# 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>).

On its website, ATAGI then proceeds to disgorge largely useless facts and obfuscation, that do not truly tell you:

- 1. What are the **declared interests** of the **26** authors of this <u>study</u>?
- 2. What is 'symptomatic COVID-19'? What are the real consequences for children and adolescents, of symptomatic COVID-19; how serious are these consequences? And just how self-sufficient are the immune systems of children and adolescents against COVID-19?
- 3. Will vaccinating children and adolescents **reduce** case numbers, **viral spread** and **transmission**? and
- 4. In the real world how successful have these gene therapies been in containing SARS-CoV-2? Will they ever be successful?
- 5. What are the true outcomes of the trials of these gene therapies? Were they ever designed to measure meaningful outcomes and long-term safety?
- 6. What are the real-world adverse events of these gene therapies? Is there a true causal link between these gene therapies and the reported adverse events?
- 7. Overall, should are these gene therapies doing more good than harm? Or is it actually the way around?

In this paper we'll explore these seven 'untolds' and question the risk/benefit conclusion of ATAGI, to recommend vaccination of children from as young as five.

We write this paper because no **ethical** society should, **without** a rigorous debate **compromise** the health of the young in the **futile hope** of protecting the not so young.

Yet the TGA, ATAGI, and every Australian medical bureaucrat and regulator is doing just that; and **without** discussion, debate, or a **credible risk/benefit analysis**.

# **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 was largely written (and funded) by Pfizer and BioNTech **employees**, **stock holders**, **patent owners**, and **company owners**.

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 <u>article</u> 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 <u>Appendix 2</u> and <u>here</u> in the New England Journal of Medicine.

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

It is inconceivable, unconscionable, and immoral that ATAGI would fill its website with largely useless and irrelevant information and obfuscation yet not prominently display these declared interests; upon which its 'independent' advice to parents and guardians is based.

# Part A - Summary of the Negligence of ATAGI and the TGA

### **Futility of Vaccinating Children and Adolescents**

In making its recommendation to vaccinate children as young as five (<u>source</u>) ATAGI (the Australian Technical Advisory Group on Immunisation) and the TGA (Therapeutic Goods Administration) have continually propagated fear by using the expression 'protection against symptomatic COVID-19'.

Yet 'symptomatic COVID-19' is **nothing more** than **testing positive** to SARS-CoV-2 while **exhibiting** one or more of the **non-specific symptoms** of fever, cough, shortness of breath, loss of taste and/or smell, sore throat, vomiting, and/or diarrhoea.

So the expression 'protection against symptomatic COVID-19', says nothing about

- a. the progression of these **non-specific** symptoms to anything **more** serious
- b. the vaccine's protection against infection and/or transmission
- c. the vaccine's **protection** against **severe disease** or **death**; and/or
- d. COVID-19 prognosis and recovery without vaccination.

In addition, statements by ATAGI such as

"strong evidence of immunogenicity and vaccine efficacy against symptomatic COVID-19 in adolescents" (source) and

"The paediatric Pfizer COVID-19 vaccine has been demonstrated to reduce COVID-19 in children 5-11 years of age" (source)

are **medically perverse** because children and adolescents are **inherently** and **significantly** immune to COVID-19; **without** COVID-19 vaccination.

It is profession misconduct to recommend and prescribe a treatment without therapeutic basis (source).

And for the adult population "strong evidence of immunogenicity and vaccine efficacy against symptomatic COVID-19" does not necessarily mean that those who would have **actually** needed help fighting COVID-19, will be **substantially** protected against the **more** serious outcomes of COVID-19.

From an **early** stage in the supposed pandemic, and well **before** the vaccination strategy was developed and deployed, it was **very** well known that that **underlying health** and **age** were the best **predictors** of COVID-19 disease **severity** and **mortality**.

So, while there are a very 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 **precipitate**, **confound**, and **exacerbate** these effects.

But we do know a number of irrefutable facts for children and adolescents:

- 1. The COVID-19 case survival rate is 99.9960%;
- 2. The **vast majority**, if not **all**, of COVID-19 deaths and hospitalisations are associated with **comorbidities** and **adverse underlying** medical conditions; and
- 3. The mortality of influenza and other respiratory diseases is **2.8 times higher** than that of COVID-19.

In summary, COVID-19 is almost always benign and absent in children and adolescents.

In addition, children and adolescents are largely **self-sufficient** against COVID-19.

Their viral load is much smaller as they have **smaller** lungs and **fewer** receptors for the SARS-CoV-2 virus to latch onto. In addition, they typically clear the virus at a faster rate than adults. Combined, these significantly lower the number of virus particles and viral load within the child and adolescent cohort.

Children and adolescents also have **efficient** and **effective** innate and adaptive immune systems. They are better equipped to deal with novel viruses.

SARS-CoV-2 infection is generally mild or asymptomatic in children. Their antibody responses against spike protein are high, their spike-specific T cell responses are more than twice as high as elderly adults, they retain antibody and cellular responses for more than six months after infection.

Without vaccination, children and adolescents generate robust, cross-reactive and sustained immune responses to SARS-CoV-2 with focused specificity for the spike protein.

Finally, children and adolescents previously exposed to the other very common human coronaviruses, will have levels of protective cross-immunity against SARS-CoV-2.

So to protect children and adolescents against a **benign almost absent** disease for which they are supremely **self-protective**, ATAGI and the TGA are recommending a **novel** gene therapy that against the **Delta** variant has a **marginal** Absolute Risk Reduction of:

- 0.004% against hospitalisation,
- 0.026% against severe disease, and
- 0.006% against death.

And against the **Omicron** variant is essentially **ineffective**.

And to justify this **medical perversion**, of administering a **marginal** medication to a cohort that does **not** require it, ATAGI and the TGA claim that the vaccination of children and adolescents will contribute to a reduction in SARS-CoV-2 transmission in the broader population.

Nothing could be further from the truth!

For England from March 2020 to December 2021, an analysis of vaccination levels and cases, by age group, showed that **irrespective of vaccination level** the current crop of gene therapies do **not** control SARS-CoV-2 infection and transmission.

In fact over the 12 months of **2021**, vaccination levels have gone from **zero** to **dose 1 91%**, **dose 2 83%**, and **dose 3 62%**; yet cases have exploded by **186%**.

And, it would be disingenuous of government and medical 'experts' to blame the cavalcade of SARS-CoV-2 variants for this explosive rise in case numbers.

From the outset, it was known that SARS-CoV-2 is an RNA virus and RNA viruses have relatively high mutation rates. And these mutations will occur irrespective of the vaccination status of an individual and irrespective of the vaccination level across a community.

None of this is novel. The only 'novel' thing was to attempt to suppress a rapidly and highly-mutating RNA virus with a vaccination strategy!

In fact the data emanating out of highly vaccinated countries such as Australia, the UK, and Israel prove that these vaccines and gene therapies have **not** reduced the **force of infection** (i.e. the number of infectious persons combined with the inherent infectiousness of the virus itself).

Finally, SARS-CoV-2 has a large and effective animal reservoir. It is capable of jumping from animal to human and back again. The latest research shows that Omicron variant likely jumped from mice to humans.

So, as long as SARS-CoV-2 has a successful reservoir in animals and is capable of jumping back and forth from animals to humans, vaccine-induced herd protection can never be achieved.

As such mass indiscriminate vaccination of children, adolescents, and adults is entirely futile.

In addition to the failure of these novel gene therapies to **contain infection** and **transmission**, across **any** age group, children and adolescents are **not** the significant drivers of transmission.

Several studies have shown that **susceptibility** to **infection** in individuals **under 20** years of age is approximately **half** that of adults aged **over 20** years. And of those **10 to 19** who do become infected only **21%** develop clinical symptoms.

And, as for **all** influenza and coronaviruses, and contrary to pronouncements by medical bureaucrats and media commentators, it is **symptomatic** individuals that are the **significant drivers** of transmission.

In addition to being less prone to infection, children and adolescents are less capable of transmission.

A large meta-analysis found that the Secondary Attack Rate for a child under 18 as the index case is 42% lower than when the index case is a person over 18.

In summary, for ATAGI to claim that vaccinating children and adolescents will contribute to a reduction in cases across the community is simply not supported by any credible unbiased real-world evidence. It is an entirely false assertion.

### ATAGI's and TGA's Negligence and Culpability

It is self-evident that any trial of a radically new treatment must measure outcomes (i.e. end-points) that are of meaning to its intended users.

And where this is not practical, then a robust scientific and ethical approach would be to measure a combination of key outcomes; together with several early warning biomarkers.

The Pfizer Randomised Control Trial (RCT) of gene therapy BNT162b2, and subsequent trials focused on children, measured a **single primary** outcome 'symptomatic COVID-19'.

As explained above, as far as children and adolescents are concerned, 'symptomatic COVID-19' is largely benign almost absent. As such, for children and adolescents this endpoint can only be described as **trivial** and **clinically meaningless**.

And yet it was based on this clinically meaningless outcome that the TGA gave provisional approval for Pfizer (BNT162b2) for

"active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older" and "for use in individuals 5 years and older"

And against this **trivial** and **clinically meaningless end-point**, between the group injected with the novel gene therapy and the placebo group, at the end of the trial there was:

- a 119% increase in adverse events of low-to-moderate seriousness;
- a 14% increase in adverse events of very high seriousness, and
- a 23% increase in adverse events of high seriousness.

And at the six month follow up to the RCT, between the injected and placebo groups, there was:

- a 117% increase in adverse events of low-to-moderate seriousness;
- a 75% increase in severe adverse events;
- a 9% increase in serious adverse events;
- 18% increase in adverse events that lead to a participant withdrawing from the vaccination group; and
- a 43% increase in deaths.

So given that the primary outcome measured by the Pfizer BNT162b2 gene therapy RCT, and subsequent trials, was essentially trivial and meaningless, compounded by significant increases across all adverse event categories, how many children and adolescents must be injected with this novel gene therapy to prevent **one** incidence of a serious COVID-19 outcome?

Based on a large Israeli **matched study** (i.e. control and placebo groups had similar age and health demographics), and against the Delta variant, the number of people that must be injected to prevent:

- a. One hospitalisation in persons aged 16 to 39, is 25,000;
- b. One case of severe disease across all ages in persons with no co-morbidities is
   3,846; and
- c. One **death** across all ages is **16,667**.

And for the one person who:

- a. Is not hospitalised, the remaining **25,000 will** face the **certain** but **unknown** medium to long term risk of this **novel** gene therapy but with **no** benefit;
- b. Does not contract severe disease, the remaining 3,846 will face the certain but unknown medium to long term risk of this novel gene therapy but with no benefit;
- c. Does not die, the remaining **16,667** will face the **certain** but **unknown** medium to long term risk of this **novel** gene therapy but with **no** benefit.

By way of comparison to prevent once hospitalization the NNV for

- human papilloma virus (HPV) is between 68 and 141,
- rotavirus (RV) is between 13 and 94, and
- measles mumps rubella is approximately 201

These extraordinarily high NNV values for the Pfizer (BNT162b2) gene therapy, for the more serious outcomes of COVID-19, proves its insignificant real-world effectiveness for outcomes that matter.

Finally, in terms of detecting the early warning signals of disease and/or deaths, all of the randomised control trials (RCT) were extremely deficient in their design and processes.

Disease and death are typically end points of processes that can take months, years, or decades to occur. During this time, many biomarkers tend to exhibit increasing abnormalities that indicate increasing predisposition for disease and/or death.

So a RCT aimed at **proving** the safety of a **radically new** gene therapy would have measured the change in critical biomarkers before, during and after the trial; and not just the very rare adverse events that happen in a relatively short time span.

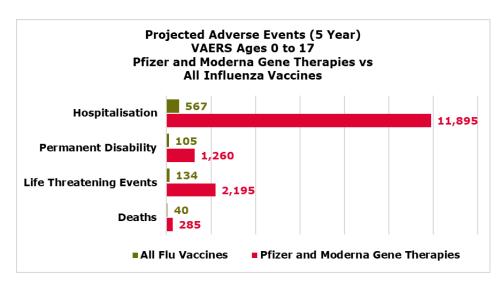
That the TGA approved these radically new gene therapies, never before used on humans, without such comprehensive biomarker analysis can only be described as negligent.

So moving beyond clinical trials what does the real world tell us about the adverse events and deaths attributed to these COVID-19 gene therapies?

To answer this question we relied upon the USA's Vaccine Adverse Event Reporting System (VAERS) as it is more robust, transparent, accessible, and informative than Australia's Database of Adverse Event Notifications for Medicines (DAEN).

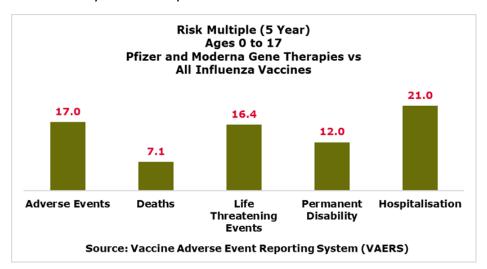
To quantify the extent of adverse events associated with (a) Pfizer (Comirnaty and BNT162b2) and (b) Moderna (SpikeVax), we queried VAERS for ages **0 to 17** for injections given in the **12 months** January to December 2021. Here's what we learnt.

- 1. All Adverse Events. A total of 33,137 adverse events have been reported and 37.6% have not recovered.
- 2. **Deaths**. A total of **57 deaths** have been reported.
- 3. **Life-Threatening Events**. A total of 439 life-threatening events have been reported and **62%** have **not** recovered.
- 4. **Permanent Disability**. A total of **252** permanent disabilities have been reported and **87%** have **not** recovered.
- 5. **Hospitalisations**. A total of **2,379** hospitalisations have been reported and **56%** have **not** recovered.



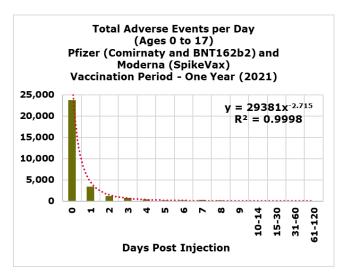
To contextualise the quantum of **Pfizer** and **Moderna** adverse events detailed above, we compared these **one-year** statistics (multiplied by five) to the **five-year** statistics (2015 to 2019) for **all** influenza vaccines.

We then calculated a rudimentary **Five-Year Risk Multiple** by multiplying the Pfizer and Moderna adverse counts by five, and dividing this by the adverse event counts for all influenza vaccines over the five years 2015 to 2019. The chart below gives these rudimentary risk multiples.



While there are assumptions made in calculating these risk multiples, our sensitivity analysis shows that they are more likely to under than over estimated.

The next question is whether these adverse events are actually being caused by the Pfizer and Moderna gene therapies.



The chart to the left shows the **number** of adverse events **per day**, for **each day post injection**.

It shows that the **vast majority** of adverse events occur on the **day** of **injection** and up to **two days** post injection; after which they decline rapidly.

If there was **no** causal link between **vaccination** and **any** of these **adverse** 

**events**, there would **not** be such an **excess of reports** of adverse events on days 0, 1 and 2 post injection. If there was no causal link, the reported events per day would be either similar or random for each day post injection.

The fact that this pattern is **consistent** and **repeated** for **all** adverse event categories (inc. death, life-threatening events, permanent disabilities, hospitalisations, and myocardial and pericardial events) is **irrefutable** proof that the vast majority of these tragic adverse events are **caused** by the injection of children and adolescents with **novel** and **untested** gene therapies.

Two of the most troubling impacts of injecting children and adolescents with a poorly tested and experimental gene therapy are myocardial and pericardial injuries.

As reported by VAERS for ages 0 to 17, a total of **855 myocardial** and **261 pericardial** events have been reported against Pfizer and Moderna gene therapies administered in the **single** year, 2021.

**80%** of all **myocardial** events occurred within the first **four** days post injection, and within the first **nine** days post injection for **pericardial** events.

There is a misconception created and propagated by ATAGI that "most reported cases have been mild, self-limiting and have recovered quickly".

This assertion is **not** supported by VAERS data. This data shows that for the **12 months** January to December 2021, for ages 0 to 17, **56%** of **myocardial** events and **61%** of **pericardial** events have **not** recovered.

Several peer reviewed studies have shown that anywhere between 20% and 50% of people diagnosed with myocarditis/pericarditis continue to have irregular heartbeat, blood clots, compromised ability of the heart to pump blood, and other associated symptoms.

Finally, several peer reviewed studies have concluded that the **long-term** risks of myocarditis and pericarditis, after injection with mRNA gene therapies, are **entirely unknown**.

In the face of these **marginal benefits**, **significant** and **causal adverse events** and **deaths**, **inordinate vaccination levels** to prevent one incidence of a serious COVID-19 outcome, it's hard to see how the risk/benefit analysis of ATAGI and the TGA for the vaccination of children and adolescents can be anything but biased, flawed, and puerile.

In summary for the Pfizer (BNT162b2) gene therapy, balancing the significant increases in adverse events (across all categories of seriousness esp. a **43%** increase in deaths) against the claimed reduction in cases (which for the vast majority of children and adolescents the disease will be benign if not absent), it is unambiguously clear that for the vast majority children and adolescents COVID-19 gene therapies will do more harm than good.

### ATAGI's and TGA's Intergenerational Theft

According to ATAGI ...

"Vaccinating adolescents is **anticipated** to **contribute** to a reduction in SARS-CoV-2 transmission in the broader population" (<u>source</u>)

and

"At the population level, reduced transmission of SARS-CoV-2 among young children (5 to 11) may lead to lower SARS-CoV-2 incidence in all age groups." (source)

These statements make it clear that ATAGI is expecting a population return on the vaccination of children as young as five.

However, there are three major reasons why this return will not eventuate and, in the process, will extract an unjustifiably high price from children and adolescents.

These reasons are:

# a. Both at the individual and community level, the therapeutic basis of COVID-19 vaccination is non-existent with:

- i. The case survival rate being **99.9960%** or better;
- ii. An innate and adaptive immune that lowers susceptibility to infection by **50%** and can quickly clear the virus with only **21%** developing clinical symptoms;
- iii. Most, if not all, **hospitalisations** and **deaths** being associated with **underlying conditions** and **co-morbidities**;

- iv. Fewer ACE2 receptors and smaller lung capacity contributing to lower viral loads leading to asymptomatic or mild symptoms;
- Natural robust, cross-reactive and sustained immune responses to ٧. SARS-CoV-2 with focused specificity on the spike protein and T cell responses twice as high as adults;
- **Cross-protective** immunity from previous coronavirus infections; vi.
- vii. The average flu season in the UK being 2.8 times more lethal than COVID-19;
- viii. Secondary Attack Rates being 42% lower than adults; and
  - A tiny fraction (8%) of households where a child developed symptoms before ix. any other household contact.

### b. Effectiveness of COVID-19 vaccines is marginal nearing useless with:

- Cases across England for ages 12+, from 01 January 2021 to 01 January 2022 exploded by 186% while over the same period vaccination levels have increased from zero to dose 1 91%, dose 2 83% and dose 3 63%;
- The **force of infection**, determined by the number of infectious cases and the inherent infectiousness of each variant, increasing not decreasing and most likely being driven by vaccine-induced evolutionary selection pressure;
- The animal reservoir for human coronaviruses, with the ability to jump iii. species, making vaccine-induced herd protection unachievable at any vaccination level;
- iv. A marginal absolute risk reduction in outcomes that matter against the Delta of 0.004% for hospitalisations in ages 16-39, 0.026% for severe disease across all ages and with no comorbidities, and 0.006% for deaths across all ages and all comorbidities;
- v. The need to vaccinate **extraordinarily** large numbers to prevent **one** incident of a **serious outcome** of COVID-19 i.e. **25,000** for one reduction in hospitalisations, 3,846 for one reduction of severe disease, and 16,667 for a single reduction in deaths (compared to **201** for MMR);
- A failure to neutralise the Omicron variant in many vaccinees;

### c. Risk and harms of COVID-19 vaccines is significant and causal with:

- The randomised control trials of Pfizer (BNT162b2) and Moderna (SpikeVax) measuring an essentially meaningless end-point 'symptomatic COVID-19', a simple focus on symptom suppression;
- The randomised control trials being **deceptively deficient** by **not** measuring ii. participant biomarkers before, during and after the trials which would have given a robust early warning signal of any potential long-term harm;

- The six-month follow up to the Pfizer (BNT162b2) trial, showing that between iii. the placebo group and the treatment group adverse events linked to the gene therapy increased by 300%, severe adverse events increased by 75%, serious adverse event increased by 9%, adverse events leading to withdrawal from the trail increased by 18%, and deaths increased by 43%;
- The VAERS database for ages 0 to 17 showing that in the **12 months** of 2021 iv. there has been 33,137 total adverse events (37.6% not recovered), 57 deaths, 439 life-threatening events (62% not recovered), 252 permanent disabilities (87% not recovered), 2,379 hospitalisations (56% not recovered), 855 myocardial events (56% not recovered), and 261 pericardial events (61% not recovered);
- v. The combined five-year risk-multiple of Pfizer (BNT162b2) and Moderna (SpikeVax) compared to all influenza vaccines being 7.1 for deaths, 16.4 for life-threatening events, 12.0 for permanent disabilities, and 21.0 for hospitalisations;
- All categories of serious adverse events showing 50% to 85% occurring within the first two days of injection, definitive sign of causality;
- All categories of serious adverse events showing a steep fall in reports per vii. day after the second day from injection, a definitive sign of causality;

Based on the facts and analysis presented in this paper it is impossible to reconcile how ATAGI can conclude that:

"Vaccination against COVID-19 is recommended for all individuals from 12 years of age" (source) and

"The Australian Technical Advisory Group on Immunisation (ATAGI) has made recommendations for the use of the Pfizer COVID-19 vaccine in children aged 5 to 11 years" (source)

It is 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 a 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 egregiously, their explanation for these recommendations is expressed in vague, almost childish terms, devoid of anything that looks like an adult riskbenefit analysis.

History will certainly 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.

# Part B - COVID19 Young Person Impacts and Self-Sufficiency

### **Symptomatic COVID19 – Definition**

According to ATAGI, (and included at Appendix 3),

"There is high level evidence *indicating* strong *immunogenicity* and vaccine efficacy against *symptomatic COVID-19* in adolescents from clinical trials of Pfizer and Moderna." (<u>source</u>) and

"The paediatric Pfizer COVID-19 vaccine has been **demonstrated** to reduce **COVID-19** in children 5-11 years of age" (<u>source</u>)

Yet 'symptomatic COVID-19' is nothing more than **testing positive** to SARS-CoV-2 while **having** one or more of the **non-specific** symptoms of fever, cough, shortness of breath, loss of taste and/or smell, sore throat, vomiting, and/or diarrhoea (<u>source</u>).

So, the statement by ATAGI "indicating strong immunogenicity and vaccine efficacy against symptomatic COVID-19" can be paraphrased as follows:

'The **novel** Pfizer (BNT162b2) gene therapy, to **some degree** creates an immune response against **symptomatic COVID-19**; where symptomatic COVID-19 is defined (and measured) during the **relatively short** trial as children and adolescents **exhibiting one** or **more** of the **non-specific** symptoms such as fever, cough, sore throat, muscle pain, chills, shortness of breath and/or vomiting while **testing positive** to SARS-CoV-2'.

Egregiously, this statement and the randomised control trial upon which it is based is simply about **symptom suppression**. It says **nothing** about:

- a. the **progression** of these **non-specific** symptoms to anything **more** serious;
- b. the vaccine's **protection** against **infection** and/or **transmission**;
- c. the vaccine's **protection** against **severe disease** or **death**; and/or
- d. prognosis and recovery without vaccination.

It is also a statement that appears to provide medical advice but which translated out of jargon actually says:

'When a synthetic chemical is injected into the human body, the immune system is triggered (i.e. immunogenicity) to create a set of proteins and immune-type cells.'

And, while there have been a plethora of trials purporting to show that these proteins and immune cells, triggered by the COVID-19 gene therapies, do provide actual protection

against COVID-19, the science of correlating these proteins and cells with actual realworld protection is still not settled. In fact, as of November 2021

"No study to date has defined a correlate of protection against SARS-CoV-2 infection or disease that can be used by regulators and vaccine developers" (<u>source</u>).

If ATAGI, is to have any credibility with parents and guardians, they must stop making trivial and obfuscatory statements dressed up as medical science. And stop propagating fear caused by the expression "protection against symptomatic COVID-19".

### **Symptomatic COVID19 – Impacts on Children and Adolescents**

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

So, while there are a small number of COVID-19 effects on children and adolescents (e.g. PIMS-TS Paediatric Inflammatory Multisystem Syndrome **Temporally** associated with SARS-CoV-2), these effects are often difficult to identify, quantify, and rigorously evaluate.

And nearly **always** underlying medical conditions **precipitate**, **confound**, and **exacerbate** these effects.

Sadly, mortality is still the most **accurate** and **verifiable** metric of the effects of COVID-19 on children and adolescents.

The table below examines childhood mortality for COVID-19 and Influenza and other Respiratory Viruses for England and the UK. 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 31 December 2021	2.9	https://coronavirus.data.gov.uk/details/download
Influenza UK 2013/2014 Ages 0 to 14	6.5	https://www.gov.uk/government/statistics/annual-
Influenza UK 2014/2015 Ages 0 to 14	13.9	<u>flu-reports</u>

Influenza UK 2015/2016 Ages 0 to 14	12.0
Influenza UK 2016/2017 Ages 0 to 14	9.5
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

The data in this table shows that, across England and the UK for children aged 0 to 14, the average mortality of influenza and respiratory viruses over the years 2013 to 2019 is 2.8 times higher than that of COVID-19.

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

- 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".
- 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. Furthermore, "COVID-19 related **morbidity** and **mortality** is **significantly higher** in the **elderly** population and **almost absent** in **school-aged children**." (source)
- 5. The COVID-19 **case survival rate** for children and adolescents (ages 0 to 19) in the UK over the period 01 March 2020 to 31 December 2021 is **99.996%**. (Source)

In summary, for children and adolescents the mortality of influenza and other respiratory diseases is 2.8 times higher than it is from COVID-19, the COVID-19 case survival rate is 99.9960% and sadly the vast majority, if not all, of COVID-19 deaths and hospitalisations are associated with comorbidities and adverse underlying medical conditions.

Finally, according to a peer-reviewed paper published in Nature Communications (source)

"COVID-19 related morbidity and mortality is significantly higher in the elderly population and almost absent in school-aged children."

Putting aside the fearmongering by medical bureaucracy and compliant media, COVID-19 is almost certainly benign almost absent for the vast majority of children and adolescents.

### **Symptomatic COVID19 – Young Person Self-Sufficiency**

Children and adolescents are **self-protective** against COVID-19 for several reasons:

- 1. Fewer ACE2 receptors driving lower viral Loads
- 2. Smaller lungs producing lower viral loads
- 3. Powerful innate immune system
- 4. Powerful adaptive immune system
- 5. Rapid virus clearance
- 6. Previous cross-immunity from other human corona viruses

### Fewer ACE2 Receptors driving Lower Viral Loads

The nose, mouth, and lungs of humans are lined with a protective barrier tissue called the epithelium. The cells in this epithelium have a protein receptor on their surface called the angiotensin-converting enzyme 2 (ACE2). This protein receptor facilitates several normal cell functions in the body.

However, the ACE2 is also the receptor onto which the SARS-CoV-2 spike protein docks and by which it enters a healthy cell.

Once inside a healthy cell, SARS-CoV-2 replicates and prevents the cell from functioning normally; i.e. cell infection.

Research published in the Journal of the American Medical Association showed that children aged 0 to 17 have significantly lower ACE2 receptors in the lining of their nose.

Based on this observation, the researchers concluded:

# "Lower, ACE2 expression in children relative to adults may help explain why COVID-19 is less prevalent in children"

### Smaller Lungs producing Lower Viral Load

The lung volume of children aged 5 to 15 is approximately 25% to 75% smaller than the average male (<u>source</u>).

Based on this smaller lung volume, a peer-reviewed study into SARS-CoV-2 viral loads (<u>source</u>) found that:

"An infected **child** is probably carrying an order of magnitude **fewer** virions" at the **height** of infection compared to an **average male**."

### Powerful Innate Immune System

In an article published in the Lancet (<u>source</u>) examining the immune system of children and its relationship to SARS-CoV-2 susceptibility, the authors state:

"The immune preparedness of children to any novel pathogens, including, SARS-CoV-2 might be based on several factors."

[First] "In the **early** phases of infection, **natural** antibodies play a most **important** role. Natural antibodies, mostly of IgM isotype and generated independently of previous antigen encounters, have a **broad reactivity** and a **variable affinity**."

"[These natural antibodies] **contain** the infection during the two weeks necessary for production of high-affinity antibodies and Memory B Cells that will clear the virus and prevent reinfection"

[Second] "Children have the ability to rapidly produce natural antibodies with broad reactivity that have not yet been selected and shaped by the reaction to common environmental pathogens."

"Children seem to benefit from more promiscuous antibody responses, **better equipped to deal with novel viruses in general**" (<u>source</u>).

In summary, in the early days of infection while we **all** have **natural** antibodies secreted by our **innate** immune system, children and adolescents produce these natural antibodies much more rapidly and with an ability to target a **broader** array of viruses.

### Powerful Adaptive Immune System

A very recent <u>study</u> (January 2022) examining the reaction of the adaptive immune system of children and adolescents to SARS-CoV-2 found that:

"SARS-CoV-2 infection is generally mild or asymptomatic in children"

"Antibody responses against spike protein were high in children"

"Spike-specific **T cell responses** were more than **twice** as high in **children**"

"Children **retained** antibody and cellular responses **six months** after infection; whereas relative **waning** occurred in **adults**."

"Children generate robust, cross-reactive and sustained immune responses to SARS-CoV-2 with focused specificity for the spike protein."

In other words, children have next to zero risk from SARS-CoV-2 infection, their symptoms are generally mild or non-existent, and they naturally develop robust and sustained immune and protective responses.

And in a further study of 328 households containing 548 children and 717 adults (<u>source</u>), conducted at the height of the **most virulent first wave** of SARS-CoV-2 in Germany in **May 2020**, the researchers found that:

"Children were **five times more likely** to have **seroconverted without symptoms** compared to adults"

"Despite the frequently asymptomatic course of infection, children had higher specific antibody levels, and their antibodies persisted longer than in adults"

"The **long-term humoral immune response** to SARS-CoV-2 infection in children is **robust** and may provide **long-term protection** even after asymptomatic infection."

As before, children have next to zero risk from SARS-CoV-2 infection, and even under conditions of extreme virulence, their adaptive immune system is more than bale to respond accordingly, if not effortlessly.

And finally, it has always been known (i.e. before the endemic gaslighting of the COVID19 era) that:

"School-aged children have shown better clinical outcomes during past influenza pandemic outbreaks" (source).

### Fast Virus Clearance

In a peer-reviewed study (<u>source</u>) researchers found that:

"There is a **rapid drop in viral loads after peak infection**; thus the total number of [circulating] viral particles is dominated by those infected individuals who are close to the infection peak."

And in another peer-reviewed study (source) the researchers found that:

"SARS-CoV-2 clearance in the upper respiratory tract may proceed at a faster rate in children compared to adults"

Combined, these two studies show that children and adolescents are not the main reservoirs of circulating virus particles.

### <u>Protective Cross-Immunity - Human Coronaviruses</u>

From the earliest days of the supposed pandemic it was known that:

"SARS-CoV-2 is a **beta-coronavirus** responsible for COVID-19" (source)

There are four species of seasonal human coronaviruses (hCoV) (source):

- a. Alpha coronavirus HCoV-NL63, HCoV-229E which are 31% 'similar' in structure (amino acid homology) to SARS-CoV-2;
- b. Beta coronavirus CoV-OC43 and HCoV-HKU1 which are approximately 37% 'similar' in structure (amino acid homology) to SARS-CoV-2;

These coronaviruses are "distributed globally, circulating continuously within the human population, causing mild-to-moderate, self-limiting [flu like] infections" (source).

Given the **structural similarity**, and that SARS-CoV-2 is from that **same family** and **sub-family** (<u>source</u>) as the already circulating human coronaviruses, it's entirely disingenuous for the WHO and medical bureaucrats to claim that it is '**novel**'.

The questions then become

- a. how does SARS-CoV-2 interact with the human immune system? and
- b. do children and adolescents have cross-protective immunity to SARS-CoV-2 from pervious infections with other human coronaviruses?

Cross-protective immunity is defined as protection against a given pathogen thanks to immunity acquired from past exposure to a related pathogen or its antigens. This protection reduces the severity of the disease caused by the pathogen, without necessarily preventing an infection.

The SARS-Cov-2 interaction with the human immune system has been researched in several peer-reviewed papers which found:

"The zoonotic coronavirus SARS-CoV-2 is unlikely to have evolved an especially divergent interaction with the mammalian immune system compared with its close coronavirus relatives." (source)

"Characteristics shared by these four seasonal coronaviruses, such as the duration of protective immunity, are representative of all human coronaviruses, including SARS-CoV-2." (source)

Combined, these research papers indicate that SARS-CoV-2 interacts in a very similar way, as with all other human coronaviruses, with the human immune system.

It's reaction and recognition by the human immune system is **not** 'novel'!

As far as children and adolescents are concerned a peer-reviewed study (<u>source</u>) found that:

"These [human] coronaviruses cause frequent mild childhood infections and antibody seroconversion occurs typically before the age of 5 years."

"Infection with one of the Alpha or Beta-coronaviruses provides short-term immunity against reinfection from coronaviruses and represents transient cross-reactive immunity within the subtypes."

"As such, recent hCoV infection might pre-sensitise children against SARS-CoV-2 infection and may explain cross-reactive SARS-CoV-2-neutralizing antibodies in some seronegative children."

And finally, in the most current peer-reviewed paper (<u>source</u> Nature Communications 10 January 2022) the researchers found

"Our results are thus consistent with **pre-existing non-spike cross-reactive** memory T cells protecting SARS-CoV-2-naïve contacts from infection"

In other words, **existing** memory T-cells from **previous infections** with human coronaviruses provide **protection** against **SARS-CoV-2**.

In summary, nearly all children would have been exposed to, and recovered from, any number of human coronaviruses by the age of five. And it is most likely that this exposure would provide a level of cross-protective immunity against SARS-CoV-2.

# Part C - Community Implications and Protecting Grandma

In Part C, we swich the focus to the role of children and adolescents in the context of the wider community.

In particular to examine two key questions:

- a. How significant is the role of children and adolescents in the transmission of SARS-CoV-2; and
- b. Will vaccinating children and adolescents reduce case numbers in the community.

# Children and Adolescents – Not the Major Drivers of Transmission

According to ATAGI and in their non-committal language:

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

And

"At the population level, reduced transmission of SARS-CoV-2 among young children may lead to lower SARS-CoV-2 incidence in all age groups." (source)

Once again, **nothing** could be further from the truth; both at the community level and at the household level.

At the community level, in a peer-reviewed article (<u>source</u>) the authors concluded that:

"We estimate that **susceptibility** to **infection** in individuals **under 20** years of age is approximately **half** that of adults aged **over 20** years"

"Clinical symptoms manifest in 21% of infections in 10- to 19-year-olds, rising to 69% of infections in people aged over 70 years."

"We find that interventions aimed at children might have a relatively small impact on reducing SARS-CoV-2 transmission, particularly if the transmissibility of subclinical infections is low."

And, in another peer-reviewed study (source) the researchers concluded

"Consistent epidemiological evidence suggesting a less significant role of children as main drivers of SARS-CoV-2 spread in the community".

In other words, children and adolescents are **less likely to become infected**, and do **not** develop **symptoms severe enough to drive significant transmission**. And **interventions** targeted at them will have a **small impact on overall community transmission**.

At the 'household' level, secondary attack rate (SAR) refers to the spread of disease in a family, household, dwelling unit, dormitory, or similar confined group. The spread of infection from an index case (the initial case, i.e. the case that introduced the organism into the population) to the rest of the group is called the secondary attack rate (SAR).

It is a good measure of person-to-person disease spread in a close environment; once the disease has been introduced into a population.

At its basic, SAR is the number of people infected by the initial case divided by the total number of people in the group.

In a **meta-analysis** of **87 studies** representing **1,249,163 household contacts** from **30 countries** published in the Journal of the American Medical Association (<u>source</u>), the authors found that

"Secondary Attack Rate was significantly higher where the index case was an adult over 18 (29.9%) than where the index case was a child under 18 (17.5%)."

And in an earlier study (<u>source</u>) during the **most virulent first wave** in Switzerland the researchers concluded

In only **8%** of households did a **child develop symptoms before** any other household contact, which is in line with previous data in which it is shown that **children** are **index cases** in **10%** of SARS-CoV-2 familial clusters.

In summary, compared to adults, children are less likely to become infected, their immune system is much more able to clear symptoms and infections before they become highly infectious and transmissible, and in far fewer cases are they the index case in a household outbreak.

### **Vaccine Failure - Irrespective of Children and Adolescents**

Real World Failure - Viral Containment

According to ATAGI (source)

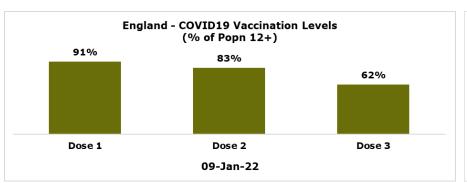
"Vaccinating adolescents is **anticipated** to **contribute** to a **reduction** in SARS-CoV-2 transmission in the broader population."

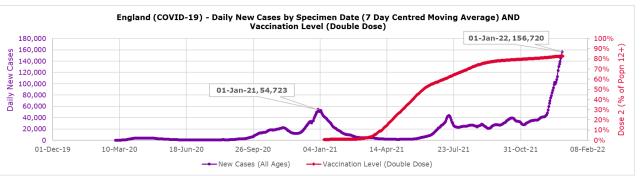
Irrespective of the **non-committal** words and **tone** of this statement, **nothing** could be further from the truth!

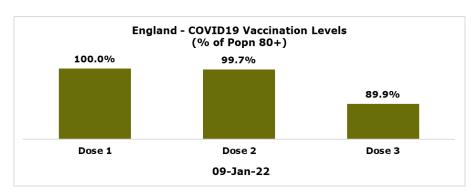
The following charts show that, for **any age group**, and **irrespective** of **vaccination level** the current crop of gene therapies does **not** control SARS-CoV-2 **infection** and/or **transmission**.

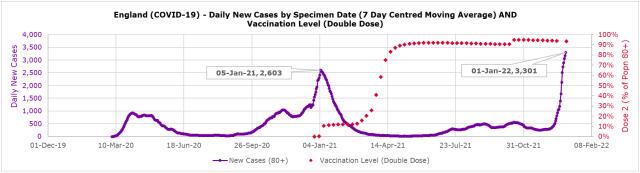
In particular, across England for ages 12+, from 01 January 2021 to 01 January 2022 cases have exploded by 186%. Over the same period vaccination levels have increased from zero to dose 1 91%, dose 2 83% and dose 3 63%.

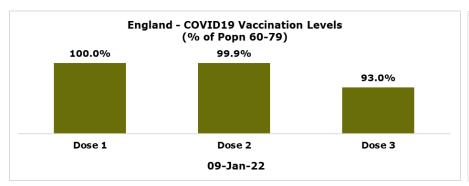
This failure, by the current crop of vaccines and gene therapies, to contain the SARS-CoV-2 virus is repeated across all highly vaccinated countries including Australia, Singapore, Iceland, South Korea, Gibraltar, and Israel.

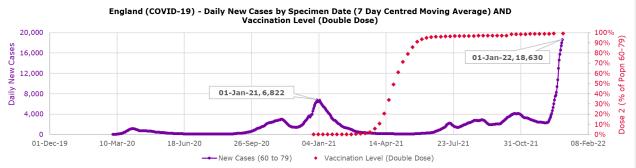


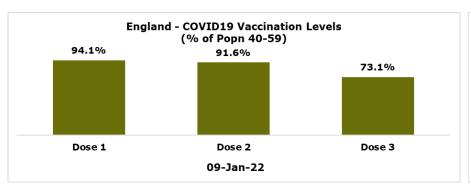


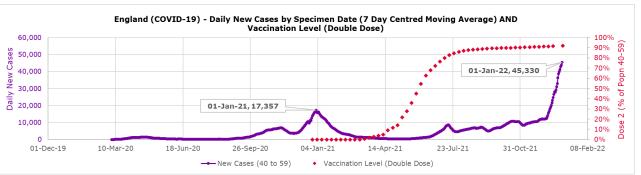


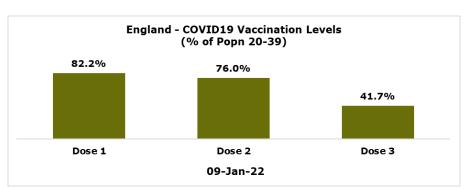


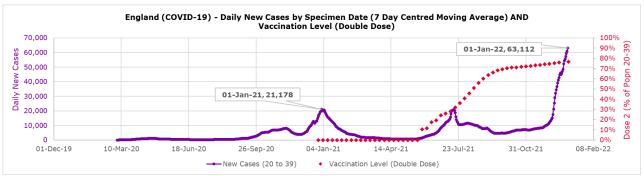


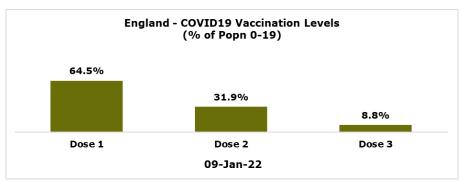


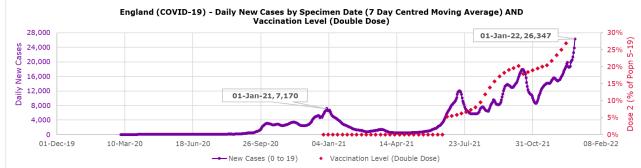












Furthermore, across England, much of the testing has been focused on the younger, more mobile, age groups as part of travel requirements imposed on English tourists over the 2021/2022 Christmas/New Year holiday season.

As such, it is certain that case numbers in the older age groups (esp. 60-79 and 80+) are under-ascertained.

It would be **disingenuous** of government and medical **experts** to **blame** the **cavalcade** of SARS-CoV-2 **variants** for this explosive **rise** in case numbers.

From the outset, it was known that SARS-CoV-2 is an RNA type virus. And irrespective of the claimed proof-reading of coronaviruses (<u>source</u>), it is well known that **RNA viruses** have **high** mutation rates that will drive a cavalcade of variants (<u>source</u>). And "since the SARS-CoV-2 RNA polymerase is intrinsically error prone, mutation of the viral genome is to be expected" (<u>source</u>).

#### None of this is novel.

The only 'novel' thing was to attempt to suppress a rapidly mutating poorly replicating coronavirus with a novel non-changing experimental gene therapy; and to expect successful virus suppression!

### Real World Failure - Reduction of Infection Force

According to established peer-reviewed science (<u>source</u>), in order to induce herd protection an effective and successful vaccine must substantially reduce the force of infection. The force of infection is largely influenced by two factors:

- a. the number of infectious people at any one time; and
- b. the inherent infectiousness of the virus itself  $(R_0)$ .

Addressing the first of these factors, it is clear from the charts above, that the current crop of gene therapies has **not** reduced the number of infectious people.

Addressing the second of these factors, it is established science that vaccines can place evolutionary selection pressure on viruses to mutate in ways that increase its transmissibility (<u>source</u>) and/or its virulence (<u>source</u>).

Furthermore, "population-genetic theory suggests that a similar **evolutionary selection process** would occur in human influenza and associated vaccines. In particular, if vaccination conferred partial or imperfect immunity, a highly immune or vaccinated population can selectively pressure the virus to evolve more quickly than usual." (source)

Given that the current crop of COVID-19 gene therapies is 'leaky', i.e. they do not provide **complete** sterilising immunity (<u>source</u>), it is not inconceivable that they are placing evolutionary selection pressure on the SARS-CoV-2 virus.

Given the **explosive** rise in cases across the world, and the **increased transmissibility** of each emerging variant, it is **difficult to see** how the current crop of gene therapies is actually contributing to a reduction in the force of infection.

By the accepted definition of an effective vaccine (i.e. to reduce the force of infection) (source), they have **clearly** failed.

### Real World Failure - The Reservoir Anomaly

It is established science that epidemic human coronaviruses (such as SARS-CoV and MERS) crossed over from animals to humans (<u>source</u>).

SARS-CoV evolved from horseshoe bat coronavirus, through civet cats or other intermediary animal hosts. And MERS-CoV also likely evolved from bat coronavirus, with dromedary camels as the intermediary hosts (<u>source</u>).

And based on genome sequencing, bats are **assumed** to be the reservoir of SARS-CoV-2 (<u>source</u>). Also, the structure of SARS-CoV-2 (ie nucleotide sequence) shows that it is **79.0%** identical to SARS-CoV and **51.8%** identical to MERS-CoV (<u>source</u>).

Finally, SARS-Cov-2 is closely related to bat-origin SARS-like coronavirus (bat-SL-CoVZC45) with a 88% identity (<u>source</u>).

Based on all of the above, it is clear that SARS-CoV-2 has large and effective animal reservoirs, including intermediary mammalian reservoirs (<u>source</u>).

Finally, in a peer-reviewed study (<u>source</u>) published on 24 December 2021, the researchers concluded that:

"We found that the Omicron spike protein sequence was subjected to stronger positive selection than that of any reported SARS-CoV-2 variants known to evolve persistently in human hosts, suggesting a possibility of **host jumping**."

"The molecular spectrum of mutations (i.e., the relative frequency of the 12 types of base substitutions) acquired by the progenitor of Omicron was significantly different from the spectrum for viruses that evolved in human patients but resembled the spectra associated with virus evolution in a **mouse** cellular environment."

"Furthermore, mutations in the Omicron spike protein significantly overlapped with SARS-CoV-2 mutations known to promote adaptation to mouse hosts, particularly through enhanced spike protein binding affinity for the mouse cell entry receptor."

"Collectively, our results suggest that the progenitor of **Omicron** jumped from **humans to mice**, rapidly accumulated mutations conducive to infecting that host, then **jumped back into humans**, indicating an **inter-species evolutionary trajectory** for the Omicron outbreak."

In summary, and in plain speak, SARS-CoV-2 has a large and diverse animal reservoir and it is quite capable of jumping between humans and animals and back again.

It's worthwhile noting that humans are the only natural hosts of the measles virus (source).

Against this backdrop, it is established science that, to achieve good herd protection, mass vaccination needs to target the correct reservoir of infection (source).

So, as long as SARS-CoV-2 has a successful reservoir in animals and is capable of jumping back and forth from animals to humans, **vaccine-induced herd protection can never be achieved**.

Proof of this is the traction and explosive spread of the Omicron variant in countries with very high vaccination levels (refer above <u>charts</u> for England).

As such mass indiscriminate vaccination of children, adolescents, and adults is entirely futile.

Unless of course the experts who have, over the last two years, failed to contain SARS-CoV-2 plan to vaccinate (every **three** months) **7.8 billion humans**, and **all** reservoir-capable animals!

# Part D - Pfizer (BNT162b2) Deceptive Harmful Ineffective

Typically, the effectiveness of a new treatment (or vaccine) is measured by comparing the number of participants, in the treatment/vaccine group vs the placebo/control group, that reach a **pre-determined end-point**.

Clearly, the pre-determined end-point must be **meaningful** to end-users. And **meaningful** endpoints must relate to outcomes which capture how a person **feels**, **functions** or **survives** (<u>source</u>).

Many decades ago, in cancer drug trials, the medical sciences learnt the importance of clinically **meaningful** end-points. Yes, it was easy to kill a cancerous tumour, but as an end-point of a drug trial that was useless if the drug also killed the patient!

Very often, **multiple** end-points make more sense than simply monitoring and evaluating a **single** end-point. These multiple end-points are called **Core Outcome Sets** (COS) (source).

The Pfizer Randomised Control Trial (RCT) of gene therapy BNT162b2 measured a **single primary** end-point.

Given the radically novel nature of the Pfizer gene therapy, it is **inconceivable** that a **single primary end-point** was measured and **not** a Core Outcome Set.

That single primary end-point was that bogeyman 'symptomatic COVID-19' (i.e. when a participant tested **PCR-positive** to SARS-CoV-2 **and** exhibited **one** or **more** of the **nonspecific symptoms** of 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, diarrhoea, or vomiting). And with symptom **onset** at least **seven days after second** injection.

According to the **WHO** 'symptomatic **COVID-19**' will "for **most** people be a **mild to moderate** respiratory illness and [they will] recover **without** requiring special **treatment**". (source)

As such the **seriousness** of the **primary** end-point of the Pfizer BNT162b2 RCT can only be described as "**mild-to-moderate**".

This **cannot** be described a **clinically meaningful** end-point.

And, it was based on this RCT, with an end-point that is **mild-to-moderate** in **seriousness** and **clinically meaningless-to-most**, that a **novel gene therapy** was given **Provisional Approval** by the TGA on 25 January 2021 (<u>source</u>).

# Pfizer (BNT162b2) Gene Therapy - Deceptively Harmful

So given that the Pfizer (BNT162b2) RCT monitored a **less than meaningful outcome**, what were the results and the adverse events observed in this trial?

The key outcomes of the Pfizer (BNT162b2) RCT published in December 2020 (source) are summarised in the table below.

End-Point	Seriousness	BNT162b2	Placebo	Risk Change
Total Participants		18,198	18,325	
Symptomatic COVID-19	Low to Moderate	8	162	-95%

And, as determined by the <u>WHO</u>, this risk reduction is for an end-point that is **low-to-moderate** in **seriousness** for the **vast majority** of people.

And against this 95% **relative** risk reduction in a **less than meaningful outcome**, the **adverse** events observed in the RCT (refer 31 December 2020 appendix of <u>source</u>) are summarised in the table below.

Adverse Event	Seriousness	BNT162b2	Placebo	Risk Change
Total Participants		21,621	21,631	
Any Event	Low to Moderate	5,770	2,638	119%
Any Serious Adverse Event	Very High	126	111	14%
Any Adverse Event Leading to Withdrawal	High	37	30	23%

Based on these two tables, it is clear that had Pfizer adopted a **Core Outcome Set**, instead of **single less than meaningful primary outcome**, this novel gene therapy would have been shown to do **more harm than good**.

As such, the Pfizer BNT162b2 gene therapy is **deceptively harmful** for the **vast majority** of the population.

In November 2021 Pfizer published its six-month update (<u>source</u>) to the original RCT. The following table shows the **updated** primary endpoint outcomes for this RCT.

End-Point	Seriousness	BNT162b2	Placebo	Risk Change
Total Participants		20,998	21,096	
Symptomatic COVID-19	Low to Moderate	77	850	-91%

Again, this table shows a **91% relative** reduction in risk for an end-point that is **low-to-moderate** in **seriousness** as classified by the <u>WHO</u>.

As of **15 September 2021**, the **updated** adverse events observed in this RCT are given in the Appendix of the updated RCT paper (<u>source</u>) and are summarised in the table below.

Adverse Event	Seriousness	BNT162b2	Placebo	Risk Change
Total Participants		21,926	21,921	
Any Event	Low to Moderate	6,617	3,048	117%
Any Event (Confirmed realtionship)	Low to Moderate	5,241	1,311	300%
Any Event (Severe)	Very High	262	150	75%
Any Serious Adverse Event	Very High	127	116	9%
Any Adverse Event Leading to Withdrawal (Confirmed Realtionship)	High	13	11	18%

Once more, across all categories of adverse event seriousness, there is a significant increase between the placebo group and the BNT162b2 gene therapy group.

And once again it is difficult to conclude that the Pfizer (BNT162b2) gene therapy is of overall benefit to the vast majority of the population.

Early in 2021, the **placebo control group** was progressively **injected** with the **BNT162b2 gene therapy**. According to Pfizer/BioNTech this was for "ethical and practical" needs (page 1771 of <u>source</u>).

And in one action, **all safety data** for a radically novel gene therapy that could be collected in a blinded, placebo-controlled manner has been **destroyed forever**.

Given this cross over (and unblinding) of the placebo group into the trial group, the update on deaths is now given in the table below.

Adverse Event	Seriousness	BNT162b2	Placebo	Risk Change
Total Participants		21,926	21,921	
Deaths before unblinding (Refer Table S4 of Supplementary Appendix)	Extreme	15	14	
Deaths after unblinding (Refer page 1767 of 6 month update)	Extreme	5	0	
Total Deaths	Extreme	20	14	43%

While the managers and observers of the trial claimed that "none of these deaths were **considered** to be related to BNT162b2" (page 1767 of <u>source</u>), real world data presented <u>below</u> certainly does not support this conclusion.

In summary, balancing the **significant increases** in **adverse events** (across all categories of seriousness esp. a **43% increase** in **deaths**) against the **claimed** reduction

in cases (which for the **vast** majority of the population will be **mild** to **moderate**), it is **unambiguously** clear that for the vast majority of the population **Pfizer (BNT162b2) gene therapy will do more harm than good**.

# Pfizer (BNT162b2) Gene Therapy – Absolute Risk Reduction (ARR)

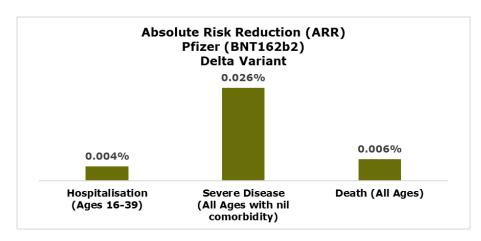
To understand the actual (and absolute) reduction in risk provided by these radically novel gene therapies, the reader needs to be aware of a mathematical trick perpetuated by pharmaceutical companies, medical bureaucrats, for-profit researchers, and the mathematically illiterate media.

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

For example, an **80%** discount on **five** cents is still **only** four cents. The more informative figure is the **Absolute Reduction** (i.e. the four cents) not the grand sounding **80%**. (Refer <u>Appendix 4</u> for Absolute Risk Reduction calculations and methodology).

Presenting and quoting vaccine efficacy **only** as the percentage **relative** risk reduction and **ignoring** the **absolute** risk reduction is **egregiously misleading**.

So **assuming** the **current** formulation of the Pfizer (BNT162b2) gene therapy is still effective, **twelve months** after its design for a **variant** that is **no longer** in circulation,



what is the **Absolute Risk Reduction** (ARR)
that children and
adolescents can expect by
being injected with the
Pfizer (BNT162b2) gene
therapy against the **more serious consequences of COVID-19**?

According to a more robust <u>study</u>, published in the New England Journal of Medicine, the **Absolute Reduction in Risk** given by Pfizer's (BNT162b2) gene therapy against the Delta variant was:

- a. Hospitalisations for ages 16-39 0.004% (i.e. 4 in 100,000);
- b. Severe Disease across all ages and with no comorbidities 0.026% (i.e. 2.6 in 10,000);
- c. **Deaths** across all ages and all comorbidities was **0.006%** (i.e. **6** in **100,000**).

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 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 difference into account.

Finally, a recent study (<u>source</u>) by a coalition of UK researchers centred around the University of Oxford, found that for the **Omicron** variant:

"There was a **substantial** fall in neutralisation titres in recipients of both AZD1222 and BNT16b2 primary courses, with evidence of some recipients **failing** to **neutralise at all**."

In other words, against the **Omicron** variant the **current** crop of gene therapies (both AstraZeneca and Pfizer) is essentially **ineffective** and that:

"This will likely lead to increased **breakthrough** infections in **double vaccinated** individuals" (source).

# Pfizer (BNT162b2) Gene Therapy – Number Needed to Vaccinate (NNV)

Not all drugs and/or vaccines are totally effective in all people at all times.

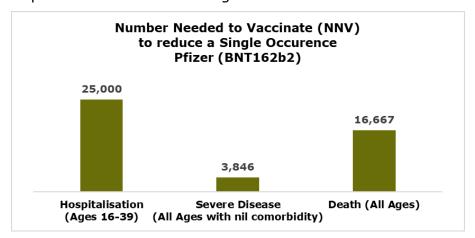
The number needed to vaccinate (NNV) is a summary metric to evaluate the possible benefits of mass immunisation programmes in preventing and controlling communicable diseases (<u>source</u>).

It is defined as the **number** of **persons** that **must** be vaccinated to prevent **one** outcome of the disease being vaccinated against. It is calculated from the Absolute Risk Reduction of the vaccine (refer methodology in <u>Appendix 4</u>).

Logically, the **lower** the **NNV** the **more effective** is a vaccine and vice versa.

Finally, **each** person that is vaccinated, will **certainly face all risks** of the vaccine, but may receive **no** personal benefit (i.e. they may have overcome the virus and its disease without the vaccine).

For the Pfizer (BNT162b2) gene therapy, the number of people that need to be vaccinated to prevent one incident of a given disease outcome is shown in the chart below.



In other words, to prevent one

- a. Hospitalisation in persons aged 16 to 39, 25,000 people would need to be vaccinated. And all 25,000 people would face the certain but unknown medium to long term risk of this novel gene therapy but with no benefit;
- b. Case of severe disease across all ages in persons with no co-morbidities, 3,846 persons would need to be vaccinated. And all 3,846 people would face the certain but unknown medium to long term risk of this novel gene therapy but with no benefit; and
- c. **Death** across all ages **16,667** people would need to be vaccinated. And all **16,667** people would face the **certain** but **unknown** medium to long term **risk** of this novel gene therapy but with **no** benefit.

By way of comparison to prevent once hospitalization the NNV for

- human papilloma virus (HPV) is between 68 and 141 (<u>source</u>),
- rotavirus (RV) is between 13 and 94 (<u>source</u>), and
- measles mumps rubella is approximately 201 (<u>source</u>)

In a similar vein to Number Needed to Vaccinate (NNV), NNT is the Number Needed to Treat, but in relation to treatments and medications.

In a landmark study by the University of Toronto, the researchers concluded that:

"NNT is a reasonably accurate predictor of treatments that provide large health benefits".

They found that an NNT of **5** or **less** was probably associated with a **meaningful** health benefit, while an NNT of **15** or **more** was quite **certain** to be associated with, **at most**, a **small** net health benefit.

For the more serious outcomes of COVID-19, these extraordinarily high NNV values for the Pfizer (BNT162b2) gene therapy prove its insignificant real-world effectiveness for outcomes that matter.

## Part E – COVID19 Vaccination Risks. A Focus on Youngsters

### Vaccine Trials - Negligent and Deficient Approach to Childhood Safety

To detect **early** warning signals of harm, the Pfizer (BNT162b2) randomised control trials (RCT) were extremely **deficient** in their **design** and **processes**.

Disease and death are typically end points of processes that can take months, years, or decades to occur. During this time, many biomarkers (e.g. blood pressure) tend to exhibit increasing abnormalities that indicate an increasing predisposition to disease and/or death.

Typically, symptoms, disease, and/or deaths that occur over a relatively short time span are rare and few in number.

So a trial that only measured symptoms, disease, and death over a **relatively short period** would only capture **rare events**; and thus **significantly** under-estimate **medium** to **long-term** safety.

Given that the trials were aimed at **proving** the **safety** of these **radically novel** gene therapies, **credible** safety science would have required a much more **expansive** and **robust** approach.

For all participants, a **credible safety trial** of a **novel** gene therapy would have captured the before, during, and after state of a range of biomarkers such as (<u>source</u>):

- d-dimers for evidence of enhanced coagulation/clotting
- C-reactive protein for evidence of enhanced inflammation
- troponins for evidence of cardiac damage
- occludin and claudin for evidence of enhanced barrier permeability
- blood oxygen levels for evidence of enhanced hypoxia
- amyloid-beta and phosphorylated tau for evidence of increased predisposition to Alzheimer's disease
- serum HMGB1, CXCL13, Dickkopf-1 for evidence of an increased disposition to autoimmune disease

Collectively, these would have served as **early warning** indicators of potentially serious disease and/or death.

In particular for children and adolescents, who have a long future that could be readily and seriously affected by an increased predisposition to the multiple serious diseases already evident from these novel gene therapies. Finally, a credible high-quality safety trial would have required measurements of bodily products indicating interactions with (a) the mRNA and/or (b) the lipoid nano-particle shell. In addition, the bodily products indicating the possible stimulation of dormant viruses by the mRNA-generated spike protein (source).

In the public domain, there is **no** evidence that biomarker-monitoring was an **integral** part of these RCTs. In addition, they would now be redundant with the vaccination of the control group in early 2021.

It is **inconceivable** (bordering on **negligent**) that a safety trial for a **novel** gene therapy did not encompass this more expansive early waring approach within its design and processes.

It is **inconceivable** that the **major** regulators around the globe allowed this **deficient** design and process to proceed.

### **Introduction – Adverse Event Reporting Systems**

For simplicity, the risks of COVID-19 vaccination for children and adolescents can be divided into (a) current and (b) medium to long term.

Current risks are adverse events that come to light 'fairly soon' after injection; typically within 120 days of injection. In this paper we will largely focus on these 'current' adverse events.

It must be noted that 'current' does **not** imply **transient**. As we will see later, a certain proportion of adverse events detected within 120 of injection have not recovered.

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 VigiBase
- 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 our experience, VAERS appears to be the most robust, transparent, accessible, and informative. As such in this paper we will be relying on VAERS data.

The learnings are largely universal between countries with similar socio-economics, health levels, and medical systems.

There are three key issues to be considered when interpreting the data from these adverse event reporting systems:

- 1. Under Reporting. It is well known that adverse events are significantly under-reported. On its website the Australian Therapeutic Goods Administration (TGA) 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).
- 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-of-causality 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. This is explored in further detail in <u>Appendix 6</u>.

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 a COVID-19 product on an adverse event report will be considered an adverse event against that COVID-19 product.

However, unlike the WHO and the ABS, we will also demonstrate a **very clear** causal link between these **gene therapies** and the reported **adverse events**.

3. Metrics and Risk Evaluation. Typically the extent of adverse events is measured as a percentage ratio, i.e. the number of adverse events divided by the of times the medicine/drug/vaccine has been dispensed or administered. This gives a rudimentary measure of risk.

Firstly, this is a deceptively flawed approach as unless an adverse event is clinically significant, i.e. severe enough to be felt, noticed, and diagnosed, it will go unreported.

For example, it is quite likely that some incidences of blood clots or myocarditis are sub-clinical and as such will go unnoticed and unreported.

And as discussed <u>above</u>, it is not unlikely that these sub-clinical incidences will initiate a sequence of events that will ultimately lead to clinical symptoms, disease, and/or death.

So the "small" risk of these gene therapies, as touted by medical bureaucrats and ignorant media, will more than certainly be under-estimated; irrespective of the number of reports.

Secondly, 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, relevant comparison, or base line.

As such we will be adopting the same approach in reporting the adverse events for COVID-19 gene therapies; i.e. we will simply report the number of adverse events.

In addition we will compare the number of adverse events for Pfizer (BNT162b2) and Moderna (SpikeVax) vs **all** influenza vaccines.

This will serve to highlight the early warning safety signal that is being **negligently ignored** by medical bureaucracy and regulators.

#### A Breakdown of COVID19 Serious Adverse Events (Ages 0 to 17)

To measure the extent of adverse events associated with (a) Pfizer (Comirnaty and BNT162b2) and (b) Moderna (SpikeVax), we queried VAERS for **ages 0 to 17** for injections administered in the **12 months January to December 2021**.

In particular for:

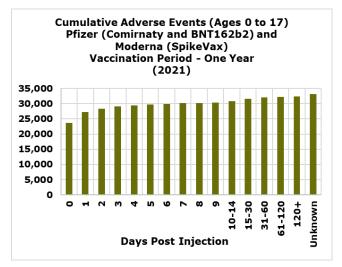
- a. Total adverse events;
- b. Deaths;
- c. Life threatening events;
- d. Permanent disabilities; and
- e. Hospitalisations.

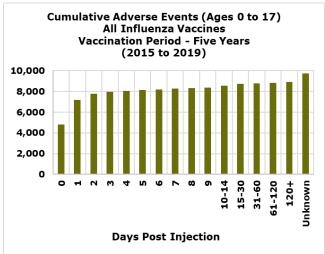
We then ran the same query for **ALL** influenza vaccines, but for the **five-year** period **2015** to **2019**.

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**

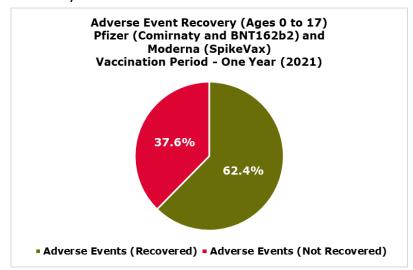
For ages **0 to 17**, a total of **33,137 adverse events** have been reported against **Pfizer** and **Moderna** gene therapies administered in the **single** year, 2021.





For the same age group, **9,736 adverse events** have been reported against **all** influenza vaccines over the **five** years 2015 to 2019.

**90%** of all **adverse events**, reported against Pfizer and Moderna gene therapies, occurred within the first **six** days post injection. And **85%** were reported within the first **two** days.

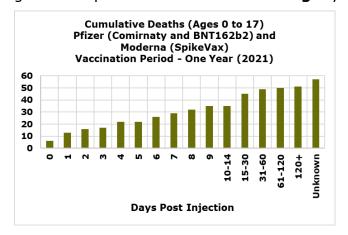


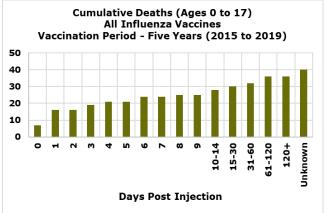
In addition, **37.6%** of all **adverse events** reported against the Pfizer and Moderna gene therapies have **not recovered**.

The 'long covid' of covid vaccination.

#### **Deaths**

For ages **0 to 17**, a total of **57 deaths** have been reported against **Pfizer** and **Moderna** gene therapies administered in the **single** year, 2021.



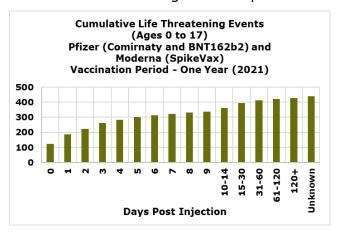


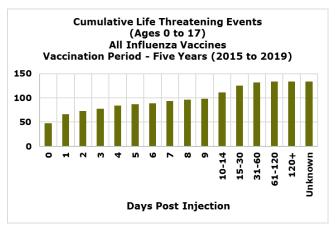
For the same age group, **40 deaths** have been reported against **all** influenza vaccines over the **five** years 2015 to 2019.

Just under **80%** of all deaths reported against Pfizer and Moderna gene therapies occurred within the first **30** days post injection. And **50%** of all deaths occurred within the first week of injection.

#### Life Threatening Events

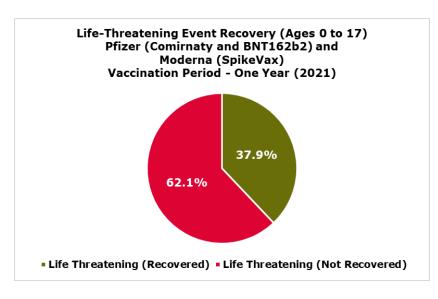
For ages **0 to 17**, a total of **439 life-threatening events** have been reported against **Pfizer** and **Moderna** gene therapies administered in the **single** year, 2021.





For the same age group, **134 life-threatening events** have been reported against **all** influenza vaccines over the **five** years 2015 to 2019.

**82%** of all life-threatening events reported against Pfizer and Moderna gene therapies occurred within the first **14** days post injection. And **50%** of all life-threatening events occurred within the first **two** days of injection.

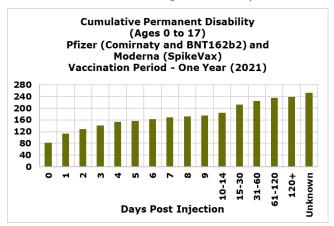


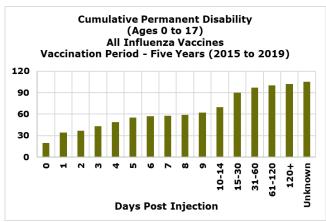
In addition, **62.1%** of all lifethreatening events reported against the Pfizer and Moderna gene therapies have **not** recovered.

The 'long covid' of covid vaccination.

### Permanent Disability

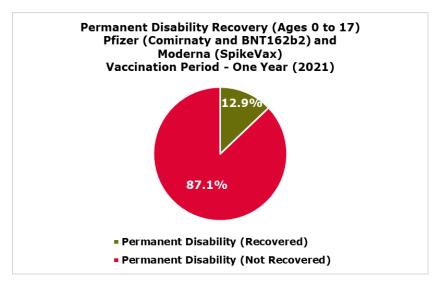
For ages **0 to 17**, a total of **252 permanent disabilities** have been reported against **Pfizer** and **Moderna** gene therapies administered in the **single** year, 2021.





For the same age group, **105 permanent disabilities** have been reported against **all** influenza vaccines over the **five** years 2015 to 2019.

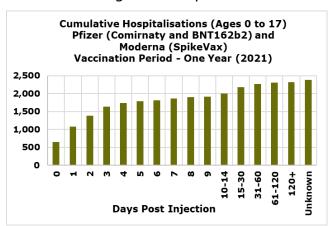
Just under **85%** of all permanent disabilities reported against Pfizer and Moderna gene therapies occurred within the first **30** days post injection. And **51%** of all permanent disabilities occurred within the first **two** days of injection.

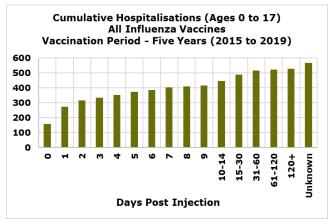


In addition, **87.1%** of all events initially classified as **permanent disabilities** against **Pfizer** and **Moderna** gene therapies have not recovered. The 'long covid' of covid vaccination.

### **Hospitalisations**

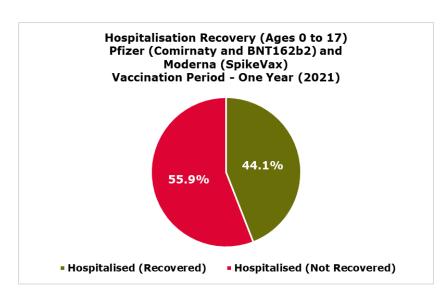
For ages **0 to 17**, a total of **2,379 hospitalisations** have been reported against **Pfizer** and **Moderna** gene therapies administered in the **single** year, 2021.





For the same age group, **567 hospitalisations** have been reported against **all** influenza vaccines over the **five** years 2015 to 2019.

**80%** of all hospitalisations reported against Pfizer and Moderna gene therapies occurred within the first **eight** days post injection. And **58%** of all hospitalisations occurred within the first **two** days of injection.



In addition, just under **56%** of all hospitalisations reported against the Pfizer and Moderna gene therapies have **not** recovered.

The 'long covid' of covid vaccination.

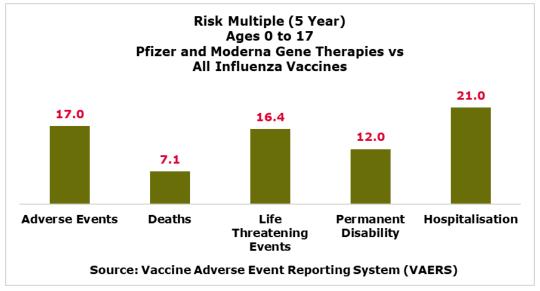
### Risk Multiple – Pfizer and Moderna vs ALL Influenza Vaccines

To obtain a rudimentary **Risk Multiple** of the Pfizer and Moderna gene therapies vs all Influenza Vaccines, we simply multiplied the number of adverse events (by category) against Pfizer and Moderna by **five**; to reflect one year of data for the gene therapies vs five years for all influenza vaccines.

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

More than likely, these risk multiples are **underestimated** as vaccination of children 12-15 was approved 10 May 2021 (<u>source</u>) and for 5-11 on 02 Nov 2021 (<u>source</u>); so the COVID-19 adverse event multiplier should be at least 7.5 not 5.0 as stated above.

The chart below shows the **Risk Multiple** of the Pfizer and Moderna gene therapies over **ALL** influenza vaccines, by adverse event category.



It's disturbing to see that based on current VAERS reporting rates, the Pfizer and Moderna gene therapies have a **risk multiple** for **deaths 7.1** times **all** influenza vaccines.

It's disturbing to see that based on current VAERS reporting rates, the Pfizer and Moderna gene therapies have a **risk multiple** for **life-threatening** events **16.4** times **all** influenza vaccines.

It's disturbing to see that based on current VAERS reporting rates, the Pfizer and Moderna gene therapies have a **risk multiple** for **permanent disabilities 12** times **all** influenza vaccines.

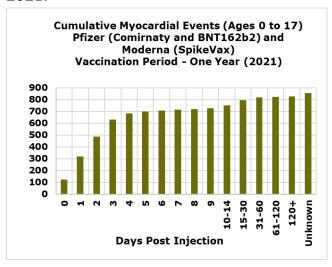
It's disturbing to see that based on current VAERS reporting rates, the Pfizer and Moderna gene therapies have a **risk multiple** for **hospitalisations 21** times **all** influenza vaccines.

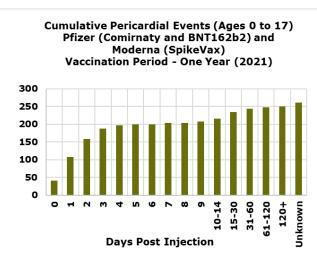
Finally, it's disturbing to see the comprehensive down-playing and obfuscation by medical regulators and bureaucracies (Australian and international) of this alarming and substantial early warning safety signal against Pfizer and Moderna gene therapies.

### 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).

For ages **0 to 17**, a total of **855 myocardial** and **261 pericardial** events have been reported against **Pfizer** and **Moderna** gene therapies administered in the **single** year, 2021.





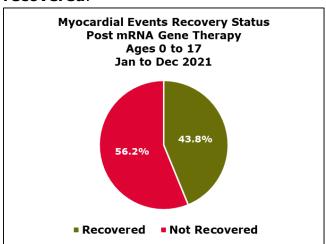
**80%** of all **myocardial** events reported against Pfizer and Moderna gene therapies occurred within the first **four** days post injection. And **57%** occurred within the first two days of injection.

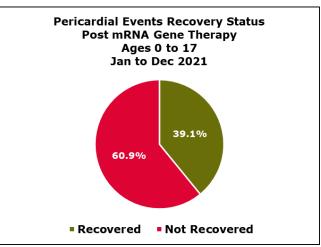
**80%** of all **pericardial** events reported against Pfizer and Moderna gene therapies occurred within the first **nine** days post injection. And **60%** occurred within the first two days of injection.

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

This assertion is **not** supported by VAERS data; which is significantly more transparent and robust compared to the soundbites issued by ATAGI.

Based on VAERS data, for the **12 months** January to December 2021, the following charts show that **56%** of **myocardial** events and **61%** of **pericardial** events have **not** recovered.





Furthermore, a 2019 study published in Circulation Research found that

"Up to **20%** of myocarditis patients may subsequently develop **chronic** inflammatory dilated cardiomyopathy (DCMi)."

In other words up **20%** of myocarditis patients will experience **ongoing** dilation of the heart muscle. And according to the Mayo Clinic

"dilated cardiomyopathy can also lead to **irregular heartbeats** (arrhythmias), **blood clots** or **sudden death**".

The same <u>study</u> also found that up to **two** years after confirmation of myocarditis, and with standard heart medication,

"for half of the patients, the **Ejection Fraction** did **not** recover to normal".

In other words for up to two years after diagnosis **50%** of myocarditis patients do **not** have **full recovery** of their heart's ability to **pump blood**.

In a further <u>harm/benefit analysis</u> focused on Cardiac Adverse Events (CAE), researchers at the University of California found that:

"For boys 12-15 without medical comorbidities receiving their second mRNA vaccination dose, the rate of CAE is 3.7 to 6.1 times higher than their 120-day COVID-19 hospitalisation risk as of August 21, 2021." and

"For **boys 16-17 without medical comorbidities**, the rate of CAE is currently **2.1** to **3.5** times **higher** than their 120-day COVID-19 hospitalisation risk.

In other words, for boys under 17 with no underlying health conditions, the risk of a Cardiac Adverse Event, after their second dose of mRNA vaccination is 2.1 to 6.1 times higher than their 120-day risk of COVID-19 hospitalisation.

The authors of the harm/benefit analysis conclude that:

"The long-term consequences of this vaccine-associated cardiac inflammation are not yet fully defined and should be studied."

Echoing this conclusion a recent <u>study</u> published in the Journal of the American Medical Association (Cardiology) also concluded that:

"The long-term risks of Myocarditis and Pericarditis in children and adolescents after vaccination with Pfizer (BNT162b2) mRNA COVID-19 vaccines are entirely unknown".

Despite the near zero risk to children and adolescents from COVID-19, the significant safety warning of serious harm and death evident in adverse event data, and multiple credible peer-reviewed studies showing irreversible and ongoing harm, ATAGI continues to:

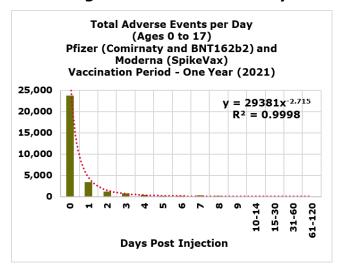
"Reaffirm that the **benefits** of Pfizer **outweigh** the risks of myocarditis and/or pericarditis for **any** age group and **strongly** recommend eligible individuals without contraindications to be offered vaccination." (Refer Appendix 7 and source).

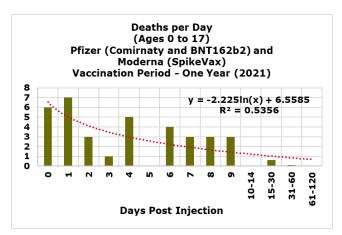
This is perhaps one of the most **egregiously damaging** and **ill-informed** statements made by any medical authority in living memory. It is **negligently devoid** of any credible and risk/benefit analysis and any precautionary foresight.

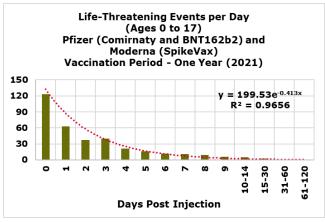
#### Causal Link - Vaccination and Adverse Events

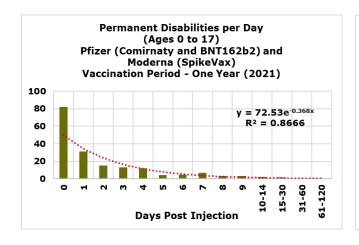
The following charts show All Adverse Events, Deaths, Life-Threatening Events, Permanent Disabilities, and Hospitalisations **per day** for **each day post injection**.

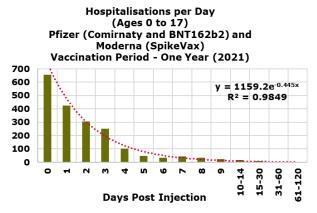
The data is sourced from VAERS for **Pfizer** and **Moderna** gene therapies administered to children **aged 0 to 17** from **January to December 2021**.

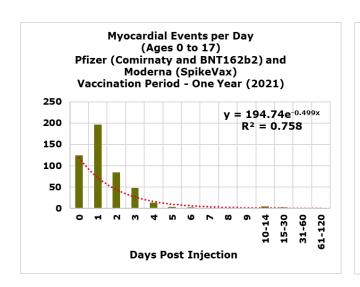


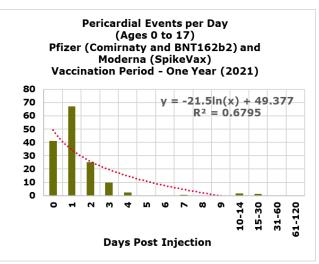












Each of these charts shows that the **vast majority** of adverse events (inc. deaths, life-threatening events, permanent disabilities, hospitalisations, and myocardial and pericardial events) occur on the **day** of **injection** and up to **two days** post injection.

If there was no causal link between vaccination and any of these adverse events:

- 1. There would **not** be an **excess of reports** of adverse events on days 0, 1 and 2 post injection; and
- 2. The reported events would either be similar or random for each day post injection.

And since this pattern is largely **consistent** and **repeated** for **all** adverse events (inc. death, life-threatening events, permanent disabilities, hospitalisations, and myocardial and pericardial events), this is **irrefutable** proof that these tragic outcomes are **caused** by the injection of children and adolescents with **novel** and **untested** gene therapies.

This causal link is not surprising, "**no** mRNA vaccine had been approved until end of 2020" (source).

And yet the head of the Australian TGA (John Skerritt) has the **negligent deceitful irresponsibility** to say the vaccine had been **extensively** tested in children with **no** safety concerns arising and that

"There were no safety signals, as we call them, no safety problems identified in those trials." (<a href="source">source</a>)

Given the information, data, and analysis provided in this paper, this statement by John Skerritt is a total **fabrication** and **not** based on any **fact** or **evidence**.

# **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 groups 1:

- 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	Х				
		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.<sup>2</sup> 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 Reduction - Hospitalisation Ages 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)

A summary of the ABS guidelines for certifying COVID-19 deaths is as follows

- "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".



# 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

Disease	or	1	Cause of Death	Interval between
condition l	eading			onset and Death
directly to de	ath.	Α	Acute respiratory distress	2 days
Antecedent (	Causes	^	syndrome	2 days
that gave rise	to the		3,114.6	
above	cause,	В	Pneumonia	10 days
stating underlying ca	the use on	С	COVID-19	10 days
the lowest lin	e.	D		
_	ificant	2		
conditions				
contributing	to			
death but	not			
related to	the			
diseases	or			
conditions c	ausing			
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		Cause of Death	Interval between onset and Death	
directly to death.  Antecedent Causes	Α	Acute respiratory distress syndrome	2 days	
that gave rise to the				
above cause,	В	Pneumonia	10 days	
stating the	С	COVID-19	10 days	

underlying cause on the lowest line.	D	
Other significant conditions contributing to death but not related to the diseases or conditions causing it.	2	Coronary artery disease, Type 2 Diabetes, COPD

# 5.3 Example of other specified immunocompromised 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	А	Acute respiratory distress syndrome	2 days		
above cause,	В	Pneumonia	10 days		
stating the underlying cause on		COVID-19	10 days		
the lowest line.					
Other significant conditions	2	Diffuse large B cell lymphoma, Ir	nmunosuppressant		
contributing to					
death but not					
related to the					
diseases or					

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

Disease or	1	Cause of Death	Interval between
condition leading			onset and Death
directly to death. Antecedent Causes	Α	Acute respiratory distress syndrome	2 days
that gave rise to the			
above cause,		Pneumonia	10 days
stating the underlying cause on		COVID-19	10 days
the lowest line.	D		
Other significant conditions	2	Cerebral palsy	
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 10<sup>th</sup> 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