COVID-19 Vaccination of Children and Adolescents Futility Danger and Intergenerational Theft

Should ATAGI, Government, Parents and Educators rely on research written and funded by Pfizer and BioNTech:

- > Employees (73% of authors)
- > Stock Holders (62% of authors)
- > The CEO and his Wife?

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Introduction

"There is high level evidence indicating strong immunogenicity and vaccine efficacy against symptomatic COVID-19 in adolescents from clinical trials of Pfizer and Moderna."

Source <u>Australian Technical Advisory Group on Immunisation (ATAGI)</u>

Dear Reader,

This statement is in part based on a <u>study</u> published in the new England Journal of Medicine and forms one of the principal supports behind ATAGI's recommendation to Australian government to vaccinate children from as young as 12 years old. (refer <u>Appendix 1</u> and <u>source</u>).

While ATAGI goes onto byzantine detail later in its website, there are five things this statement fails to succinctly tell you:

- 1. What are the **declared interests** of the **26** authors of this <u>study</u>?
- 2. What is **'symptomatic COVID-19'**?
- 3. What are the **consequences** for **children and adolescents**, of 'symptomatic COVID-19' and how serious are they?
- 4. What is the **Actual Reduction in Risk** for children and adolescents of being vaccinated against 'symptomatic COVID-19'? and
- 5. What are the **detailed** and **quantified** risks for children and adolescents of COVID-19 vaccination?

In this paper we'll explore these five 'untolds' and question the risk/benefit conclusion of the Australian Technical Advisory Group on Immunisation (ATAGI) to recommend vaccination of children from as young as 12.

Vaccination Proponents - Declared Interests

One of the key <u>articles</u> relied upon by ATAGI to strongly recommend COVID-19 vaccination of children and adolescents as young as 12 was largely written (and presumably funded) by Pfizer and BioNTech employees, stock holders, patent owners, and fiduciary office holders.

Surprisingly this is not unusual in today's intertwined and for-profit academia, pharmaceutical industry, and product approval regulators.

So, of the 26 authors of this article here is a summary of their declared interests:

- a. 73% of the authors are employed by Pfizer/BioNTech (the makers and patent holders of the novel gene therapy being recommended by ATAGI);
- b. 62% of the authors have stock and/or options in Pfizer/BioNTech; and
- c. Two of the authors are the owners and CEO's of BioNTech, who are in turn the holders of the patents of the novel mRNA technology used in these gene therapies.

The full funding and disclosure statements of this study, crucially relied upon by ATAGI to endorse the vaccination of children and adolescents, can be found at Appendix 2 and here in the New England Journal of Medicine.

In nearly all other fields of business and commerce such declarations of interest would be required to be publicly and prominently displayed.

We look forward to ATAGI sharing and publicly displaying the declared interests of the many authors of papers on which it relies for its advice to the Australian public.

Part A – Definitions Impacts and Efficacy

Definition - Symptomatic COVID-19

According to <u>ATAGI</u>, (refer <u>Appendix 3</u>), "there is high level evidence *indicating* strong immunogenicity and vaccine efficacy against *symptomatic COVID-19* in adolescents from clinical trials of Pfizer and Moderna."

ATAGI's "**symptomatic COVID-19**" sounds ominous but in reality, says **nothing** about disease severity.

In this <u>study</u> relied upon by ATAGI, as in many such studies including the Randomised Control Trials (RCT) of these COVID-19 vaccines and gene therapies, "symptomatic COVID-19" is broadly defined as:

"The presence of one or more symptoms (i.e., fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, vomiting) and being SARS-CoV-2 NAAT-positive during, or within 4 days before or after, the symptomatic period".

So, the statement by ATAGI "indicating strong immunogenicity and vaccine efficacy against symptomatic COVID-19" can be paraphrased, with a few forward-looking additions, as saying ...

'The novel Pfizer (BNT162b2) gene therapy, with **unknown** medium to long term **safety profiles**, to **some degree** creates an immune response against symptomatic COVID-19; where symptomatic COVID-19 was defined and measured during the **relatively short trial** as children and adolescents **not testing positive** to SARS-CoV-2 while **exhibiting one or more** of the **non-specific symptoms** such as fever, cough, sore throat, muscle pain, chills, shortness of breath and/or vomiting'

Sadly, this statement says **nothing** about the **more** crucial protections for children and adolescents, if any, against **severe disease**, **hospitalisation**, **and/or death**.

Finally on its <u>website</u>, ATAGI goes to byzantine complexity to say that **underlying health** and **age** are still the best **predictors** of COVID-19 **disease severity** and **mortality** (<u>source</u>).

<u>Impacts – 'Symptomatic COVID-19' for Children and Adolescents</u>

While there are a small number of COVID-19 effects on children and adolescents, e.g. Paediatric Inflammatory Multisystem Syndrome Temporally associated with SARS-CoV-2

(PIMS-TS), these effects are often difficult to identify, quantify, and rigorously evaluate. And nearly always underlying medical conditions precipitate, confound, and exacerbate these effects.

Sadly, the most accurate and verifiable metric of the effects of COVID-19 on children and adolescents is the number of deaths.

We've summarised this for England and the UK in the table below; and by way of comparison we've also included the deaths due to influenza and respiratory viruses for the most recent seasons. We've used UK data as it is infinitely more robust and transparent than Australian data for influenza and/or COVID-19.

Rates of Death COVID-19 vs Influenza and other Respiratory Viruses	Deaths (per 1M)	Source
England COVID-19 Ages 0 to 14 01 March 2020 to 10 October 2021	2.3	https://coronavirus.data.gov.uk/details/download
Influenza UK 2013/2014 Ages 0 to 14	6.5	
Influenza UK 2014/2015 Ages 0 to 14	13.9	
Influenza UK 2015/2016 Ages 0 to 14	12.0	
Influenza UK 2016/2017 Ages 0 to 14	9.5	https://www.gov.uk/government/statistics/annual- flu-reports
Influenza UK 2017/2018 Ages 0 to 14	1.7	
Influenza UK 2018/2019 Ages 0 to 14	6.5	
Influenza UK 2019/2020 Ages 0 to 14	6.4	

To add clarity and context to the table above, it's important to note the following:

- 1. It's been well established in several <u>studies</u> that "children with comorbidities have a higher risk of severe COVID-19 and associated mortality than children without underlying disease".
- 2. In a recent <u>study</u> it was found the "odds of Paediatric Intensive Care Unit (PICU) admission with COVID-19 were increased for children and young patients with any comorbidity and were highest for children and young patients with multiple medical problems."

- 3. In another recent <u>study</u> it was found that "childhood mortality in England during the first year of the SARS-CoV-2 pandemic was the lowest on record, with over 300 fewer deaths than the preceding 12 months";
- 4. Comparing the death rate from COVID-19 to the average of flu and respiratory viruses over the years 2013 to 2019, shows that the rate of **deaths from flu and respiratory viruses is 3.5 times higher than from COVID-19**.
- 5. The COVID-19 survival rate for children and adolescents (ages 0 to 19) in the UK over the period 01 March 2020 to 08 October 2021 is 99.995%. (Source)

In summary, for children and adolescents in the UK the death rate from flu and other respiratory diseases is 3.5 times higher than it is from COVID-19, the COVID-19 survival rate for children and adolescents (ages 0 to 19) is 99.995% and sadly the vast majority, if not all, of COVID-19 deaths and hospitalisations are associated with comorbidities and adverse underlying medical conditions.

<u>Pfizer (BNT162b2) Gene Therapy – Actual Risk Reduction (ARR)</u>

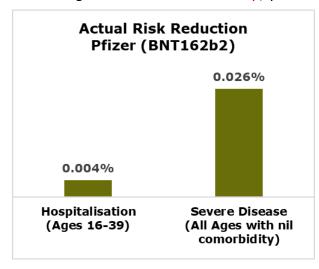
To understand the actual reduction in risk afforded by these novel vaccines and gene therapies, the reader needs to be aware of a mathematical trick perpetrated by medical bureaucrats, for-profit researchers, and mathematically illiterate media.

Grand sounding results such as **95% efficacy** are of little value if the **95%** is of a **small** nearly insignificant number.

For example, **80%** of **five** cents is still **only** four cents. The more informative figure is the **Actual Reduction** (i.e. four cents) not the grand sounding **80%**. Presenting and quoting **only** the **80%** is **deceptive** and **misleading**.

So assuming the current formulation of the Pfizer (BNT162b2) gene therapy is still effective, nine months after its design for a variant that is no longer in circulation, what is the Actual Reduction in Risk (ARR) that children and adolescents can expect by being injected with Pfizer (BNT162b2) against the more 'serious' consequences of COVID-19? Refer Appendix 4 for Actual Risk Reduction calculation methodology.

According to a more robust study, published in the New England Journal of Medicine, the



actual reduction in the **risk** of **hospitalisation** afforded by Pfizer's (BNT162b2) for age group **16-39** was **0.004** percentage points (i.e. **4** in **100,000**).

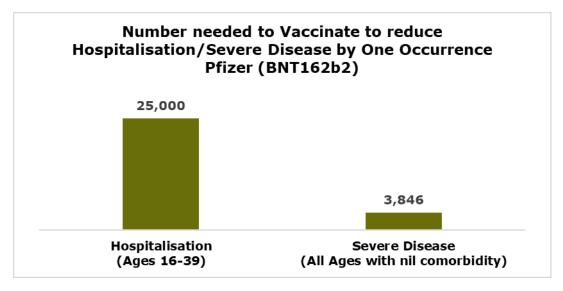
This same study also found that, across **all ages**, for those with **no comorbidities**, the **actual reduction** in the **risk** of **severe disease** afforded by Pfizer's (BNT162b2) gene therapy was **0.026** percentage points (i.e. **2.6** in **10,000**).

This <u>study</u> was more robust, than that relied upon by ATGAI, as it **matched** the vaccinated group against the placebo group by **age** and **underlying health status**.

This is crucial as children and adolescents nearly always have far fewer underlying health conditions and co-morbidities compared to older age groups. Parents, educators, and guardians should be wary and question any COVID-19 statistics and data for children and adolescents that do not explicitly take this factor into account.

Pfizer (BNT162b2) Gene Therapy - Number Needed to Vaccinate (NNV)

Based on these Actual Risk Reductions, the number of people that need to be vaccinated to prevent one incident of hospitalisation and/or severe disease can be calculated. These are shown in the chart below, and refer methodology in Appendix 4.



In other words, to prevent one hospitalisation in persons aged 16 to 39, 25,000 people would need to be vaccinated. And all these 25,000 people would face the certain but unknown medium to long term risk of this novel gene therapy but with no benefit.

Similarly, across all ages to prevent one case of severe disease in persons with no comorbidities 3,846 persons would need to be vaccinated. And all these 3,846 people would face the certain but unknown medium to long term risk of this novel gene therapy but with no benefit.

Part B - COVID-19 Vaccination Risks. A Focus on Youngsters

<u>Introduction - Adverse Event Reporting Systems</u>

The risks of COVID-19 vaccination for children and adolescents can be basically categorised into (a) current and (b) medium to long term.

Current risks are the adverse events that come to light 'fairly soon' (typically around 120 days after injection). It should be noted that 'current' does **not** imply that the observed adverse events are transient. As we will see later in this paper, a certain proportion of 'current' adverse events are permanent and on-going.

Adverse events and vaccine reactions are typically captured through national and multinational Adverse Reporting structures such as:

- USA <u>Vaccine Adverse Event Reporting System (VAERS)</u>
- UK Coronavirus Yellow Card
- World Health Organisation <u>VigiBase</u>
- European Union <u>EudraVigilance</u>
- Australia <u>Database of Adverse Event Notifications for Medicines (DAEN)</u>

While none of these systems is perfect and/or complete, based on the author's experience, VAERS appears to be the most robust, transparent, and accessible. As such we will be relying on its data in this report. The learnings are largely universal between countries with similar socio-economic and health levels and structures.

There are three key issues up for debate when interpreting the data from these adverse event reporting systems:

- 1. Under Reporting. It is well known and publicised that adverse events are significantly under-reported. On its website the Therapeutic Goods Administration (TGA) of Australia states "adverse event reports from consumers and health professionals to the TGA are voluntary, so there is under-reporting by these groups of adverse events related to therapeutic goods in Australia. This is the same around the world" (refer Appendix 5 and source).
- 2. Causality. Every adverse event database listed above goes to great length to minimise causality between the reported adverse event and the device/medicine/drug/vaccine against which it is reported. According to the <u>TGA</u> "although the medicine or vaccine searched for is suspected of causing the adverse events reported, the link between the medicine and the adverse event is unlikely to be certain".

Disingenuously, this level of due diligence and rigour was never applied to proof-ofcausality in the case of COVID-19 deaths. In fact the Australian Bureau of Statistics (<u>ABS</u>) and the World Health Organisation (<u>WHO</u>) went to extraordinary lengths to ensure that any death that could in any way be conceivably associated with COVID-19 was attributed and counted as a COVID-19 death; as evidenced by the ABS guidelines below (and refer <u>Appendix 6</u>):

- "The new coronavirus strain (COVID-19) should be recorded on the medical cause of death certificate for ALL decedents where the disease caused, or is assumed to have caused, or contributed to death"
- > "Due to the **public health importance** of COVID-19, the **immediate** recommendation is to record COVID-19 in **Part 1** of the Medical Certificate of Cause of Death".
- The Australian Bureau of Statistics assign codes from the International Classification of Disease 10th Revision to all conditions listed on the Medical Certificate of Cause of Death. In response to the COVID-19 pandemic the WHO has issued emergency code U07.1 COVID-19 to be assigned to all mentions of COVID-19 on the death certificate".

In this paper we will apply the same level of **proof-of-causality**, as used by the ABS and WHO for COVID-19 deaths, in counting and attributing adverse events reported on VAERS. As such, **all mentions** of COVID-19 products on the adverse event report will be considered an adverse event against that COVID-19 product.

3. **Measurement and Comparison**. Typically the quantum and extent of adverse events is measured as a percentage of the administrations or amount of the medicine/drug/vaccine has been dispensed. This gives a rudimentary measure of risk.

In relation to COVID-19 deaths, this risk-metric approach was never applied by any nation or international body. The only metric ever reported was the purported number of COVID-19 deaths; devoid of any context or explanation or any base line comparison. As such we will be adopting the same approach in reporting the adverse events of COVID-19 gene therapies.

Furthermore, a risk-metric approach may be acceptable where free choice based on informed consent is present. In the absence of free choice and informed consent, **individual** and **personal** risk assessment is **stripped** away. As such only raw numbers are relevant.

We will however, compare adverse events against Pfizer (BNT162b2) vs **all** influenza vaccines; to highlight the early warning safety signal that is being negligently ignored by medical bureaucracy.

Finally, in a forthcoming paper we will explore the early warning signals of the medium to long term risks associated with these novel mRNA technologies; again being negligently ignored by medical bureaucracy.

A Breakdown of COVID-19 Adverse Events (0 to 17 Years)

To evaluate and compare the extent of adverse events associated with the Pfizer (BNT162b2) gene therapy we queried VAERS for **all ages up to 17** in the **six-month** period **April to September 2021** for the number of:

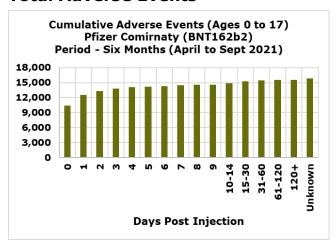
- a. adverse events;
- b. deaths;
- c. life threatening events;
- d. permanent disabilities; and
- e. hospitalisations.

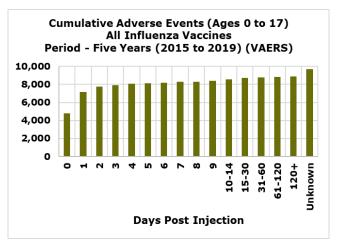
We then ran the same query for **ALL** influenza vaccines but for the **five-year** period 2015 to 2019.

We also queried the database for the recovery status of all reported adverse events (except of course for deaths).

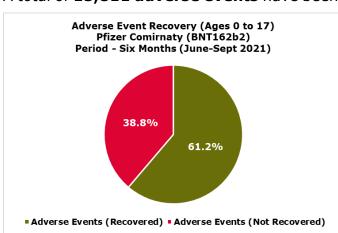
Our findings are detailed below.

Total Adverse Events





A total of 15,811 adverse events have been reported against Pfizer (BNT162b2) gene

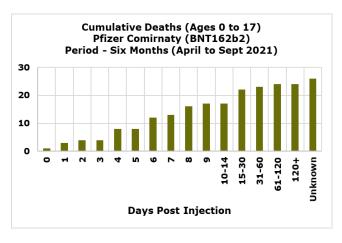


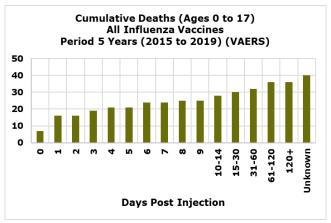
therapy in the **six months** April to Sept 2021, compared to **9,724** against **all** influenza vaccines combined over the **five** years 2015 to 2019.

Just over **90%** of all adverse events against Pfizer Comirnaty (BNT162b2) occurred within the first **seven** days post injection.

In addition, **38.8%** of all adverse events reported against the **Pfizer (BNT162b2)** gene therapy have not recovered. The 'long covid' of covid vaccination.

Deaths

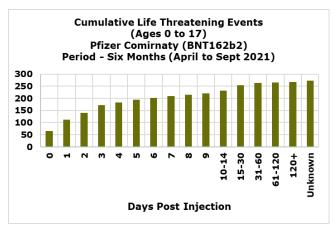


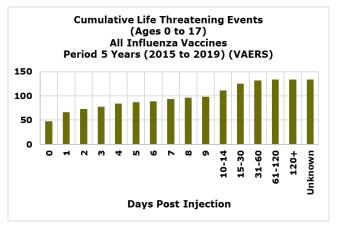


A total of **26 deaths** have been reported against **Pfizer (BNT162b2)** gene therapy in the **six months** April to September 2021, compared to **40** against **all** influenza vaccines combined over the **five** years 2015 to 2019.

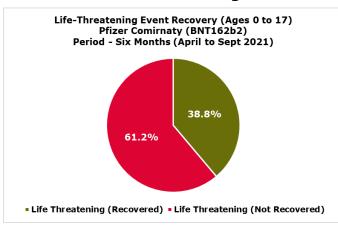
Just under **85%** of all deaths reported against **Pfizer (BNT162b2)** occurred within the first **30** days post injection.

Life Threatening Events





A total of 273 life-threatening events have been reported against Pfizer (BNT162b2)

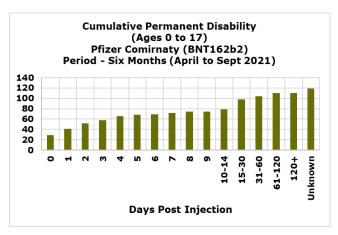


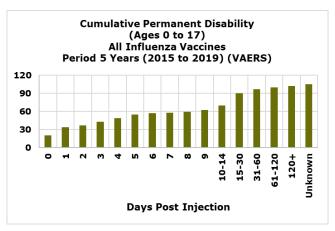
gene therapy in the **six months** April to September 2021, compared to **134** against **all** influenza vaccines combined over the **five** years 2015 to 2019.

Approximately **80%** of all lifethreatening events reported against **Pfizer (BNT162b2)** occurred within the first **nine** days post injection.

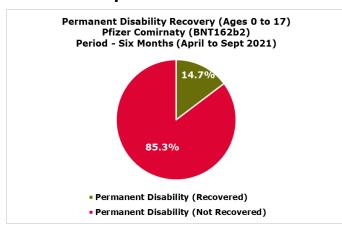
In addition, **61.2%** of all life-threatening events reported against the **Pfizer Comirnaty** (**BNT162b2**) gene therapy have not recovered. The 'long covid' of covid vaccination.

Permanent Disability





A total of 119 permanent disabilities have been reported against Pfizer (BNT162b2)

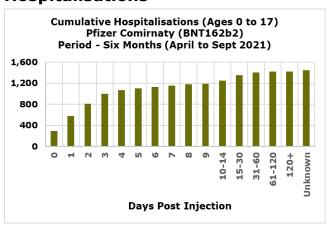


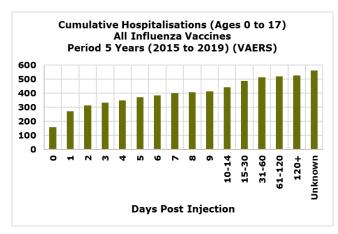
gene therapy in the **six months** April to September 2021, compared to **105** against **all** influenza vaccines over the **five** years 2015 to 2019.

Just over **80%** of all permanent disabilities reported against **Pfizer (BNT162b2)** occur within the first **thirty** days post injection.

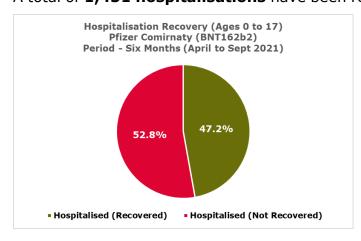
In addition, **85.3%** of all events initially classed as **permanent disabilities** reported against the **Pfizer Comirnaty (BNT162b2)** gene therapy have not recovered. The 'long covid' of covid vaccination.

Hospitalisations





A total of 1,451 hospitalisations have been reported against Pfizer (BNT162b2) gene



therapy in the **six months** April to September 2021, compared to **563** against **all** influenza vaccines over the **five** years 2015 to 2019.

80% of all hospitalisations reported against **Pfizer (BNT162b2)** occur within the first **seven days** post injection.

In addition, just under 53% of all

hospitalisations reported against the **Pfizer (BNT162b2)** gene therapy have not recovered. The 'long covid' of covid vaccination.

Risk Multiple - Pfizer (BNT162b2) vs ALL Influenza Vaccines

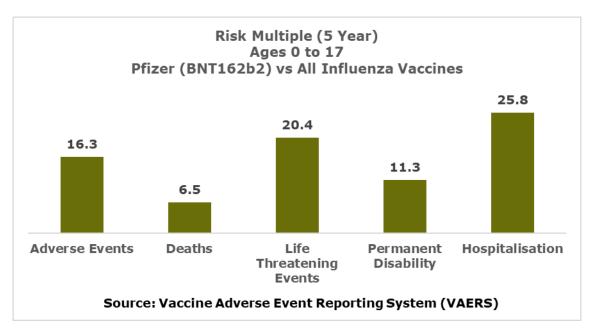
As it appears that COVID-19 booster shots will be required on an annual basis (<u>source</u>), we annualised the number of Pfizer (BNT162b2) adverse events presented above by multiplying by two. For a five-year projection we then multiplied by five.

To obtain a **Risk Multiple** of **Pfizer (BNT162b2)** gene therapy vs **Influenza Vaccines**, we divided the annualised five-year number of adverse events against Pfizer (BNT162b2) by the number of adverse events for **all** influenza vaccines over the five years 2015 to 2019.

We repeated this process for each category of adverse events detailed above.

Note: We acknowledge that this approach makes a number of assumptions and simplifications, which we will refine in a forthcoming paper, however preliminary sensitivity analysis shows that the risk multiples are robust and fit-for-purpose.

The chart below shows the **risk multiple** of Pfizer (BNT162b2) vs **ALL** influenza vaccines combined, by adverse event category.



It's disturbing to see that based on current VAERS reporting rates, Pfizer (BNT162b2) has a **risk multiple** for **deaths 6.5** times higher than **all** influenza vaccines **combined**.

It's disturbing to see that based on current VAERS reporting rates, Pfizer (BNT162b2) has a **risk multiple** for **life-threatening events** just over **20** times higher than **all** influenza vaccines **combined**.

It's disturbing to see that based on current VAERS reporting rates, Pfizer (BNT162b2) has a **risk multiple** for **permanent disabilities** just over **11** times higher than **all** influenza vaccines **combined**.

It's disturbing to see that based on current VAERS reporting rates, Pfizer (BNT162b2) has a **risk multiple** for **hospitalisations** just under **26** times higher than **all** influenza vaccines **combined**.

Finally, it's disturbing to see the comprehensive down-playing and obfuscation by medical regulators and bureaucracies, Australian and international, in relation to this troubling and substantial early warning safety signal against Pfizer (BNT162b2).

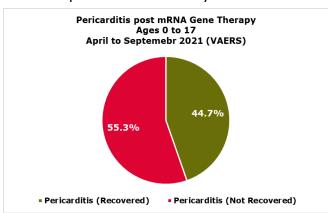
Myocarditis and Pericarditis - Perilous Risks of novel mRNA Technology

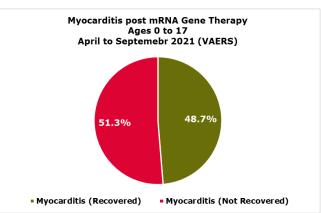
In addition to the many well-publicised <u>side effects</u> of COVID-19 vaccines and gene therapies, two of the most troubling side-effects of injecting children and adolescents with a novel mRNA gene therapy, such as Pfizer's (BNT162b2) and Moderna's (Spikevax), are 'myocarditis' (inflammation of the heart muscle) and 'pericarditis' (inflammation of the tissue sac around the heart).

There is a misconception created and propagated by ATAGI that "most reported cases have been mild, self-limiting and have recovered quickly" (refer <u>Appendix 7</u> and <u>source</u>).

This is sadly false and not supported by USA (VAERS) data; which is infinitely more transparent and robust compared to the soundbites issued by ATAGI.

For the six months April to September 2021 the following charts show that **over 50%** of cases of pericarditis and myocarditis have **not recovered**.





ATAGI continues to "reaffirm that the **benefits** of Pfizer **outweigh** the risks of myocarditis and/or pericarditis for **any** age group and **strongly** recommend eligible individuals without contraindications to be offered vaccination." (refer <u>Appendix 7</u> and <u>source</u>).

This is perhaps one of the most egregiously damaging and ill-informed statements made by any medical authority in my living memory. It is devoid of any objective risk/benefit analysis and any precautionary foresight. Our indictment of ATAGI is based on a recent <u>study</u> published in the Journal of the American Medical Association (Cardiology) which concluded that **the long-term risks of Myocarditis and Pericarditis in children and adolescents after vaccination with Pfizer (BNT162b2) mRNA COVID-19 vaccines were** "<u>entirely unknown</u>".

Part C - Summary and Questioning the Narrative

Summary - What have we Learned

Throughout this paper we have presented verifiable insights and learnings from credible sources. In addition, we have included primary research and analysis using verifiable and credible data; and included all statistical methodologies. All sources have been provided.

A summary of this paper on the COVID-19 vaccination of children and adolescents is:

- Declared Interests. The declared interests of the authors of one of the key articles relied upon by ATAGI to strongly recommend COVID-19 vaccination of children and adolescents as young as 12 were:
 - a. 73% employed by Pfizer/BioNTech;
 - b. 62% had stock and/or options in Pfizer/BioNTech; and
 - c. **two** were the husband/wife **owners** and **CEOs** of BioNTech, the **patent owners** of the **novel mRNA technology** used in these gene therapies.
- Symptomatic COVID-19. While this bogeyman slogan is often bandied about by vested medical bureaucrats and ill-informed media, it says nothing about disease severity.

It is typically defined over some arbitrary timeframe as **testing positive for SARS-CoV-2** while exhibiting **one or more** of the **non-specific symptoms** such as fever, cough, shortness of breath, chills, muscle pain, loss of taste or smell, sore throat, diarrhea, and/or vomiting.

The outcomes measures of the large majority of trials related to SARS-CoV-2 and COVID-19 were aimed at minimising this **trivial** objective.

None of the Randomised Control Trials (RCT) that were relied upon by the TGA to grant provisional approval for the current crop of COVID-19 vaccines and gene therapies were large enough, long enough, or robust enough to measure outcomes that matter (i.e. reduction in risk of hospitalisation, severe disease, and/or death).

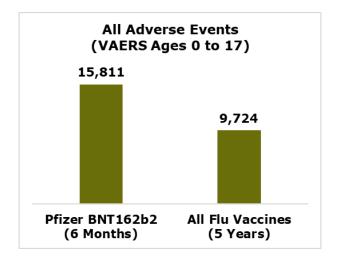
3. COVID-19 Impacts on Children and Adolescents. There are a small number of COVID-19 effects on children and adolescents. These effects are often difficult to identify, quantify, and rigorously evaluate. And nearly always underlying medical conditions and comorbidities precipitate, confound, and exacerbate these effects.

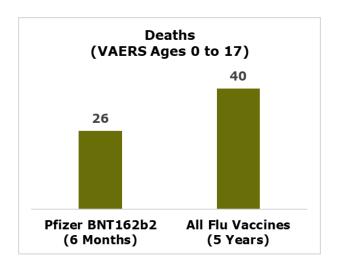
For the **vast majority** of **healthy children** and **adolescents** SARS-CoV-2 and COVID-19 pose **no** threat.

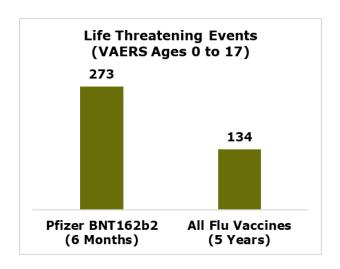
In fact, the **COVID-19 survival rate** for children and adolescents (ages 0 to 19) is **99.995%**, and in the UK the death rate of influenza and other respiratory diseases is **3.5** times **higher** than that of COVID-19.

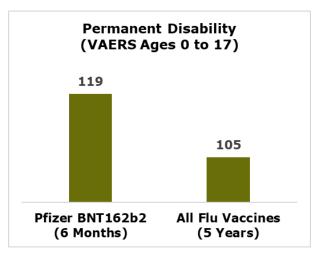
- 4. Pfizer (BNT162b2) Gene Therapy Actual Risk Reduction.
 - a. Hospitalisation. The actual reduction in the risk of hospitalisation afforded by Pfizer's (BNT162b2) for age group 16-39 is 0.004 percentage points (i.e. 4 in 100,000).
 - b. **Severe Disease**. Across **all ages**, for those with **no** comorbidities, the **actual reduction** in the **risk** of **severe disease** afforded by Pfizer's (BNT162b2) gene therapy is **0.026** percentage points (i.e. **2.6** in **10,000**).
- 5. Pfizer (BNT162b2) Gene Therapy Number Needed to Vaccinate
 - a. Hospitalisation. To prevent one hospitalisation in people aged 16 to 39,
 25,000 persons would need to be vaccinated. And all these 25,000 people would face all the risks of this novel gene therapy but with no benefit.
 - b. Severe Disease. Across all ages to prevent one case of severe disease in people with no co-morbidities 3,846 persons would need to be vaccinated. And all these 3,846 people would face all the risks of this novel gene therapy but with no benefit.
- 6. **The Quantum of Adverse Events against Pfizer (BNT162b2)**. There can be no doubt that there is an early warning safety signal associated with this novel gene therapy.

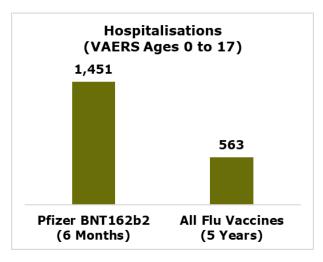
The following charts compare several categories of adverse events for ages 0 to 17 on VAERS for (a) Pfizer (BNT162b2) during April to September 2021 and (b) **all** influenza vaccines over the five years 2015 to 2019.



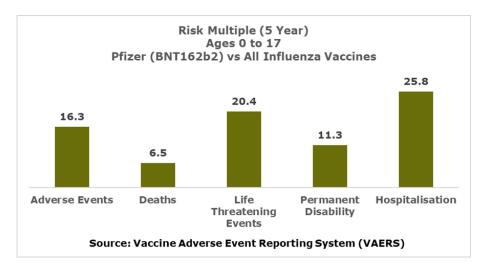








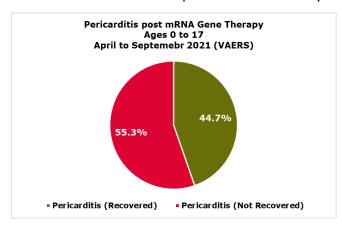
7. Risk Multiple – Pfizer (BNT162b2) vs ALL Influenza Vaccines. To obtain a pragmatic and fit-for-purpose risk multiple, we divided the annualised five-year number of adverse events against Pfizer (BNT162b2) gene therapy by the combined number of all influenza vaccine adverse events over the five years 2015 to 2019. The chart below summarises this risk multiple.

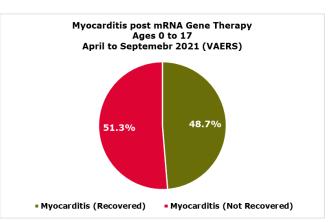


8. Myocarditis and Pericarditis - Perilous Risks of novel mRNA Technology.

There is a misconception created and propagated by ATAGI that "most reported cases have been mild, self-limiting and have recovered quickly." This is sadly false and not supported by USA (VAERS) data; which is more transparent and robust compared to the soundbites issued by ATAGI.

For the six months April to September 2021 the following charts show that over 50% of cases of pericarditis and myocarditis have not recovered.





Finally, a <u>study</u> published in the Journal of the American Medical Association (Cardiology) concluded that **the long-term risks of Myocarditis and Pericarditis in children and adolescents after vaccination with Pfizer**(BNT162b2) mRNA COVID-19 vaccines were "<u>entirely unknown</u>".

Vaccinating Children and Adolescents - ATAGI's Intergenerational Theft

According to ATAGI (source) ...

"Vaccinating adolescents is **anticipated** to **contribute** to a reduction in SARS-CoV-2 transmission in the broader population".

and

"While there is some **uncertainty** regarding the relative **contribution** by **adolescents** to the transmission of SARS-CoV-2 in the wider community, studies published in 2020 exploring SARS-CoV-2 spread within family clusters have reported children as index cases in about **4%** of households".

And given that in the context of **children** and **adolescents**, we can definitively conclude that:

- 1. The **survival** rate of COVID-19 is **99.995%** (<u>source</u>);
- Childhood mortality in England during the first year of the SARS-CoV-2
 pandemic was the lowest on record (<u>source</u>);
- Nearly all deaths in this age group are sadly associated with underlying conditions and co-morbidities (source);

- 4. The average flu season in the UK is approximately **3.5** times more lethal than COVID-19 (source);
- 5. In the six months April to September 2021, **38.8%** of all adverse events reported against the **Pfizer (BNT162b2)** gene therapy have not recovered (<u>source</u>);
- 6. There is a significant early warning safety signal emerging for Pfizer (BNT162b2) gene therapy (<u>source</u>); and
- 7. The long-term risks of these vaccines (esp. for myocarditis and pericarditis) are "entirely unknown" (source);

It is impossible to reconcile how ATAGI can <u>conclude</u> that "vaccination against COVID-19 is recommended for all individuals from 12 years of age".

It is clear that, for children and adolescents, COVID-19 poses a near insignificant threat.

It is also clear that the COVID-19 vaccines and gene therapies pose a quantum increase in risks; many of which with entirely unknown future impacts.

Finally, it is also clear that the primary and over-whelming reason that ATAGI is recommending the vaccination of children and adolescent is the *anticipation* that this will *contribute* an *uncertain* degree of reduction in SARS-CoV-2 transmission in the broader population.

This trading of the future health of children and adolescents for the anticipated benefit of current adults can only be characterised as intergenerational theft.

And history will condemn those who **formulated**, **perpetrated**, **enacted**, **condoned**, **coerced**, **cheered**, and **stood silent** while the health of our youngest was **gambled** for a beer on a Friday afternoon.

Appendix 1. ATAGI Recommendations COVID-19 Vaccination

https://www.health.gov.au/news/atagi-recommendations-on-the-use-of-covid-19-vaccines-in-all-young-adolescents-in-australia

Summary of ATAGI recommendations

- Vaccination against COVID-19 is recommended for all individuals from 12 years of age, extending the current recommendation for those aged 16 years and older.
- A two-dose schedule using Comirnaty (Pfizer) or Spikevax (Moderna) is recommended.

Introduction

The Australian Technical Advisory Group on Immunisation (ATAGI) previously recommended vaccination using Comirnaty (Pfizer) for adolescents from 12 years of age that belong to the following groups¹:

- Individuals with specified medical conditions that increase their risk of severe COVID-19, including NDIS participants
- Aboriginal and Torres Strait Islander individuals
- Those in remote communities, as part of broader community outreach vaccination programs.

The Therapeutic Goods Administration (TGA) provisional registration of Pfizer was extended on 23 July to include all people from 12 years of age and above in a two-dose schedule, and on 4 September Moderna was provisionally registered for use in 12 to 17 year old adolescents.

ATAGI has developed these current recommendations for all individuals aged 12 years and above by carefully considering the relevant benefits, risks, uncertainties and evidence on the following:

- Safety, efficacy and effectiveness of COVID-19 vaccines in adolescents from clinical trials and overseas vaccination programs
- Epidemiology of COVID-19 in adolescents including disease severity and complications, and their role in transmission in the population
- Safety of COVID-19 vaccines, including risk of myocarditis and pericarditis after receiving mRNA vaccines in adolescents and young adults reported overseas

Appendix 2. Declared Interests of Vaccination Proponents

Declared Interests of the authors of <u>Safety</u>, <u>Immunogenicity</u>, <u>and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents</u>. It is left to the reader to decide whether these 'declared interests' are 'conflicts of interest'. We have no opinion on this matter.

#	Author	Employment	Consultatnt	Stock	Grant	Patent
1	Alejandra Gurtman	Х				
2	David Cooper	X		X		
3	Dina B. Tresnan	x		X		
4	Donald M. Brandon					
5	Emmanuel B. Walter				X	
6	Hua Ma	X		X		
7	John L. Perez	X				
8	Judith Absalon	X		X		
9	Kathrin U. Jansen	X		X		
10	Kena A. Swanson	X		X		
11	Kenneth Koury	X		X		
12	Nicholas Kitchin	X		X		
13	Nicola P. Klein				X	
14	Özlem Türeci	X		X		X
15	Philip R. Dormitzer	X		X		
16	Robert W. Frenck				X	
17	Ruth Bailey	X		X		
18	Shelly Senders					
19	Stephen J. Thomas		x			
20	Stephen Lockhart	x		X		
21	Susan Mather	X		X		
22	Timothy Jennings					
23	Uğur Şahin	X		X		X
24	Warren V. Kalina	X		X		
25	William C. Gruber	x		X		
26	Xia Xu	X				
		19	1	16	3	2

Appendix 3. ATAGI Vaccine Claims

https://www.health.gov.au/news/atagi-recommendations-on-the-use-of-covid-19-vaccines-in-all-young-adolescents-in-australia

Direct benefits against COVID-19 in children

Vaccine efficacy, immunogenicity and effectiveness: There is high level evidence indicating strong immunogenicity and vaccine efficacy against symptomatic COVID-19 in adolescents from clinical trials of Pfizer and Moderna. In results of an ongoing phase III Comirnaty trial with over 2,000 participants aged 12-15 years, vaccine efficacy against symptomatic COVID-19 from 7 days after dose two was 100% (95% CI 78.1-100%) with no cases reported in the vaccine arm.² After dose one and before dose two, there were 3 COVID-19 cases (within 11 days after dose one) among Pfizer recipients compared with 12 cases in the placebo group resulting in vaccine efficacy of 75% (95% CI, 7.6 to 95.5%). Neutralising antibody titres post dose two were 1.8-fold higher in the 12–15 years age group compared to 16–25 years age group.

Appendix 4. Methodology - ARR and NNV

In the <u>study</u> "BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting", the researchers monitored 1.2M participants over a period of 43 days from 20 Dec 2020 to 01 Feb 2021.

These 1.2M participants were distributed between two groups; vaccinated and control/placebo. In addition they were identically matched between the two groups; i.e. equivalent medical characteristics between those in the vaccinated group vs. those in the placebo group.

The trial monitored and reported gene therapy performance by age, by sex (male/female), and by various risk-factors. It also reported results on five outcomes. The outcomes of most relevance to children and adolescents were (a) protection against hospitalisation for age group 16 to 39, and (b) protection against severe disease for all ages for people with no comorbidities.

The following table presents Pfizer (BNT162b2) gene therapy reported performance for these two outcomes, where:

Actual Risk Reduction = Risk (Control/Placebo) - Risk (Vaccinated)

Actual Risk Redu	iction - Hospi	italisation Ag	es 16 to 39	
Group	No. of Participants (16 to 39)	Hospitalised (Yes)	Hospitalised (No)	Risk (Hospitalised/P articipants)
Vaccinated	213,000	3	212,997	0.000014
Control/Placebo	213,000	12	212,988	0.000054
Risk Difference (number) = 0.000054 - 0.000014	0.00004			
Risk Difference (percentage points)	0.004%			
Number Needed to Vaccinate = 1/Risk Difference	25,000			

Actual Risk Reduction - Severe Disease All Ages No Comorbidities						
	No. of Participants	Severe Disease (Yes)	Severe Disease (No)	Risk (Disease/Partic ipants)		
Vaccine	338,384	13	338,371	0.000039		
Placebo	338,384	101	338,283	0.000299		
Risk Difference (number) = 0.000299 - 0.000039	0.00026					
Risk Difference (percentage points)	0.026%					
Number Needed to Vaccinate = 1/Risk Difference	3,846					

Appendix 5. TGA Adverse Events Under Reporting

https://www.tga.gov.au/about-daen-medicines in the medicine or vaccine. Safety information • For prescription medicines assessed by the TGA since the end of 2009, information about the benefit-risk profiles is Report a problem or side effect often available in the Australian Public Assessment Reports (AusPARs). Alerts About the data • The Database does not include information about the benefits of the medicine or vaccine, so the search results Prescription opioids cannot be used to determine if the benefits of taking the medicine or vaccine outweigh the risks. • The Database does not include information about medicines including vaccines accessed via the Special Access Medicine shortages Scheme, Authorised Prescriber scheme, clinical trial notification scheme or clinical trial exemption scheme; except Early warning system where the adverse event report also includes a suspected general marketed medicine or vaccine. • The Database does contain reports involving medicines or products advertised as a medicine or vaccine that are not > Black Triangle Scheme on the Australian Register of Therapeutic Goods (ARTG). • The information in the Database does not include all known side effects. Additional information about side effects is in the Consumer Medicines Information and the Product Information available on the TGA website Medicines safety • The search results do not include information from the last 14 days. This is to allow TGA time to review the new reports submitted and code the information. • The information in the database is based on the information provided by the reporter. Database of Adverse Event • The report entry date does not necessarily reflect the date of the adverse event. Notifications (DAEN) • The data does not include any personal information within the meaning of the *Privacy Act 1988*. COVID-19 • Each adverse event report is <u>coded</u> when it is entered into the database, and this process is subject to the limitations of the coding terminology being used. > COVID-19 treatments • When follow-up reports of a single case are received, the case details may be updated. This means that the search > COVID-19 vaccines results can change over time. • Despite regular checking, it is possible that the database contains some duplicate reports, as a single case can be reported by multiple sources, and this is not always easy to identify. Reporting levels The number of reports received is influenced by various factors including: o the market share of the medicine or vaccine o the length of time the medicine or vaccine has been on the market $\circ\,$ publicity about a possible link between an adverse event and a medicine or vaccine regulatory actions. · Adverse event reports from consumers and health professionals to the TGA are voluntary, so there is under-reporting by these groups of adverse events related to therapeutic goods in Australia. This is the same around the world. • It is mandatory under the Therapeutic Goods Act 1989 for sponsors to report to the TGA all serious adverse events suspected of being related to their medicines including vaccines. As a result, the search results in the DAEN may reflect a higher ratio of serious to non-serious adverse event reports.

Category: Medicines safety
Tags: reporting problems
URL: https://www.tga.gov.au/node/4588

Appendix 6. Guidance for Certifying Deaths due to COVID-19 (ABS)



Australian Bureau of Statistics



1205.0.55.001 - Information Paper: Cause of Death Certification Australia, 2008

ARCHIVED ISSUE Released at 11:30 AM (CANBERRA TIME) 25/11/2008

This document was added or updated on 25/03/2020.

Guidance for Certifying Deaths due to COVID-19

This guide published by the Australian Bureau of Statistics is intended to provide some immediate guidance on how the new coronavirus disease strain, i.e. COVID-19, should be recorded on the Medical Certificate of Cause of Death. Examples are included in section 5 of this document.

1. Recording covid-19 on the death certificate

The new coronavirus strain (COVID-19) should be recorded on the medical cause of death certificate for ALL decedents where the disease caused, or is assumed to have caused, or contributed to death.

2. Terminology

The use of World Health Organization terminology **COVID-19** or **Coronavirus Disease 2019** should be certified on the death certificate. Terminology such as SARS-CoV-2 can be used but it must be clear that it is the 2019 strain of disease. WHO terminology is preferred.

The term "coronavirus" should not be used in place of COVID-19 or Coronavirus Disease 2019. This will introduce uncertainty for coding cause of death which may lead to under reporting in national statistics.

3. Chain of events

Due to the public health importance of COVID-19, the immediate recommendation is to record COVID-19 in Part I of the Medical Certificate of Cause of Death. Specification of the causal pathway leading to death in Part I of the certificate is important and all conditions and symptoms should be included. For example, in cases when COVID-19 causes pneumonia and fatal respiratory distress, both pneumonia and respiratory distress should be included along with COVID-19 in Part I alongside the duration of each disease and symptom. Certifiers should include as much detail as possible based on their knowledge of the case, medical records, laboratory testing, etc.

4. Co-morbidities

Existing conditions, especially those which are chronic in nature, that may have also contributed to death should be certified in Part II of the Medical Certificate of Cause of Death. Chronic conditions may include but are not limited to: coronary artery disease, COPD, diabetes, cancer or disabilities.

5. Example medical certificate of cause of death cases5.1 Example of train of events in part I of medical certificate of cause of death

Medical Data: Part 1 and 2			
Disease or condition leading	1		Interval between onset and Death
directly to death. Antecedent Causes that gave rise to the	Α	Acute respiratory distress syndrome	2 days
above cause,	В	Pneumonia	10 days
stating the underlying cause on	С	COVID-19	10 days
the lowest line.	D		

Other significant	2
conditions	
contributing to	
death but not	
related to the	
diseases or	
conditions causing	
it.	

5.2 Example of chronic conditions in part II of medical certificate of cause of death

Medical Data: Part	1	and 2	
Disease or condition leading	1	Cause of Death	Interval between onset and Death
directly to death. Antecedent Causes that gave rise to the		Acute respiratory distress syndrome	2 days
above cause,	В	Pneumonia	10 days
stating the underlying cause on		COVID-19	10 days
the lowest line.	D		
Other significant conditions	2	Coronary artery disease, Type 2	Diabetes, COPD
contributing to death but not related to the			
diseases or			
conditions causing it.			

5.3 Example of other specified immunocompromised conditions in part II of medical certificate of cause of death

Medical Data: Part	t 1	and 2	
Disease or	1	Cause of Death	Interval between
condition leading			onset and Death
directly to death.	Α	Acute respiratory distress	2 days
Antecedent Causes		syndrome	2 ddy3
that gave rise to the		Synar Sinc	
above cause,		Pneumonia	10 days
stating the underlying cause on		COVID-19	10 days
the lowest line.	D		
Other significant conditions	2	Diffuse large B cell lymphoma, Ir	nmunosuppressant
contributing to		therapy	
death but not			
related to the			
diseases or			
conditions causing			
it.			

5.4 Example of disability in part II of medical certificate of cause of death

Medical Data: Par	t 1	and 2	
condition leading	1	Cause of Death	Interval between onset and Death
directly to death. Antecedent Causes that gave rise to the		Acute respiratory distress syndrome	2 days
above cause,	D	Pneumonia	10 days
stating the underlying cause on	C	COVID-19	10 days
the lowest line.	D		

Other significant	2	Cerebral palsy
conditions		
contributing to		
death but not		
related to the		
diseases or		
conditions causing		
it.		

6. Coding of deaths due to covid-19

The Australian Bureau of Statistics assign codes from the International Classification of Disease 10th Revision to all conditions listed on the Medical Certificate of Cause of Death. In response to the COVID-19 pandemic, the WHO has issued emergency code **U07.1 COVID-19** to be assigned to all mentions of COVID-19 on the death certificate.

Due to the public health importance of COVID-19, the WHO have directed that the new coronavirus strain be recorded as the underlying cause of death, i.e., the disease or condition that initiated the train of morbid events, when it is recorded as having caused or contributed to death.

Following the guidelines above will assist in the accurate coding of these deaths and the production of robust national mortality statistics.

This page last updated 24 March 2020

Appendix 7. ATAGI Statement on Pericarditis and Myocarditis

https://www.health.gov.au/news/atagi-update-following-weekly-covid-19-meeting-22-september-2021

getting vaccinated with any available vaccine including AstraZeneca.

At this time, there is no update to the <u>ATAGI statement</u> from 17 June 2021 in relation to the use of AstraZeneca, except to note that further clarification has been provided (above) in regards to its use in outbreak settings.

Comirnaty (Pfizer)

Myocarditis and/or Pericarditis

ATAGI continues to review and closely monitor reports of rare but potentially serious adverse events following immunisation with Pfizer, including myocarditis and/or pericarditis. These conditions can occur in the absence of vaccination and are also a recognised complication of COVID-19.

ATAGI notes that the TGA is investigating 660 reports of suspected myocarditis and/or pericarditis following Pfizer. International data demonstrates that the rate of disease is higher in younger individuals, particularly young males and more frequently occurs following the second dose. Most reported cases have been mild, self-limiting and have recovered quickly, although further follow-up of these cases is ongoing. ATAGI noted that a small number of cases were more severe, requiring hospitalisation. More information can be found in the TGA Weekly Report.

Risks and benefits

ATAGI reaffirms that the benefits of Pfizer outweigh the risks of myocarditis and/or pericarditis for any age group and strongly recommend eligible individuals without contraindications to be offered vaccination.

Resources

ATAGI recommends review of the following key resources:

Use of AstraZeneca and/or TTS