral disorder	1		0.03%
Pain of skin	1		0.03%
Panic attack	1		0.03%
Paraesthesia oral	1		0.03%
Penile pain	1		0.03%
Perioral dermatitis	1		0.03%
Periorbital oedema	1		0.03%
Petechiae	1		0.03%
Petit mal epilepsy	1		0.03%
Pharyngeal erythema	1		0.03%
Pharyngeal paraesthesia	1		0.03%
Pleurisy	1	x	0.03%
Pneumothorax	1		0.03%
Polydipsia	1		0.03%
Polyuria	1		0.03%

MedDRA reaction	Count	Potentially Serious	% of Total
Post-acute COVID-19 syndrome	1		0.03%
Posterior reversible encephalopathy syndrome	1		0.03%
Posture abnormal	1		0.03%
Protein urine present	1		0.03%
Radius fracture	1		0.03%
Rectal haemorrhage	1		0.03%
Red blood cell count decreased	1		0.03%
Red blood cell sedimentation rate	1		0.03%
Respiratory distress	1		0.03%
Respiratory symptom	1		0.03%
Respiratory syncytial virus infection	1		0.03%
Rhinitis	1		0.03%
Rhinovirus infection	1		0.03%
Scarlet fever	1		0.03%
Scrotal oedema	1		0.03%
Scrotal pain	1		0.03%
Sepsis	1		0.03%
Serum ferritin increased	1		0.03%
Serum sickness	1		0.03%
Sinus bradycardia	1		0.03%
Sinus rhythm	1		0.03%
Sinusitis	1		0.03%
Skin reaction	1		0.03%
Skin warm	1		0.03%
Sleep terror	1		0.03%
Splenomegaly	1		0.03%
Staphylococcal bacteraemia	1		0.03%
Staphylococcal infection	1		0.03%
Staphylococcus test positive	1		0.03%
Status epilepticus	1		0.03%

MedDRA reaction	Count	Potentially Serious	% of Total
Streptococcus test	1		0.03%
Superior sagittal sinus thrombosis	1		0.03%
Supraventricular tachycardia	1		0.03%
Swelling of eyelid	1		0.03%
Tardive dyskinesia	1		0.03%
Temperature regulation disorder	1		0.03%
Testicular pain	1		0.03%
Tic	1		0.03%
Tongue dry	1		0.03%
Tonic clonic movements	1		0.03%
Tonic convulsion	1		0.03%
Trismus	1		0.03%
Troponin normal	1		0.03%
Vaccination site reaction	1		0.03%
Weight decreased	1		0.03%
White blood cell count increased	1		0.03%
Yellow skin	1		0.03%
Total	3635		100.00%

SCHEDULE E – Screenshots of total Adverse Events reported by DAENs per Covid-19 Vaccine type

- ***PFIZER VACCINE (01FEB2021TO08JUN2022):***



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Database of Adverse Event Notifications - medicines

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Important information! The TGA uses adverse event reports to identify when a safety issue may be present.

- An adverse event report does **not** mean that the medicine is the cause of the adverse event.
- If you are experiencing an adverse event, or think you may be experiencing one, please **seek advice** from a health professional as soon as possible.
- The TGA strongly advises people taking prescription medicines **not** to change their medication regime without prior consultation with a health professional.

Related information

- About the DAEN - medicines
- Report an adverse event
- Consumer Medicines Information
- Product Information
- DAEN - medicines: consumer questions and answers

1 medicine selected between 01/02/2021 - 08/06/2022.

Search results

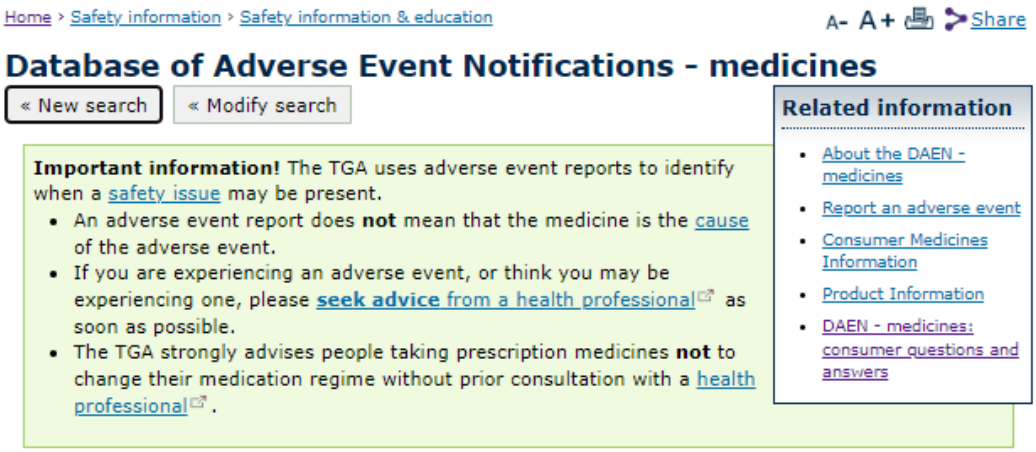
The results are shown in two tabs.

Number of reports (cases): **76938**

Number of cases with a single suspected medicine: **75110**

Number of cases where death was a reported outcome: **370**

- ***ASTRAZENECA (01FEB2021TO08JUN2022):***



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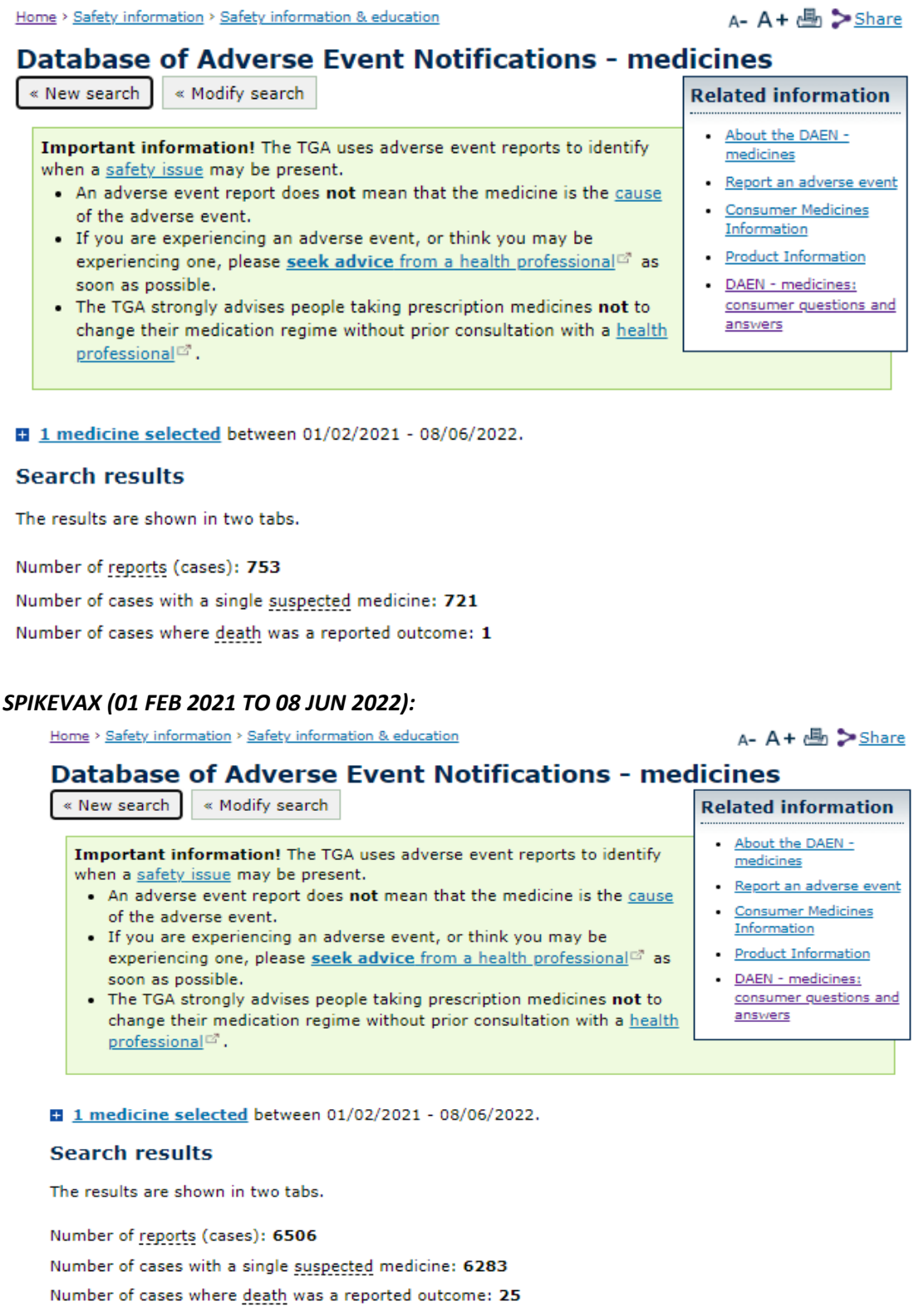
Number of reports (cases): **47567**

Number of cases with a single suspected medicine: **46553**

Number of cases where death was a reported outcome: **464**

- ***NUVAXOVID (01FEB2021TO08JUN2022):***



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Search results

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Number of reports (cases): **753**

Number of cases with a single suspected medicine: **721**

Number of cases where death was a reported outcome: **1**

- ***SPIKEVAX (01 FEB 2021 TO 08 JUN 2022):***

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- Product Information
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1 medicine selected between 01/02/2021 - 08/06/2022.

Search results

The results are shown in two tabs.

Number of reports (cases): **6506**

Number of cases with a single suspected medicine: **6283**

Number of cases where death was a reported outcome: **25**

- ***TYPE NOT SPECIFIED (01EB2021TO08JUN2022):***

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1 medicine selected between 01/02/2021 - 08/06/2022.

Search results

The results are shown in two tabs.

Number of reports (cases): **620**

Number of cases with a single suspected medicine: **577**

Number of cases where death was a reported outcome: **25**