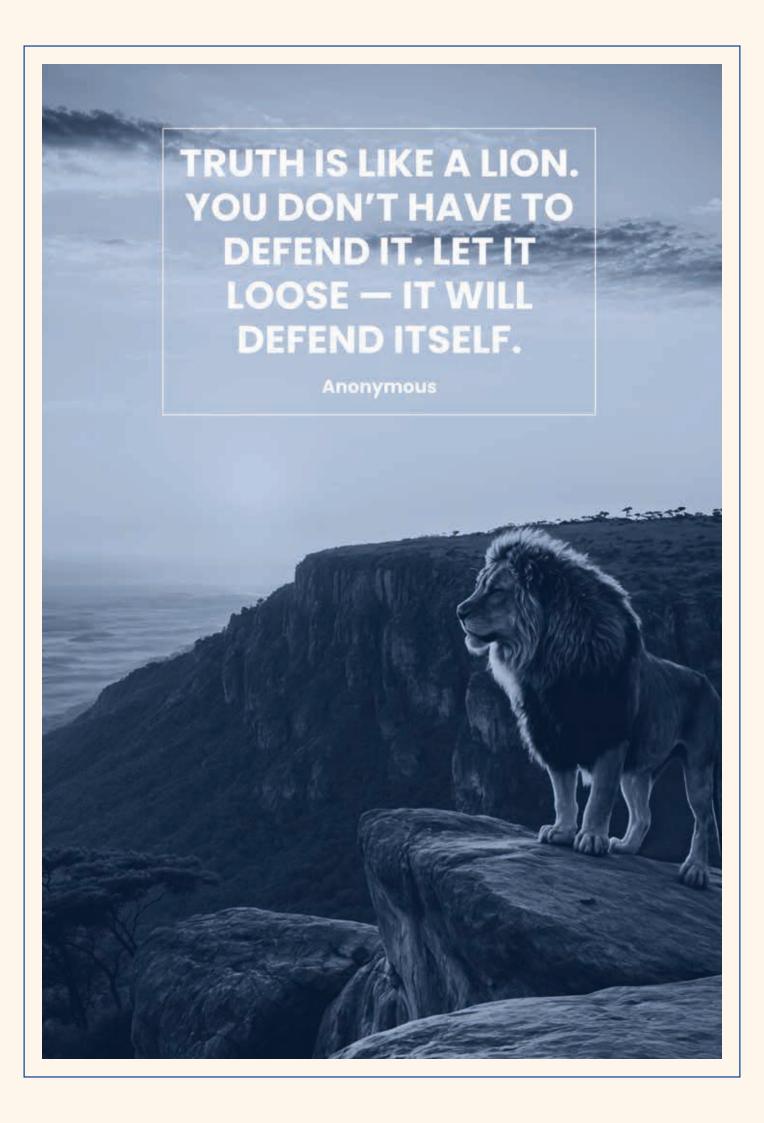




# THE PEOPLE'S POSITION

COVID-19 LESSONS LEARNED | PHASE TWO

Special Report: New Zealand Royal Commission of Inquiry



# THE PEOPLE'S POSITION

**COVID-19 LESSONS LEARNED | PHASE TWO** 

Special Report: New Zealand Royal Commission of Inquiry



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### **Dedication**

To the individuals, families, and communities whose lives were forever altered by New Zealand's COVID response:

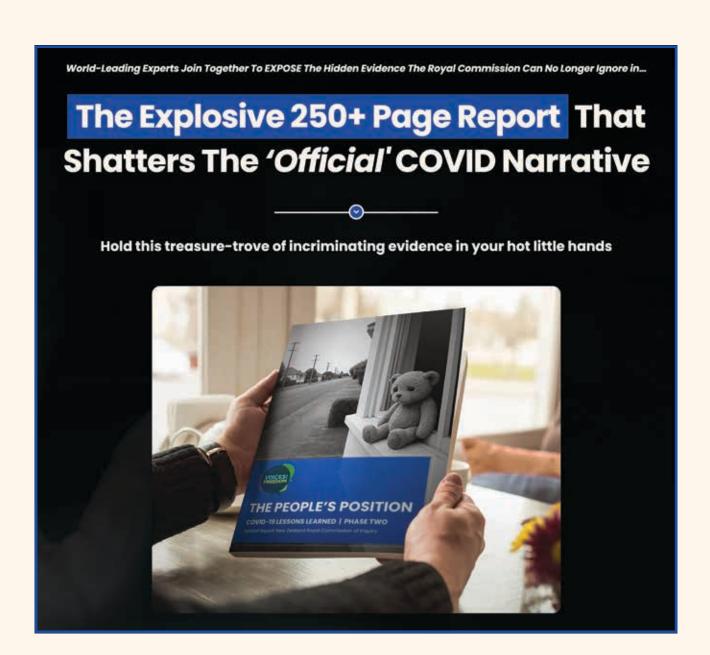
Those who lost livelihoods, relationships, health, and hope, yet found the strength to begin again. Your courage and endurance are the quiet heartbeat of this work.

And to the resisters—those who refused to stay silent. You spoke up, stood firm, asked the hard questions, and carried truth through storm after storm.

Whether you gave your time, your skills, your voice, or your financial support, you made this movement possible.

This book is for all of you.

It stands as proof that when everyday people rise with purpose, unity, and resolve, we can ensure the truth is told.



### **MAKE THIS MATTER**

Had The People's Position report been formally commissioned by the commercial sector, it would have carried a multiple six-figure price tag. Instead, we've made it available to the Royal Commission freely in the spirit of transparency, accountability, and public service. And now it's available to you.

However, its true value lies in what you do with it next.

### HOW TO MAKE THE MOST OF THIS BOOK: Talk about it. Loudly.

This work is designed to spark discussion and empower action, but only if it's seen and shared. Mention it in conversations with friends, colleagues, and family. Ask questions. Debate. Be brave. Post about it online

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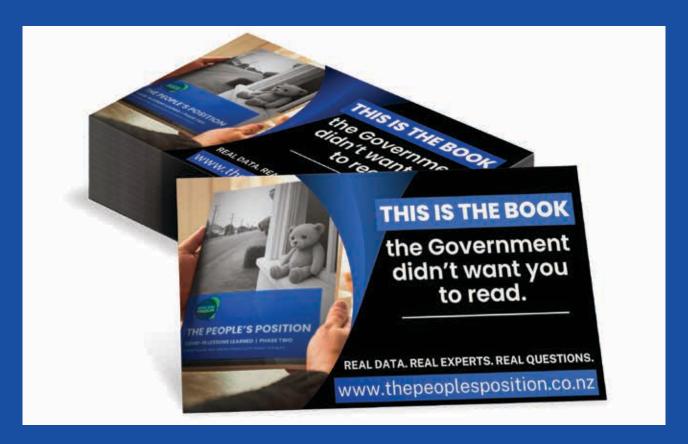
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### **FOREWORD**

The People's Position has been created as a foundational tool to assist the Commissioners of New Zealand's Phase Two COVID-19 Royal Commission of Inquiry. Our aim is to offer a clear, credible, and accessible overview of the key issues, assumptions, and consequences of the COVID years, particularly those perspectives unlikely to be presented by government agencies, mainstream media, favoured experts, or academic institutions involved in New Zealand's response.

This report provides a succinct summary of what was overlooked in Phase One of the Inquiry and offers an essential lens through which to assess the decisions made and their far-reaching impacts. It has been designed to inform the Commissioners' lines of questioning, engagement with key decision-makers, and their eventual report.

The People's Position is not a deep dive. Instead, it offers a structured series of concise, referenced

summaries intended to be read and absorbed in short sittings. The material covers:

- Foundations & Frameworks
- · Health & Science
- Legal & Ethical Considerations
- Social Impacts & Civil Liberties
- Media, Messaging & Narrative Control
- International Context & Global Influence
- Moving Forward

Within these broad sections are targeted subsections that distill complex topics into digestible insights. The goal is not to cover every angle, but rather to highlight what the Commissioners likely don't know they don't know. It includes information long recognised by those in the global freedom movement, but obscured from the general public through censorship, narrative control, and the vilification of dissent.



This project has been driven by a deep desire to see the truth acknowledged and acted upon.

We extend our heartfelt thanks to every contributor to this report. Many have endured professional and personal cost for continuing to speak out. Their courage and integrity have been vital to this work.

Special thanks must go to Katie Ashby-Koppens, who gave months of her life to bring this project together. She lived and breathed it, pulled together a remarkable team, and ensured every piece of information came from those with the right expertise and experience to speak on it.

We are deeply grateful for the contribution of Michelle, CJ, and Dianne – this project would not exist in its current form without their input and support. To our wider VFF and RCR crew, and to our families who have given up so much time with us over the years, thank you. We couldn't do this without you.

We acknowledge there are gaps. The compressed timeframe and scale of the task have meant prioritising what mattered most. In many ways, this report is a world first. It has been read in full by all three Commissioners. We've had the opportunity to meet with them several times, accompanied by international and local experts, to present and discuss these issues in person.

Thanks to those conversations, the Commissioners have heard perspectives they otherwise would not have encountered.

We hope this work will help ensure that the lessons of the past five years are truly understood and that the mistakes of the COVID era are never repeated.

### **Alia Bland & Claire Deeks**

Co-Founders, Voices for Freedom



# INTRODUCTION

### A message from the coordinator of the People's Position

My name is Katie Ashby-Koppens, and it has been a privilege to both walk and work alongside those who made this project possible. A special thank you to Michelle who has brought these words to life and provided a stark reminder to what we all lived.

I am a Kiwi and serve as Head of Legal for Voices for Freedom and Reality Check Radio - organisations that faced censorship and vilification during the COVID-19 pandemic for challenging prevailing narratives and advocating for civil liberties.

In addition, I am a practising lawyer in New South Wales, Australia. Throughout the COVID-19 era and following, I have supported thousands of individuals and organisations across both sides of the Tasman and internationally, assisting those affected by this crisis. I continue to provide legal support to many who are still grappling with the ongoing repercussions of the pandemic-related health measures.

We lobbied for the establishment of this Phase Two Royal Commission because the original terms of reference (Phase One) omitted critical areas. That advocacy resulted in both Coalition agreements including commitments to a new or extended inquiry to address the gaps.

We also engaged constructively with the Phase One Commissioners, who initiated contact with us and invited us back for a second meeting. After our meetings with the Phase One Commissioners, Professor Blakely acknowledged that societal divisions run deep in the wake of COVID and that "many people have felt and actually been wronged." \(^1\)

Professor Blakely described Voices for Freedom: as representative of a "substantial minority;" that we had a "very valid perspective scientifically and socially;" and that discussions with us moved his thinking, particularly on the vaccine mandates.

Given the scale of censorship and the intensity of political vilification, some of the information in this document may be unfamiliar or surprising. We've compiled it not only to inform, but also to provide a foundation for understanding the broader picture, one shaped by lived experiences, unanswered questions, and concerns that have long been suppressed from public view.

We have included suggested questions for agencies and key decision-makers. These are not hypothetical—many have gone unanswered for nearly five years. In some cases, we never even received an acknowledgement when questions were asked.

This raises a fundamental question: why the secrecy if the pandemic response was truly about our health; funded through our taxpayer dollars; and justified as necessary for our safety?



### An invitation to the Commission

Each contributor to this document extends a standing invitation to speak with the Commissioners directly, should they wish to hear their perspective firsthand. The dramatis personae about each begins on page 267.

We welcome the opportunity to meet with the Commissioners, to walk you through this document, and bring these pages to life with the depth and clarity they deserve.

### Overview of this document:

The People's Position is structured according to the Royal Commission Phase Two Terms of Reference, in three parts. But first there is an Introduction: An opening section that sets out the foundational premises – the lens through which we approach this submission and the **propositions** that underpin our knowledge, expectations, and experiences. We have numbered this section 0.

The Phase Two of the Royal Commission of Inquiry into lessons learned from the COVID-19 public health response is split into three parts, which we have responded to as follows:

- 1.0 The largest section corresponds to what Phase Two describes as: Vaccines including mandates, approval processes, and safety (including the monitoring and reporting of adverse events). This is our most extensive section, reflecting the central role vaccines played in the government's COVID-19 response, and the breadth of unresolved concerns they caused that persist for many.
- 2.0 The second section the Phase Two Commission described this as: Testing, tracing, and other public health tools, for example RAT tests and masks. We have touched on only a handful but the key non-pharmaceutical health interventions that fall within this category.
- 3.0 The third section addresses: Lockdowns in particular, the nationwide lockdown of August–September 2021 and the prolonged restrictions in Auckland and Northland later that year. This section is our smallest section we have left that section to those who will be sharing their lived experiences with the Commission. The decision to confine healthy populations for extended periods in some cases, nearly two years will be remembered as one of the most socially and economically damaging policy decisions in our nation's history.

Phase Two is a critical opportunity – not just to review the past, but to confront it – let's shed some sunlight on the last five years that has changed all our lives, let's give a voice to the silenced, and air to the gaslit.

The COVID-19 response left deep scars: broken trust, divided communities, and real human suffering. The Commission now has a rare chance to uncover what was done well, expose what went wrong, and begin the long process of healing. Acknowledging what happened, and why, is the first step toward restoring public confidence, professional integrity, and democratic accountability. The defining government decisions of 2020 and 2022 reshaped lives across the country. Vaccine mandates. Lockdowns. School closures. Border controls. These were not abstract policies—they disrupted childhoods, tore families apart, meant missed farewells, shuttered businesses, and triggered cascading harm throughout society. The damage was not incidental. It was foreseeable.

**The Phase Two Terms of Reference call for a real life view:** Were these decisions truly informed, necessary, balanced, and proportionate?

- Were officials warned about the fallout from isolation, school closures, and economic collapse, and did they listen?
- Did they weigh the social costs against the promised benefits?
- And most critically, did they follow the advice and information they had, or ignore it?

This is the Commission's moment to prove that accountability still matters.

- https://www.rnz.co.nz/news/national/526362/covid-19-inqui
- <sup>2</sup> https://x.com/voices\_nz/status/1862239178362335440?t=wvZ
- <sup>3</sup> https://x.com/voices\_nz/status/1862239178362335440
- 4 https://x.com/voices\_nz/status/1862232458181460419

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# 0.0 STARTING POINT

This document is presented to support the work of the Royal Commission as it undertakes Phase Two of its inquiry into New Zealand's COVID-19 response. It challenges a number of core assumptions that underpinned Phase One – assumptions that were never adequately explained or justified. Namely: that COVID-19 was an unusually dangerous virus with a high fatality rate; that government messaging was accurate; and that vaccination was the only viable path out of the pandemic. These assumptions were not only incorrect—they became the basis for policies that caused widespread and lasting harm.

From early on, the Infection Fatality Rate (IFR) for COVID-19 was known to be low for the vast majority of people, yet this was obscured through the strategic use of modelled IFRs and inflated Case Fatality Rates (CFRs).

Those who questioned the official line were not met with open dialogue, but with censorship, gaslighting, and discrimination. Medical professionals were silenced, investigated and their careers threatened. Community groups were deplatformed.

Ordinary citizens were made to feel dangerous, selfish, or unstable for asking legitimate questions.

This project brings forward evidence that was deliberately buried, dismissed, or suppressed. Many of the issues presented here will be new to the public - not because they lacked merit, but because they were denied a fair hearing. The information vacuum was not accidental; it was the result of deliberate coordination between government agencies, media outlets, and social media platforms.

While not specifically topics within the Royal Commission Phase Two purview, the introduction sets out the foundational premises – the lens through which we approach this submission and the propositions that underpin our knowledge, expectations, and experiences. It is the starting point for the rest of the document.

- 0.1 How Dangerous was COVID-19?
- 0.2 NZ's Pandemic Planning
- 0.3 Treatment
- 0.4 Psychological Techniques
- 0.5 Cornerstone Principles
- 0.6 Censorship
- 0.7 World Health Organization



# 0.1 MISREPRESENTED RISK

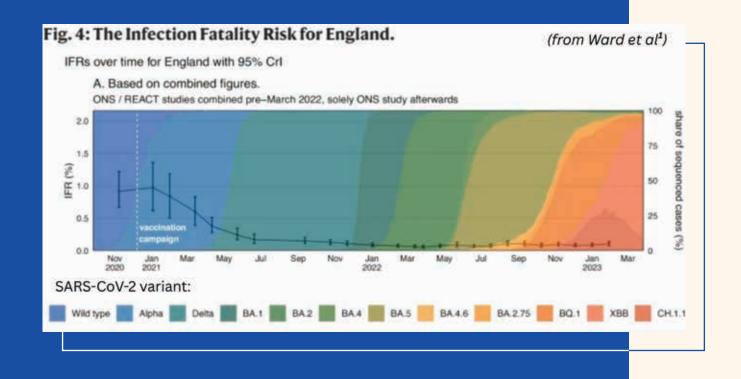
Early in the pandemic, governments and media consistently overstated the danger of COVID-19. The true measure of risk, the Infection Fatality Rate (IFR), was often replaced in public messaging by the far higher Case Fatality Rate (CFR), creating the illusion of a deadlier virus. In reality, global IFR estimates settled around 0.15% in 2020, comparable to a severe influenza season (0.13%). For people under 70, the IFR was even lower, with those under 60 facing risks as low as 0.035%.

This inflated perception was compounded by widespread misuse of PCR testing. Designed to detect genetic fragments – not diagnose infectious disease – the PCR test was authorised for emergency use in the U.S. and used at high cycle thresholds (up to 40), generating significant numbers of false positives. As a result, many non-infectious individuals were counted as active COVID-19 cases, artificially boosting infection statistics and justifying extreme public health measures. Combined, these factors exaggerated the threat and distorted risk communication, contributing to policies that many now question as disproportionate.

### In this section:

A. Infection Fatality Rate vs Case Fatality Rate

B. Asymptomatic infection, PCR testing and false positives



# 0.1 COVID-19 - DANGEROUS?

HOW DANGEROUS WAS COVID-19?

0.1A. Infection Fatality Rate (IFR) and Case Fatality Rate (CFR)

Dr Simon Brown and Katie Ashby-Koppens

### Why this issue is relevant:

The perceived risk of death from SARS-CoV-2 infection (COVID-19) was a central justification for unprecedented non-pharmacological public health interventions - border closures, lockdowns, school and business shutdowns, mask mandates, and social distancing.

However, the **Infection Fatality Rate (IFR)** of COVID-19 was significantly overestimated early in the pandemic. Moreover, the **Case Fatality Rate (CFR)** was often conflated with the IFR in public communication, misleading the public into believing the disease was far deadlier than it actually was for most people.

In reality, the IFR of COVID-19 was not dramatically different from that of a severe influenza season: global IFR in 2020 was ~0.15% (where a bad flu season was ~0.13%). This misrepresentation shaped public perception, media messaging, and policy decisions with wide-reaching social, economic, and psychological consequences.

The Infection Fatality Rate (IFR) is the probability of death among all infected individuals - symptomatic and asymptomatic - and is a central metric for determining the real danger of a virus.

The Case Fatality Rate (CFR) measures deaths among confirmed symptomatic cases and does not account for unreported or mild/asymptomatic infections, which can significantly inflate the apparent risk.

Early estimates of COVID-19's lethality were based on CFRs from overwhelmed regions (e.g. Wuhan), and these were widely misinterpreted as representing IFRs.

COVID-19 IFR varies by population demographics, age, comorbidities, and outbreak context. In general:

- Global IFR in 2020 (pre-vaccine): ~0.15%<sup>2,3,4</sup> (bad flu season ~0.13%)<sup>5</sup>
  - IFR for people 0-59: ~0.035%<sup>4</sup>
  - IFR for people 0-69: ~0.095%4

COVID-19 mortality risk increases sharply with age, and the majority of deaths in many Western countries occurred in nursing homes or among the elderly with comorbidities.

By presenting CFRs as if they were IFRs, authorities and media distorted public understanding, escalating fear and justifying extreme measures.

The IFR is critical to assess for understanding risk communication, evaluating proportionality of responses, and ensuring accountability.

Seroprevalence studies are undertaken to understand the IFR. **Key Expert:** Prof. John loannidis (Stanford), most-cited living biomedical scientist is the principal author of the global COVID-19 IFR studies found early IFRs to be not too dissimilar from a bad influenza season.<sup>2,3,4</sup>

### **Details:**

#### CFR vs IFR

- CFR: Deaths / reported symptomatic cases → Overestimates risk
- IFR: Deaths / all infections (incl. asymptomatic) → More accurate for public risk

### 0. Early Estimates Inflated the Pandemic Risk:

- IFR: ~1.0%, 10x that of seasonal influenza.
- Actual influenza IFR: up to 0.13% (seasonal, non-pandemic)<sup>5</sup>
- Global IFR ~0.15% before vaccines<sup>3</sup>
  - IFR 0-59 yrs: ~0.035%<sup>4</sup>
  - IFR 0-69 yrs: ~0.095%4

### IFR by Variant and Context:

- 1. Wuhan / Ancestral Strain
- IFR: ~0.23% all ages<sup>3</sup>
   IFR under 70: median ~0.05%<sup>2,3</sup>
- Early CFRs: Wuhan (3.4%), USA (1%) Dr. Fauci testimony, March 2020<sup>6</sup>

### Diamond Princess (Feb 2020):

- IFR: ~1.3% among elderly; no deaths under 60
- 712 infections on board; 9 deaths
- "Rare and extremely valuable" opportunity for closedpopulation study<sup>7, 8, 9</sup>

### 2. Alpha (B.1.1.7)

- IFR: ~0.5%
- CFR: ~0.9%
- Higher hospitalisation risk than ancestral strain<sup>10</sup>

#### 3. Delta (B.1.617.2)

- Justified NZ's August 2021 lockdown
- IFR: <0.2%<sup>1</sup>, ~0.4%<sup>11</sup>
- CFR: ~0.6%<sup>11</sup>

### 4. Omicron (B.1.1.529 and sublineages)

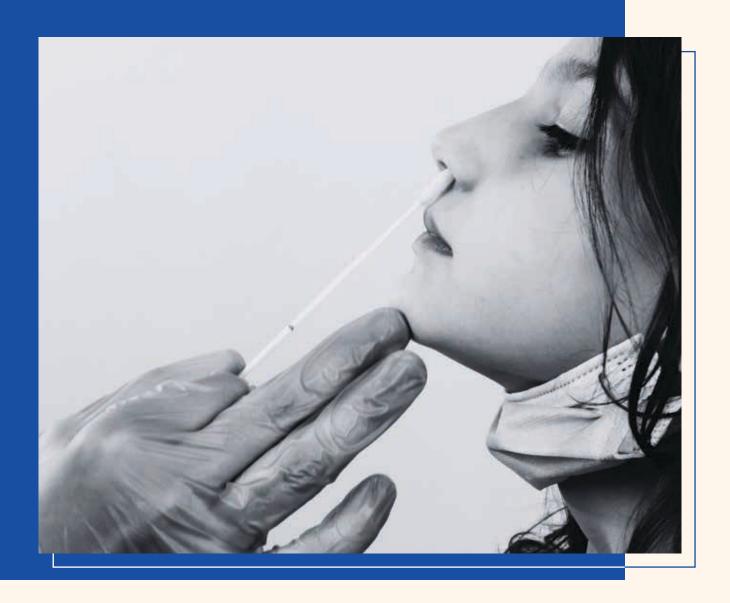
- IFR: <0.1% (Austria, UK), ~78.7% lower than earlier variants
- Highly transmissible but much lower fatality<sup>12</sup>

### Important Questions for the Commissioners to Ask — and of Whom:

### Ministry of Health Medsafe / COVID-19 Technical Advisory Group (CV TAG):

- Was the government aware of the distinction between CFR and IFR early in the pandemic?
- What seroprevalence studies did the MOH and health advisors rely upon, and ther dates, in order to provide to the relevant decision makers about IFR rates for COVID-19 and annual bad flu seasons?
- Was CFRs used in public messaging instead of IFRs?
- Was this conflation intentional to induce fear and justify extreme measures?
- What guidance did the Ministry receive or give regarding risk communication?
- What role did media and behavioural science units play in shaping this messaging?
- Was the early inflated IFR numbers, which predominantly reflected infections amongst the elderly and infirm, inflated by medical protocols that e.g. refused antibiotic treatment, over prescribing of midazolam?

- https://doi.org/10.1038/s41467-024-47199-3
- <sup>2</sup> https://onlinelibrary.wiley.com/doi/10.1111/eci.13554
- <sup>3</sup> Ioannidis WHO Bulletin review (2020): https://iris.who.int/bitstream/handle/10665/340124/
- <sup>4</sup> https://doi.org/10.1016/j.envres.2022.114655
- <sup>5</sup> https://www.cdc.gov/flu-burden/php/about/index.html
- 6 https://www.c-span.org/clip/house-committee/
- <sup>7</sup> https://pmc.ncbi.nlm.nih.gov/articles/PMC7202311/
- 8 https://www.hdruk.ac.uk/news/131952/
- <sup>9</sup> https://en.wikipedia.org/wiki/COVID-19\_pandemic\_on\_Diamond\_
- <sup>10</sup> https://link.springer.com/article/10.1007/s00705-022-05365-2
- https://www.sciencedirect.com/science/article/pii/
- <sup>12</sup> https://doi.org/10.1016/j.ijid.2022.04.029



# 0.1 COVID-19 - DANGEROUS?

**HOW DANGEROUS WAS COVID-19?** 

0.1.B Asymptomatic Infection, False Positives and Polymerase Chain Reaction (PCR) Testing

Katie Ashby-Koppens

### Why this issue is relevant:

PCR testing was granted Emergency Use Authorization for COVID-19 detection. It is an unreliable method for diagnosing active infections, and as a result, the test produced a significant number of false positives, which were included in daily infection tallies, leading to an inflated count of COVID-19 cases.

Moreover, alternative testing methods were not made available until later in 2021, further restricting options for accurate diagnosis or self testing. This limited testing landscape essentially controlled the narrative of infection rates and impacted public perception and policy decisions.

Polymerase Chain Reaction (PCR) is a laboratory technique designed to amplify DNA sequences. Dr. Kary Mullis, the inventor of PCR in 1983, publicly stated that the test was never intended for diagnosing infectious diseases. It should not have been used to detect COVID-19.

Despite its original purpose, the PCR test was granted Emergency Use Authorization by the FDA for COVID-19 detection, a use for which it had never been tested or validated (see Issue 1.3). This decision raised significant concerns, as the PCR test was applied in a context for which it was neither designed nor proven effective.

#### **Details:**

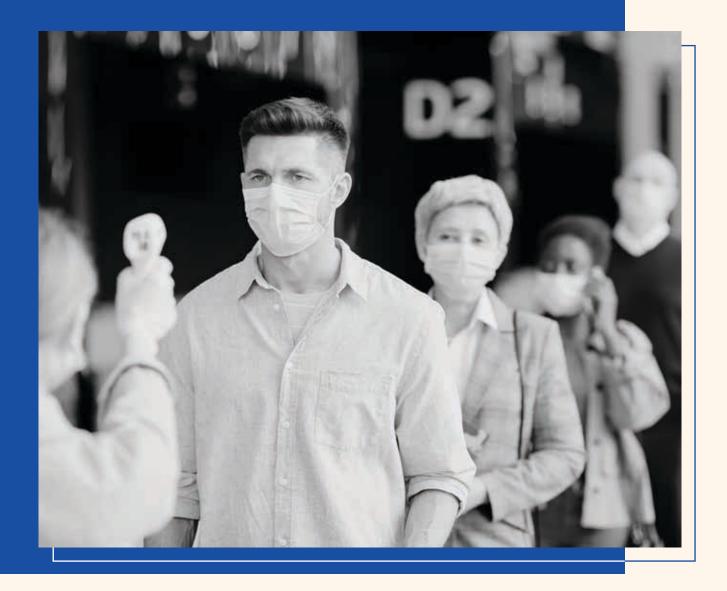
- On 4 February 2020, the FDA granted emergency use of the 2019-nCoV Real-Time RT-PCR Diagnostic Panel. To date, this test has been limited to use at CDC laboratories; today's authorisation allows the use of the test at any CDC-qualified lab across the country.<sup>1</sup>
- The PCR test is known to be extremely unreliable in terms of accurately identifying the presence of a "live" or infectious COVID-19 virus in humans.<sup>2</sup>
- The PCR test used up to 40 cycles, meaning it was able to identify 'dead nucleotides' (old infection), which was treated as a positive infection and included in daily tallies.<sup>3</sup>
- The PCR test does not distinguish between replicative virus and inactive viral fragments. The test is, therefore, indeterminate for the presence of transmissible SARS-CoV-2 viruses in a tested individual.<sup>4</sup>
- Early estimates indicate that 50–75% of the time when an individual shows a positive PCR result, the subject is postinfectious, whether with COVID-19 or another virus.<sup>5</sup>
- This means that current estimates are likely to produce high levels of false positives when the test is used in people who are at low risk of infection.<sup>6</sup>
- The test does not have a known value, Ct (cycle threshold), at which an individual poses a public health risk. A recent study of subjects with tests positive with Ct values between 35 and 40 found only 5/60 (8%) had a positive viral culture - a surrogate for infectious virus.<sup>7</sup>
- According to several reports, the diagnostic accuracy of many of the currently available RT-PCR tests for SARS-CoV-2 may be lower than optimal, as false-positive and falsenegative results are seen in a small but significant proportion of individuals.<sup>8</sup>

### Important Questions for the Commissioners to Ask — and of Whom:

### Ministry of Health Medsafe / COVID-19 Technical Advisory Group (CV TAG):

- Why was the PCR test used as the primary diagnostic tool for active infection despite known limitations in distinguishing live virus from viral debris?
- What specific evidence was reviewed prior to the approval of PCR for Emergency Use Authorization in New Zealand?
- Was the Ministry aware of the risks associated with high Ct values (e.g. over 35) when reporting positive test results? If so, why was no guidance provided on maximum cycle thresholds for diagnostic relevance?
- Why were rapid antigen tests or other methods not introduced sooner to complement or replace PCR testing?
- Were health professionals and the public adequately informed about the potential for false positives and the distinction between infectious and non-infectious individuals?

- <sup>1</sup> FDA EUA announcement 4 Feb 2020: https://www.fda.gov/news-events/press-announcements/
- <sup>2</sup> External peer review of the RT-PCR test: https://www.researchgate.net/publication/346483715\_Exter
- <sup>3</sup> NZ Ministry of Health OIA response (via NZDSOS) confirming up to 40 PCR cycles used: https://eadn-wc05-8442974.nxedge.io/cdn/wp-content/
- <sup>4</sup> Bossuyt, PM (2020). Testing COVID-19 tests faces methodological challenges: <a href="https://pubmed.ncbi.nlm.nih.gov/32622902/">https://pubmed.ncbi.nlm.nih.gov/32622902/</a>
- Mina, MJ, et al. (2021). Clarifying the evidence on SARS-CoV-2 antigen rapid tests: https://pubmed.ncbi.nlm.nih.gov/33609444/
- <sup>6</sup> Surkova, E, et al. (2020). False positive COVID-19 results: hidden problems and costs: https://www.thelancet.com/journals/lanres/article/PIIS2213-
- <sup>7</sup> Singanayagam, A, et al. (2020). Duration of infectiousness and RT-PCR Ct values: <a href="https://pubmed.ncbi.nlm.nih.gov/32794447/">https://pubmed.ncbi.nlm.nih.gov/32794447/</a>
- <sup>8</sup> Zou, Y, et al. (2021). Analytical performance of COVID-19 detection methods (RT-PCR): scientific and societal concerns: https://pmc.ncbi.nlm.nih.gov/articles/PMC8305061/



# 0.2 NZ'S PANDEMIC PLAN

## 0.2 NZ's influenza pandemic plan not followed - elimination strategy preferred

Simon Thornley

### Why this issue is relevant:

New Zealand abandoned its long-standing influenza pandemic plan in favour of an extreme elimination strategy, imposing harsh lockdowns for a virus that ultimately had a minimal impact on overall mortality. This unprecedented shift raises serious questions about the basis for decision-making and the dismissal of established protocols.

New Zealand had a national influenza pandemic plan in place for decades, which underwent a significant revision in 2017 following lessons learned from the mild 2009 'swine flu' pandemic.<sup>1</sup>

The core principle of the national influenza pandemic plan was to calibrate the response according to the severity of the threat while preserving normal economic and social activity as much as possible. However, in early 2020, New Zealand abruptly departed from this approach and adopted an elimination strategy instead.

This radical shift occurred despite COVID-19 having a relatively low fatality rate, as reflected in the stable all-cause mortality figures prior to the vaccine rollout.

In early April 2020, then Director-General of Health Dr Ashley Bloomfield stated there was "no Plan B" and that lockdowns would remain in place until COVID-19 was "stamped out."

### **Details:**

New Zealand had a pandemic plan in 2017, entitled New Zealand Influenza Pandemic Plan: A Framework for Action (2nd edition).<sup>2</sup> It was planned around a severe viral illness with a fatality ratio of 2%. It was estimated that in the first eight-week period, 38,000 deaths would occur, compared with New Zealand's usual weekly death rate of about 600 deaths a week. This would entail a death rate (per week) 8x normal. It was also recognised that some so-called 'pandemics' had little impact on death rates.

Features of the COVID-19 response, such as elimination and vaccine mandates, were never a part of previous pandemic planning in New Zealand. During COVID-19, until the vaccines were rolled out, overall death rates were no different to background, despite forecasts of mass deaths. It is not readily apparent that COVID-19 necessitated a response that went beyond the 2017 plan, since it did not meet the fatality rate of  $2\%^2$  —nowhere near the fatality rate forecast in the 2017 document.<sup>3</sup>

No mention was ever made of the necessity of lockdowns or long-term elimination of the virus.

### Important Questions for the Commissioners to Ask — and of Whom:

Ministry of Health officials, particularly the Director of Public Health and Director-General of Health, Dr Ashley Bloomfield:

Did the Ministry of Health formally assess the severity of COVID-19 in early 2020, and how did this assessment compare with past pandemics, such as the 2009 HINI outbreak?

Cabinet Ministers involved in COVID-19 decision-making, especially Prime Minister Jacinda Ardern, Minister of Health, and officials from the Department of the Prime Minister and Cabinet (DPMC), including the COVID-19 Response Group:

On what evidence or advice did the government base its decision to abandon the existing pandemic plan in favour of an elimination strategy?

Ministry of Health, Cabinet officials, and the COVID-19 Technical Advisory Group (CV-TAG):

Why were extreme measures like nationwide lockdowns and strict border closures implemented for a virus with a relatively low fatality rate, despite the 2017 plan emphasising proportionality and continuity of normal life?

- 1 https://link.springer.com/chapter/10.1007/978-981-16-7385-6\_18
- <sup>2</sup> 2017 version of pandemic plan: https://ndhadeliver.natlib.govt.nz/delivery/DeliveryManagerServlet?dps\_pid=IE53291176
- <sup>3</sup> Even generous fatality estimates were about 0.6%: https://www.sciencedirect.com/science/article/pii/S1201971220321809



# 0.3 TREATMENT

# Abandonment of Holistic Health and Suppression of Early Treatments in COVID-19 Response

Zealand's COVID-19 response sidelined well-established health practices treatment options in favour of a narrow, non and pharmaceutical-only strategy. Despite scientific evidence and international precedents, the government failed to promote basic health measures such as vitamin D supplementation, sunlight exposure, exercise, nutrition, and metabolic health key contributors to immune resilience. Instead, public messaging focused solely on compliance, lockdowns, and eventual vaccination.

At the same time, safe, approved medications like Ivermectin and Hydroxychloroquine - legally available for off-label use - were effectively prohibited through regulatory intimidation and professional sanctions. Doctors were blocked from using clinical judgement and censured for offering early outpatient treatment options, even when global evidence suggested potential benefit.

This abandonment of ordinary, low-risk treatments and lifestyle promotion deprived New Zealanders of basic tools to manage their health during a critical time. This project brings forward evidence that was deliberately buried, dismissed, or suppressed. Many of the issues presented

here will be new to the public - not because they lacked merit, but because they were denied a fair hearing. The information vacuum was not accidental; it was the result of deliberate coordination between government agencies, media outlets, and social media platforms.

While not specifically topics within the Royal Commission Phase Two purview, the introduction sets out the foundational premises – the lens through which we approach this submission and the propositions that underpin our knowledge, expectations, and experiences. It is the starting point for the rest of the document.

It also created a false perception that COVID-19 was untreatable without vaccination, undermining informed consent and eroding trust in public health leadership.

### In this section

- A. Healthy living was not promoted
- B. Benefits of Vitamin D
- C. Repurposed drugs Ivermectin
- D. Repurposed drugs Hydroxychloroquine



# **0.3 TREATMENT**

### A. Staying healthy was never promoted

Dr Cindy de Villiers

### Why this issue is relevant:

For all the millions spent on government advertising, not once was the simple, empowering message shared: your health is your greatest defence. Instead, public health measures often undermined health – isolating people indoors, closing gyms and parks, and ignoring nutrition, sunlight, and mental well-being. If the COVID-19 response was truly about health, it was built on a hollow, distorted view of what health really means.

At the start of the pandemic, no vaccine was available. Good health is the foundation of a strong immune system, which is our body's best defence against infections like COVID-19. Despite this, the New Zealand government failed to meaningfully promote healthy lifestyle practices during the pandemic. Evidence shows that diet, exercise, sunlight, sleep, and key nutrients like vitamin D and zinc can significantly enhance immune resilience. Empowering individuals to improve their "terrain", their body's internal environment, should have been a frontline strategy.

#### **Details:**

### The Missed Opportunity: NZ's Lack of Health Promotion

The New Zealand government emphasised lockdowns, mandates, and pharmaceutical interventions while neglecting a vital message: your body has built-in defences that can be strengthened naturally.

### Nutrition & Metabolic Health

- Nutrition directly influences gene expression and immune signalling. Every meal sends messages to your genes.<sup>1</sup>
- Nutrient deficiencies increase susceptibility and can make viruses more virulent.<sup>1</sup>
- A diet rich in quality protein, vegetables, and healthy fats, while avoiding processed carbs, helps fortify the immune system. A ketogenic diet has even been explored as protective.<sup>2</sup>

### Lifestyle Changes

- Moderate exercise boosts antioxidant levels and immune response.<sup>3</sup>
- Sunlight and fresh air improve vitamin D status and can reduce viral survival in the environment.<sup>4</sup>
- Alcohol suppresses the immune system and affects mental clarity.<sup>5</sup>

- Adequate sleep is key to immune regulation.<sup>6</sup>
- Contact with nature, laughter, and social connection all play key roles in resilience.<sup>7</sup>

### Supplements with Scientific Backing

- Vitamin D reduces respiratory infections, especially in those deficient.<sup>9</sup>. See also Issue 0.5.B.
- Vitamin C supports prevention and treatment of infection.<sup>9</sup>
- Zinc is essential to immune modulation; deficiency is common.<sup>10</sup>
- Selenium supports immunity; deficiency promotes viral mutation.<sup>11</sup>
- N-Acetyl-Cysteine protects lung tissue and boosts  $\mbox{glutathione.}^{\mbox{\scriptsize 12}}$
- Probiotics support the gut-lung axis and respiratory immunity.<sup>13</sup>
- Melatonin may have antiviral effects via immune and inflammation modulation.<sup>14</sup>

See also Immunity - Boosting It.15

### A comparative study confirming the benefits of a healthy lifestyle versus vaccination

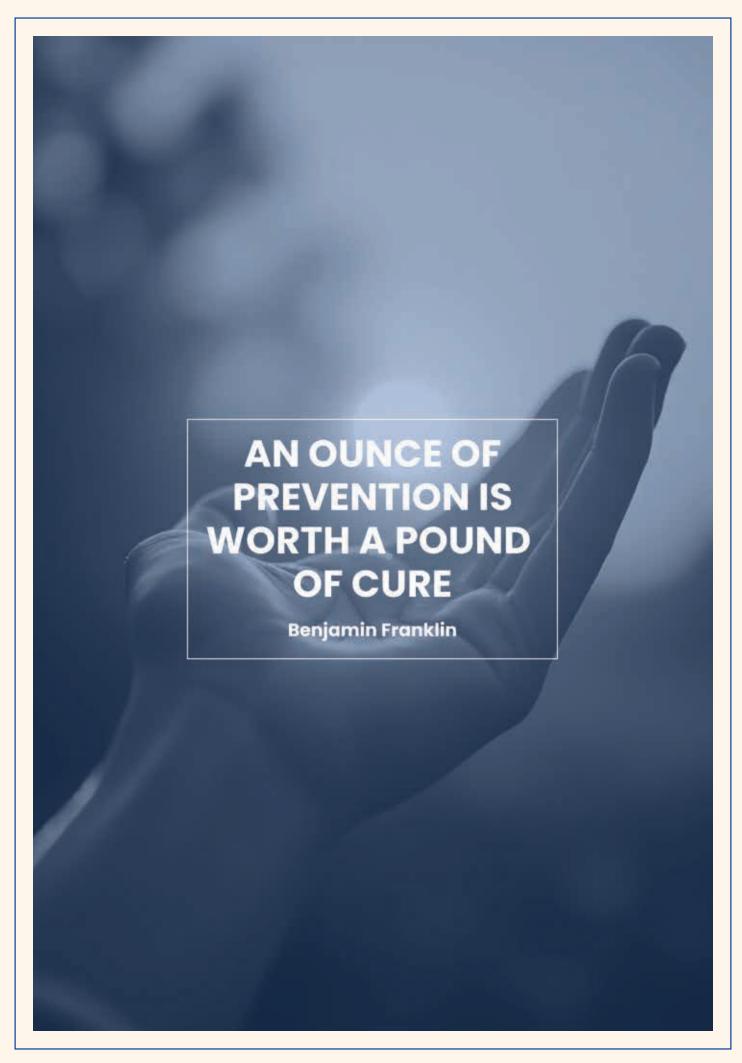
The position of maintaining health versus receiving the vaccine was studied in 2019 and 2020 in a nationwide Control Group Survey of Unvaccinated Americans (CGS) that showed that those that did not receive a COVID-19 vaccine thrived while those that did were being injured and met with a multiplicity of grave injuries as well as sudden unexpected death. The survey quantified the long-term health risks of total vaccine avoidance against the health outcomes observed in the 99.74% vaccine-exposed.

### Important Questions for the Commissioners to Ask — and of Whom:

### Ministry of Health, Minister for COVID Health Response:

- Why was the role of natural immunity and personal health resilience never part of the public messaging, despite clear scientific evidence that diet, exercise, and lifestyle directly impact immune function?
- How do you justify spending in excess of \$150 million on advertising and compliance messaging while providing no guidance on how people could strengthen their health naturally?
- Why were public health measures, such as lockdowns, closure of outdoor spaces, and discouragement of social connection, implemented when evidence shows these actions can weaken mental and physical health?
- What scientific criteria were used to exclude evidence-based recommendations on vitamin D, zinc, exercise, sleep, sunlight, and metabolic health from your official COVID-19 strategy?
- Was there any internal analysis or debate about the potential harms caused by sidelining holistic health in favour of pharmaceutical interventions alone? If so, where is that record?
- Why were doctors and health professionals who spoke out about natural health and early treatment options censored, sanctioned, or silenced?
- Given the high rate of obesity, diabetes, and poor metabolic health in New Zealand, which were also major risk factors for severe COVID-19 outcomes, why was there no national campaign to address these issues during the pandemic?
- How do you define "health"? Does your department acknowledge that physical, mental, emotional, and social well-being are essential to a functioning immune system?
- What steps, if any, are now being taken to restore public confidence in health leadership by integrating holistic, preventative health into future planning?
- Will you publicly acknowledge that your definition and strategy for "health" during the pandemic was incomplete, and in some cases, counterproductive?

- <sup>1</sup> Beck et al., 2004 Trends Microbiology: https://www.cell.com/trends/microbiology/fulltext/S0966–
- <sup>2</sup> Kamepalli, University of Louisville, 2020: https://ir.library.louisville.edu/cai/viewcontent.cai?arti
- 3 Yan & Spaulding, Redox Biology, 2020: https://www.sciencedirect.com/science/article/pii/
- <sup>4</sup> Bukhari & Yusuf, SSRN, 2020: This needs to be changed to the following studies. That one is no longer relevant: https://pmc.ncbi.nlm.nih.gov/articles/PMC9300299/ and https://pmc.ncbi.nlm.nih.gov/articles/PMC9131791/
- Sarkar et al., Alcohol Research, 2015: https://pmc.ncbi.nlm.nih.gov/articles/PMC4590612/
- <sup>6</sup> Besedovsky et al., Physiological Reviews, 2019: https://journals.physiology.org/doi/pdf/10.1152/phys
- <sup>7</sup> Franco et al., IJERPH, 2017: https://www.mdpi.com/1660-4601/14/8/864
- 8 Martineau et al., BMJ, 2017: https://www.bmj.com/content/356/bmj.i6583
- <sup>9</sup> Carr & Maggini, Nutrients, 2017: https://www.mdpi.com/2072-6643/9/11/1211
- <sup>10</sup> Gammoh & Rink, Nutrients, 2017: https://www.mdpi.com/2072-6643/9/6/624
- <sup>11</sup> Harthill, Biological Trace Element Research, 2011: https://link.springer.com/article/10.1007/s12011-011-8977-
- <sup>12</sup> De Flora et al., Eur Respir J, 1997: https://publications.ersnet.org/content/erj/10/7/1535
- <sup>13</sup> Samuelson et al., Front Microbiol, 2015: https://www.frontiersin.org/journals/microbiology/arti
- <sup>14</sup> Zhang et al., Life Sciences, 2020: https://www.sciencedirect.com/science/article/pii/
- 15 https://nzdsos.com/2021/11/21/immunity-boosting-it/





# **0.3 TREATMENT**

### B. Healthy Lifestyle - Cost Benefit Economic Analysis

Dr Martin Lally

### Why this issue is relevant:

New Zealand's pandemic response was based almost exclusively on pharmaceutical interventions - particularly vaccines - while virtually ignoring the role of personal health and metabolic resilience. Yet evidence presented by Dr. Martin Lally shows that for many people, lifestyle improvements could have reduced their risk of death from COVID-19 by significantly more than vaccination alone. This represents a serious policy oversight with public health implications extending far beyond the pandemic.

The reduction in the Infection Fatality Rate (IFR) from vaccination is compared with the reduction achievable through lifestyle changes. Among those with certain pre-existing health conditions including diabetes and heart disease - conditions often caused or aggravated by poor lifestyle - shifting to a healthier state dramatically reduces their COVID-19 mortality risk. For example, an unvaccinated 20–29 year-old with at least one of these pre-existing conditions and who eliminates these pre-existing conditions, would reduce their risk of death to just 4% of its previous level. Vaccination alone would reduce it only to 24%. In other words, lifestyle change offers 6x the benefit. Despite this, the New Zealand government offered no advice or campaign to promote such measures. That omission cost lives.

#### **Details:**

IFR Is Not Uniform: The IFR for COVID-19 is not a single figure – it varies substantially by age and health status. Table 1 shows that an unhealthy 75+ individual had a 1 in 13 chance of dying if infected, while a healthy child faced virtually no risk.

Impact of Lifestyle Changes: Pre-existing conditions such as Type 2 Diabetes and heart disease substantially increase IFR. Many of these conditions are preventable or reversible. Shifting from unhealthy to healthy status can reduce COVID fatality risk by 86-99% depending on age group.

Vaccination Comparison: According to government-adopted modelling (Vattiato et al., 2022), vaccination after a third dose reduces fatality risk by 76%, leaving 24% residual risk. But lifestyle change outperforms this in many cases.

Population-Level Implications: One-third of New Zealand adults are obese. Obesity is a key driver of COVID risk. And yet, 79% of COVID-19 deaths in people under 65, and 88% in those over 65, occurred in people with pre-existing conditions. The majority of these conditions are lifestyle-related.

Government Neglect: No significant public messaging promoted healthier living during the pandemic. A potential high-impact mitigation strategy was simply ignored.

### Important Questions for the Commissioners to Ask — and of Whom:

### Ministry of Health and Policy Leaders:

- Why did government COVID-19 strategies ignore evidence that lifestyle change could reduce mortality risk by more than vaccination for many?
- Given the widespread prevalence of metabolic disease, why was there no national effort to address the root causes of COVID-19 vulnerability?
- What modelling, if any, was done to compare the impact of lifestyle change versus vaccination across different age groups?
- Will future public health strategies be adjusted to include metabolic health, fitness, and nutrition as core pillars of pandemic response?
- Why was advice on preventive health, despite its life-saving potential, never issued alongside vaccination messaging?

Table 1: Risk of Death from Omicron if Infected and Unvaccinated				
	Healthy	Not Healthy	Ratio	
0-9	1/1,100,000	1/16,000	1%	
10-19	1/700,000	1/23,000	3%	
20-29	1/160,000	1/8,000	5%	
30-39	1/43,000	1/3,000	7%	
40-49	1/10,000	1/1,000	10%	
50-59	1/2,500	1/300	12%	
60-69	1/1,000	1/100	10%	
70-74	1/400	1/40	10%	
75+	1/100	1/13	13%	



# **0.3 TREATMENT**

### C. Vitamin D

Professor Ian Brighthope

### Why this issue is relevant:

Vitamin D is a safe, affordable, effective and well-researched nutrient (hormone) that plays a critical role in immune function. Evidence shows low vitamin D levels are linked to worse outcomes in respiratory illnesses, including COVID-19 which result in hospitalisation.

Vitamin D status was a modifiable risk factor during the COVID-19 pandemic, yet public health advice did not reflect its potential benefits. Studies showed a correlation between low vitamin D levels and severe COVID-19 outcomes with severe deficiencies resulting in death, and expert reviews recommended supplementation for at-risk groups. Simple measures like sun exposure encouragement, blood tests for vitamin D status and widespread supplementation could have supported better optimal public health outcomes. Despite its safety, low cost, and ready availability, vitamin D was overlooked in New Zealand's official guidance. In contrast, UK authorities recognised its value early in the pandemic and acted to protect vulnerable groups. The New Zealand government's failure to act similarly, despite reviewing and acknowledging the evidence, represents a serious public health oversight.

#### Details:

#### 1. Long-studied and known benefits of vitamin D

Long before COVID-19, vitamin D was recognised as a safe, affordable, effective and well-researched nutrient (hormone)!

- Established Immune System Support vitamin D has long been understood to modulate both innate and adaptive immune responses, reduce inflammation, and enhance antiviral mechanisms. These functions provided a scientifically plausible basis for its protective role in infectious diseases, including respiratory illnesses.
- Widespread Deficiency in High-Risk Groups Long before COVID-19, vitamin D deficiency was recognised as prevalent among elderly populations, people with darker skin, and those with limited sun exposure - groups also at higher risk of severe illness from viral infections. This overlap underscores the importance of addressing deficiency as a public health measure.<sup>2</sup>
- Cost-Effective Preventative Strategy Even before COVID-19, economic modelling showed that routine vitamin D supplementation could prevent illness and reduce healthcare costs, especially in populations with high deficiency rates.<sup>3</sup>
- Latitude and Deficiency Risk Numerous studies established that vitamin D levels are lower at higher geographical latitudes, increasing risk during winter months and in countries like those in Northern Europe, and likewise in southern hemisphere countries such as New Zealand during winter.<sup>4</sup>
- Proven Role in Preventing Respiratory Infections A 2017 metaanalysis in The BMJ, involving over 10,000 participants, found that vitamin D supplementation reduced the risk of acute respiratory tract infections by 12%, with especially strong effects in those who were deficient. This reinforced its reputation as a safe and effective immune support nutrient.<sup>5</sup>
- Therapeutic Potential Demonstrated in Early Studies -Pilot clinical studies showed that high-dose calcifediol (25-hydroxyvitamin D) administration significantly reduced the need for ICU care in hospitalised COVID-19 patients,

further supporting its known immunomodulatory and protective roles. <sup>6</sup>

### 2. Evidence Linking vitamin D Status to COVID-19 Outcomes

A peer-reviewed study published in The American Journal of Clinical Pathology found that serum 25(OH)D levels at hospital admission were significantly associated with COVID-19 severity and mortality. Lower levels of vitamin D correlated with worse disease outcomes, suggesting a strong relationship between deficiency and vulnerability to severe illness. <sup>7</sup>

### 3. Jun 2020 - Government Acknowledgement but Limited Action (NZ Rapid Review)

The New Zealand Prime Minister's Chief Science Advisor (PMCSA) conducted a review concluding that vitamin D supplementation was more cost-effective than testing and recommended GPs continue supplementing those at risk of deficiency. Notably, the review acknowledged this same approach could be appropriate for managing at-risk individuals for severe COVID-19 until more clinical data emerged.<sup>8</sup>

### 4. November 2020 - UK

The UK government announced that all residents in residential and nursing care homes in England would receive a free fourmonth supply of daily vitamin D supplements containing 10 micrograms (400 international units). This initiative aimed to support the general health of care home residents, especially since many had limited exposure to sunlight due to lockdown measures. The supplements provided were classified as food supplements, not prescription medicines.

In addition, the government advised that everyone in the UK should consider taking a daily vitamin D supplement during the autumn and winter months to maintain bone and muscle health. This advice was particularly emphasised for individuals who had limited exposure to sunlight, such as those who were housebound or living in care homes.<sup>9</sup>

In 2020, New Zealand, in contrast, took no equivalent public action. Vulnerable populations were not offered supplementation, nor were the public advised to increase vitamin D intake, despite evidence and internal review support.

### 5. Feb 2021 - GP Guidance Issued

In February 2021, NZ general practitioners received bulletin guidance supporting the population-wide use of vitamin D. It recommended daily dosing of 800 IU or the standard local regimen of 50,000 IU monthly, on the grounds that the benefits outweighed any risks. However, this advice was not prominently communicated to the wider public.<sup>10</sup>

### 6. Missed Opportunities for Preventive Health Messaging

Despite mounting evidence, there was no proactive national message to encourage behaviours that support vitamin D synthesis - like sunlight exposure - or to promote supplementation. Authorities such as Dr. Bloomfield and the Ministry of Health missed a low-cost, low-risk opportunity to potentially improve outcomes, especially for vulnerable populations.



### Important Questions for the Commissioners to Ask — and of Whom:

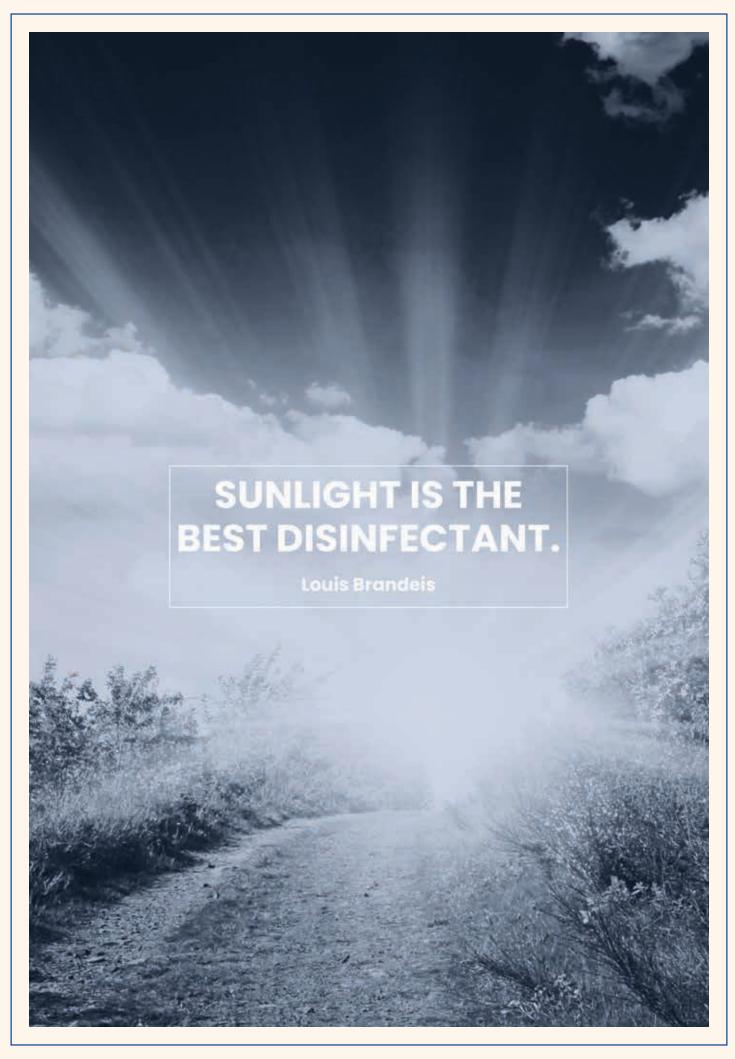
### To the Ministry of Health:

- Why did the Ministry of Health not issue clear, nationwide public advice on vitamin D supplementation or sun exposure, despite evidence of its relevance in respiratory health and its safety profile?
- Why were elderly and care-home residents not proactively supplemented as in the UK?
- Given that the PMCSA's June 2020 review concluded supplementation was cheaper than testing and could benefit those at risk of severe COVID-19, why was no public health campaign launched to act on this advice?
- Why were vulnerable groups, such as the elderly, those with darker skin, or people living in aged care, not proactively targeted with vitamin D interventions?
- Why did the Director-General of Health not advocate for the public to safely access sunlight or take supplements during lockdowns, especially in winter?
- What mechanisms exist within the Ministry to ensure low-cost, low-risk interventions like vitamin D are rapidly evaluated and implemented during a public health crisis?
   Were these mechanisms activated during COVID-19?

### To Medsafe:

- Given vitamin D's established safety and widespread use, what was Medsafe's role in reviewing or advising on its potential utility in COVID-19 prevention or mitigation?
- Was any formal risk-benefit analysis conducted by Medsafe regarding vitamin D supplementation during the pandemic? If not, why not?
- What criteria did Medsafe use to prioritise treatments or preventive measures for public communication, and why did vitamin D not meet those criteria despite positive evidence and minimal downside?

- https://pmc.ncbi.nlm.nih.gov/articles/PMC9065668/
- <sup>2</sup> https://pmc.ncbi.nlm.nih.gov/articles/PMC9065668/
- <sup>3</sup> https://jamanetwork.com/journals/jama/fullarticle/2776738
- <sup>4</sup> https://www.cambridge.org/core/journals/british-jour
- <sup>5</sup> https://www.bmj.com/content/356/bmj.i6583
- 6 https://www.bmj.com/content/356/bmj.i6583
- <sup>7</sup> https://academic.oup.com/ajcp/article
- 8 https://www.dpmc.govt.nz/sites/default/files/2022-04/PMC
- 9 https://www.gov.uk/government/publications/vita
- 10 https://bpac.org.nz/bulletin/bestpractice/nineteen.aspx#6





## **0.3 TREATMENT**

D. Repurposed drugs - off label - Ivermectin (IVM)

Dr Alison Goodwin

#### Why this issue is relevant:

Ivermectin (IVM) is a well-established medication with a strong global safety record spanning decades, including winning a Nobel Peace Prize in 2015 in Physiology and Medicine. In New Zealand, it was legally available for off-label prescription. Despite growing international evidence of its effectiveness against COVID-19, authorities actively discouraged its use without clear scientific or legal justification.

While IVM was not legally banned during COVID-19, doctors who discussed or prescribed IVM faced regulatory sanctions from the MCNZ, including conditions on their Annual Practising Certificates. At the same time, the Pharmacy Council advised pharmacists to challenge IVM prescriptions, further limiting patient access to this potentially beneficial treatment.

IVM faced similar sanctions globally.

If treatments were available for COVID-19 such as affordable off label repurposed drugs, then the COVID-19 vaccines would not have been able to receive Emergency Use Authorization in the U.S. (see Issue 1.3, page 126).

#### **Details:**

Ivermectin was discovered in the 1970s as an anti-parasitic. It has had global success in treating diseases like river blindness and scabies and is included on the WHO's list of essential medicines.<sup>1</sup>

#### 2020 IVM and early treatment of COVID

- In 2020, early responders to COVID-19, such as the Front Line COVID-19 Critical Care Alliance (FLCCC), recommended IVM as part of early COVID-19 treatment protocols, citing its antiviral and anti-inflammatory properties. Dosage guidelines, FAQs, and global adoption data were made available.<sup>2</sup>
- In December 2020, Dr. Kory, representing the FLCCC, gave testimony to the U.S. Senate's Homeland Security Committee.
   He advocated for IVM based on emerging evidence, calling it a "miracle drug" and urging immediate adoption into treatment protocols.<sup>3</sup>
- Jan 2021 Dr. Lawrie, a UK-based health researcher with prior experience advising the WHO, presents a systematic review of IVM studies.<sup>4</sup>
- Dr. Andrew Hill, a pharmacologist working in the Dept of Pharmacology at the University of Liverpool, conducted a meta-analysis in late 2020/early 2021 evaluating the efficacy of Ivermectin in treating COVID-19.<sup>5</sup> This was later retracted. In a call with Dr Lawrie in Jan 2021, Dr Hill refers to external pressures - alluding to funding sources - that influenced the tone and conclusions of his published work.<sup>6</sup>

### Official Positions on Ivermectin: Medsafe, MCNZ, Pharmacy Council & Medsafe

- Sept 2021 Ministry of Health Medsafe Alert Communication: Ivermectin is NOT APPROVED to prevent or treat COVID-19, which means that Medsafe has not assessed the safety and efficacy for this use. Inappropriate use of Ivermectin can be dangerous.<sup>7</sup>
- Medical Council NZ (MCNZ) Prescribing Guidelines The MCNZ expects doctors to follow evidence-based practices and use sound clinical judgement.<sup>8</sup>
- While Medsafe provided safety guidance, it did not instruct the MCNZ to penalise doctors for prescribing Ivermectin (OIA response dated 8 August 2022).<sup>9</sup> Yet for doctors that did prescribe IVM, the MCNZ sought Voluntary Undertakings e.g. "I will not prescribe, import or sell Ivermectin." and have placed conditions on APCs, eg "Dr X must not prescribe Ivermectin in the context of COVID-19 vaccine injuries, and/or for the treatment and/or prevention of COVID-19." Information to be supplied directly to the commission.
- Oct 2021 Pharmacy Council of New Zealand Professional Guidance to Pharmacists - In newsletters and communications (e.g. Oct 2021), the Pharmacy Council reminded pharmacists of their responsibility to:
- Challenge Ivermectin prescriptions intended for COVID-19.
- Consult with the prescribing doctor.
- Use their own clinical judgement in dispensing.10

## Important Questions for the Commissioners to Ask — and of Whom:

#### Medical Council of New Zealand (MCNZ):

- Why did the MCNZ take regulatory action against doctors who spoke about or prescribed Ivermectin, when multiple OIA responses confirm that its prescription was legal?
- Why did some doctors have 'Voluntary Undertakings' or conditions placed on their Annual Practising Certificates prohibiting them from prescribing or even discussing Ivermectin?

#### Medsafe / Ministry of Health:

- Why were doctors effectively prohibited from prescribing Ivermectin for COVID-19, despite it being legally available for off-label use?
- If the government was concerned about the use of Ivermectin, why did it not invoke Section 48 of the Medicines Act to formally prohibit its use?
- Would the recognised availability of Ivermectin as an effective treatment have affected the Pfizer vaccine's eligibility for provisional approval in New Zealand, given that Emergency Use Authorization or provisional consent requires that no adequate alternative treatment is available?

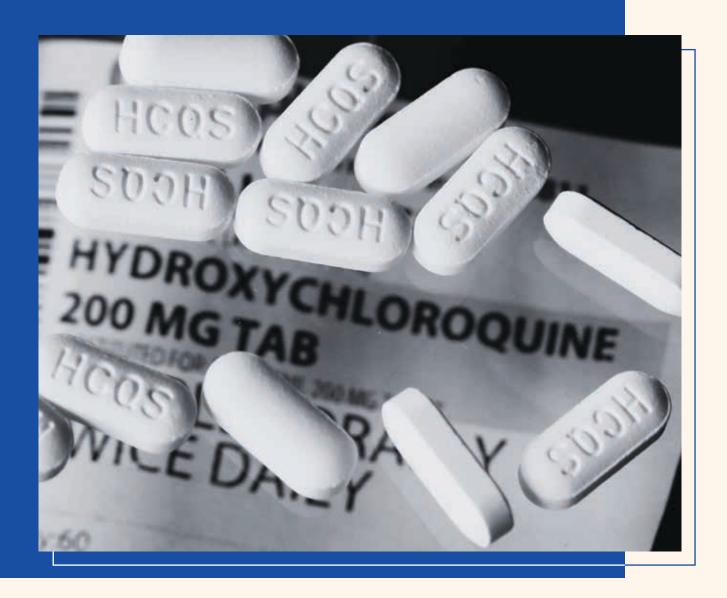
#### Director-General of Health:

 Could New Zealand have delayed vaccine rollout and awaited more robust clinical trial data, had early treatment options like Ivermectin been acknowledged and made accessible?

## Ministry of Health / Crown Law (re Pfizer contract):

 Does the New Zealand Pfizer contract contain clauses that prohibit or discourage the use of alternative COVID-19 treatments such as lyermectin?

- 1 https://imahealth.org/lvermectin/
- <sup>2</sup> https://imahealth.org/protocol/i-care-early-covid-treatment/
- <sup>3</sup> https://www.bitchute.com/video/FXy0Dyb9xYMm/
- 4 https://c19ivm.org/meta.html\_and https://bird-group.org/video-dr-tess-lawrie-appeals-to-pm-
- <sup>5</sup> https://pmc.ncbi.nlm.nih.gov/articles/PMC8420640/
- 6 https://rumble.com/vwfia3-a-letter-to-andrew-hill-dr-tess-
- <sup>7</sup> https://www.medsafe.govt.nz/safety/Alerts/Ivermectincovid19
- 8 https://www.mcnz.org.nz/our-standards/current-standards/
- <sup>9</sup> https://www.health.govt.nz/information-releases/informa
- 10 https://pharmacycouncil.org.nz/wp-content/uploads/2021/10/



## **0.3 TREATMENT**

E. Repurposed drugs - off label - Hydroxychloroquine (HCQ)

Dr Alison Goodwin

#### Why this issue is relevant:

Patients were denied access to a safe, potentially helpful medication during a time of high fear and uncertainty. This not only prevented early treatment but also contributed to the proposition that COVID-19 was untreatable without vaccines, which were not introduced for another year, resulting in a significant period of time where people with COVID-19 were denied treatment.

Hydroxychloroquine (HCQ) is a long-standing, widely used medication with a well-established safety profile. During the early months of the COVID-19 pandemic, early treatment protocols by first responders were being used internationally with reported benefits.

However, in March 2020, in New Zealand, doctors were advised against prescribing it. This action removed a potential treatment option, increased public fear, and set a precedent for restricting access to safe, approved medications. If treatments were available for COVID-19 such as affordable off label repurposed drugs, then the COVID-19 vaccines would not have been able to receive Emergency Use Authorization (see Issue 1.3).

#### Details:

- HCQ has been used for decades to treat malaria and autoimmune conditions like lupus and rheumatoid arthritis.
- March 2020 Despite its known safety, especially for shortterm use, it was effectively banned from early COVID-19 treatment protocols in NZ.
- 27 March 2020 BPAC Bulletin to NZ Doctors: Advises against prescribing HCQ outside of a clinical trial.<sup>1</sup>
- The rationale for this restriction included a now-infamous fabricated study published in The Lancet (May 2020), which falsely claimed that HCQ increased mortality. This study was later retracted, but the damage to public trust and medical freedom was done.<sup>2</sup>
- Doctors were advised not to prescribe HCQ despite the fact that no superior treatment options were available at the time. This echoed later restrictions placed on Ivermectin in September 2021.
- The move signalled a shift in medical autonomy; for the first time, doctors were told not to use a fully approved medicine based on weak or misleading evidence.
- If treatments were available for COVID-19 such as affordable off label repurposed drugs, then the COVID-19 vaccines would not have been able to receive Emergency Use Authorization (see Issue 1.1.4).

## Important Questions for the Commissioners to Ask — and of Whom:

#### **Ministry of Health:**

- On what specific evidence did the Ministry base its March 2020 advice to discourage or prohibit doctors from prescribing Hydroxychloroquine (HCQ)?
- Were alternative viewpoints or early clinical experiences from overseas considered?
- Why was a safe, approved medication, used for decades, effectively removed from the standard doctor's toolkit, especially during a public health emergency?
- Did the Ministry consider changing its position before or after the Lancet study was retracted?
- What internal review process was undertaken following the retraction?
- Why were New Zealand doctors not permitted to exercise their clinical judgement regarding HCQ use with informed consent from patients?
- Was there a formal legal or ethical review of this restriction?
- What communication or influence did the Ministry receive from international bodies (e.g. WHO, FDA, pharmaceutical companies) in forming its position on HCQ?
- Were any conflicts of interest declared or reviewed?
- Why was no guidance provided on early treatment options, despite the known trajectory of COVID-19 illness and HCQ's potential antiviral and anti-inflammatory properties?
- Has the Ministry since reviewed or reassessed its position on HCQ in light of evolving international data and multiple meta-analyses suggesting potential benefit when used early?
- What safeguards are now in place to prevent reliance on fraudulent or low-quality studies from influencing national medical policy in the future?
- How did the Ministry weigh the risks of not offering any early outpatient treatment versus the low-risk profile of short-term HCQ use?
- What accountability measures exist for decisions that may have adversely affected public health by limiting treatment options during a crisis?

- https://bpac.org.nz/bulletin/covid-19/27-3-2020.aspx#2
- <sup>2</sup> https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31324-6/fulltext



# 0.4 PSYCHOLOGICAL TECHNIQUES CONTROL AND CONDITIONING

#### Psychological Conditioning in the COVID-19 Response: A Global Phenomenon of Influence without Consent

During the COVID-19 response, governments around the world deployed a powerful set of psychological tools to shape public behaviour – tools drawn from behavioural science, influence theory, and mass communication. These weren't just public service announcements; they were carefully crafted strategies, designed to steer emotions, reinforce conformity, and reduce dissent. And they worked.

From fear-based messaging to emotionally charged slogans like "We're all in this together," the techniques tapped into deeply human instincts: the drive to protect others, to belong, to be seen as good. Language was used to signal virtue or shame - terms like "anti-vaxxer" and "non-essential worker" carried powerful emotional weight. Posters, dashboards, and risk charts maintained a constant sense of threat. And behind it all were behavioural experts—often working within governments or global advisory networks - guiding these efforts with the explicit aim of increasing compliance.

#### We didn't know this was happening. And that's the point.

These methods are effective precisely because they operate below conscious awareness. They are designed to feel like your own thoughts, your own fears, your own choices. In that sense, compliance wasn't a moral failure or naivety - it was a predictable human response to sustained psychological

pressure. Understanding this is key: the techniques worked because they were meant to. Many who complied did so with the best of intentions – caring for others, trying to do the right thing, trusting the institutions meant to protect them.

The real issue lies not with those who followed the rules, but with the absence of transparency, consent, and ethical guardrails. Behavioural science was not disclosed, debated, or regulated. Instead, it was used en masse, with no assessment of the long-term psychological or social costs.

Now, as we reflect on this period, the question is not "Why did people fall for it?" but "Why were these powerful techniques used without public knowledge or accountability?" But first we need to recognise what happened and ensure that no future crisis is met with manipulation in place of open, democratic engagement and debate.

#### In this section

- A. Fear as the Driver
- B. Conditioning
- C. Examples NZ and UK



## 0.4 PSYCHOLOGICAL TECHNIQUES

#### A. Fear as the Driver

David Charalambous, Gary Sidley and Sinead Stringer

#### Why this issue is relevant:

Carefully coordinated public communication campaigns were implemented globally to drive high compliance with COVID-19 public health measures and to encourage people to receive the COVID-19 vaccine. Advanced psychological techniques and influence tactics commonly associated with behavioural science and strategic messaging were used.

Institutions employed psychological techniques during the COVID-19 pandemic to influence public perception and behaviour. The methods, often subtle, shaped decisions and reinforced certain beliefs, guiding public opinion in ways that benefitted institutional interests.

The psychological techniques flowed throughout the world, with messaging in one place soon being echoed in another, e.g. "pandemic of the unvaccinated" was echoed by politicians throughout the Western world.

#### **Details:**

Psychological techniques used during the COVID-19 pandemic included:

#### 1. Fear

Fear-conditioned audiences show four times higher compliance rates with authority demands.<sup>0</sup>

#### 2. Behavioural Nudges

The use of subtle prompts, unconsciously, that guide behaviour without overt coercion. These nudges were often presented as common-sense actions or moral duties. The three main types of nudges were fear, peer pressure and shaming:

- a. Fear inflation/'affect' nudge
- b. Shaming / equating compliance with virtue/ 'ego' nudge
- c. Peer pressure/ social proof/ 'normative pressure' nudge
- Mask compliance was encouraged through slogans like "Mask up to protect others", triggering a sense of social responsibility and guilt for non-compliance.
- Floor markings in stores and arrows in public spaces gently herded people to conform to movement rules without questioning.
- The phrase "We're all in this together" reinforced group identity and discouraged outlier behaviour.
- The use of emotive posters showing elderly people or masked children triggered protective instincts, emphasising group loyalty.
- Colour-coded risk charts and daily case dashboards created a sense of ever-present danger, nudging risk perception.
- Behavioural scientists nudgers were embedded into governments (e.g. the UK's BIT and SPI-B) and give relevant refs/links.<sup>1</sup>
- Mass compliance was shaped by social identity and group norms—tools of behavioural nudging.<sup>2</sup>

#### 3. Manipulation of Language

Changing the meaning or emotional framing of words influenced perception and discouraged dissent.

 The term "anti-vaxxer" was used pejoratively to discredit anyone questioning the vaccine, even those who were previously vaccinated but had concerns.

- "Vaccine passes" redefined access to ordinary community spaces and events as a privilege granted for compliance rather than acknowledging it as the removal of a basic right to move freely within one's community. Public health terms like "following the science" implied that any disagreement was irrational or dangerous, even when legitimate scientific debate existed.
- Terms like "COVID denier" or "non-essential workers" were used to divide and demoralise. Laura Dodsworth's book "A State of Fear".
- Terms like "circuit breaker" softened the language of lockdowns, hiding the harsh reality of personal and economic restrictions

#### 4. Amplification of Emotional Vulnerabilities

Institutional messaging repeatedly triggered fear, guilt, and hope to drive compliance. These emotional levers were key to shaping public opinion and decision-making.

- Constant updates on death tolls and infection numbers created sustained anxiety, leading to the acceptance of restrictive measures.<sup>3</sup>
- Campaigns focused on protecting the vulnerable or "saving grandma" pushed individuals to suppress personal hesitations
- Vaccine passes were positioned as the key to returning to normal, leveraging people's desperation for human connection and freedom.<sup>4</sup>
- Fear messaging was central to behavioural strategies especially messages linking non-compliance with death or moral failure.
- Mental health risks for healthcare workers indicate that fear messaging affected not only the general public but also led to extreme psychological pressure on professionals.

#### 5. Social Conformity & Silencing Dissent

Repetition, group pressure, and fear of social exclusion were used to suppress dissenting voices during COVID-19, creating the illusion of consensus and discouraging open debate.

- Fear and repetition were used to create an inescapable narrative.<sup>6</sup>
- Social pressure alters perception—relevant to widespread silence among professionals and the public alike. See Asch conformity experiments (1951)<sup>7</sup>
- Neural responses to social exclusion reinforce how lockdowns, isolation, and the fear of ostracisation drove compliance.
- Medical professionals who raised questions were labelled "dangerous" or "unethical," resulting in job losses or public shaming.
- Families turned against dissenting members due to mediafuelled narratives portraying sceptics as a threat to public health.<sup>9</sup>

## Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health, Minister for COVID-19 Response and Prime Minister:

#### What briefing did you receive on messaging: On Behavioural Nudges

- Which behavioural science frameworks or behavioural insights teams informed New Zealand's COVID-19 communication strategy, and were any foreign advisory groups (e.g. SPI-B from the UK) consulted?
- Was the government aware that visual and verbal cues, such as floor arrows, emotive posters, and slogans like "We're all in this together", were forms of behavioural nudging intended to influence public perception and suppress dissenting behaviour?
- Did the Ministry ever conduct or commission risk assessments on the ethical implications of using behavioural nudges without explicit public consent?

#### On Manipulation of Language

- Why did the government adopt polarising language, such as "anti-vaxxer", "COVID denier", and "non-essential worker", given the known psychological effects of such labels in silencing legitimate dissent and debate?
- How does the government justify framing vaccine passes as a "pathway to freedom" when in practice they removed the right to freely access one's community unless compliant with a medical directive?
- Was public health messaging vetted for linguistic bias or reviewed by independent ethics panels to ensure it didn't manipulate public sentiment or marginalise minority viewpoints?

#### On the Amplification of Emotional Vulnerabilities

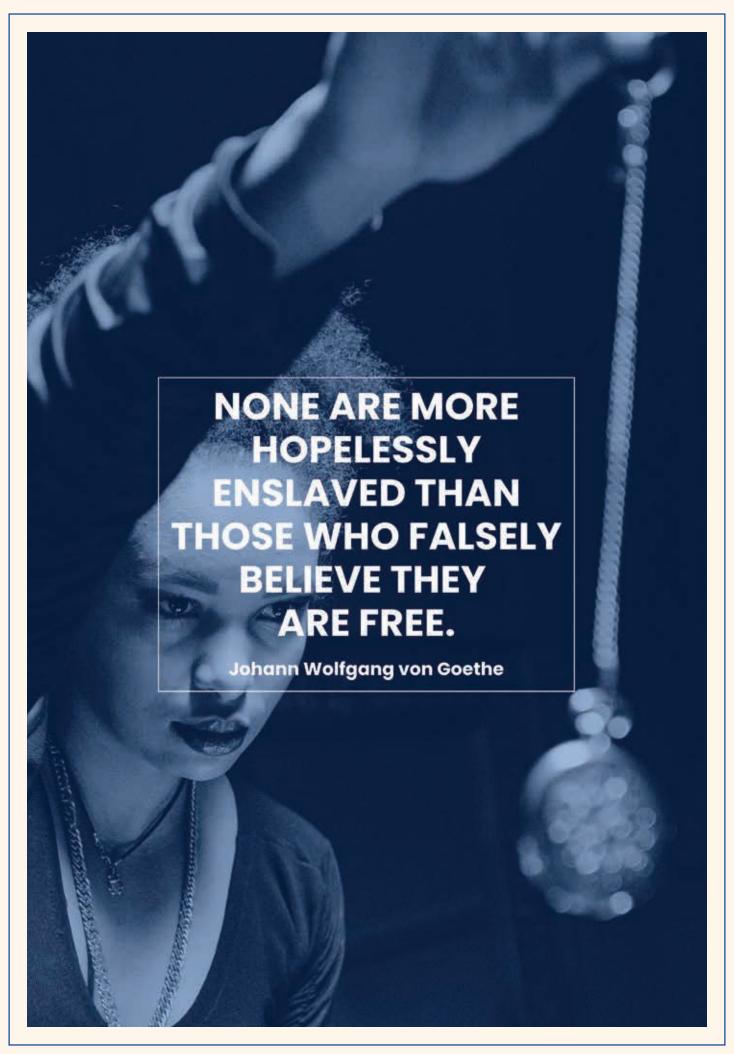
 Was the continuous release of case numbers and death tolls assessed for psychological harm to the public, particularly in light of known effects on anxiety, depression, and emotional decision-making?

- What was the rationale behind messaging that suggested people who did not comply could harm or kill others, and was any modelling done on the mental health toll of this guiltbased messaging?
- Were any internal assessments conducted on the impact of fear-based messaging on healthcare workers, who were subjected to both public pressure and professional risk?

#### On Social Conformity & Silencing Dissent

- Was the government aware of the psychological mechanisms, such as fear of ostracism and conformity pressure, that discouraged professionals and the public from questioning COVID-19 policies?
- Can the Ministry explain what safeguards were in place to protect whistleblowers, medical professionals, or scientists who questioned elements of the pandemic response?
- Did the government, directly or indirectly, participate in media messaging that framed dissent as morally dangerous or socially deviant, and if so, under what justification?

- https://pmc.ncbi.nlm.nih.gov/articles/PMC10426013/
- https://pmc.ncbi.nlm.nih.gov/articles/PMC11005480/
- <sup>2</sup> https://www.cambridge.org/core/journals/bjpsych-open/article/public-behaviour-in-response-to-the-covid19-pandemic-
- <sup>3</sup> https://pmc.ncbi.nlm.nih.gov/articles/PMC11089312/
- <sup>4</sup> https://centrist.nz/experts-and-critics-unite-in-christchurch-to-challenge-covid-narrative/
- <sup>5</sup> https://doi.org/10.1016/j.encep.2020.04.008 (Will need translation)
- 6 https://scholarworks.sjsu.edu/cgi/viewcontent.cgi?article=1087&context=secrecyandsociety
- https://psycnet.apa.org/record/1952-01430-001
- 8 https://pmc.ncbi.nlm.nih.gov/articles/PMC5706563/
- 9 https://www.chrislynchmedia.com/news-items/christchurch-conference-to-unite-global-experts-and-critics-of-mainstream-





## 0.4 PSYCHOLOGICAL TECHNIQUES

#### **B.** Conditioning

David Charalambous, Gary Sidley and Sinead Stringer

#### Why this issue is relevant:

Conditioning leverages known psychological patterns – cognitive biases, emotional triggers, and social identity dynamics – to influence behaviour in highly predictable ways. While individual differences exist, repeated exposure to targeted messaging reliably shifts public attitudes and actions. This predictability enables powerful institutions to shape beliefs, manufacture consent, and suppress dissent. When used manipulatively or coercively, this is not public health or education – it is propaganda.

Behavioural conditioning techniques – especially those rooted in fear, revenge, and identity manipulation – have been shown to produce measurable, predictable responses in human populations. Controlled studies reveal that certain propaganda strategies (e.g. revenge rhetoric, fear appeals, group conformity triggers) reliably shift moral judgements, increase compliance, and suppress empathy. Automated analysis confirms high emotional response predictability (up to 82%) across message types. Identity-based appeals and individual attachment styles further refine the targeting of these techniques.

Despite these powerful effects, limitations do exist. Critical thinking, message fatigue, and exposure to competing narratives reduce predictability. Nevertheless, modern behavioural models combining emotional, social, and psychological metrics can still predict population responses with up to 76% accuracy. In short, mass persuasion is not guesswork – it's science-backed manipulation.

#### Details:

David Halpern, a leading figure in the application of behavioural insights to public policy, has consistently advocated for greater transparency and public involvement in the use of nudges. He argues that if governments are to use behavioural techniques to influence choices, the public should be aware of these interventions and have a say in their deployment.

For governments to use behavioural approaches like nudges, they must ensure public permission and transparency. Nudges should not be covert or manipulative but instead open to public debate and scrutiny: "If national or local governments are to use these approaches, they need to ensure that they have public permission to do so – i.e. that the nudge is transparent, and that there has been appropriate debate about it." 1

Yet during COVID-19, permission was not sought. Governments did not follow these basic principles and obligations; instead, psychological techniques were rolled out en masse and unchecked.

## Breakdown of Psychological Techniques and Predictive Behavioural Patterns

#### 1. Message-Type Specific Conditioning

Revenge rhetoric<sup>2</sup> and fear-based appeals<sup>3</sup> demonstrate the strongest predictive power:

- Revenge narratives increase moral justification for violence by 37% compared to control groups.<sup>4</sup>
- Fear-conditioned audiences show 4x higher compliance rates with authority demands.<sup>5</sup>
- Dehumanisation campaigns paradoxically reduce predicted violence justification despite increasing moral outrage.<sup>6</sup>

#### 2. Emotional Salience Patterns

Automated propaganda analysis tools detect predictable emotional responses:

Propaganda Technique	Dominant Emotion	Response Prediction Accuracy <sup>7</sup>
Loaded Language	Anger (r=0.71)	82%
Slogans	Contempt	77%
Flag Waving	Pride	68%

#### 3. Social Identity Activation

Identity-based propaganda creates response patterns through:

- In-group amplification: 92% conformity rate with groupendorsed positions.<sup>8</sup>
- Out-group devaluation: 63% reduction in empathy metrics.9
- Norm internalisation: 41% increase in prescribed behaviours when framed as group duty.<sup>10</sup>

#### 4. Attachment Style Vulnerabilities11

Neurosocial research reveals differential susceptibility:

- Anxious attachment: 89% compliance with fear-based messaging.
- Avoidant attachment: 72% resistance to direct persuasion attempts.
- Secure attachment: 54% critical analysis of emotional appeals.

#### 5. Predictive Limitations

While conditioning creates response tendencies, three factors limit absolute predictability:

- Cognitive Dissonance Thresholds: 28% of subjects spontaneously reject conditioned narratives when confronted with irrefutable counter-evidence.<sup>12</sup>
- 2. Message Saturation Effects: Response predictability peaks at seven exposures, then declines due to desensitisation (inverted U-curve pattern).<sup>13</sup>
- 3. Cross-Messaging Interference: Concurrent counterpropaganda reduces prediction accuracy by 39%<sup>14</sup>.

Advanced modelling combining emotional salience metrics<sup>15</sup>, identity reinforcement patterns,<sup>16</sup> and attachment profiles<sup>17</sup> currently achieves 76% mean prediction accuracy across controlled studies. However, real-world applications must account for the "propaganda paradox" - the most heavily conditioned individuals often develop sophisticated rationalisation strategies that mask predictable responses.

## Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health, COVID-19 Health Response:

#### 1. Public Mandate and Transparency

- What public permission, if any, was sought before deploying behavioural science techniques to influence public compliance with COVID-19 health directives?
- Were any ethical reviews or public consultations undertaken to evaluate the appropriateness of using psychological nudging, fear appeals, or identity-based messaging during the pandemic?
- How does the government reconcile its actions with David Halpern's (and the Behavioural Insights Team's) foundational principle that such interventions must be transparent and subject to public debate?

#### 2. Use of Psychological Conditioning Techniques

- Were officials or contractors employed by the Ministry of Health, Department of the Prime Minister and Cabinet, or any other agency instructed to use or advise on specific behavioural conditioning tools such as fearbased messaging, social identity manipulation, or dehumanising rhetoric?
- Which government departments or agencies were responsible for approving or coordinating these messaging strategies?
- What behavioural insights or frameworks (e.g. COM-B, MINDSPACE, EAST, or similar) were explicitly used in shaping COVID-19 communication campaigns?

#### 3. Oversight and Scientific Integrity

- What internal oversight mechanisms were in place to ensure psychological techniques used in public communications remained ethical and non-coercive?
- Were there any briefings, collaborations, or external recommendations from international behavioural science or intelligence organisations (e.g. the WHO, UK Behavioural Insights Team) that influenced New Zealand's strategy?

### 4. Population Targeting and Psychological Profiling

- Did the government, knowingly or unknowingly, segment the population by psychological vulnerabilities such as attachment styles, conformity tendencies, or emotional susceptibility in order to increase messaging efficacy?
- Were any data analytics tools or Al-driven emotional salience models used to tailor public messaging or predict compliance?

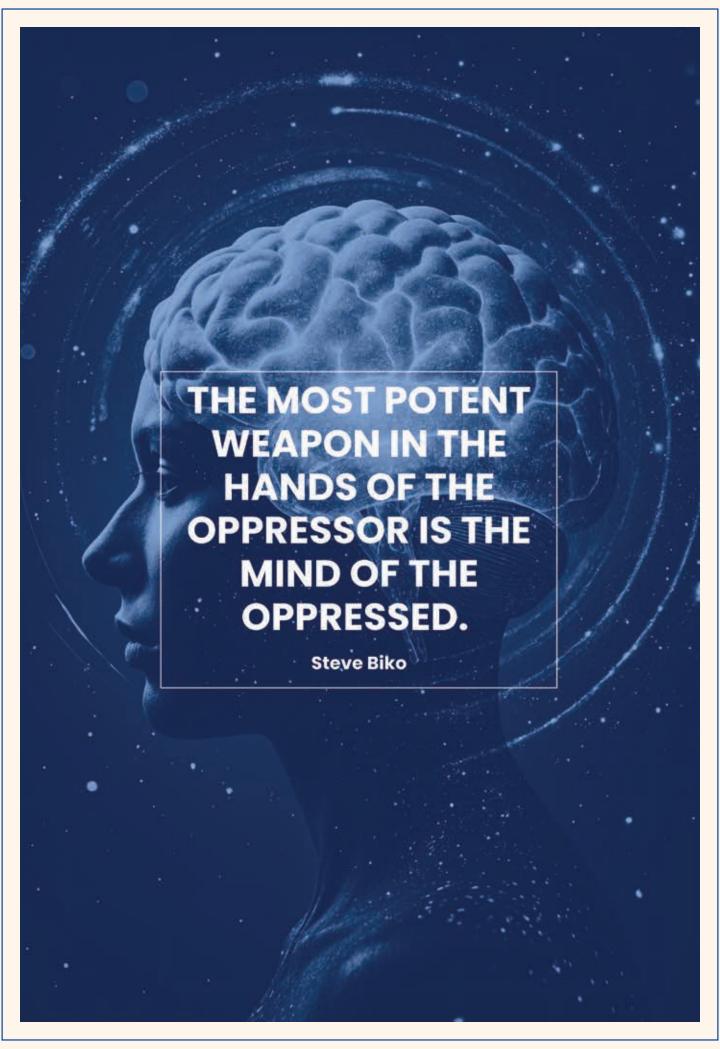
#### 5. Impact on Public Trust and Social Cohesion

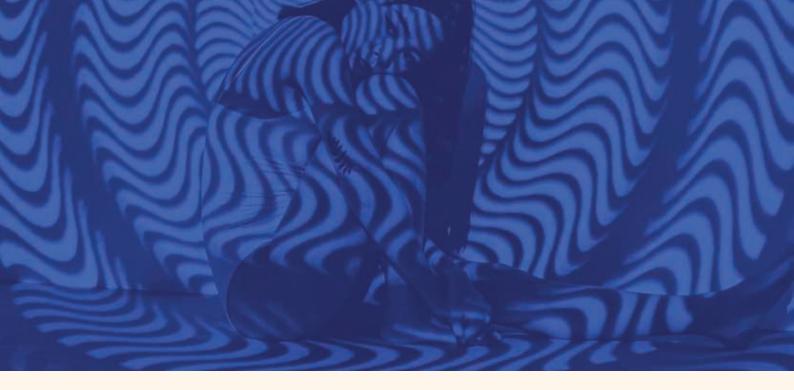
- What assessment has the government conducted to determine the psychological impact of its communication strategies on social trust, mental health, or community division?
- Does the government recognise that certain COVID-19 messaging, particularly those relying on fear, blame, or group polarisation, may have increased stigma and social hostility toward dissenting individuals?

#### 6. Planning for Future Safeguards

- What measures will be implemented to ensure that any future behavioural interventions during public health crises are transparently disclosed, ethically justified, and subjected to parliamentary and public scrutiny?
- Will a register of behavioural interventions be established, listing the psychological tools used and their intended effects?

- https://www.bps.org.uk/psychologist/interview-david-halp
- <sup>2</sup> https://en.wikipedia.org/wiki/Propaganda\_techniques
- <sup>3</sup> https://aclanthology.org/2020.semeval-1.235.pdf
- 4 https://www.ias.edu/ideas/2015/wilson-lillie-propaganda
- <sup>5</sup> https://pmc.ncbi.nlm.nih.gov/articles/PMC10426013/
- 6 https://www.frankwbaker.com/mlc/propaganda-ex
- https://aclanthology.org/2020.semeval-1.235.pdf
- 8 https://www.cambridge.org/core/journals/british-journal
- https://www.ias.edu/ideas/2015/wilson-lillie-propaganda
- https://www.cambridge.org/core/journals/british-journal
- https://self-transcendence.org/the-psychological-theories
- 12 https://www.armyupress.army.mil/Portals/7/military-review/
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## **20 EXAMPLES**

## of Alleged Unethical Psychological Manipulation by UK and NZ Governments During the COVID Pandemic

#### 1. Fear Inflation Through Messaging

Deliberate use of frightening slogans such as "If you go out you can spread it, people will die" and "Look him in the eyes" campaigns, featuring images of patients in distress, to heighten public anxiety and compliance.<sup>12,8</sup>

#### 2. Use of Graphic Imagery

Displaying images of acutely unwell patients in intensive care units on billboards and TV adverts to evoke fear and emotional distress.\(^{12}\)

#### 3. Monofocus on COVID Deaths

Focusing public messaging almost exclusively on COVID-19 deaths, omitting context such as deaths from other causes or normal daily mortality rates, to exaggerate perceived risk.<sup>1</sup>

#### 4. Scapegoating and Shaming

Campaigns and official statements that implied non-compliance equated to endangering others, e.g. "killing your granny," and encouraging social disapproval for those not following rules.<sup>2,7,8</sup>

#### 5. Social Approval and Disapproval Nudges

Encouraging communities to provide social approval for compliance and disapproval for non-compliance, fostering peer pressure and potential scapegoating.<sup>7</sup>

#### 6. Manipulation of Threat Perception

SPI-B (Scientific Pandemic Insights Group on Behaviour) minutes explicitly recommended increasing the "perceived level of personal threat" among the public using "hard-hitting emotional messaging".<sup>6,7</sup>

#### 7. Isolation and Control of Social Interaction

Enforcing strict limits on social gatherings, closing venues, and restricting association, which not only limited virus spread but also curtailed opportunities for dissent and alternative viewpoints.<sup>3</sup>

#### 8. Suppression of Dissent

Censoring or marginalising scientists and citizens who questioned the dominant narrative, equating dissent with being "on the side of disease and death".

#### 9. Mystical Manipulation of Data

Publicising worst-case scenario models (e.g. Imperial College's 500,000 deaths prediction) as certainties, amplifying fear and urgency for compliance.<sup>3</sup>

#### 10. Induced Guilt and Shame

Messaging that implied non-compliance was selfish or immoral, leading to feelings of guilt and shame for those questioning or breaking rules.<sup>257</sup>

#### 11. Use of "Purity" Messaging

Framing compliance as a sign of caring for loved ones, and non-compliance as a lack of care, to leverage moral emotions for behavioural control.<sup>3</sup>

#### 12. "Act Like You Have COVID" Messaging

Instructing the public to behave as if they were infected, fostering suspicion and fear of others, and encouraging hypervigilance.<sup>5</sup>

#### 13. Exaggeration of Surface Transmission Risks

Policies such as banning trying on clothes in shops, despite evidence that surface transmission was minimal, to reinforce a sense of omnipresent danger.<sup>3</sup>

#### 14. Omnipotence Demonstrations

Frequent changes in rules and regulations, sometimes without clear scientific basis, to reinforce government authority and public dependence on official guidance.<sup>3</sup>

#### 15. Occasional Indulgences

Allowing brief relaxations of restrictions (e.g. "Christmas bubbles") as rewards for compliance, mirroring intermittent reinforcement techniques.3

#### 16. Induced Debilitation

Prolonged uncertainty, repeated lockdowns, and shifting goalposts leading to psychological exhaustion and learned helplessness.<sup>3,6</sup>

#### 17. Use of "Nudge" Units

Deployment of the Behavioural Insights Team (BIT) and SPI-B to design covert psychological interventions, often without public awareness or consent.<sup>38</sup>

#### 18. Manipulation of Media Environment

Dominating mainstream media with government messaging, limiting exposure to alternative perspectives and reality-checking.<sup>3,5</sup>

#### 19. Vaccine Mandate Coercion

Imposing vaccine mandates and passports, with social and economic penalties for non-compliance, leading to social division and loss of autonomy.<sup>4</sup>

#### 20. Emotionalising and Moralising Public Health

Framing public health compliance as a moral duty, using emotionally charged language to override rational risk assessment and debate.<sup>6,8</sup>

"The perceived level of personal threat needs to be increased among those who are complacent, using hard-hitting emotional messaging."

- SPI-B minutes, 22 March 2020<sup>7</sup>

### Practical Outputs for Behavioural Science and Communication Research

- Critical analysis of "nudge" ethics: Examine the boundary between persuasion and manipulation, especially when interventions are covert or exploit fear and shame.
- Transparency in public health messaging: Advocate for clear disclosure when psychological techniques are used, and for the inclusion of diverse expert opinions in policy formation.
- Safeguards against overreach: Develop frameworks to ensure behavioural interventions respect autonomy, informed consent, and proportionality.
- Restoration of trust: Propose strategies for rebuilding public trust post-crisis, including public inquiries and accountability for misuse of psychological tactics.

This list draws on the style of Rory Sutherland's Alchemy, highlighting the often counterintuitive and sometimes ethically ambiguous power of psychological levers, and the research-driven approach of John Bargh, Leonard Mlodinow, and Robert Cialdini, who all stress the profound, often unconscious, impact of context and authority on human behaviour.

- https://www.telegraph.co.uk/politics/2022/01/28/grossly-un
- https://www.spectator.co.uk/article/britain-s-unethical
- <sup>3</sup> https://www.stephypublishers.com/jpssr/pdf/JPSSR.
- 4 https://www.nzherald.co.nz/nz/covid-response-deliberate-
- https://www.bleadon.org.uk/media/other/24400/UKC-Ethi
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- 8 https://centrist.nz/nudge-nudge-wink-wink-how-govern
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- https://cassandravoices.com/society/government-precau
- https://www.stephypublishers.com/jpssr/pdf/JPSSR.
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- https://bpspsychub.onlinelibrary.wiley.com/doi/10.1111/
- <sup>19</sup> <a href="https://thecritic.co.uk/a-year-of-fear/">https://thecritic.co.uk/a-year-of-fear/</a>
- 20 https://en.wikipedia.org/wiki/List\_of\_-gate\_scandals\_and\_
- <sup>21</sup> https://theconversation.com/topics/employees
- 22 https://hsph.harvard.edu/news/how-jacinda-ardern-tack
- <sup>23</sup> https://www.yahoo.com/lifestyle/fannie-mae-fires-
- https://read.dukeupress.edu/jhppl/article/49/6/989/388122/
- <sup>25</sup> https://www.dpmc.govt.nz/our-programmes/national-se
- <sup>26</sup> https://www.cambridge.org/core/journals/language
- https://pmc.ncbi.nlm.nih.gov/articles/PMC9009625/
- 28 https://pmc.ncbi.nlm.nih.gov/articles/PMC11005480/
- <sup>29</sup> <a href="https://committees.parliament.uk/writtenevidence/15458/">https://committees.parliament.uk/writtenevidence/15458/</a>
- https://pmc.ncbi.nlm.nih.gov/articles/PMC10619172/
- https://www.theatlantic.com/politics/archive/2020/04/
- 32 https://pmc.ncbi.nlm.nih.gov/articles/PMC9325658/



Discarded During the COVID-19 Response

New Zealand's pandemic response saw the erosion of foundational legal, ethical, and human rights protections – principles that exist precisely to safeguard individuals during times of crisis.

#### 1. Informed Consent

The legal right to make a free and informed choice about medical treatment was compromised.

Consent was neither voluntary nor informed when people faced job loss, social exclusion, or denial of education for refusing a provisionally approved vaccine.

The Health and Disability Commissioner (HDC) Code, the Medical Council New Zealand (MCNZ), and the NZ Bill of Rights Act all enshrine the right to refuse treatment—yet these were sidelined through coercive mandates and fear-based messaging.

#### 2. Medical Ethics

Longstanding ethical standards, like the Hippocratic Oath, the Nuremberg Code, and MCNZ's "Good Medical Practice", were disregarded.

Doctors were discouraged or punished for dissenting from government policy, compromising their duty to act in the best interest of their patients.

Patients were not informed of the experimental nature of mRNA vaccines, nor were they offered alternatives.

#### 3. Confidentiality and Privacy

Medical privilege was eroded as vaccination status was routinely disclosed to employers, schools, and public venues, often without patient consent.

This breached the Health Information Privacy Code and undermined trust in the healthcare system.

#### 4. Pharmacovigilance

Medsafe failed to uphold robust post-market safety monitoring, despite growing evidence of serious adverse effects, particularly in low-risk groups like children.

There was no clear reevaluation of the risk-benefit profile as international safety data emerged.

#### 5. Human Rights

Basic rights, including freedom of movement, bodily autonomy, the right to work, protest, and be free from discrimination, were restricted without formal derogation or proper justification.

The principle of proportionality was often ignored, and vulnerable groups were disproportionately harmed.

These principles are not theoretical. They are meant to function as guardrails, especially during emergencies. Discarding them sets a dangerous precedent and demands serious reflection to prevent future overreach.

#### In this section:

- A. In this section:
- B. Human Rights
- C. Medical Ethics
- D. Informed Consent
- E. Pharmacovigilance
- F. Patient Confidentiality



#### A. Human Rights

Katie Ashby-Koppens

#### Why this issue is relevant:

New Zealand's lockdowns and public health response were not too dissimilar to Australia's. The **Australian Human Rights Commission** has recently released a landmark report, Collateral Damage, based on the lived experiences of thousands of Australians during the COVID-19 pandemic. It reveals systemic human rights failures and is highly relevant for comparison with New Zealand's experience. The report exposes how emergency measures left many behind, disproportionately harmed already vulnerable groups, and eroded public trust through excessive, inconsistent, and often inhumane enforcement.

Australia's Human Rights Commission, like New Zealand's, was largely absent during the COVID-19 pandemic, failing to safeguard human rights, a cornerstone of any democratic society. This comparison raises important questions about whether New Zealand's Human Rights Commission fulfilled its mandate during this time and whether similar failures occurred here.

- Human rights were not always protected. While emergency measures aimed to safeguard public health, many were found to be disproportionate, inconsistently applied, lacking viable exemptions, and implemented without proper oversight.
- Key rights infringed: Freedom of movement, right to bodily autonomy, right to enter one's own country, right to work, freedom of expression, and the right to be treated with dignity at the end of life.
- No formal derogation from rights was declared under international law, even as extreme measures were imposed.
   Australia restricted key rights without the transparency or legal notification required under Article 4 of the ICCPR.
- A recurring theme: People became "collateral damage" to a single-minded public health agenda that failed to accommodate diversity, compassion, or flexibility.

#### Details:

#### Scathing Highlights & Findings:

#### · Border closures:

- Citizens were effectively denied their right to return home.
   Over 45,000 Australians remained stranded overseas in 2021, and at least 54 died while waiting to return.
- The India travel ban criminalised returnees, imposing penalties of up to five years in jail and \$66,000 in fines. UN bodies raised serious concerns about racial discrimination and breach of international law.

#### · Hotel quarantine:

- Described as "inhumane," with reports of no access to fresh air, poor nutrition, and trauma during end-of-life separation from loved ones.
- "Mandatory hotel quarantine was a form of detention", raising concerns under Article 9 of the ICCPR (right to liberty).

#### · Vaccine mandates and coercion:

- "Being forced to take a vaccine under the threat of losing your job does not constitute consent" – Submission 524.
- The Commission noted "very real consequences", including job loss, exclusion from society, and coercion without informed consent.
- WHO advised against mandates; the Commission acknowledged mandates risked trust, caused discrimination, and may not have met proportionality thresholds.

#### • Children's rights neglected:

- Extended school closures ignored expert advice, particularly in Victoria (36 weeks), leading to regression, learning loss, and mental health issues.
- Vulnerable students, especially those with disability, were disproportionately affected.

#### • Right to protest suppressed:

 Peaceful protests, including those conducted in cars, were banned. Notably, a pregnant woman was arrested in her home for a Facebook post promoting a protest.

#### · Police overreach & selective enforcement:

 Officers described protesters being profiled as "radicals" and refusing to enforce unjust orders.

#### • Discriminatory enforcement & inequality:

- Celebrities and athletes gained easier entry, while citizens were denied. This "offends the rule of law" and "highlighted the importance of transparency".
- Regional and border communities were treated unfairly under inflexible, city-centric rules.



## Important Questions for the Commissioners to Ask — and of Whom:

### New Zealand's Human Rights Commissioner:

Based on findings in the Australian Human Rights Commission's 2025 Report – "Collateral Damage"

#### **Proportionality & Oversight**

- What role did the Human Rights Commission play in reviewing the proportionality and lawfulness of public health orders, such as lockdowns, mandates, and border closures?
- Did the Commission raise concerns, either publicly or privately, about whether emergency measures risked breaching New Zealanders' fundamental rights under the NZ Bill of Rights Act or international human rights law?
- In hindsight, does the Commission believe the balance struck between public health and individual rights was reasonable and evidence-based throughout 2020–2022?

#### Mandates, Consent & Discrimination

- How did the Commission assess the human rights implications of making employment, education, and access to public spaces conditional on vaccination, particularly for provisionally approved products?
- Did the Commission investigate claims of medical coercion or unequal treatment of individuals who declined vaccination? If so, what were the findings?
- What public or behind-the-scenes action did the Commission take to protect the right to informed consent and freedom from discrimination during the vaccine rollout?

#### Borders, Quarantine & Right to Return

- Was the Commission consulted, or did it issue any statement, regarding the prolonged closure of New Zealand's border to its own citizens and residents?
- Were concerns raised about citizens being denied the right to return home, and if so, what position did the Commission take on whether this complied with domestic or international human rights law?

 Did the Commission review whether the MIQ system and denial of exemptions were administered fairly and proportionately?

#### **Equality, Transparency & Enforcement**

- How did the Commission respond to public concerns that restrictions were inconsistently applied, such as exemptions for highprofile individuals while others faced rigid enforcement?
- Did the Commission assess whether the legal and ethical principles of equality before the law and transparency were upheld?

#### Children's Rights & Education

 Were the extended school closures, especially for at-risk and disabled children, reviewed by the Commission in light of children's rights to education, development, and mental health?

#### **Impact on Vulnerable Groups**

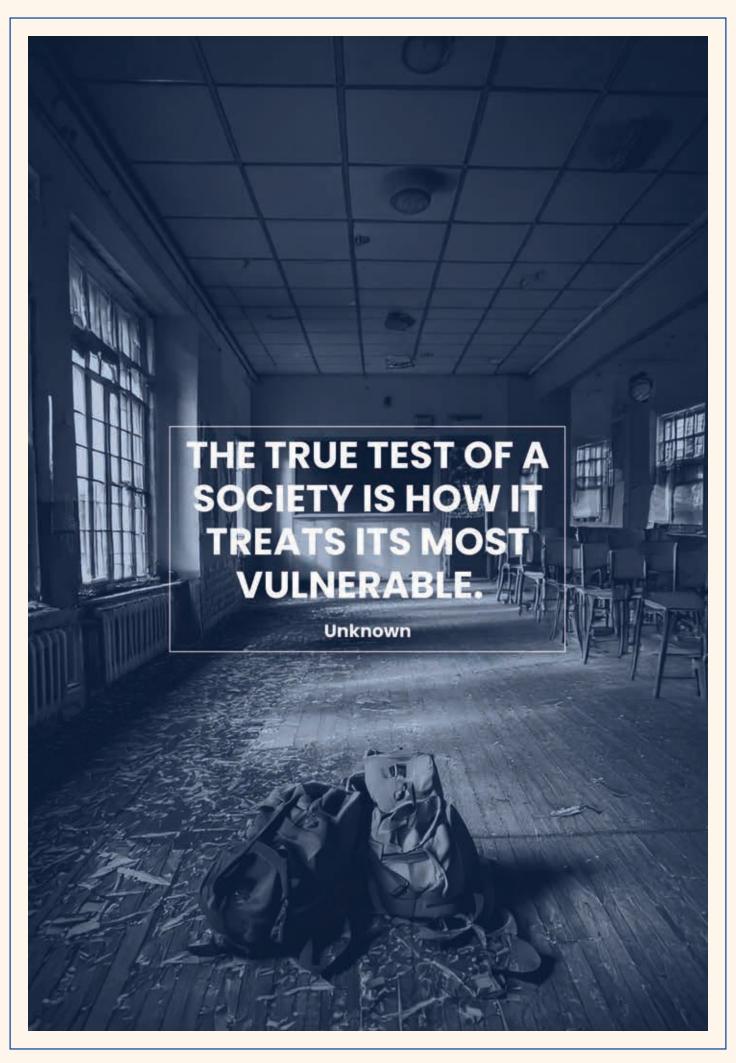
 Did the Commission independently assess the differential impacts of COVID-19 measures on Māori, Pacific peoples, disabled persons, the elderly, and those with limited digital access?

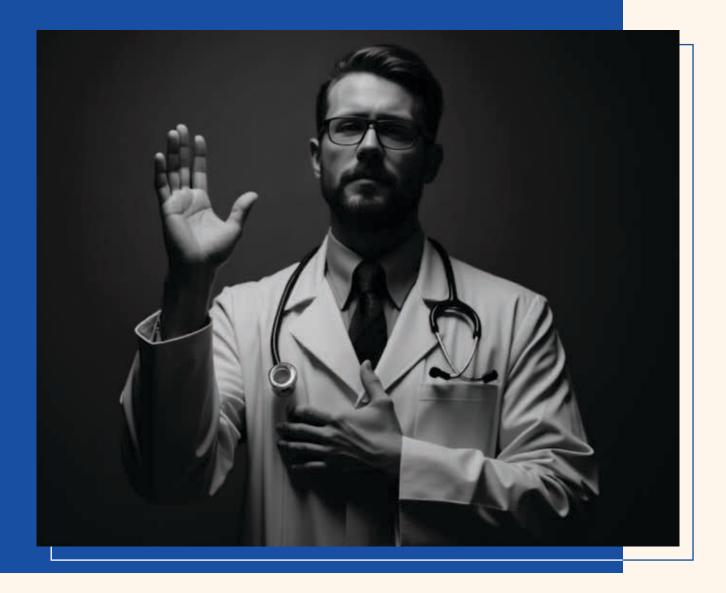
#### Freedom of Protest & Expression

- Did the Commission review or intervene in cases where New Zealanders were penalised or arrested for peacefully protesting public health restrictions?
- Was the right to freedom of expression adequately protected in New Zealand, particularly for those who questioned official narratives or policies?

#### Post-Pandemic Review & Future Reform

- Will the Commission conduct a full, publicfacing review of New Zealand's COVID-19 response, similar to the AHRC's Collateral Damage report?
- What reforms does the Commission believe are necessary to prevent rights violations in future public health emergencies?





#### **B. Medical Ethics**

Katie Ashby-Koppens

#### Why this issue is relevant:

Medical ethics are not abstract ideals - they are designed specifically for moments of crisis. In times like the COVID-19 pandemic, when uncertainty, fear, and political pressure are high, these principles provide a moral and professional compass to protect patients and guide practitioners.

The very reason we have codified rights, oaths, and international ethical standards is to ensure that an emergency does not justify ethical shortcuts. Upholding them is what distinguishes legitimate medical practice from coercion, experimentation, or harm.

#### New Zealand's framework for ethical medical care includes:

- The Code of Health and Disability Services Consumers' Rights
- Medical Council of New Zealand (MCNZ) professional standards

#### Which hail from internationally respected ethics:

- The Hippocratic Oath
- The Nuremberg Code

Each enshrines informed consent, voluntary choice, non-maleficence, and professional independence.

#### Yet during COVID-19, these cornerstones were sidelined:

- · Mandates undermined voluntary consent.
- The provisional and experimental nature of mRNA vaccines was not clearly communicated.
- · Dissenting professionals were silenced or disciplined.
- Patients were denied alternative options and open discussion.

These ethical principles exist precisely for times like COVID-19, to guide decision-making under pressure and prevent overreach.

#### **Details:**

### A. Code of Health and Disability Services Consumers' Rights (1996) 1

At the heart of New Zealand's patient rights framework is the Code of Health and Disability Services Consumers' Rights, a legally enforceable code overseen by the Health and Disability Commissioner (HDC). Among its most critical provisions is Right 7: Informed Choice and Consent, which states:

"Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent."

This right ensures that no medical treatment can lawfully proceed unless the patient has been fully informed of all material information, including potential benefits, risks, side-effects, and alternative options. Consent must be both voluntary and competent. This becomes especially important during a public health crisis, where state pressure and institutional policies may blur the line between encouragement and coercion. If individuals felt compelled to accept a medical intervention, such as vaccination, under the duress of losing employment or access to education, the legitimacy of that consent must be called into question.

#### B. MCNZ Statement on Informed Consent (June 2021)<sup>2</sup>

The Medical Council of New Zealand (MCNZ) issued a formal statement in March 2020 reaffirming that the ethical obligation to obtain informed consent applies in all clinical interactions, including public health emergencies. Doctors are required to ensure that patients:

- Fully understand the risks, benefits, and alternatives to the proposed treatment;
- Are not subjected to coercion, manipulation, or undue influence, and;
- Are free to decline medical treatment without punishment or disadvantage.

This guidance is explicit: medical professionals must not assume consent based on silence or treat compliance as evidence of understanding. Instead, a genuine dialogue is required. This principle directly conflicts with the practice of linking COVID-19 vaccination to access to employment, travel, or social participation, particularly where the long-term safety of the vaccine was still being studied.

#### C. MCNZ Good Medical Practice (November 2021 Edition)<sup>3</sup>

MCNZ's Good Medical Practice document sets out broad expectations for ethical behaviour and professionalism. It emphasises that doctors must practise in a way that is:

 Patient-centred, prioritising the individual's needs, values, and choices;

- Transparent, with honest communication about treatments and uncertainties; and
- Guided by professional integrity, rather than external pressure or political directives.

This standard also requires that doctors remain free to express concerns about health policy if they believe it compromises patient care. During COVID-19, however, some doctors were cautioned or disciplined for questioning government messaging. This raises questions about whether the profession's regulatory body maintained its commitment to ethical independence and open scientific discourse, or instead contributed to an environment of fear and censorship.

#### Foundational International Standards

#### D. The Hippocratic Oath4

- Do no harm (non-maleficence)
- · Respect for the patient's autonomy
- Use of independent judgement in care decisions
- Confidentiality

The Hippocratic Oath binds doctors to act in the best interest of each patient, regardless of public pressure or political expediency. During COVID-19, doctors faced unprecedented institutional pressure to comply with rapidly shifting public health orders. In such cases, the Hippocratic tradition would require practitioners to question whether actions such as enforcing vaccine mandates, suppressing alternative treatments, or failing to provide full disclosure violated their deeper duty to do no harm and uphold the dignity and autonomy of each individual.

The principle of confidentiality is rooted in the Hippocratic Oath and is a core tenet of medical ethics. It reflects the understanding that patients need to feel safe and secure in sharing personal information with their healthcare providers. Doctor-patient confidentiality, also known as medical privilege, is a fundamental ethical principle and is based on the idea that doctors and healthcare professionals have a duty to protect the privacy and confidentiality of patient information. This duty is crucial for maintaining trust and encouraging open communication in the doctor-patient relationship. This is further codified in NZ legislation, see Issue 0.5.E, page 68.

#### E. The Nuremberg Code (1947)<sup>5</sup>

Established after the atrocities of non-consensual human experimentation during WWII, the Nuremberg Code laid down universal principles for ethical medical research and practice. Its first and most important rule is:

"The voluntary consent of the human subject is absolutely essential."

This principle holds that consent must be:

- Informed with complete disclosure of all material information
- Voluntary given without threat, manipulation, or undue pressure
- Freely withdrawable without consequence to the subject

The Code applies not only to research but to any experimental medical intervention, and is particularly relevant in the context of COVID-19, where mRNA vaccines were provisionally approved under emergency provisions. If people were not clearly told that the vaccines were experimental in nature, or if they felt coerced by mandates and exclusions, the ethical validity of that consent is severely compromised.

## Important Questions for the Commissioners to Ask — and of Whom:

#### Medical Council of New Zealand (MCNZ):

- Did the MCNZ assess whether doctors were able to obtain genuine informed consent from patients receiving the COVID-19 vaccine, given the use of mandates and social pressure?
- How did the MCNZ reconcile its ethical obligations to support open professional debate with its disciplinary action or warnings against doctors who questioned official health advice?
- Were MCNZ standards on Good Medical Practice and Informed Consent updated or suspended during the pandemic, and if so, under what authority?
- Did MCNZ receive complaints from practitioners about being unable to fulfil their ethical duties due to Ministry directives or employer mandates?
- How does the MCNZ propose to protect clinical independence and ethical decision-making in future health emergencies?

#### Health and Disability Commissioner (HDC):

- Did the HDC investigate whether COVID-19 vaccine recipients were adequately informed of:
  - The vaccine's provisional approval status?
  - · The lack of long-term safety data?
  - Alternative treatment options or the right to decline?
- How did the HDC interpret Right 7 (Informed Choice and Consent) in circumstances where mandates created indirect coercion (e.g. loss of employment or access to education)?
- What processes did the HDC have in place to monitor or respond to systemic breaches of patient rights during the national rollout?
- Has the HDC retrospectively assessed complaints made during COVID-19 with a view to improving future response frameworks?

#### Ministry of Health and former Director-General of Health (continued):

- Why were members of the public not explicitly informed that COVID-19 vaccines were granted only provisional consent under section 23 of the Medicines Act?
- What risk-benefit analysis was used to justify excluding the right of refusal in certain sectors through mandates or pressure-based campaigns?
- Was public communication about the vaccine's safety and efficacy based on independent evidence, or were key uncertainties downplayed?
- Did the Ministry review its public health messaging to ensure it met the MCNZ and HDC standards for informed consent?
- Will future emergency communication strategies include a requirement to present clear, balanced, and legally accurate information to the public?
- Did New Zealand's COVID-19 response meet domestic and international ethical standards, including the Nuremberg Code and Hippocratic principles?
- To what extent were coercive mandates and lack of risk disclosure incompatible with informed consent requirements under the HDC Code?
- How did the suppression of dissenting clinical opinions affect medical ethics, scientific integrity, and public trust?
- Will the Commission recommend the establishment of independent ethical oversight during future national emergencies?
- How will the Royal Commission assess whether breaches of ethics occurred, and what accountability mechanisms will be proposed future health emergencies?

- https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/
- <sup>2</sup> https://www.mcnz.org.nz/assets/standards/55f15c65af/Statement-on-informed-consent.pdf
- <sup>3</sup> https://www.mcnz.org.nz/assets/standards/b3ad8bfba4/Good-Medical-Practice.pdf
- 4 https://www.nlm.nih.gov/hmd/topics/greek-medicine/index.html#casel
- ${}^{5} \ \ \, \underline{\text{https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code} \\$





#### C. Informed Consent

Katie Ashby-Koppens

#### Why this issue is relevant:

Informed consent is fundamental to ethical healthcare and human rights. During the COVID-19 pandemic, questions arose as to whether the public - particularly those under mandates - were properly informed and able to give free, voluntary consent to medical procedures such as vaccination. Revisiting informed consent is essential to uphold bodily autonomy, restore trust in medical institutions, and ensure future practices are aligned with both law and ethics.

New Zealand law and medical ethics require that patients give informed consent before any medical treatment. This is not optional – it is a legal and ethical duty. Informed consent must be voluntary, competent, and based on full disclosure of relevant information, including risks, benefits, alternatives, and the right to decline. These obligations are codified in law, enforced through professional standards, and supported by moral principles such as autonomy and non-maleficence.

During the pandemic, broad policies and employer-enforced mandates created conditions where many individuals may have felt coerced or misled, raising serious concerns about whether informed consent was respected in practice...

#### **Details:**

- A. The Code of Health and Disability Services Consumers' Rights  $(HDC\ Code)^1$
- Right 7(1): Services may be provided only if the consumer makes an informed choice and gives informed consent.
- Right 6(1): Every consumer has the right to the information necessary to make an informed choice or give informed consent.
- This includes information on risks, side-effects, benefits, costs, and alternatives.
- B. The Medical Council of New Zealand (MCNZ) "Informed Consent"  $\mbox{Guide}^2$
- MCNZ guidelines require doctors to:
  - Provide accurate and balanced information about treatment options.
  - Explain the risks and benefits clearly.
  - Ensure the decision is made freely, without pressure or coercion.
  - Respect a patient's right to decline treatment.
- C. New Zealand Bill of Rights Act  $1990^{3}$
- Section 11: Everyone has the right to refuse to undergo any medical treatment.

 This enshrines bodily autonomy as a fundamental human right.

#### D. Ethical Foundations

- Autonomy: The right of individuals to make decisions about their own bodies.
- Non-maleficence: Duty to avoid causing harm—including psychological or societal coercion.
- Justice: Fair treatment without discrimination or undue pressure.
- Informed consent: As not sought or given for the risk of COVID-19, risk of vaccines or risk of masks.

## Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health and Medical Council:

- How was informed consent ensured in contexts where refusal led to loss of employment or access to essential services?
- Were individuals fully informed of known and unknown risks, including those documented in Medsafe data sheets?
- How were doctors supported—or pressured by government policy in relation to their duty to obtain genuine consent?
- What systems of redress exist for those who believe their right to informed consent was violated?

- https://www.hdc.org.nz/vour-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/
- <sup>2</sup> https://www.mcnz.org.nz/our-standards/current-standards/informed-consent/
- https://www.legislation.govt.nz/act/public/1990/0109/latest/DLM224792.html



#### D. Pharmacovigilence

Katie Ashby-Koppens

#### Why this issue is relevant:

Pharmacovigilance is the science and activity of detecting, assessing, understanding, and preventing adverse effects or any other drug- or vaccine-related problem! It is fundamental to public health because clinical trials, while essential, are limited in size, scope, and duration, i.e. they cannot detect all safety issues before mass rollout.

As such, post-marketing surveillance is the mechanism by which regulators protect the population after approval, especially for novel technologies like mRNA vaccines. In New Zealand, Medsafe holds this responsibility. The failure to uphold strong pharmacovigilance practices can lead to the avoidable exposure of populations, especially children, to unnecessary and serious harm.

Pharmacovigilance is critical for detecting rare and long-term adverse effects that may not surface during clinical trials. As New Zealand's medicines regulator, Medsafe is responsible for monitoring and acting on safety signals after product approval.

In the case of Pfizer's COVID-19 mRNA vaccine, Medsafe failed to meet its obligations. Early warning signs from international databases, such as the U.S. VAERS, Australian DAEN, indicated serious harms, including myocarditis and death, yet no precautionary action was taken.

Compounding this failure was a lack of required short, medium or long-term safety studies, known underreporting of adverse events voluntary reporting systems, and political pressures. Despite mounting evidence of risk, especially for children, Medsafe continued to endorse the product for low-risk populations without adequate re-evaluation.

#### Details:

#### Pharmacovigilance in Context

Defined by the WHO as essential for protecting public health, pharmacovigilance involves detecting and evaluating adverse effects after a medicine is approved. It informs regulatory actions such as usage restrictions, label changes, or market withdrawals.<sup>1</sup>

Medsafe is expected to continuously assess post-market data to ensure a favourable risk-benefit profile, especially for novel technologies such as mRNA vaccines.

#### Historical Precedent

Several vaccines, such as Rotavirus, Swine Flu, and Dengue, were only withdrawn or restricted after post-market surveillance revealed serious adverse effects (Altman,<sup>2</sup> p.13).

#### Evidence of Failure<sup>2</sup>

- U.S. VAERS showed a significant spike in deaths and hospitalisations within 48 hours of mRNA COVID-19 vaccination (Altman,<sup>2</sup> pp.40 - 42).
- Despite this, Medsafe continued to grant provisional consent to younger healthier cohorts without seeming to evaluate the risk-benefit ratio in light of this local and global data.
- A failure to conduct or demand critical short, medium and long-term safety studies, including genotoxicity and carcinogenicity assessments - tests standard for new drug classes but waived due to the reclassification of gene-based products as "vaccines" (Altman,<sup>2</sup> pp.50-53).
- Children, at virtually no risk from COVID-19 itself, were exposed to the documented risks of myocarditis, stroke, and even death (Altman,<sup>2</sup> pp.30-33, 43-47).

 Medsafe's evaluator relied on surrogate immune markers, not actual disease prevention, in approving the vaccine's use in children (Altman,<sup>2</sup> p.35-36).

#### **Underreporting & Suppression**

- Serious underreporting (by factors of 5 to 30) is inherent to adverse event systems (Altman,<sup>2</sup> p.13).
- Additional suppression occurred due to fear of professional reprisal among doctors who reported vaccine harms (Altman,<sup>2</sup> p.14, 43).

## Important Questions for the Commissioners to Ask — and of Whom:

## Medsafe leadership or the Ministry of Health:

- How does Medsafe define and operationalise its pharmacovigilance responsibilities, especially for novel gene-based therapeutics reclassified as vaccines?
- What processes are in place to ensure international pharmacovigilance data (e.g. VAERS, EudraVigilance, DAENS) trigger timely reviews or warnings?
- What specific risk-benefit adjustments were made in light of emerging evidence of myocarditis and other serious adverse effects?
- Why were genotoxicity, carcinogenicity, and long-term fertility studies not required before approving COVID-19 vaccines for healthy children?
- What steps has Medsafe taken to address known limitations and underreporting in the CARM system?

#### **Director-General of Health:**

 What mechanisms exist to ensure timely and transparent public communication about safety concerns as post-marketing data evolves?

- https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance
- <sup>2</sup> Dr Altman Report Kiwi Kids' Case https://drive.google.com/file/d/1gs3HQqw8GwUVIKwFovIh9JBpSvgsXJaK/view?usp=share\_link



#### E. Medical Privilege - Patient/Doctor Confidentiality

Katie Ashby-Koppens

#### Why this issue is relevant:

Patient confidentiality belongs to the patients. It is a cornerstone of ethical medical practice and a protected legal right in New Zealand. Yet, during the COVID-19 response, these consent-based privacy protections were progressively undermined, and health data were repurposed for compliance and enforcement, often without clear legal justification. These developments highlight the urgent need for stronger safeguards in future public health emergencies.

Confidentiality is one of the most sacred duties in the doctor-patient relationship, forming the basis of medical privilege. Under New Zealand law and ethical practice, any information shared by a patient with their doctor must remain confidential, except in tightly defined legal exceptions (such as risk of serious harm to others). This principle ensures that patients can seek care, disclose sensitive information, and make informed choices without fear of surveillance or reprisal.

During COVID-19, however, this principle came under strain. Instances where vaccination status was recorded, reported, or shared with employers or public agencies raised serious ethical concerns, breach of medical privacy and an undermining of patient confidentiality. Some workplaces demanded direct access to medical records, and some healthcare providers were required to report uptake data, thereby blurring the boundary between healthcare and compliance enforcement. Such intrusions undermined trust in the medical system, especially as patients feared that their private health decisions were used against them socially or professionally. E.g. if people refused to confirm their vaccine status they were treated as unvaccinated.

The erosion of medical confidentiality during the COVID-19 pandemic, especially without individual consent, should be considered in light of future safeguards.

#### Details:

Despite the foundational principle of patient confidentiality being legislated in New Zealand, patient confidentiality and patient/doctor confidentiality were not upheld.

## A. Health Information Privacy Code 2020 (New Zealand Privacy Commissioner)<sup>1</sup>

This Code outlines the specific rules governing the handling of personal health information by health agencies, including obligations related to the collection, use, disclosure, and storage of identifiable data.

Key principles include:

- Health information must only be collected for lawful purposes.
- Disclosure requires patient consent, unless exceptions apply.
- Individuals have a right to access and correct their health information

### B. Medical Council of New Zealand – Patient Confidentiality (from Good Medical Practice)<sup>2</sup>

MCNZ outlines that doctors must treat patient information as confidential and only share it:

- With the patient's informed consent.
- · When required by law.
- When it is necessary to protect the patient or others from harm.

### Code of Health and Disability Services Consumers' Rights (1996)<sup>3</sup>

Specifically:

 Right 1(2): Right to have services provided in a manner that respects privacy.

- Right 4(1): Services must be provided with reasonable care and skill.
- Right 5: Right to effective communication, including about the use of personal information.

## Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health and COVID-19 Response Minister:

- Did the Ministry of Health authorise or encourage the disclosure of individual vaccination status to third parties such as employers, schools, or public event organisers? If so, under what legal authority or public health provision?
- What safeguards were in place to ensure that individuals' vaccination status was not shared beyond their healthcare provider without their informed consent?
- Were the principles outlined in the Health Information Privacy Code 2020 upheld throughout the COVID-19 vaccination programme, particularly the requirement that disclosure be consent-based and for lawful, specific purposes only?
- How did the Ministry reconcile public health objectives with the obligations outlined by the Medical Council of New Zealand that medical information should only be disclosed with patient consent, unless legally required or in cases of serious harm?
- Was there any formal legal review or privacy impact assessment conducted before implementing policies that required or encouraged the sharing of vaccination status?
- What guidance, if any, was issued to health professionals or District Health Boards regarding the maintenance of patient confidentiality during the COVID-19 vaccine rollout and the introduction of vaccine passes?
- Given the ethical obligation to protect patient/ doctor confidentiality, does the Ministry believe it was appropriate for health professionals to be placed in the position of reporting vaccination data for non-clinical purposes?
- Will the Ministry commit to reviewing and reporting on potential breaches of confidentiality and to establishing a future protocol that strengthens the firewall between personal medical records and public compliance mechanisms?

- https://www.privacy.org.nz/privacy-principles/codes-of-practice/hipc2020/
- 2 "Good Medical Practice" (2021): https://www.mcnz.org.nz/assets/standards/b3ad8bfba4/Good-Medical-Practice.pdf (See page 17: "Confidentiality and privacy")
- https://www.hdc.org.nz/your-rights/about-the-code/code-of-health-and-disability-services-consumers-rights/



## 0.6 CENSORSHIP

#### Censorship and Narrative Control During New Zealand's COVID-19 Response

During the COVID-19 period, New Zealand experienced an unprecedented suppression of dissenting voices across multiple domains - media, science, social platforms, and public discourse.

The government actively coordinated with mainstream media and social media platforms to silence views that diverged from official COVID-19 narratives, often labelling them as "misinformation." Citizen-led groups such as Voices for Freedom were deplatformed without warning or recourse, despite relying on mainstream sources and official data.

Through its Public Interest Journalism Fund and strategic partnerships with groups like The Disinformation Project, the government also influenced media content, framing dissent as extremism and eroding editorial independence. Intelligence agencies tracked lawful protesters and critics under the guise of public safety, while behavioural science tactics were used to pre-emptively shape public perception and suppress opposition.

Simultaneously, the scientific research environment was tightly controlled, with funding mechanisms structured to discourage enquiry into politically inconvenient topics - especially those that might question vaccine safety or promote non-commercial interventions.

This systematic censorship undermined New Zealanders' rights to freedom of expression, access to information, and informed consent, raising serious concerns about democratic integrity and government overreach in times of crisis.

Censorship is the reason you did not hear about many of the things set out in these submissions. The censorship was harsh, coordinated and targeted.

#### In this section

- **A.** Censorship Information and Media Government narratives and public communication during COVID-19
- B. Censorship Mainstream media and social media
- C. Censorship Silencing experts globally
- D. Censorship Science Funding



## O.6 CENSORSHIP -THROUGH THE WHOLE SYSTEM

## A. Information and Media – Government narratives and public communication during COVID-19

Alia Bland

#### Why this issue is relevant:

During the COVID-19 pandemic, the New Zealand government led a coordinated effort to monitor and suppress what it labelled "mis- and disinformation." Intelligence agencies, academics, media platforms, and international partners collaborated to shape public opinion and marginalise dissent. This included outsourcing surveillance, directing media narratives through targeted funding, and framing critics as threats to public safety. Many New Zealanders remain unaware of these efforts due to the very censorship the strategy enabled.

Between 2020 and 2023, the New Zealand government coordinated an extensive effort to shape public discourse around COVID-19. Documents obtained under the Official Information Act (OIA) and reports from The Disinformation Project (TDP) and Te Pūnaha Matatini (TPM) reveal that this approach involved:

- Inter-Agency Coordination: The Department of Prime Minister and Cabinet (DPMC) led a multi-agency group that included intelligence services and various ministries to oversee narrative control efforts.
- Outsourced Surveillance and Narrative Framing: The
  Disinformation Project, operating under TPM and led by
  Kate Hannah, received government support to define
  "disinformation" and guide policy. Their outputs linked
  scepticism and dissent to extremism and foreign influence.
- Media Manipulation and Censorship: The Public Interest Journalism Fund (PIJF) incentivised alignment with the official COVID-19 narrative. Media outlets received training from TDP, and dissenting views were actively suppressed on social media
- International Coordination: New Zealand collaborated with Five Eyes partners and adopted tactics used in the UK and Canada to monitor and counter disinformation.
- Behavioural Influence Tactics: "Prebunking" and behavioural science were employed to steer public opinion and preempt dissent.
- **Demonisation of Dissent:** Protests and criticism of mandates were portrayed as threats to democracy and public health.

This system led to the suppression of alternative viewpoints and entrenched a government-approved narrative across media and civil society.

# Details:

# Government Strategy and Coordination:

- An inter-agency group, led by DPMC, coordinated ministries and intelligence services (including the GCSB and NZSIS) under a "whole-of-society approach."
- Collaboration extended to civil society, academia, and private media to monitor and suppress perceived misinformation.

# Role of The Disinformation Project and TPM:

- TPM began disinformation-related work in early 2020, with TDP becoming a key player in framing dissent as extremism.
- TDP's government-funded research heavily influenced media content and official policies, though funding sources were not fully disclosed.

# Media Influence and Funding:

- The \$55 million PIJF incentivised pro-government reporting across mainstream media.
- Journalists received training from TDP, while dissenting voices were delegitimised or deplatformed.
- Proposed structural changes, like the TVNZ/RNZ merger, signalled a push for tighter state control over media narratives
- Outlets such as Stuff, Newsroom, and The Spinoff closely followed government-aligned messaging.

## Targeting of Dissent:

- Government agencies monitored critical social media content and tracked protests.
- Protesters were portrayed as dangerous, and groups like Voices for Freedom were treated as national security concerns by intelligence agencies.

# Public Manipulation and Prebunking:

- Techniques like "prebunking" and "infodemic" management were used to influence how citizens perceived and processed information
- Behavioural psychology underpinned campaigns designed to build compliance and suppress alternative views.

# Important Questions for the Commissioners to Ask — and of Whom:

Jacinda Ardern & Chris Hipkins (former Prime Ministers):

What directives were issued to the inter-agency group on defining and countering "mis- and disinformation"?

# Kate Hannah (The Disinformation Project):

What are the full funding sources for The Disinformation Project?

# **Department of Internal Affairs:**

What methods were used to monitor social media and how was this information shared with other agencies?

# NZSIS:

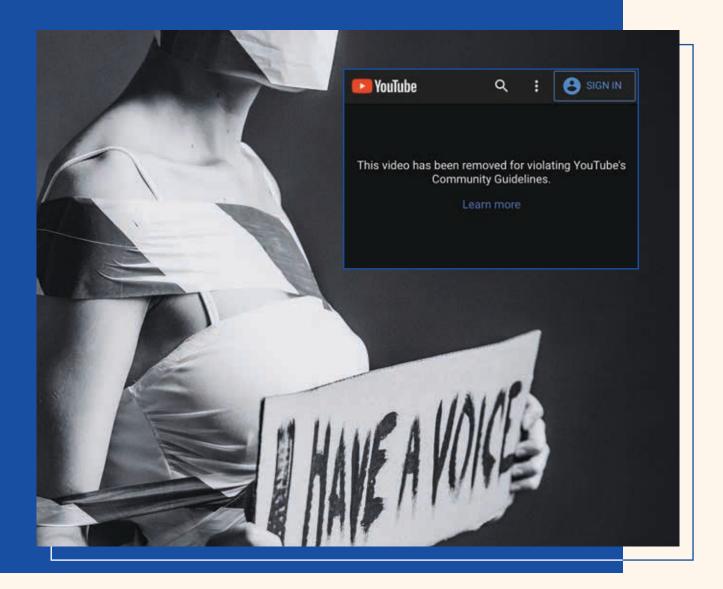
How were individuals and groups designated as security threats based on their views of COVID-19 policies?

# Ministry of Health:

What role did the Disinformation Assessment and Response Team (DART) play in monitoring vaccine scepticism?

# References:

https://www.thelookingglass.co.nz/meet-the-new-thought-police-the-orwellian-researchers-working-to-pathologise-dissent/https://www.thelookingglass.co.nz/ministry-of-truth-nz-the-documents-that-reveal-the-governments-many-tentacled-approach



# O.6 CENSORSHIP -THROUGH THE WHOLE SYSTEM

# B. Mainstream Media and Social Media

Alia Bland

# Why this issue is relevant:

During the COVID-19 response in New Zealand, dissenting voices were supressed which distorted the information environment in which only government-endorsed narratives were promoted. Independent groups, including Voices for Freedom (VFF), faced extreme censorship online and significant barriers to sharing alternative information, scientific debate, and public questions. This raises serious concerns regarding freedom of expression, the right to access diverse viewpoints, and the health of democratic discourse in times of crisis.

Voices for Freedom (VFF), a citizen-led group formed in response to New Zealand's COVID-19 measures, experienced extensive censorship on mainstream and social media platforms during the pandemic. Despite efforts to comply with platform policies and share information sourced from mainstream media, international health authorities, and official government documents, VFF's social media presence was dismantled without warning. The government and media openly acknowledged direct communication with social media platforms to request the removal of content and pages. The resulting information vacuum limited public access to diverse perspectives and led to the dominance of a single narrative. VFF was forced to adopt alternative offline methods to reach the public, while also facing the withdrawal of services from print and advertising providers under pressure. This situation highlights the need to investigate the extent and coordination of censorship, its justification, and its impact on public discourse and informed consent.

### **Details:**

During the COVID-19 response, the New Zealand government became the dominant force in the country's media and advertising landscape, acting as the single largest advertising client. This unprecedented concentration of influence enabled government messaging to saturate public information channels across all major platforms. Media outlets, reliant on advertising revenue to remain solvent during lockdown-induced economic downturns, had strong incentives to align editorially with the government narrative or risk losing critical funding.

Government Advertising Spend: Government advertising rose from \$71m in 2019 to \$93m in 2020, peaking at \$116m and \$117m in 2021 and 2022. Despite the pandemic's official end, \$50m was spent in the first half of 2023 alone, indicating sustained government dominance in the media landscape.

At the same time, the government admitted to working directly with social media platforms, such as Facebook, to report and request the removal of content deemed 'misinformation'.<sup>2</sup> These removals often included posts that cited official sources but questioned the prevailing COVID-19 response or raised legitimate scientific debate. Pages and accounts were removed without warning, with no recourse or appeal. Public commentary about these takedowns suggested an informal alliance between the government, journalists, and platforms to silence dissenting views.

In addition to its role in shaping the advertising and media environment, the government actively surveilled groups and individuals who were critical of the COVID-19 narrative. Official Information Act (OIA) responses and Privacy Act requests reveal that entire dossiers³ were compiled by 'disinformation' units within government agencies. These files, which can be made available upon request, document the monitoring of New Zealand citizens based on their speech and associations—raising serious concerns about civil liberties and state overreach during a time of public crisis.

Censorship extended beyond online platforms. As alternative voices were de-platformed or shadow-banned, critical-thinking Kiwis were pushed toward lesser-known or stigmatised platforms like Telegram and Odysee. These were labelled 'dangerous' by officials and the media, creating a chilling effect that discouraged public engagement with alternative perspectives.

Independent print and advertising suppliers also faced indirect pressure. Companies previously willing to work with dissenting groups reported conflicts of interest, citing their dependence on government contracts or their own financial vulnerability due to the economic climate. As a result, public communication became highly one-sided, with very limited space for alternative views to be shared, tested, or debated.

This environment severely undermined informed consent, particularly in relation to medical decision-making and public health policy. It stifled open discourse and created a feedback loop in which public trust in media, government, and health institutions was eroded. The absence of visible and credible counter-narratives contributed to societal polarisation and the delegitimisation of legitimate questions and concerns.

# Important Questions for the Commissioners to Ask — and of Whom:

# Department of Internal Affairs and Prime Minister's Office:

- What systems were in place to coordinate with social media platforms regarding content removal?
- What criteria were used to determine which accounts or content to report?
- Were New Zealand citizens monitored for lawful dissenting speech, and under what authority were dossiers compiled?

# Social media platforms (Facebook/Meta, Google/YouTube):

- What processes were followed when removing New Zealand-based accounts or posts flagged by government representatives?
- Why were users not given warning, justification, or appeal pathways?

# Media executives and government officials:

- What impact did government advertising revenue have on editorial independence during the COVID-19 response?
- Were any informal pressures applied to media outlets or advertising service providers regarding groups like VFF?

- https://www.whitehouse.gov/lab-leak-true-origins-of-covid-19/
- <sup>2</sup> https://fyi.org.nz/request/21009/response/79981/attach/4/Letter%20to%20Mark%20Wong.pdf
- https://drive.google.com/file/d/10FE61\_qPtL4jHjVzt\_X\_YORo8llSKA-p/view?usp=sharing



# O.6 CENSORSHIP -THROUGH THE WHOLE SYSTEM

# C. Doctors who had questions/concerns were censored & censured

Katie Ashby-Koppens

# Why this issue is relevant:

Experts who raised legitimate concerns during the COVID-19 response were censored, silenced, and professionally threatened. This was part of a global pattern where debate was replaced by dogma, criticism, and coercion. The cost: undermined science, broken public trust, and a generation of experts now too afraid to speak. As the Royal Commission Phase Two reviews decisions made and lessons learned for future health crises, safeguards must be put in place to protect, not punish, those who dare to question.

Rather than engaging in transparent scientific discussion, authorities and institutions often resorted to punitive tactics against dissenters.

Dr. Alina Chan, who proposed that a lab origin for SARS-CoV-2 was plausible, endured death threats, accusations of racism, and blacklisting from professional opportunities. Her experience reflects a broader trend: science was not only politicised but policed, with devastating personal and professional consequences for those who spoke up.

Dr. Byram Bridle, who expressed caution over mRNA vaccine safety and the spike protein's distribution, faced coordinated harassment and professional exile, despite no evidence of misconduct.

### Details:

# Dr. Alina Chan (USA)1

A molecular biologist at MIT and the Broad Institute, Dr. Chan was among the first scientists to publicly entertain the possibility of a lab-based origin for SARS-CoV-2.

## Key consequences included:

- Branded a "race traitor" and subjected to death threats for questioning the zoonotic origin theory.
- Dismissed and discredited by media and fellow academics despite meticulous, evidence-based analysis.
- Faced career consequences for challenging the dominant narrative—even though her position has since gained significant credibility within the scientific community.
- Chan has spoken out about the toxic culture of intimidation and conformity, calling the suppression of legitimate scientific enquiry "morally repugnant".

# Dr. Byram Bridle (Canada)<sup>2,3</sup>

An immunologist and vaccine researcher, Dr. Bridle faced severe backlash after raising concerns about the biodistribution of the spike protein used in mRNA COVID-19 vaccines (see Issue 1.9, page 168).

# Associate Professor Bridle (Canada)<sup>2,3</sup>

A viral immunologist at the University of Guelph, Ontario was the first scientist to speak about Pfizer's own biodistribution study provided to the Japanese regulators.

# Key consequences included:

- Was publicly misrepresented and vilified after his comments were amplified in the media.
- Despite no findings of wrongdoing, was banned from his own laboratory and office for 3.5 years. Multiple investigations confirmed he posed no threat to colleagues. Some complainants admitted they hoped to provoke him into retaliating.
- Saw his research programme effectively destroyed and was told not to seek further funding until reinstated, which never fully occurred.

Legal documents reveal prolonged institutional obstruction, with ongoing legal battles aiming to restore his rights and reputation.

# New Zealand Context

New Zealand professionals were not immune to persecution, prosecution, coercion, and censorship. Medical professionals who questioned decisions about the public health response also faced consequences—see Issue 1.15.B, page 238.

# Important Questions for the Commissioners to Ask — and of Whom:

# Ministry of Health and Medical Professional Councils:

# 1. Transparency and External Influence

- What formal or informal communications did the Ministry or Councils receive from international agencies, such as the WHO, CDC, or foreign regulatory bodies, regarding how to manage dissenting medical voices during the COVID-19 pandemic?
- Were there any briefings or policy directives, explicit or implied, recommending the suppression or discrediting of professionals who raised concerns about vaccine safety, origins of the virus, or public health policies?

# 2. Safeguards for Academic and Clinical Freedom

- What protections, if any, were in place during the pandemic to ensure clinicians and scientists could voice professional concerns without fear of reprisal?
- Given the demonstrated harms of silencing credible professionals, what legislative or regulatory changes are being considered to prevent such censorship in future public health emergencies?

# 3. Accountability for Retaliatory Measures

- In cases where doctors or researchers were suspended, referred for investigation, or faced professional exclusion solely due to expressing dissenting but evidence-based opinions, what review processes have been or will be initiated to assess whether those actions were justified?
- Have any apologies, reinstatements, or reparations been offered to those whose reputations and careers were damaged by institutionally sanctioned censorship?

# 4. Ethical Oversight and Patient Care

- How did the censorship of doctors impact their ability to maintain honest, transparent relationships with patients during COVID-19?
- What steps are being taken to restore public trust in the medical profession, particularly where it was undermined by perceived political interference in scientific communication?

# 5. Forward-Looking Protections

- Will the Ministry or Council commit to establishing a formal framework to protect whistleblowers and dissenting experts in the health sector, particularly during declared health emergencies?
- How will New Zealand ensure that future responses to pandemics do not sacrifice open scientific debate in favour of narrative control?

- https://www.dailymail.co.uk/news/article-14505321/Covid-created-lab-biologist-Alina-Chan-death-threats-race-traitor
- <sup>2</sup> <a href="https://viralimmunologist.substack.com/p/baby-steps-back-in-my-office">https://viralimmunologist.substack.com/p/baby-steps-back-in-my-office</a>
- 3 Police Report https://web.archive.org/web/20241122211733/http://canucklaw.ca/wp-content/uploads/Byram-Bridle-Peel-Police-Identity-Theft.pdf



# O.6 CENSORSHIP -THROUGH THE WHOLE SYSTEM

# D. Science Funding

J.R. Bruning (B.Bus.Agribus, M.A. (Sociology, Research)

# Why this issue is relevant:

The structure and priorities of funding mechanisms effectively censor scientific enquiry by shaping what research can and cannot be conducted. Media, the judiciary, and the public will be unaware that science funding policy in New Zealand is so tightly controlled as to act as a form of censorship. During COVID-19, the only research that was undertaken was research specifically contracted by the agencies in charge of the COVID-19 campaign.

New Zealand's science research system has been systematically and broadly decoupled from serving the public purpose (2000–2025). To access long-term funding, scientists and researchers must prioritise the development of commercial innovations or undertake research that has been pre-approved.

Healthy, functioning democracies require resilient, trustworthy informational systems. To sustain public trust, evidence-based policy formulation should be based on transparent, accountable, and unbiased information. The scientific process and procedural fairness are critical, particularly in an emergency situation, which will resemble 'the fog of war'.

During COVID, New Zealand scientists and doctors lacked the capacity to freely undertake research to review the risk status of SARS-CoV-2 and to enquire into the safety of physical and pharmacological interventions. Instead, funding was directly controlled by agencies that signalled the novel vaccine as the predominant therapeutic intervention. MBIE was a signatory to the vaccine agreement and also controlled the science budget. MBIE's policy approach has the effect of restricting enquiry to politically safe or commercially profitable topics, silencing research that challenges dominant narratives, questions policy, or addresses inconvenient truths.

# **Details:**

## 1. Prioritisation of Innovation Over Public Good

Funding is primarily directed toward projects promising innovation, excellence, and impact, typically linked to commercial or IP outcomes. Public benefit is treated as secondary or even tertiary, and researchers must frame public good projects within the narrow constraints of innovation language or risk being unfunded. Funding of nutritional therapies that do not produce IP for COVID-19 treatment would be out of scope.

# 2. Suppression of Politically Inconvenient Topics

Scientists are discouraged from proposing research that challenges established norms, scientific consensus, government policies, or the interests of powerful industry partners. Topics such as biologic drug contamination are essentially off-limits for significant funding. This work does not align with narratives around 'safety' and innovation-focused agendas.

# 3. Self-Censorship and Fear of Rejection

Scientists engage in self-censorship, avoiding controversial or unconventional topics to protect their careers and ensure future funding. The need for "safe" proposals creates a path dependency, where only previously accepted or politically neutral topics continue to receive support, while larger societal problems go unexamined.

# 4. Structural Control as a Censorship Mechanism

The focus on innovation and 'excellence' in tightly contested funding environments ensures conformity to discipline norms.

Original, interdisciplinary, or disruptive ideas cannot be viewed as 'excellent.' For example, research to identify the risk of the mRNA vaccine based on age group and gender, considering genetic/biological pathways, using machine learning and surveying New Zealanders for adverse events would be out of scope. Oversight by entities like MBIE has led to a "conservative policy police" environment, where even minor challenges to conventional thinking are dis-incentivised.

## 5. Decline of Scientific Freedom and Collegiality

The commercialisation imperative leads to competition and distrust among researchers, eroding the collaborative spirit needed to address complex issues. Scientists and researchers in universities and CRIs/PROs disclosed this problem in the Te Ara Paerangi consultation, discussed in the PSGR paper cited below.

# 6. Specific Examples of Censored Topics

Funding is virtually unattainable for long-term research to:

- Identify optimum nutrient levels by age and developmental stage.
- Establish drivers of metabolic syndrome, which was a noted risk factor for COVID-19.
- Explore biological risks from mRNA vaccines, including contamination risk.

# Important Questions for the Commissioners to Ask — and of Whom:

Ministry of Health and COVID-19 Technical Advisory Groups (TAGs):

- Did COVID-19 TAGs provide Ministers with an update on:
  - (a) the risk from COVID-19 variants causing hospitalisation and death; and
  - (b) a review of the scientific literature on vaccine risk—by age, gender, and health status—prior to publishing mandates using secondary legislation?

# References:

Bruning, J.R. 2022. University of Auckland Masters' Thesis. Innovation and Ignorance: How Innovation Funding Cultures Disincentivise Endocrine Disruption Research.

PSGR (2025). When powerful agencies hijack democratic systems. Part II: The case of science system reform. Bruning, J.R. ISBN 978-1-0670678-1-6

https://researchspace.auckland.ac.nz/handle/2292/57929



# 0.7 WHO

# **World Health Organization**

The World Health Organization (WHO), as the United Nations' leading health agency, has significant influence over national pandemic responses through its International Health Regulations (IHR). During COVID-19, the WHO abandoned its own evidence-based pandemic plans, instead endorsing extreme and disruptive measures – lockdowns, mass masking, border closures, quarantines of the healthy, mass vaccination irrespective of risk category and immune status – that had previously been advised against due to their broader societal harms. These recommendations were adopted by countries like New Zealand despite the lack of evidence to do so, rigorous cost-benefit analysis or long-term impact modelling.

At the same time, WHO failed to carry out a credible investigation into the origins of SARS-CoV-2 (COVID-19), prematurely dismissing the lab-origin hypothesis despite compelling evidence, including the Wuhan Institute of Virology's known gain-of-function research. This undermined transparency, delayed accountability, and damaged public trust at a critical moment.

Compounding these failures is WHO's deeply compromised funding model. Over 75% of its funding is now 'specified' – meaning it is tied to donor priorities rather than independent public health assessments. A growing share of its budget (25%) comes from private and corporate sources, especially those with vested pharmaceutical interests. This has shifted WHO's focus toward vertical, commodity-driven health responses (e.g. mass vaccination), and away from sustainable, holistic, population health strategies.

In the aftermath of COVID-19, WHO has spearheaded efforts to rewrite the IHRs and draft a sweeping new Pandemic Agreement. It says the new Pandemic Agreement is

necessary followng the "catastrophic failure of the international community in showing solidarity and equity in response to the coronavirus disease (COVID-19) pandemic."

These reforms overlook WHO's own failings: from endorsing unprecedented, unproven interventions, to misrepresenting pandemic risks and failing to address the pandemic in the context of competing health priorities and long-term health risks – especially the lab-leak theory involving the Wuhan Institute of Virology.

Finally, the risk of future pandemics is being systematically overstated. Analyses show that WHO and its partners, including the World Bank and G20, are using inflated and poorly evidenced models to justify more than U.S.\$31 billion annually for pandemic preparedness – money that risks being diverted from higher-burden health priorities like tuberculosis, malaria, and basic nutrition. All of this is being done, despite the risk of naturally occurring pandemics being low!

These structural, procedural, and ethical failures demand urgent scrutiny before New Zealand accepts further obligations under the proposed WHO Pandemic Agreement or IHR amendments. The Royal Commission must ask: is this the right institution to direct our future health response?

# In this section

- A. WHO's recommendations changed for COVID-19
- B. Investigations into Origin of Virus
- C. Independence of the WHO
- D. WHO's Pandemic Financing
- E. WHO's New Pandemic Treaties
- F. Risk of pandemics overstated



# 0.7 WORLD HEALTH ORGANIZATION

A. WHO's pandemic recommendations changed for COVID-19

Dr David Bell, Re-Evaluating the Pandemic Preparedness And Response Agenda (REPPARE), University of Leeds

# Why this issue is relevant:

World Health Organization (WHO) is the United Nations agency responsible for advising on and coordinating the world's response to health emergencies.

During COVID-19, a pandemic it declared in March 2020, WHO changed its recommendations for managing pandemics, abandoning previous evidence-based approaches aimed at minimising broader harm, poverty, and inequality.

Non-pharma	WHO: prior	WHO: post	New Zealand:
intervention	to COVID <sup>1</sup>	declaring COVID	implemented
Border Closures	Not	Temporarily useful	2.5 years borders
and Entry Screening	recommended	- isolated <sup>6</sup>	closed and MIQ
Contact Tracing	Not recommended	Critical tool to interrupt transmission <sup>7</sup>	2 years of various types contact tracing
Quarantine the Healthy	Not recommended	Recommended <sup>8</sup>	1.5 years countrywide and regional lockdowns
Masking the	No evidence masks	Advised <sup>9</sup>	2 years-masks
Healthy	have any effect		mandated
Closure - School - Workplace	Limited circs: -High severity - Ext severtiy	Use with Caution <sup>10</sup>	1.5 years countrywide & regional -intermittent
Social	Silent	Recommended	1.5 years 1+ metre
Distancing 6'		1+ metre <sup>11</sup>	social distancing

WHO recommendations carry considerable weight to any member nation, especially during an emergency. Previously, WHO internal review processes helped ensure that guidelines were aligned with evidence and considered broad public health implications. This is no longer the case.

In 2019, WHO issued recommendations for non-pharmaceutical interventions (NPIs) for pandemic influenza, based on such a systematic review. These emphasised **never (under any circumstances):** 

- Undertake contact tracing in established outbreaks.
- Quarantine of exposed (non-sick) individuals.
- Close borders.
- · Conduct entry and exit screening.

Similarly, recommendations to member nations affected by a Public Health Emergency of International Concern (PHEIC) prioritised avoiding harmful interventions.

In 2018, WHO's Managing Epidemics handbook<sup>2</sup> considered quarantine "unacceptable to many populations." Mask use was only recommended for sick individuals during severe pandemics and was viewed as an "extreme measure."

Early in the COVID-19 pandemic, WHO initially advised against "any travel or trade restrictions." After many countries acted contrary to this advice, WHO changed its recommendations - endorsing disruptive policies despite acknowledging their role in worsening poverty and inequality.

2023 WHO advice<sup>3</sup> indicates a normalisation of these COVID-19 NPIs, despite an ongoing 'research agenda' still assessing their effectiveness or effects. WHO no longer regards quarantine as unacceptable and now recommends general community masking – even for seasonal influenza – despite a Cochrane review and other meta-analyses failing to show benefit.<sup>4</sup>

Meanwhile, a new IHR (International Health Regulations)<sup>5</sup> benchmark calls for states to develop the capacity to implement NPIs, said to "range from surveillance, contact tracing, mask wearing and physical distancing to social measures, such as restricting mass gatherings and modifying school and business openings and closures".

WHO's process for developing pandemic management recommendations is no longer evidence-based<sup>5</sup> and requires major reform.

# Important Questions for the Commissioners to Ask — and of Whom:

## To former Director-General of Health:

- What evidence and modelling assessed health and economic trade-offs of unprecedented NPIs like lockdowns, border closures, and quarantine of healthy people?
- Did you question WHO's departure of ordinary evidence-based NPIs?

# To the New Zealand Ministry of Health (or WHO-aligned advisory bodies):

- On what basis did New Zealand adopt revised WHO NPI guidance during COVID-19, especially when it contradicted the 2019 pandemic influenza plan focused on minimising societal harm?
- Was any independent New Zealand review conducted on the effectiveness and harms of revised WHO measures like mass masking and school closures before implementation? If so, please provide the findings.

- WHO's 2019 recommendations for pandemic influenza: https://tinyurl.com/5n6t3ndb
- <sup>2</sup> The 2018 version of 'Managing Epidemics': https://tinyurl.com/3scmtju8
- The 2023 update of 'Managing Epidemics': https://tinyurl.com/ej3k9shu
- Cochrane Review on masks: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.
- New IHR Benchmarks: https://tinyurl.com/2cmybu8d
- https://www.who.int/news-room/articles-detail/updated
- https://www.who.int/publications/m/item/contact-tracing
- https://iris.who.int/bitstream/handle/10665/333901/WHO-
- 9 https://www.who.int/docs/default-source/coronaviruse/
- https://www.who.int/docs/default-source/coronaviruse/
- https://www.who.int/westernpacific/emergencies/covid-19/



# 0.7 WORLD HEALTH ORGANIZATION

B. WHO's Investigations into the Origin of COVID-19

Katie Ashby-Koppens

# Why this issue is relevant:

World Health Organization, mandated as the world's leading authority on public health, failed to seriously examine the Wuhan Institute of Virology, as a cause for the outbreak being manmade. This is despite its well-documented involvement in high-risk coronavirus and gain-of-function research. This omission not only undermined efforts to understand and contain the virus, but also meant the world was denied critical insights into the virus' potential development and construction - knowledge that could have informed more suitable diagnostics.

Instead, this opportunity was lost to narrative management, at the cost of transparency, accountability, and scientific integrity, precisely when global health depended on them most.

WHO's Field Visit in early 2020 and its investigation in March 2021 to Wuhan China failed to properly investigate and determine that the likely origin of the virus was the Wuhan Institute of Virology (WIV) and therefore manmade. In March 2021, WHO's Director General was making emphatic statements that the lab leak was the less likely hypothesis.

Other reports did not so readily dismiss the lab origin, had WHO not done so, then as the organisation responsible for global health, it would have:

- Identified the true origin of SARS-CoV-2, which likely emerged from risky virological manipulation rather than a natural zoonotic spillover.
- Held responsible institutions to account, including those engaged in or funding dangerous research with pandemic potential.
- Implemented immediate biosafety reforms, to prevent future lab-related incidents worldwide.
- Insisted a moratorium be placed on all gain-of-function research.
- Informed the public honestly, rather than protect political and institutional reputations at the cost of truth.
- · Preserved scientific integrity.

Instead, WHO and global institutions chose narrative management over rigorous enquiry.

The virus was allowed to spread unchecked, by a wall of geopolitical silence. The failure to identify a lab-based origin in real time allowed WIV and its international partners to avoid scrutiny, destroyed public trust, delay meaningful reforms in the governance of high-risk pathogen research, which will impact pandemic preparedness for the future.

# Chronology:

- Dec 31, 2019: China reported a cluster of pneumonia cases in Wuhan.<sup>1</sup>
- Jan 1, 2020: WHO activated its Incident Management Support

  Today

  Today
- Jan 5, 2020: WHO issued its first Disease Outbreak News bulletin.<sup>2</sup>
- Jan 10, 2020: WHO released technical guidance on detecting, testing, and managing the virus.<sup>3</sup>
- Jan 12, 2020: China shared the genetic sequence of the novel coronavirus.
- Jan 13–14, 2020: WHO acknowledged possible limited human-to-human transmission.
- Jan 20-21, 2020: WHO Field Visit in Wuhan: A team of WHO experts conducted an on-site assessment in Wuhan. Key findings included:
  - Evaluation of surveillance, airport screening, and hospital infection control.
  - Release of RT-PCR diagnostic tools by China, aiding global detection efforts.
  - Confirmation of human-to-human transmission, including healthcare worker infections.
- No mention was made of the Wuhan Institute of Virology or other labs as possible sources.<sup>4</sup>
- Jan 22–23, 2020: WHO convened an Emergency Committee, which postponed declaring a global emergency.
- Jan 30, 2020: WHO declared a Public Health Emergency of International Concern (PHEIC).<sup>5</sup>

- May 2020: The World Health Assembly passed a resolution calling for a study into the virus' origins.<sup>6</sup>
- Early 2021: An international WHO-led team visited Wuhan for a formal origins study. Their findings were published in March 2021. The 2021 report concluded that the most likely origin of the virus was transmission through an intermediate host species—a spillover from animals to humans, potentially via the Huanan Seafood Market.<sup>7</sup>
- Lab Origin Considered "Extremely Unlikely": The possibility that the virus leaked from a laboratory, such as the Wuhan Institute of Virology, was evaluated but ultimately classified as "extremely unlikely."<sup>8</sup>
- WHO's Continued Position: Despite these findings, WHO Director-General Dr. Tedros stated that all hypotheses remain on the table and called for further studies, greater transparency, and access to raw data.9

## Other reports that investigated the origin of the virus:

Other reports did not so readily dismiss the lab origin as the organisation responsible for world health did:

- March 2020 U.K. Classified dossier compiled by Sir Richard Dearlove, the former head of MI6, was passed to then-Prime Minister Boris Johnson: 'It is now beyond reasonable doubt that COVID-19 was engineered in the WIV.'10
- 2020 German Foreign Intelligence Service (BND): BND reportedly believed in 2020 that a lab leak was 80-90% likely origin, but the report remained undisclosed until 2025.
- August 2021 U.S. Office of the Director of National Intelligence (ODNI): Declassified report concluded both lab and natural origins are plausible but inconclusive.<sup>12</sup>
- Commences 2021 U.S. House Committee on Oversight and Reform (report final report December 2024): Ongoing congressional investigations focused on potential lab origin; claims growing evidence points to a WIV lab leak.<sup>13</sup>
- February 2023 U.S. Energy Department: Assessed COVID-19 likely resulted from lab leak, furthering U.S. intel divide over virus origin.<sup>14</sup>
- February and March of 2023 U.S. DOE and FBI: Publicly acknowledged their respective assessments that COVID-19 likely resulted from a lab incident.<sup>15</sup>
- June 2023 U.S. ODNI COVID-19 Origin Act Report:
   Declassified report: Detailed assessment of the Wuhan
   Institute of Virology's research, relationships, and biosafety
   risks 16
- December 2024 U.S. House of Representatives Select Subcommittee on the Coronavirus Pandemic - Committee on Oversight and Accountability: AFTER ACTION REVIEW OF THE COVID-19 PANDEMIC: The Lessons Learned and a Path Forward - COVID-19 ORIGIN: COVID-19 most likely emerged from a laboratory in Wuhan, China. The arguments in support:
  - The virus possesses a biological characteristic that is not found in nature.
  - Wuhan is home to China's foremost SARS research lab, which has a history of conducting gain-of-function research at inadequate biosafety levels.
- WIV researchers were sick with a COVID-like virus in the fall of 2019, months before COVID-19 was discovered at the wet market.
- By nearly all measures of science, if there was evidence of a natural origin it would have already surfaced.<sup>17</sup>

 April 2025 - U.S. Whitehouse Publication on Origins referencing Select Subcommittee on the Coronavirus Pandemic Report.<sup>18</sup>
 "The Proximal Origin of SARS-CoV-2" publication — which was used repeatedly by public health officials and the media to discredit the lab leak theory — was prompted by Dr. Fauci to push the preferred narrative that COVID-19 originated naturally. Dr. Fauci received from the former government:

'A Full and Unconditional Pardon for any offenses against the United States which he may have committed or taken part in... from Jan 1, 2014."

See U.S. Whitehouse Statement In Full Overleaf

# Important Questions for the Commissioners to Ask — and of Whom:

# Ministry of Health:

WHO has been drafting amendments to the International Health Regulations and negotiating a new Pandemic Agreement, citing what it describes as the catastrophic failure of the international community to act with solidarity and equity during the COVID-19 pandemic. Given the WHO's own failure to transparently and rigorously investigate the origin of SARS-CoV-2—particularly its reluctance to scrutinise the Wuhan Institute of Virology despite early indications of high-risk research—how comfortable are you with the WHO leading future pandemic preparedness and response reforms, and what safeguards will New Zealand seek to ensure scientific independence, accountability, and early transparency in global outbreak investigations?

# Michael Baker:

As there is more evidence that the origin of COVID was a lab leak - does this change your reliance on the WHO as a global health organisation?

# References:

- https://www.who.int/news/item/27-04-2020-who-timeline---covid-19
- https://www.who.int/emergencies/disease-outbreak-news/item/2020-DON229
- <sup>3</sup> https://www.who.int/health-topics/coronavirus#tab=tab\_1
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- https://oversight.house.gov/release/final-report-covid-select-concludes-2-year-investigation-issues-500-page-final-re
- 18 https://www.whitehouse.gov/lab-leak-true-origins-of-covid-19/



# THE ORIGIN

\*The Proximal Origin of SARS-CoV-2" publication — which was used repeatedly by public health officials and the media to discredit the lab leak theory — was prompted by Dr. Fauci to push the preferred narrative that COVID-19 originated naturally.

1.

The virus possesses a biological characteristic that is not found in nature.

2.

Data shows that all COVID-19 cases stem from a single introduction into humans. This runs contrary to previous pandemics where there were multiple spillover events.

3.

Wuhan is home to China's foremost SARS research lab, which has a history of conducting gain-of-function research (gene altering and organism supercharging) at inadequate biosafety levels.

4.

Wuhan Institute of Virology (WIV) researchers were sick with COVIDlike symptoms in the fall of 2019, months before COVID-19 was discovered at the wet market.

5.

By nearly all measures of science, if there was evidence of a natural origin it would have already surfaced. But it hasn't.

# The WHITE HOUSE

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# The WHITE HOUSE

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## SOCIAL DISTANCING:

The "6 feet apart" social distancing recommendation — which shut down schools and small business across the country — was arbitrary and not based on science. During closed door testimony, Dr. Fauci testified that the guidance "sort of just appeared."

## MASK MANDATES:

There was no conclusive evidence that masks effectively protected Americans from COVID-19. Public health officials flipped-flopped on the efficacy of masks without providing Americans scientific data — causing a massive uptick in public distrust.

# The WHITE HOUSE

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# DR. DAVID MORENS:

Dr. Fauci's Senior Advisor, Dr. David Morens, deliberately obstructed the Select Subcommittee's investigation, likely lied to Congress on multiple occasions, unlawfully deleted federal COVID-19 records, and shared nonpublic information about NIH grant processes with EcoHealth President Dr. Peter Daszak.

# NEW YORK OBSTRUCTION:

New York's Executive Chamber — led presently by Governor Kathy Hochul — redacted documents, offered numerous illegitimate privilege claims, and withheld thousands of documents without an apparent legal basis to obstruct the Select Subcommittee's investigation into former Governor Cuomo's pandemicera failures.

# ECOHEALTH OBSTRUCTION:

EcoHealth President Dr. Peter Daszak obstructed the Select Subcommittee's investigation by providing publicly available information, instructing his staff to reduce the scope and pace of productions, and doctoring documents before releasing them to the public. Further, Dr. Daszak provided false statements to Congress.

# LOCKDOWNS:

Prolonged lockdowns caused immeasurable harm to not only the American economy, but also to the mental and physical health of Americans, with a particularly negative effect on younger citizens. Rather than prioritizing the protection of the most vulnerable populations, federal and state government policies forced millions of Americans to forgo crucial elements of a healthy and financially sound life.

## NEW YORK PANDEMIC FAILURES:

Former New York Governor Andrew Cuomo's March 25
Order — which forced nursing homes to accept
COVID-19 positive patients — "was medical
malpractice." Evidence shows that Mr. Cuomo and his
Administration worked to cover up the tragic aftermath
of their policy decisions in an apparent effort to shield
themselves from accountability.



Evidence suggests Mr. Cuomo knowingly and willfully made false statements to the Select Subcommittee on numerous occasions about material aspects of New York's COVID-19 nursing home disaster and the ensuing cover-up. The Select Subcommittee referred Mr. Cuomo to the DOJ for criminal prosecution.

# ANDREW CUOMO FAILURE

# = The WHITE HOUSE Q

# GAIN-OF-FUNCTION RESEARCH:

A lab-related incident involving gain-of-function research is the most likely the origin of COVID-19.

Current government mechanisms for overseeing this dangerous gain-of-function research are incomplete, severely convoluted, and lack global applicability.

# ECOHEALTH ALLIANCE INC. (ECOHEALTH):

EcoHealth — under the leadership of Dr. Peter Daszak — used U.S. taxpayer dollars to facilitate dangerous gain-of-function research in Wuhan, China. After the Select Subcommittee released evidence of EcoHealth violating the terms of its National Institutes of Health (NIH) grant, the U.S. Department of Health and Human Services (HHS) commenced official debarment proceedings and suspended all funding to EcoHealth.

New evidence also shows that the Department of Justice (DOJ) has opened an investigation into EcoHealth's pandemic-era activities.

# = The WHITE HOUSE

# NIH FAILURES:

NIH's procedures for funding and overseeing potentially dangerous research are deficient, unreliable, and pose a serious threat to both public health and national security. Further, NIH fostered an environment that promoted evading federal record keeping laws — as seen through the actions of Dr. David Morens and "FOIA Lady" Marge Moore.





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# The WHITE HOUSE

# WORLD HEALTH ORGANIZATION (WHO):

The WHO's response to the COVID-19 pandemic was an abject failure because it caved to pressure from the Chinese Communist Party and placed China's political interests ahead of its international duties. Further, the WHO's newest effort to solve the problems exacerbated by the COVID-19 pandemic — via a "Pandemic Treaty" — may harm the United States.

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Q

# The WHITE HOUSE

## HHS OBSTRUCTION:

The Biden Administration's HHS engaged in a multiyear campaign of delay, confusion, and nonresponsiveness in an attempt to obstruct the Select Subcommittee's investigation and hide evidence that could incriminate or embarrass senior public health officials. It appears that HHS even intentionally underresourced its component that responds to legislative oversight requests.

# COVID-19 MISINFORMATION:

Public health officials often mislead the American people through conflicting messaging, knee-jerk reactions, and a lack of transparency. Most egregiously, the federal government demonized alternative treatments and disfavored narratives, such as the lab leak theory, in a shameful effort to coerce and control the American people's health decisions.

When those efforts failed, the Biden Administration resorted to "outright censorship—coercing and colluding with the world's largest social media companies to censor all COVID-19-related dissent."

## **References:**

https://www.whitehouse.gov/lab-leak-true-origins-of-covid-19/



# 0.7 WORLD HEALTH ORGANIZATION

C. WHO's inability to prioritise population health over vested interests

Dr David Bell, REPPARE, University of Leeds

# Why this issue is relevant:

WHO was intended to be a vehicle for all countries to cooperate on major health priorities. Its loss of independence in policy development and implementation, mainly due to its changed funding structure and overreliance on private-public partnerships, raises questions regarding its role as a multilateral convenor and expert advisor on public health.

### Details:

The WHO's recommendations, as the health agency of the United Nations, carry significant influence. However, its funding model has shifted markedly in recent decades, raising serious concerns about conflicts of interest:

- 1. Private sources now contribute approximately 25% of WHO's total budget.
- 2. Nearly 80% of funding is 'specified', meaning the WHO must carry out work directed by funders, reducing its operational independence

This has led to a prioritisation of vertical health approaches that rely heavily on manufactured commodities, particularly pharmaceuticals, rather than locally driven capacity-building, sustainable systems, or foundational health strategies such as improved nutrition and sanitation.

These shifts were evident in WHO's pandemic guidance, which changed markedly from its 2019 influenza recommendations to its 2020 COVID-19 response (see Issue 0.7.A, page 82). The latter favoured population restrictions and mass vaccination campaigns over more holistic public health strategies. This shift increased long-term burdens by exacerbating poverty and food insecurity.

Although it is expected that private donors and countries with large pharmaceutical sectors may wish to steer WHO priorities, this undermines the agency's original intent, to base public health guidance on independent, evidence-based assessments. Further, WHO's structure, where every Member State has an equal vote regardless of capacity or alignment, makes it a potentially suitable technical adviser and convenor, but ill-suited to direct policy actions within sovereign nations.

# Important Questions for the Commissioners to Ask — and of Whom:

# Ministry of Health:

- What is the constitutional basis for WHO to give instruction impacting NZ citizens?
- Has New Zealand undertaken any independent review of WHO's evolving role and funding model to assess its continued reliability as an objective source of public health guidance?

# Former Director-General Health:

Given that most WHO funding is 'specified' and influenced by private donors or pharmaceutical-aligned countries, what safeguards are in place to ensure recommendations reflect balanced, evidence-based public health priorities rather than funder interests?

# References:

WHO's biennial budgets demonstrate domination by private interests and a few countries with strong Pharma sectors, with funding specified (directed). Core contributions (including voluntary core) equal just 17% of total. <a href="https://open.who.int/2022-23/contributors/contributor">https://open.who.int/2022-23/contributors/contributor</a>

https://open.who.int/2024-25/contributors/contributor

Whereas the WHO 1980-81 budget: Core (Assessed) contributions were 51.7% of total. https://iris.who.int/bitstream/handle/10665/154368/EB65\_8\_eng.pdf?sequence=1&isAllowed=y.



# 0.7 WORLD HEALTH ORGANIZATION

D. Unclear and misrepresented return on investment from proposed financing of the Pandemic Prevention, Preparedness and Response (PPPR)

Dr David Bell, REPPARE, University of Leeds

# Why this issue is relevant:

There is a significant concern that the high levels of financing proposed for Pandemic Prevention, Preparedness and Response (PPPR) will absorb a disproportionate level of global health funds, with highly uncertain levels of return and potential for overall negative public health outcomes.

### **Details:**

Key documents from WHO, World Bank, and G20 Secretariat form the basis for proposed funding estimates for the Pandemic Prevention<sup>1</sup>, Preparedness and Response (PPPR) agenda, totalling over U.S.\$31 billion annually<sup>1</sup>. This figure is approximately 6 to 10 times greater than global spending on tuberculosis or malaria, which each impose a far higher disease burden.

Analysis by REPPARE at the University of Leeds² highlights that the methodology behind both cost and return-on-investment estimates is opaque. These estimates rely on weakly supported assumptions about pandemic risk, preparedness, and response costs and effectiveness, while failing to account for financial diversion and opportunity costs. For example, WHO and World Bank data inflate pandemic costs by including stimulus packages and severely understate endemic disease costs, by over 20x in the case of tuberculosis.

This raises serious concerns about value for money and whether such large investments will yield net benefits—or cause harm by diverting resources from proven public health priorities. Evidence of reduced funding for core health needs, such as nutrition, suggests this shift is already occurring.

# Important Questions for the Commissioners to Ask — and of Whom:

# Ministry of Health:

- Has New Zealand committed funding to global PPPR initiatives, and what due diligence or costbenefit analysis was undertaken before doing so?
- How is New Zealand ensuring that investment in pandemic preparedness does not compromise domestic funding for core public health needs such as nutrition, primary care, and communicable disease control?

# Former Director-General Health:

- What specific assumptions and methods underpin the estimated U.S.\$31 billion annual cost for PPPR, and how were these independently validated?
- Why were stimulus and bailout packages included in pandemic cost estimates, and how does WHO justify their use as a basis for returnon-investment calculations?
- Has WHO conducted any modelling or published analysis comparing the health impact of investing in PPPR versus scaling up interventions for high-burden endemic diseases such as tuberculosis or malnutrition?

## References:

- 1 WHO-World Bank estimates (note Figure 1): https://thedocs.worldbank.org/en/doc/5760109c4db174f
- 2 REPPARE analysis of WHO, World Bank and G20 estimates: Costing policy brief:

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Costing report

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# 0.7 WORLD HEALTH ORGANIZATION

# E. New WHO Pandemic Treaties

Katie Ashby-Koppens

# Why this issue is relevant:

By mid-2025, New Zealand faces two major global commitments via the WHO Pandemic Agreement and amendments to the 2005 International Health Regulations (IHRs). Together, they propose sweeping changes to how pandemics are defined, declared, managed, and surveilled - with serious implications for national sovereignty, privacy, financial burden, and civil liberties.

## 1. WHO Pandemic Agreement (to be voted May 2025)2

This is a new international treaty aimed at establishing binding pandemic response obligations, coordinated by the WHO under a new Conference of the Parties (COP). The Pandemic Agreement functions as a commercial and logistical framework that centralises control over pandemic preparedness and response, raising questions about its impact on national decision making and resource allocation. It significantly expands WHO authority over national policies during pandemics—including control over surveillance, supply chains, health data, and medical product access. Despite claims of sovereignty protections, it embeds the WHO as the "directing and coordinating authority", with implementation subject to international oversight. If passed, withdrawal is locked for two years.

# 2. 2024 IHR Amendments (automatically binding unless rejected by 19 December 2025)<sup>1</sup>

These amendments update the 2005 International Health Regulations to expand the WHO's powers in areas such as surveillance, digital tracking, and enforcement. Countries will be required to align their domestic laws with WHO standards and take on new obligations related to misinformation control, diagnostics, risk communication, and data sharing. New Zealand will also be financially responsible for supporting pandemic responses in other nations.

## Details:

# 1. WHO Pandemic Agreement

**Status:** Final vote expected at 78th World Health Assembly,  $19 \text{ May } 2025.^2$ 

**Notable withdrawals:** The U.S. has stopped paying the WHO, indicated it is leaving the WHO, and ceased participation in negotiations.<sup>3</sup> Argentina has made similar overtures.<sup>4</sup>

The WHO Pandemic Agreement is being presented to the public as a treaty to "prevent pandemics, protect the vulnerable, and promote health equity." The Agreement is a blueprint for globalised control and commercial consolidation in the name of pandemic preparedness. It is a framework for a bio-surveillance economy with rules dictated by unelected international bodies that are no longer independent, and implemented through trade leverage.

## 2. Centralised Authority:

The Agreement empowers WHO, to oversee national pandemic responses. This includes coordination of surveillance systems, data sharing, and enforcement of treaty obligations.

- Article 1: WHO is the "directing and coordinating authority"
- Article 3.1: States retain sovereignty... but only in theory
- Article 21: Establishes the COP to monitor compliance and issue recommendations
- Article 24: WHO Secretariat coordinates implementation

## 3. Commercial Leverage

While presented as "equity," the Agreement mandates technology transfer, IP sharing, and access to manufacturing

infrastructure, potentially overriding patent protections and national innovation systems.

- Article 11: Technology transfer and intellectual property
- Article 10: Access to medical products
- Article 13: Global supply chain and logistics network

### Pathogen & Data Control

Countries must share pathogens, genetic data, health information, and clinical trial results, feeding into a global surveillance and research system governed by the WHO.

- Article 12: Pathogen Access and Benefit-Sharing (PABS) System.
- · Article 9: Clinical trial transparency and data sharing
- Article 11: IP rights and research outcomes.
- Article 5: One Health surveillance across people, animals, and ecosystems.

# Supply Chain Realignment

WHO will direct global supply flows of pandemic-related goods, potentially determining where vaccines, diagnostics, and treatments are produced and allocated.

- Article 13: Coordination of supply chains and delivery systems.
- Article 14: Regulatory harmonisation to streamlined approvals' to 'reduced regulatory requirements'.

Responsible Government Body: Ministry of Foreign Affairs and Trade (MFAT). No public National Interest Assessment has been released.

# 2. Pandemic Regulations

- The 2024 IHRs amend the 2005 International Health Regulations - the version in force during the COVID-19 pandemic.
- Status: Adopted by consensus at the 77th World Health Assembly in May 2024.<sup>5</sup> New Zealand must formally reject by 19 December 2025 to avoid automatic adoption and requirement to implement the amendments into our domestic legislation by July 2026.
- Concerns Over Process:
  - Final text not circulated within the required four-month window (Article 55).
  - Voted on in late-night sessions with limited state presence.
  - WHO's authority arguably exceeded under its Constitution<sup>6</sup> (Article 21 limits).
- Implications for New Zealand:
  - Loss of Privacy: Increased surveillance and digital IDs (Articles 5, 18, 23, 31, 35, 36).
  - Legal Alignment: Requires domestic law changes to comply with WHO mandates (Article 4, Annex 1).
  - Costs: Undisclosed but substantial financial and administrative burden—including mandatory contributions to other nations (Article 44A).
- Responsible Government Body: Ministry of Health.



# Important Questions for the Commissioners to Ask — and of Whom:

# New Zealand Government - MFAT, MOH:

- Has the government conducted and published a comprehensive National Interest Assessment regarding the WHO Pandemic Agreement and the 2024 IHR amendments? Given the significant implications for national sovereignty and public health policy, transparency in this assessment is crucial.
- Public feedback was sought on earlier versions of both pandemic treaties early in 2024, will similar opportunity be provided to comment on the final versions of the Pandemic Treaties?
- How does the government plan to safeguard New Zealand's legislative autonomy in light of provisions in the Pandemic Agreement that designate the WHO as the "directing and coordinating authority" (Article 1) and establish a Conference of the Parties with oversight capabilities (Article 21)?
- What measures are in place to protect the privacy of New Zealanders' health data and genetic information, considering the Agreement's requirements for sharing such data under the Pathogen Access and Benefit-Sharing System (Article 12)?
- Has the government evaluated the financial obligations imposed by the 2024 IHR amendments, particularly the mandatory contributions to support developing nations (Article 44A)? How will these commitments affect New Zealand's economy, especially during times of fiscal constraint?
- What steps has the government taken to ensure meaningful public and parliamentary engagement in the decision-making process related to these international agreements? Are there plans to hold public consultations or parliamentary debates before finalising any commitments?

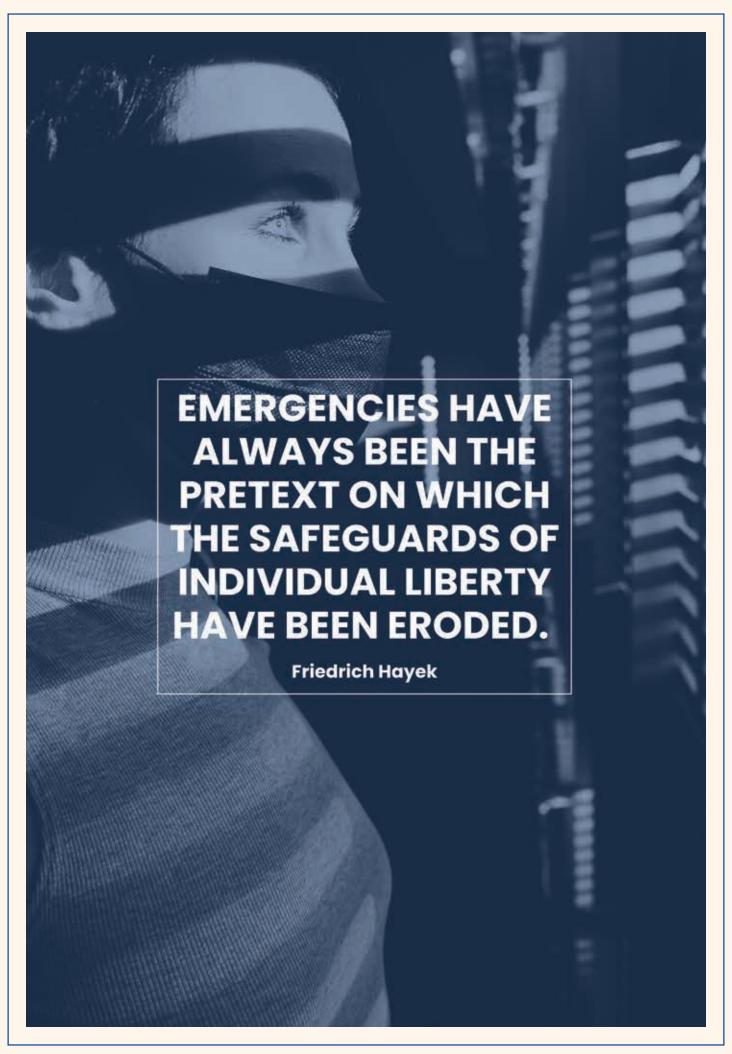
# Former Director-General of Health:

- 1. Role in WHO and Influence on Policy
- In your current capacity within WHO, how are you influencing the development and promotion of the Pandemic Agreement and the 2024 IHR amendments? What is your stance on the balance between global health coordination and New Zealand's national sovereignty?

# 2. Reflection on New Zealand's Pandemic Response

- Given the lessons of the COVID-19 response, how can New Zealand ensure future pandemic preparedness does not come at the expense of its legislative autonomy or democratic oversight?
- 3. Ensuring Accountability and Oversight
- What mechanisms do you propose to ensure that international bodies like WHO remain accountable to member states and respect the diverse legal and cultural contexts of countries like New Zealand?

- https://apps.who.int/gb/inb/pdf\_files/inb9/A\_inb9\_3Rev1-en.pdf
- ${}^{2} \underline{\ \ } \underline{\ \ \ \ \ } \underline{\ \ \ \ \ } \underline{\ \ \ \ \ } \underline{\ \ \ \ \ } \underline{\ \ \ \ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ \ } \underline{\ \ \ } \underline{\ \ \ \ \ \ } \underline{\ \ \ } \underline{\$
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- 4 https://edition.cnn.com/2025/02/05/americas/argentina-says-leaving-who-intl/index.html
- <sup>5</sup> https://alignedcouncilofaustralia.com.au/wp-content/uploads/2024/12/Notification-WHO\_C.L.40.2024-IHR-amendments
- 6 https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf





# 0.7 WORLD HEALTH ORGANIZATION

# F. Risk of pandemics is overstated

Dr David Bell, REPPARE, University of Leeds

# Why this issue is relevant:

The risk of major naturally-occurring pandemics is greatly overstated, with limited evidence supporting claims of increased future frequency or mortality.

A report from the University of Leeds highlights major misrepresentation of pandemic risk by the WHO, World Bank, and other institutions. It calls for a more measured, evidence-based approach to future pandemic preparedness. Current estimates rely on flawed models based on incorrect assumptions, failure to account for historical trends in risk and detection, and speculative data, leading to panic-driven policy responses.

## **Details:**

Exaggerated assumptions inflating pandemic risk include:

- Increasing Frequency of Pandemics Claims that pandemics are becoming more frequent are not well supported by historical data. Apparent increases may be explained by improved diagnostics and data collection. In fact, global mortality from infectious diseases is declining, even when accounting for COVID-19, which was likely of non-natural origin.<sup>1</sup>
- Zoonotic Spillover Probability Predictions often assume increasing likelihood of animal-to-human disease transmission, but true picture is far more complex.
- High Pandemic Mortality Models Some widely-quoted models massively overestimate annualised pandemic mortality by including events from the medieval and preantibiotic era. REPPARE (University of Leeds) released a paper directed to the Phase One Commissioners on the assumption Professor Blakley took that the risk of naturally occurring pandemics was high.<sup>2</sup>

# Important Questions for the Commissioners to Ask — and of Whom:

# Ministry of Health:

- Have you critically reviewed the evidence that naturally occurring pandemics are increasing in frequency or severity, and how are advances in diagnostics and surveillance accounted for in these assessments?
- Why are PCR tests for bird flu and other pathogens being run at high cycle thresholds, and what protocols are in place to avoid inflating case numbers and public fear?

# Former Director-General of Health and Government Pandemic Advisors:

- Why do pandemic risk models continue to include mortality data from the pre-antibiotic era, and how does this affect the credibility of current risk projections?
- How is the current emphasis on theoretical pandemics justified against the far higher disease burden posed by non-communicable and endemic diseases such as heart disease, cancer, and malnutrition?

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- https://essl.leeds.ac.uk/downloads/download/254/when-models-and-reality-clash-a-review-of-predictions-of-epidem-ic-and-pandemic-mortality



# TERMS OF REFERENCE PART 1 - VACCINES

# **Overview**

This inquiry cannot meaningfully address the outcomes of New Zealand's COVID-19 response without first examining the ground it was built on. Part 1 confronts the terms, definitions, and legal mechanisms that shaped the framework for every major decision in 2020 and 2022 – from vaccine rollout to public messaging, from mandates to mortality: they cover the Part 1 Terms for Phase Two.

Part 1 of the Royal Commission Phase Two's terms is: Vaccines, including the use of mandates, the approval of vaccines, and vaccine safety (including monitoring and reporting of adverse events)

# **Vaccine Approvals**

At the centre lies the redefinition of language itself: "vaccine," "vaccinated," and even "case" were reengineered to serve a narrative of urgency and control. These semantic shifts were not just technicalities – they were the foundation on which sweeping powers were justified and deployed. "Provisional consent," once a narrowly defined mechanism for restricted use, was reinterpreted into a licence for mass administration of vaccines. When the courts ruled this unlawful, the government amended the law within a day – without consultation, without pause.

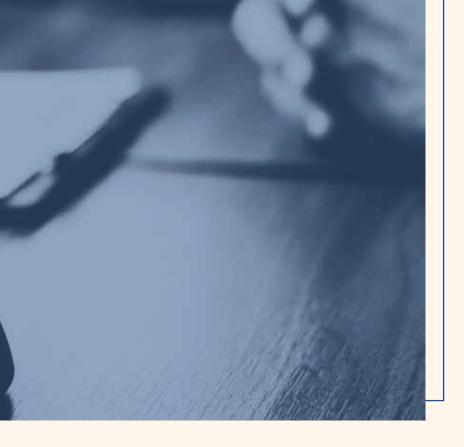
# **Vaccine Safety**

Throughout this period, scientific uncertainty was hidden behind slogans of certainty. The phrase "safe and effective" became a mantra - despite regulators knowing of serious risks, including myocarditis in young people and the presence of DNA contamination in vaccine vials. Rather than empowering the public with the complexity and nuance that informed consent demands, authorities presented a curated version of the facts, sidelining expert advice and suppressing early warnings.

This erosion of transparency culminated in avoidable harm. Reports of serious adverse events began to accumulate globally and locally. The public turned to official channels, social media, and even the Prime Minister's own Facebook page to report their experiences.

These accounts were not met with compassion or investigation, but with silence, deletion, and denial. The public pharmacovigilance system was overwhelmed, under-resourced, and deliberately kept in the background.

Even as thousands of CARM reports and over 4,000 ACC claims mounted, the rollout continued unabated.



# **Mandates**

What followed was a mandate regime unprecedented in scope and severity. Under the banner of public health, bodily autonomy was compromised, and the right to work, study, and participate in society became conditional upon compliance. Adolescents were coerced through vaccine passes. Employers were deputised to enforce mandates. And when thousands gathered in peaceful protest at Parliament, they were ignored, smeared, and ultimately displaced by force.

# All cause mortality

Behind the political slogans and policy decisions lies a more sobering truth – rising mortality rates that were never adequately investigated. The promised benefits of the vaccine campaign did not manifest in the mortality data. Instead, excess deaths began climbing in mid-2021 and remained elevated well into 2023. These trends were dismissed or misrepresented by flawed projections and statistical sleight-of-hand. Autopsies were not ordered.

Coroners were not empowered. And post-mortem scrutiny was weakened by legislative reform - just when it was needed most.

# Conclusion

Part 1 is not a retrospective. There is no need for

the benefit of hindsight. It is a confrontation with the architecture of decision-making: how law was amended, language was weaponised, and science was selectively used to justify a predetermined course of action. It compels us to ask not only what happened, but how - and whether the structures of accountability can withstand another crisis built on the same unstable ground.

# This is where accountability must begin.

As New Zealand, and most other countries, followed the regulators of other countries (mainly the United States), what occurred internationally is very relevant.

# Part 1 is divided by:

**Vaccine Approval - International** which covers definition changes, the Pfizer trials, U.S. Emergency Use Authorization, manufacturing changes and DNA contamination (Sections 1.1–1.4).

Vaccine Approval - New Zealand which covers the Gene Technology Bill, the procurement contracts between Pfizer and the NZ government, NZ's Provisional Consent approval process, NZ's Environmental Protection Agency, Biodistribution, and LNPs (Sections 1.5-1.10).

Before moving on to other key topics including **Adverse Events**, Mortality Coercion, Gaslighting, and Censorship (Sections 1.11-1.15).

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# 1.1 DEFINITIONS CHANGED

During the COVID-19 pandemic, several key public health terms underwent definitional changes that significantly influenced how the public understood risk, how policies were justified, and how data was interpreted. Terms like "vaccine," "vaccinated," "pandemic," and "case" were all redefined by national and international agencies. These changes were not always clearly communicated, nor were they accompanied by transparent explanations about their rationale or implications. As a result, these shifts had the potential to alter regulatory pathways, public expectations, and scientific reporting in ways that many members of the public – and even professionals – were unaware of at the time.

These redefinitions were not minor linguistic updates; they represented foundational shifts that enabled new products, policies, and narratives to take hold. In many cases, the updated definitions allowed for broader or more flexible interpretations that aligned with political and pharmaceutical objectives, such as justifying emergency authorisations or expanding mandates.

Yet they also contributed to confusion, mistrust, and inconsistency in both public communication and data reporting. Recognising that these changes occurred is essential for understanding the context in which decisions were made and for restoring transparency and accountability in future public health responses.

## In this section

- A. Vaccine
- B. Vaccinated
- C. Pandemic
- D. Case



# 1.1 DEFINITIONS CHANGED

RC Term - Vaccine Approval - International
A. Definition changed: vaccine

Katie Ashby-Koppens

# Why this issue is relevant:

The definition of "vaccine" was modified which enabled the classification of mRNA-LNP gene-based therapeutics to be described as "vaccines." This allowed these products to proceed through less rigorous regulatory pathways (in addition to Emergency Use Authorization) and benefit from public trust in traditional vaccines.

mRNA-LNP products differ fundamentally from traditional vaccines and meet Food & Drug Administration (FDA) definitions for gene therapy. To classify them as vaccines, the U.S. Center for Disease Control (CDC) and other agencies revised the definition of "vaccine" multiple times.

A formal Citizen Petition submitted to the FDA in January 2025<sup>1</sup> alleges that reclassifying mRNA-LNP products as vaccines was inappropriate and legally flawed, enabling the avoidance of environmental assessments, bypassing gene therapy regulatory oversight, and contributing to a lack of transparency and informed consent.

### Details:

The CDC's definition of "vaccine" has undergone significant changes:  $^{\rm 2}\,$ 

- Pre-2015: Injection of a killed or weakened infectious organism to prevent disease.
- 2015–2021: The act of introducing a vaccine into the body to produce immunity to a specific disease.
- September 2021: The act of introducing a vaccine into the body to produce protection from a specific disease; a preparation that is used to stimulate the body's immune response against diseases.

Dr Phillip Altman's expert report<sup>3</sup> filed in the Kiwi Kids' Case, points out that mRNA-LNP products constitute gene therapies based on their mechanisms:

- 1. Synthetic lipid nanoparticles deliver mRNA into cells.
- 2. Modified synthetic RNA is released within the cell.
- 3. Cells then produce a modified spike protein.
- The LNPs are engineered for biodistribution across organs, including the brain—unlike traditional vaccines that act locally.

# Important Questions for the Commissioners to Ask — and of Whom:

# Ministry of Health:

- Was any assessment undertaken to determine whether mRNA-LNP products met New Zealand's legal or regulatory definition of a vaccine?
- Were the implications of classifying a genebased product as a vaccine, including under the HSNO Act, considered?
- How did the government's decision to conceal this information from the public align with the patient's right to informed consent under the HDC Code?

# Medsafe:

- Did Medsafe assess whether mRNA-LNP products should be regulated as gene therapies or genetically modified organisms?
- Was Medsafe aware of and influenced by international changes to the definition of "vaccine" in its classification decisions?

# Environmental Protection Authority (EPA):

 Was the EPA consulted about the classification of mRNA-LNP products under the HSNO Act, and if not, why?

# COVID-19 Vaccine Technical Advisory Group (CV TAG):

 Was advice given on whether the mechanism of mRNA-LNP products aligned with traditional vaccines or gene therapies?

# **Human Rights Commission:**

 Was the public adequately informed about the novel mechanism of mRNA-LNP products to ensure informed consent before mandates were introduced?

- https://www.regulations.gov/document/FDA-2025-P-0335-0001
- <sup>2</sup> https://www.researchgate.net/figure/Evolution-of-the-CDC-definition-for-vaccination\_figl\_367030584
- 3 https://www.thehoodnz.com/storage/app/media/Kids%20Case/PhillipAltmanReport.pdf (page 6)



# 1.1 DEFINITIONS CHANGED

RC Term - Vaccine Approval - International B. Definition changed: vaccinated

Dr Alison Goodwin

# Why this issue is relevant:

The definition of "vaccinated" changed throughout the pandemic. These shifting definitions altered who was considered vaccinated, partially vaccinated, or unvaccinated at any given time. This impacted how case, hospitalisation, and death data were recorded and interpreted. The changing criteria obscured early safety signals, made risk assessments less reliable, and complicated evaluation of vaccine efficacy.

The definition of "vaccinated" evolved over time and was applied inconsistently, enabling the misclassification of COVID-19 cases, adverse events, hospitalisations, and deaths. At various stages, individuals were not counted as vaccinated until 7 or more days after receiving their second dose or their last dose, which meant that those who experienced adverse events or caught COVID-19 between doses were often classified as "unvaccinated." This conflated risk profiles and undermined accurate safety assessments. The introduction of booster doses further changed the definition of "fully vaccinated." Additionally, the interchangeable use of the terms "vaccinated" and "immunised" added to public confusion.

### Details:

The ordinary definition of "vaccinated" is:

"If a person or animal is vaccinated, they have been given a vaccine (= a substance that is put into your body to prevent you from getting a disease or from being badly affected by it)."

In November 2021, the COVID-19 Vaccine Technical Advisory Group (CV TAG) recommended defining "fully vaccinated" as:

"7 or more days after the last dose in an accepted primary vaccination schedule."

This was based on immunological principles suggesting that neutralising antibodies typically develop within a week of the second dose.<sup>1</sup>

As the effectiveness of the primary course waned and booster doses were introduced, the legal definition of "vaccinated" was formalised through a Gazette Notice. On 26 November 2021, Dr Ashley Bloomfield, Director-General of Health, declared:

"The doses of each COVID-19 vaccine or combination of COVID-19 vaccines specified... are required for a person to be 'vaccinated' for the purposes of all or any legislation..." <sup>2</sup>

This allowed the legal definition of "vaccinated" to be updated over time as additional doses (such as boosters) were incorporated into the vaccine programme.

# In practice, this meant:

- People who had received only one dose could be classified as "unvaccinated."<sup>3</sup>
- Adverse events or COVID-19 infections occurring between doses or shortly after vaccination could be recorded under the "unvaccinated" category.
- The legal definition of "vaccinated" evolved in line with dose requirements, though the public health term "fully vaccinated" was not always clearly distinguished.
- The terms "vaccinated" and "immunised" were used interchangeably by health authorities, despite no consistent definition of their distinct meanings.

These changing definitions introduced significant ambiguity into public health messaging and data interpretation, making it more difficult to assess vaccine effectiveness or detect safety signals accurately.

• See the Biodistribution Issue 1.9

# Important Questions for the Commissioners to Ask — and of Whom:

# Ministry of Health:

- What was the basis for classifying individuals with only one COVID-19 dose as "unvaccinated" in public health data and communications?
- How did the evolving definitions of "vaccinated," "fully vaccinated," and "up to date" affect data reporting and risk assessment?
- Were adverse events and COVID-19 infections occurring after dose one or before dose two routinely recorded as occurring in the "unvaccinated" group? If so, why?

## Medsafe:

 Was any advice provided on how vaccination status should be defined for the purposes of safety signal monitoring and data transparency?

# COVID-19 Vaccine Technical Advisory Group (CV TAG):

 Was the impact of changing definitions on public understanding and data integrity considered when recommending definitions such as "fully vaccinated"?

# Stats NZ / Ministry of Health data teams:

 How were definitions of "vaccinated" applied in epidemiological modelling and public reporting, and were alternate approaches considered?

- 1 CV TAG:
  - https://www.tewhatuora.govt.nz/assets/About-us/Who-we-are/Expert-groups/COVID-19-Vaccine-Technical-Advisory-Group-
- Gazette Notice 26 Nov 2021: https://gazette.govt.nz/notice/id/2021-go5122
- 3 https://pmc.ncbi.nlm.nih.gov/articles/PMC10203532/



# 1.1 DEFINITIONS CHANGED

RC Term - Vaccine Approval - International C. Definition changed: pandemic

Dr Alison Goodwin

# Why this issue is relevant:

The definition of "pandemic" was historically associated with both the widespread nature of a disease and its severity. Changes to World Health Organization's definition removed the need for high mortality or serious illness, allowing diseases with broad but mild spread to be declared pandemics. This change affects when global emergency responses can be triggered, with implications for national policies, restrictions, and public trust.

WHO's definition of "pandemic" has shifted over time. Earlier versions included references to disease severity, mortality, and population immunity. In its current form, the definition focuses on the geographic spread of a disease, with no requirement for serious illness or death. This change allows for the declaration of a pandemic based solely on widespread transmission, regardless of clinical impact. The definitional shift has significant implications for global responses, emergency powers, and public understanding.

#### **Details:**

#### Historical WHO definitions (pre- and early 2009):

"An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in several simultaneous epidemics worldwide with enormous numbers of deaths and illness."

"An influenza pandemic may occur when a new influenza virus appears against which the human population has no immunity." (Revised May 2009)

These earlier definitions included explicit references to population immunity, illness, and mortality, framing pandemics as severe and high-impact events.

#### Current WHO definition (as of 2025):

 "An epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people."

#### The updated definition omits any mention of:

- Disease.
- · Mortality or morbidity.
- · Population immunity.

This change broadens the applicability of the term "pandemic," allowing declarations to be made based on geographic spread alone. While this may facilitate faster international coordination, it also lowers the threshold for invoking emergency measures. The change may also affect public perception and trust, particularly if significant restrictions are applied to relatively mild diseases.

## Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health:

- Was the change in the WHO's pandemic definition considered when determining New Zealand's thresholds for pandemic response or emergency declarations?
- Does the Ministry have its own working definition of "pandemic," or is it entirely reliant on WHO declarations?

#### **Director-General of Health:**

 What criteria would be used to determine whether New Zealand should adopt WHO pandemic declarations in the future, particularly for diseases with low mortality?

#### Ministry of Foreign Affairs and Trade:

 Has New Zealand formally accepted the revised WHO definition of "pandemic" under international agreements such as the International Health Regulations?

#### Te Whatu Ora:

 Were internal response plans or risk assessments revised following the definitional change to account for the possibility of lowerseverity pandemics?

## COVID-19 Vaccine Technical Advisory Group (or equivalent planning bodies):

 Was there any analysis of how changes to the definition of "pandemic" might impact public messaging, trust, or proportionality of health measures?

#### References:

Source: WHO definition via PublicHealth.com.ng: https://www.publichealth.com.ng/world-health-organization-who-pandemic-definition/



# 1.1 DEFINITIONS CHANGED

RC Term - Vaccine Approval - International D. Definition changed: case

Dr Alison Goodwin

#### Why this issue is relevant:

The term "case" has traditionally referred to someone who is unwell and exhibits clinical symptoms. During the COVID-19 pandemic, this definition was broadened to include asymptomatic individuals who tested positive, regardless of whether they were actually sick. This shift inflated case numbers, confused the public, and undermined accurate assessments of disease severity and public health risk.

Traditionally, a "case" in medicine refers to a symptomatic individual requiring clinical attention. However, during the COVID-19 pandemic, people who tested positive via PCR or RAT — even without symptoms — were often classified as "cases." This departure from standard clinical practice made it difficult to distinguish between infection and illness. High cycle thresholds on PCR tests (e.g. 40 cycles) further complicated interpretation, as they could detect non-infectious viral fragments. These definitional changes obscured the true burden of disease and enabled daily reporting of high case numbers, many of which involved people who were not unwell. This had significant implications for public perception, health policy, and risk communication.

#### **Details:**

- In clinical medicine, a "case" traditionally refers to a patient with symptoms of disease. This allows for the assessment of severity, transmission risk, and resource needs.
- During the COVID-19 pandemic, the definition was broadened.
   Asymptomatic individuals who returned a positive PCR or RAT result were classified as "cases," even in the absence of illness.
- The Te Whatu Ora COVID-19 case definition included confirmed cases based on positive tests, regardless of symptoms.<sup>1</sup>

#### This approach enabled:

- Daily case reporting that did not differentiate between mild, moderate, or asymptomatic infections.
- The potential for inflation of case numbers depending on PCR cycle thresholds — with higher thresholds (e.g. 40 cycles) increasing the likelihood of detecting clinically irrelevant viral fragments.

These definitional changes blurred the line between false positive, asymptomatic infection, or infection with disease. For example:

- A person in hospital for an unrelated issue (e.g. a fracture) who tested positive could be reported as a COVID-19 case, even if they showed no respiratory symptoms.
- Many "cases" would previously have been diagnosed as colds or influenza, and not reported as distinct public health events

The use of a test-based definition of "case" introduced uncertainty into public understanding, scientific communication, and health system planning.

# Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health / Te Whatu Ora:

- Why were asymptomatic individuals with positive PCR or RAT results classified as "cases," despite not meeting traditional clinical criteria for illness?
- Were case numbers ever reported publicly with a breakdown between symptomatic and asymptomatic individuals?
- What PCR cycle threshold was used nationally, and how was the clinical significance of highcycle positives assessed or communicated?

#### Medsafe or the Office of the Director-General of Health:

 Was any internal advice given regarding the implications of redefining "cases" for public health messaging and statistical interpretation?

#### Major media outlets and editors:

- Why was the redefinition of "case" to include asymptomatic positive tests — not interrogated in media coverage?
- Were editorial decisions made to avoid distinguishing between infection and illness when reporting daily case numbers?

#### References:

https://www.tewhatuora.govt.nz/for-health-professionals/



# 1.2 PFIZER TRIALS

The integrity of New Zealand's COVID-19 vaccination strategy rested heavily on the strength and transparency of the clinical trial evidence underpinning vaccine approvals. However, the Pfizer trials, on which these approvals were largely based, were short in duration, underpowered to detect rare but serious adverse events, and fundamentally limited in scope. They did not assess prevention of transmission, severe disease, or death, and relied heavily on surrogate endpoints such as mild symptom reduction and antibody response.

Government leaders and public health officials were aware of these limitations - particularly for younger and younger cohorts - yet still approved and promoted these novel gene-based vaccines for widespread use. The trials did not provide the robust data needed to justify such far-reaching public health decisions, especially for low-risk populations.

Despite this, officials repeatedly assured the public that the vaccines were "safe and effective." This language was not only overly simplistic – it was misleading. Internal agencies knew the limitations, yet public communications failed to reflect the narrow scope of what the trials actually tested. New Zealand approved formulations that had not been tested in the pivotal trials and launched mass rollouts before long-term safety data had been collected.

A national survey found that 96% of New Zealand adults mistakenly believed the COVID-19 vaccine trials had tested for prevention of infection or mortality. This misunderstanding did not arise organically; it was shaped by official messaging. Senior health bureaucrats and political leaders made repeated claims that went far beyond the evidence base. Some likened the vaccines to the measles vaccine in terms of efficacy, a scientifically inaccurate and dangerously misleading comparison. As a result, public expectations were set impossibly high, eroding trust once

real-world performance failed to meet the promises.

These structural, procedural, and ethical failures demand urgent scrutiny before New Zealand accepts further obligations under the proposed WHO Pandemic Agreement or IHR amendments. The Royal Commission must ask: is this the right institution to direct our future health response?

Even more concerning, the trials were unblinded within months of commencement, eliminating placebo groups and undermining the ability to monitor long-term safety. New Zealand provisionally approved vaccine formulations with ingredients that differed from those tested, such as tromethamine in the paediatric version. Serious adverse events were recorded during the trials, and early postmarketing data, such as Pfizer's 5.3.6 report, revealed thousands of injuries and hundreds of deaths within the first three months of rollout. Yet none of this was included in public-facing risk communication.

This section examines the Pfizer trials across age cohorts (adults, adolescents, children, and infants), as well as Pfizer's own early adverse event reporting. It raises pressing concerns about informed consent, regulatory rigour, and whether public health decisions were grounded in sound science or political expediency. These issues are not academic, they go to the heart of ethical governance, scientific accountability, and the public's right to truthful, transparent information in matters of health.

#### In this section

- A. Pfizer Trials Adults
- B. Pfizer Trials 12-15
- **C.** Pfizer Trials 5-12
- D. Pfizer Trials 6 months +
- E. Pfizer 6 month adverse event report (Report 5.3.6)
- F. Widespread public misunderstanding of trials



# 1.2 TRIALS

RC Term - Vaccine Approval - International
A. Pfizer Trials - Adults 16+

Katie Ashby-Koppens

#### Why this issue is relevant:

The evidence produced by Pfizer's trials fell far short of what is required to credibly claim safety or efficacy - especially for use in healthy populations.

Pfizer conducted COVID-19 vaccine trials in three age cohorts: adults (16+ years), adolescents (12–15 years), and children (5–11 years). In the adult trial, the placebo group was unblinded within months, eliminating the control group and compromising the ability to assess long-term outcomes, removing the gold standard of randomised control trials.

In addition, the trial used vaccine material from Process 1, whereas New Zealand provisionally approved the Process 2 formulation – a version not tested in the pivotal trial (see Issue 1.4B, page 132). Serious adverse events were recorded even within the short follow-up period. The claimed "95% efficacy" was based on relative risk reduction, which gave a misleading impression of the vaccine's real-world benefit.

#### Details:

#### Short Duration and Early Unblinding

- Trial of almost 44,000: Vaccine group: Just under 22,000; Placebo group: Just under 22,000.
- · Only two months of follow-up in the pivotal Phase 3 trial.
- 93% of placebo participants were vaccinated by March 2021.
- Unblinding removed the ability to detect delayed side-effects or assess sustained efficacy.

#### Relative vs. Absolute Risk

- 95% efficacy based on relative risk reduction; actual absolute risk reduction was <1%.</li>
- Primary endpoint was prevention of mild symptoms, not hospitalisation, severe disease, or death.

#### Serious Adverse Events

- More deaths occurred in the vaccine group (15) than placebo (14) during blinded follow-up.
- More severe adverse events occurred in the vaccine group.

#### Methodological Critiques

- 371 participants were excluded from analysis: 311 from vaccine group, 60 from placebo.
- Pfizer ignored 3,410 "suspected but unconfirmed" COVID cases—would have reduced efficacy to 19%.
- Trial not designed to assess severe disease, death, or transmission.

#### General Trial and Regulatory Concerns

- Excluded pregnant women, immunocompromised, and many subgroups.
- Pfizer withheld raw data; FDA tried to delay access by 75 years
- · Public health decisions were based on early, incomplete data

#### Key Study:

 Peer-reviewed reanalysis (Vaccine journal): 1 serious adverse event per 800 doses.<sup>1</sup>

See: Prof. Nikolai Petrovsky's reply affidavit in the Kiwi Kids Case.<sup>2</sup>

# Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe:

- Was Medsafe concerned that Pfizer unblinded the trial only months after it began?
- Why did Medsafe allow Pfizer's 95% efficacy claim to be promoted without clarification of ARR?
- How did Medsafe assess vaccine risk vs. benefit for healthy adults given modest absolute benefit?
- Did Medsafe independently review raw trial data?
- Why were post-marketing safety conditions not strengthened?
- What steps were taken to ensure the public understood the trial limitations?

#### Ministry of Health:

- Did the Ministry independently verify Pfizer's claims?
- Why weren't limitations in the data (e.g. lack of assessment of transmission) disclosed?
- How did the Ministry ensure compliance with the Medicines Act and Fair Trading Act?
- Has the Ministry reviewed its messaging in light of safety signals and updated data?

- https://www.tewhatuora.govt.nz/for-health-professionals/clinical-guidance/communicable-disease-control-manual/
- https://drive.google.com/file/d/182z2Z6NIw1eHG-2C1cd0KA06JXRAx98m/view?usp=share\_link



# 1.2 TRIALS

RC Term - Vaccine Approval - International B. Pfizer Trials - Adolescents 12-15+

Katie Ashby-Koppens

#### Why this issue is relevant:

The evidence produced by Pfizer's trials fell far short of what is required to credibly claim safety or efficacy, especially for use in healthy, young populations with much of their life ahead of them.

Pfizer's adolescent trial included only 2,306 participants, far too few to detect rare side-effects like myocarditis. No severe COVID-19 cases occurred in either group. The trial lacked sufficient follow-up and did not assess transmission or long-term protection. Serious adverse events and systemic reactions occurred at concerning levels, raising questions about the justification for approval in this low-risk age group.

#### Details:

#### Underpowered for Safety

- · Only 2,306 participants.
- No severe COVID-19 cases in either group.
- Sample size too small to detect myocarditis (~1 in 5,000 risk).
- Serious Adverse Events and Systemic Reactions.

#### Serious adverse events: 0.4% (vaccine) vs 0.2% (placebo)

- 7 severe (Grade 3) reactions occurred for every mild case prevented.
- No severe COVID-19 in either group.

#### Limitations

- Only one month of post-dose-2 safety data.
- Did not assess transmission or long-term protection.

#### General Trial and Regulatory Concerns (relevant overlap)

- Exclusion of key populations.
- · Lack of data transparency.
- Public decisions based on incomplete data.

#### Key Study:

 Peer-reviewed reanalysis (Vaccine journal): 1 serious adverse event per 800 doses.<sup>1</sup>

See: Prof. Nikolai Petrovsky's affidavit.2

## Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe:

- Why approve a vaccine based on underpowered trials that could not detect myocarditis?
- How was the risk-benefit ratio assessed for healthy adolescents?

#### Ministry of Health:

- What data supported public promotion of safety and efficacy for adolescents?
- Why were parents not informed of the short duration and sample size limitations?

- https://www.sciencedirect.com/science/article/pii/S0264410X22010283
- <sup>2</sup> https://drive.google.com/file/d/182z2Z6NIw1eHG-2C1cd0KA06JXRAx98m/view?usp=share\_link



# 1.2 TRIALS

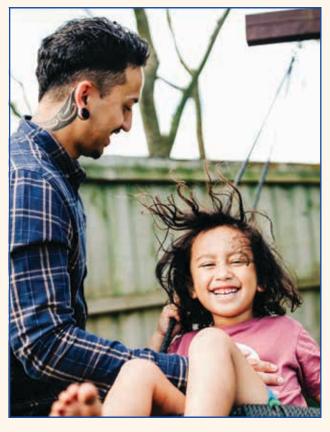
RC Term - Vaccine Approval - International

C. Pfizer Trials - Children 5-12

Katie Ashby-Koppens

#### Why this issue is relevant:

The evidence produced by Pfizer's trials fell far short of what is required to credibly claim safety or efficacy, especially for use in healthy children.



Cover image from 'COVID-19-vaccines\_protecting-your-tamariki' brochure from MoH

Pfizer's paediatric trial had only 2.3 months of follow-up and was not designed to detect rare, but serious, events such as myocarditis. Efficacy was assessed using antibody levels rather than clinical outcomes. Additionally, a different vaccine formulation (with tromethamine) was approved and used in New Zealand than the one tested in the trial.

#### **Details:**

#### Sample Size and Duration Issues

- Follow-up: 2.3 months.
- Trial used immune response as a proxy for efficacy.
- Not powered to detect myocarditis or rare events.
- No severe COVID-19 in either group.

#### **Adverse Events**

- Phase One: Up to 50% experienced adverse reactions depending on dose.
- 3 severe adverse events in 3,109 children.
- Even a 1 in 1,000 risk could scale to hundreds of harmed children nationally.

#### Regulatory and Ingredient Concerns

- Tromethamine added post-trial to stabilise formulation.
- NZ approved this version without specific trial data.

#### General Trial and Regulatory Concerns (relevant overlap)

- · Lack of data transparency.
- Premature decisions without robust long-term analysis.

#### Key Study:

 Peer-reviewed reanalysis (Vaccine journal): 1 serious adverse event per 800 doses.<sup>1</sup>

See: Prof. Nikolai Petrovsky's affidavit.<sup>2</sup>

## Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe:

- Why approve a formulation with new ingredients that had not been tested?
- What risk-benefit analysis justified the approval for healthy children?

#### Ministry of Health:

- On what evidence was the vaccine promoted as safe for children?
- How did the Ministry justify using slogans like "no corners were cut" despite short trials and limited data?

#### Safety of the Pfizer vaccine

The Pfizer vaccine for 5 to 11-year-olds has been through clinical trials with children in this age group. In general, the side effects that were reported were mild, didn't last long, and were similar to side effects from other routine vaccines.

The vaccine is recommended for tamariki with food allergies. Unlike some other vaccines, there is no food, gelatin or latex in the Pfizer vaccine.

The only reason that someone may not be able to have this vaccine due to allergy is if they have had a severe allergic response (anaphylaxis) to a previous dose of the Pfizer vaccine or an ingredient in the vaccine. The child (paediatric) Pfizer vaccine has gone through the same rigorous approval process as other routine childhood vaccines. No clinical trials were skipped and no corners were cut in the testing of its safety.

Excerpt from 'COVID-19-vaccines\_protecting-your-tamariki' brochure from MoH

- https://www.sciencedirect.com/science/article/pii/S0264410X22010283
- <sup>2</sup> https://drive.google.com/file/d/182z2Z6Nlw1eHG-2C1cd0KA06JXRAx98m/view?usp=share\_link



# 1.2 TRIALS

RC Term - Vaccine Approval - International
D. Pfizer Trials - Babies and Infants (6 months to 5 years)

Katie Ashby-Koppens

#### Why this issue is relevant:

The data used to approve the Pfizer vaccine for babies and young children fell short of standard scientific rigour. These children faced minimal risk from COVID-19 and had no personal medical need for vaccination. Approving the vaccine primarily to protect others, such as older adults, is ethically questionable.

Pfizer's babies and infants trial in children aged 6 months to 5 years involved just 4,526 participants, each receiving two 3µg doses, later modified to three doses. The study was changed mid-trial and had significant design flaws:

Only 992 of the 3,013 children in the vaccine group completed all three doses and were included in the final analysis.

Participants were unblinded, and the placebo group was offered vaccination, compromising trial integrity.

The trial did not assess real-world effectiveness, instead relying on immunobridging (a comparison of antibody levels to those of 16 to 25-year-olds).

Only 10 qualifying COVID-19 cases were available for interim analysis—far fewer than the 21 required by the original trial protocol.

A total of 365 COVID-19 cases (97%) were excluded from the efficacy analysis because they occurred before 7 days post-dose 3, distorting the outcome.

#### **Details:**

#### Trial Limitations and Protocol Changes

- Trial included 4,526 children aged 6 months to 5 years, all given 3µg doses.
- Median follow-up: only 2.1 months.
- Mid-trial protocol change added a third dose.
- Timing of dose 3 varied greatly from 42 to 245 days.
- Participants unblinded; placebo group later offered the vaccine.

#### Data and Analysis Flaws

- Only 992 out of 3,013 children in the vaccine group received all three doses and were included in the efficacy analysis.
- No assessment of real-world effectiveness; relied solely on immunobridging.
- Only 10 qualifying cases used for interim analysis; 21 cases were required by protoco.
- 365 COVID-19 cases (97% of all observed cases) were excluded from analysis because they occurred before 7 days post-dose 3.

#### Representation Issues

- · No Māori or Pacific children included.
- Only 3 Native Hawaiian/Pacific Island children aged 2-4 years participated.

#### Regulatory Context:

On 15 November 2023, Medsafe provisionally approved Comirnaty Omicron for use in babies and infants:

- NZ Gazette Approval Notice.<sup>1</sup>
- Pfizer Risk Management Plan (Medsafe).<sup>2</sup>

#### Trial Source:

FDA VRBPAC Briefing Document, June 2022.3

### Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe:

- How could you provisionally approve a vaccine for babies and infants that targeted a variant that had passed through New Zealand five seasons earlier?
- How did a trial with limited data, high dropout rates, and extensive exclusions form the basis for approval?
- Why was the vaccine approved for healthy children with negligible COVID-19 risk based on such inadequate safety data?

#### Ministry of Health:

- What data or evidence supported the Ministry's public messaging that the vaccine was safe and effective for this age group?
- Why were parents not informed about the short follow-up period, small sample size, and significant changes to the trial protocol?

- https://gazette.govt.nz/notice/id/2023-go5223
- <sup>2</sup> https://www.medsafe.govt.nz/COVID-19/Comirnaty-RMP.pdf
- https://www.scribd.com/document/582857920/VRBPAC-06-14-22-06-15-22-Meeting-Briefing-Document-FDA-Pfizer-COVID19



# 1.2 TRIALS

RC Term - Vaccine Approval - International E. Pfizer 6 month adverse event report (Report 5.3.6)

Katie Ashby-Koppens

#### Why this issue is relevant:

Pfizer's report of adverse events post-authorisation is dated 30 April 2021 - 3 months after the New Zealand rollout commenced.

42,086 case reports of adverse effects were submitted in just the first 90 days after release, including 1,223 deaths.

Despite the signals, which should have prompted immediate review, the new Zealand public was repeatedly assured of the product's safety, while those raising concerns were systematically silenced.

This is a report Pfizer prepared as it was responsible for the management of post-authorisation safety data. These adverse event reports are submitted voluntarily. The level of underreporting is not known. The Pfizer report highlights significant injuries in 16 key areas. The report lists over 1,201 adverse events of special interest (Appendix 1).

#### **Details:**

This report shows that 6 months after the Pfizer vaccine was authorised, there were 89,716 adverse events that were voluntarily reported. The following major areas of injury were:

### 1. General Disorders and Administration Site Conditions – 35,772 cases

- Pyrexia (fever): 7,666
- Fatigue: 7,338
- Chills: 5,514
- Vaccination site pain: 5,181
- Pain: 3,691
- Malaise: 2,897
- Asthenia (weakness): 2,285
- Drug ineffective: 2,201

#### 2. Nervous System Disorders - 16,350 cases

- · Headache: 10,131
- Dizziness: 3,720
- Paraesthesia (tingling): 1,500
- Hypoaesthesia (numbness): 999

### 3. Musculoskeletal and Connective Tissue Disorders – 12,399 cases

- Myalgia (muscle pain): 4,915
- Pain in extremities: 3,959
- Arthralgia (joint pain): 3,525

#### 4. Gastrointestinal Disorders - 8,760 cases

- Nausea: 5 182
- · Diarrhoea: 1,880
- Vomiting: 1,698

#### 5. Skin and Subcutaneous Tissue Disorders - 4,757 cases

- Pruritus (itching): 1,447
- Rash: 1,404
- Erythema (redness): 1,044
- Urticaria (hives): 862

### 6. Respiratory, Thoracic, and Mediastinal Disorders – 4,151 cases

- Dyspnoea (difficulty breathing): 2,057
- · Cough: 1,146
- Oropharyngeal pain (throat pain): 948

#### 7. Infections and Infestations – 1,927 cases

COVID-19 (post-vaccination cases): 1,927

#### 8. Cardiovascular Events – 1,369 cases

- Tachycardia (rapid heart rate): 1,098
- Arrhythmia: 102
- Myocardial infarction (heart attack): 89
- Cardiac failure: 80

#### 9. Anaphylaxis and Severe Allergic Reactions - 1,833 cases

#### 10. Thromboembolic (Blood Clot) Events - 33 cases

(Only thrombocytopenia was specified)

#### 11. Neurological Events - 677 cases

- · Seizures: 204
- Guillain-Barré Syndrome: 24
- Facial paralysis (Bell's Palsy): 449

#### 12. Hematological (Blood) Disorders – 193 cases

- Epistaxis (nosebleeds): 127
- Petechiae (small blood spots): 50
- Haematuria (blood in urine): 16

#### 13. Hepatic (Liver) Disorders – 29 cases

- Increased liver enzymes: 16
- Liver function abnormalities: 8
- Liver injury: 5

#### 14. Renal (Kidney) Issues – 70 cases

- Acute kidney injury: 40
- Renal failure: 30

#### 15. Respiratory Failures – 96 cases

• Respiratory failure: 44

- · Hypoxia (low oxygen): 42
- Acute respiratory distress syndrome (ARDS): 10

#### 16. Pregnancy-Related Concerns - 299 cases

- Pregnancy cases reported: 274
- Spontaneous abortions: 23
- Premature birth with neonatal death: 2

The report states that approximately 126,212,580 doses of the Pfizer-BioNTech COVID-19 vaccine (BNT162b2) were shipped worldwide from December 1, 2020, to February 28, 2021. It does not say how many doses had been administered by this date.

# Important Questions for the Commissioners to Ask — and of Whom:

#### Chris James (Medsafe):

- If Medsafe received this report, what actions were taken in response?
- Did Medsafe seek independent analysis of the data?
- Was there any review of halting or modifying the vaccine rollout based on early adverse event signals?

#### Ministry of Health officials:

- Was this report shared with senior decisionmakers (e.g. Director-General, Minister, Cabinet)?
- Did the Ministry receive similar safety signal reports from Pfizer or other sources independently of Medsafe?

# Ministry of Health / IMAC (Immunisation Advisory Centre):

- Were the adverse events in the Pfizer 5.3.6 report included in the information given to patients and GPs?
- Why were official communications so confident in the vaccine's safety despite the findings in this report?

#### PM or Communications Advisors:

 Was this report considered when planning public health messaging?

## The Royal New Zealand College of General Practitioners / GPs:

- Were GPs made aware of the adverse event profiles in this report? If not, why?
- Were protocols provided for identifying and treating vaccine-related injuries?

#### Medsafe / Ministry of Health:

- Was New Zealand's approval process influenced by Pfizer's data or other international regulators?
- Were similar reports received from other regulators or flagged by WHO/EMA?

#### Centre for Adverse Reactions Monitoring:

- Did the patterns in this report match adverse events reported in New Zealand?
- Was active surveillance initiated to follow up on these signals domestically?



# 1.2 TRIALS

RC Term - Vaccine Approval - International
F. Widespread Public Misunderstanding of Pivotal Trials for COVID-19 Vaccines

Katie Ashby-Koppens summarising Professor John Gibson's paper

#### Why this issue is relevant:

Political messaging and health bureaucrats' overstatements assisted in creating the fundamental misunderstanding that nearly all New Zealanders surveyed (96%) mistakenly believed that COVID-19 vaccine trials were tested for infection prevention or reduction in mortality - when in fact, they only assessed reduction in symptomatic disease.

Pfizer's pivotal COVID-19 vaccine trials did not test for prevention of infection or mortality - only for reduction in symptoms.

A national survey showed that 96% of New Zealand adults misunderstood this, believing more robust outcomes were trialled. Misleading statements from health officials and political leaders likely shaped this misunderstanding. The resulting mismatch between public expectations and real-world vaccine performance may fuel vaccine hesitancy, not just for COVID-19 vaccines but for vaccines in general.

Public trust may only be rebuilt with transparent communication about what these vaccines can and cannot do.

#### Details:

What the trials tested: Only for reduced risk of symptomatic COVID-19, not infection or death (p.1-2). Moderna's Chief Medical Officer explicitly stated this was due to trial feasibility limits.

False public expectations: The public's understanding largely stemmed from government messaging, not medical literature (p.2–3).

**Survey findings:** 96% of adults in a representative NZ sample believed the trials tested for prevention of infection or mortality (Figure 1, p.2).

**Impact of misinformation:** Overconfidence in vaccine performance may have led to less caution (e.g. asymptomatic spread), worsening transmission (p.3).

Loss of public trust: When vaccines did not deliver what people were led to believe, future vaccine programmes may be jeopardised (p.3-4).

**BMJ** warning: Even before rollout, experts predicted that vaccines may offer short-lived immunity and could damage trust if oversold (p.3).

**New Zealand example:** Politicians claimed vaccines could "make COVID like measles," a misleading comparison given very different vaccine profiles (p.4).

## Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health and Medsafe:

- Has any review of the communication strategy around vaccine trial endpoints been undertaken?
- What steps are being taken to address the significant misunderstanding uncovered by this study?
- How was public consent to vaccination meaningfully informed if foundational facts about what trials tested were not disclosed?

#### **Director-General of Health:**

- How did the Director-General ensure that public messaging accurately reflected the clinical trial endpoints?
- Was the Director-General made aware of the limits of the Pfizer trial design, and if so, how was this reflected in public health guidance?

# COVID-19 Response Ministers (e.g. Chris Hipkins) and Former Prime Ministers (e.g. Jacinda Ardern):

- Why did government leaders and health officials consistently claim that COVID-19 vaccines were tested for infection and death prevention when they were not?
- Given this finding, how does the government plan to rebuild trust in public health communication?

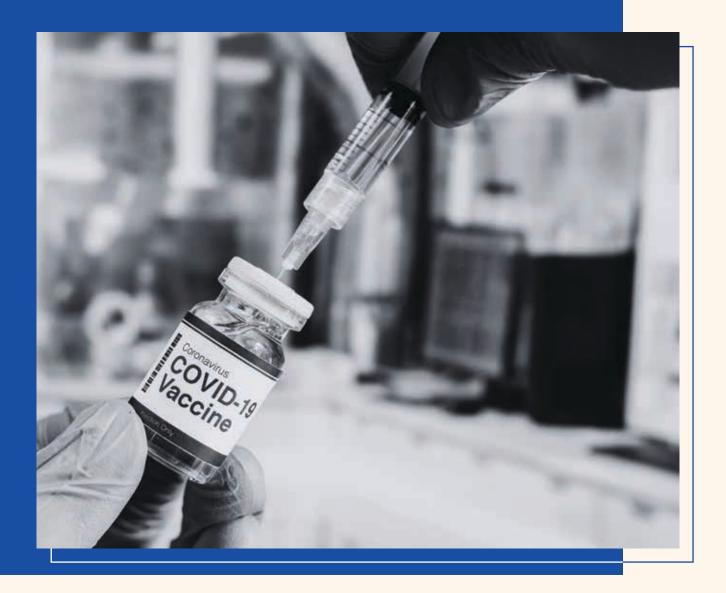
# Department of the Prime Minister and Cabinet (DPMC):

- What role did the DPMC's COVID-19 Response Unit play in shaping the messaging around vaccine effectiveness?
- Were internal briefings or risk assessments conducted about the potential public backlash from overselling vaccine capabilities?

#### References:

Professor John Gibson, Waikato University March 2022 Widespread Public Misunderstanding of Pivotal Trials for COVID-19 Vaccines May Damage Public Confidence in All Vaccines

https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2022.847658/full



# 1.3 U.S. EUA - APPROVAL

RC Term - Vaccine Approval - International FDA / U.S. Emergency Use Authorization (EUA)

Katie Ashby-Koppens

#### Why this issue is relevant:

Emergency Use Authorization (**EUA**) marked a major departure from the traditional regulatory process for new vaccines. Under the EUA, COVID-19 vaccines were made available to the public without completed clinical trials or long-term safety data. This lowered evidentiary threshold created ethical and legal challenges, especially once mandates were imposed, while undermining trust in regulatory oversight.

The FDA's EUA pathway allowed COVID-19 vaccines to be deployed after only two months of safety data: far below the standard 2–3 years normally required for vaccine approval. This was justified by the declared state of emergency, but the short- and long-term implications were profound. EUA products remain legally experimental, meaning recipients must give fully informed, voluntary consent. Despite this, governments and employers implemented mandates, effectively coercing individuals into receiving a product that was not fully approved. Regulatory bodies, including the FDA and Medsafe, acknowledged data limitations but proceeded with mass rollouts and failed to enforce transparency or secure complete follow-up data. This raises serious ethical, legal, and scientific concerns about the integrity of the EUA process and the authorities' obligations under such circumstances.

#### **Details:**

#### Departure from Standard Vaccine Approval

- EUA allows deployment before Phase III trials are complete and without long-term safety data. Traditional approvals typically require several years of data to detect rare or delayed adverse effects (Petrovsky<sup>1</sup> paras 66 and 68).
- The Pfizer-BioNTech vaccine was granted EUA on December 11, 2020, based on interim data from just 2 months of followup.<sup>2</sup>

#### Inadequate Duration of Safety Monitoring

 Participants in Pfizer's Phase III trial had a median follow-up of only 2 months at the time of EUA. This is exceptionally short by normal vaccine standards and fails to detect long-term risks such as myocarditis or autoimmune reactions (Petrovsky<sup>1</sup> paras 52–53).

#### Ethical Implications of EUA Products

- EUA products are still classed as experimental and thus fall under international bioethical standards (e.g. the Nuremberg Code, CIOMS Guidelines, and U.S. federal regulations 21 CFR §50). These require voluntary consent free from coercion and full disclosure of the investigational status of the product (Petrovsky<sup>1</sup> para 74).
- Mandating EUA products, therefore, contravenes ethical norms and, potentially, legal standards. This is especially problematic when individuals were misled to believe the vaccines were fully approved (Petrovsky<sup>1</sup> para 67).

#### FDA and Medsafe Acknowledged Limitations

 Both the FDA and Medsafe explicitly stated in their early documents that ongoing trial results would be necessary to support full approval. However, there is little evidence of consequences or transparency when these data were delayed, incomplete, or failed to meet original expectations (Petrovsky<sup>1</sup> para 80).

#### Transparency Failures

 The FDA initially sought to delay the public release of Pfizer's clinical data for 75 years before being compelled by a court order to release the documents. This raised widespread concern about the transparency of the EUA process and regulatory accountability: Pfizer's FOIA document release Public Health and Medical Professionals for Transparency v. FDA.<sup>3</sup>

#### Legal Definition of EUA

- · U.S. law permits EUA only when:
  - There is a declared public health emergency.
  - · No adequate, approved, and available alternatives exist.
  - The known and potential benefits outweigh known and potential risks.
  - See FDA EUA Legal Framework<sup>4</sup>.

### Important Questions for the Commissioners to Ask — and of Whom:

# Medsafe, Ministry of Health and COVID-19 Minister:

- Was Medsafe aware that the FDA granted Emergency Use Authorization (EUA) for the Pfizer vaccine based on only two months of safety data—particularly given that mRNA technology lacked long-term human safety data?
- Did Medsafe consider the legal and ethical implications of the FDA's EUA classification, including the fact that the vaccine was still considered experimental under U.S. law?
- What steps did Medsafe take to ensure that individuals in New Zealand were clearly informed that the vaccine had only provisional approval and did not have full market authorisation?
- What safeguards were implemented in New Zealand to ensure that recipients of a provisionally approved product gave fully informed, voluntary consent in line with the ethical standards that apply to experimental use?
- Was Medsafe monitoring the status of the FDA's EUA and the integrity of the ongoing trial data, especially in light of protocol changes, unblinding, or incomplete follow-up?
- On what basis did New Zealand justify mandating a provisionally approved product, and what legal remedies exist for individuals who may have been harmed by a product still under EUA or provisional status?
- Has Medsafe undertaken any review or investigation into whether Pfizer met the conditions of its post-market surveillance obligations, and what consequences, if any, have been enforced for failures to comply?

- Petrovsky Affidavit 1 (NP1) https://drive.google.com/file/d/182z2Z6NIw1eHG-2C1cd0KA06JXRAx98m/view?usp=sharing\_
- <sup>2</sup> https://www.fda.gov/media/144245/download (Page 5)
- 3 https://foiaproject.org/case\_detail/?title=on&style=foia&case\_id=34599
- 4 https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency



# 1.4 DNA CONTAMINATION

#### DNA contamination confirmed in vials

The DNA contamination found in Pfizer and Moderna COVID-19 vaccines represents a serious regulatory and public health concern. Independent scientists, including author of this section, Kevin McKernan, discovered significant levels of synthetic DNA - far exceeding internationally accepted thresholds - in multiple batches of mRNA vaccines across eight countries. More alarmingly, this DNA is encapsulated in lipid nanoparticles, which are engineered to enter human cells, thus raising the risk of genomic integration, cancer, and long-term genetic consequences. This contamination includes undisclosed components such as the SV40 promoter, a genetic sequence associated with oncogenesis, which Pfizer failed to declare to regulators worldwide. Subsequent tests have confirmed the presence of vaccine-derived DNA in both human tumours and blood, long after administration, suggesting persistent biological effects.

These findings point to a larger failure of regulatory oversight. New Zealand's Medsafe provisionally approved the Pfizer vaccine with 58 manufacturing-related conditions, yet did not act despite being notified of these serious issues. Likewise, the Environmental Protection Authority (EPA), which is responsible for genetically modified organisms

(GMOs) under New Zealand law, has failed to respond to the allegation of contamination despite synthetic DNA meeting the statutory definition of a new organism. Globally, regulators have minimised the significance of DNA contamination, despite emerging evidence and internal communications contradicting their public reassurances. The shift from Process 1 to Process 2 in Pfizer's manufacturing introduced this contamination, yet Process 2 was never part of the vaccines used in Pfizer's trials and process 2 has not been trialled at scale. The scope of these oversights, and the refusal to investigate or communicate them transparently, raise urgent questions for health authorities and demand accountability.

#### In this section

- A. DNA Contamination
- B. Change in manufacturing process
- c. SV40 promoter-enhancer
- D. Synthetic DNA contamination including Pfizer's SV40 promoter confirmed in tumour and blood
- E. DNA confirmed in vials sourced from eight countries
- F. Regulators efforts to downplay the importance of this issue



# 1.4 DNA CONTAMINATION

# RC Term - Vaccine Approval - International A. DNA Contamination

Kevin McKernan

#### Why this issue is relevant:

Excessive synthetic foreign DNA has been found in Pfizer and Moderna COVID-19 vaccine vials.

This DNA, encapsulated in lipid nanoparticles (LNPs), can integrate into human cells, potentially leading to genomic instability, cancer, immune system disruption, and adverse hereditary effects.

Pfizer's vaccines are also adulterated with the SV40 promoter, which was not disclosed in the expression vector map provided to regulators.

The DNA contamination may also be considered a genetically modified organism (GMO).

#### Details:

In February 2023, DNA contamination was accidentally discovered in Pfizer and Moderna COVID-19 vaccine vials during unrelated testing. The SV40 promoter was also discovered in the Pfizer vials, which had not been disclosed to any regulators globally.<sup>1</sup>

The DNA contamination and SV40 promoter was subsequently confirmed in peer reviewed studies.<sup>2</sup>

The level of DNA contamination exceeds the regulatory threshold of 10 nanograms – a limit intended for 'naked DNA', which refers to un-encapsulated DNA i.e. DNA not in lipid nanoparticle (LNP). The contamination is more serious when encapsulated in LNPs, as the LNPs are the delivery system specifically designed to transport mRNA into human cells (see Issue 1.9 Biodistribution Study, page 168).<sup>3</sup>

According to World Health Organization terminology, this DNA is considered a contaminant.<sup>4</sup>

#### How is it here and what are the consequneces?

The DNA contamination is from a change in the manufacturing process and should have been filtered out (see Issue 1.4.B Change in Manufacturing Process).

The Pfizer vials contain the SV40 promoter sequence which was not disclosed to any regulators (see Issue 1.4.C, page 134).

Synthetic DNA contamination including Pfizer's SV40 promoter have been found in tumour and blood samples (see Issue 1.4.D, page 136).

Independent testing has confirmed excessive DNA contamination and SV40 presence in vials from numerous countries (see Issue 1.4.E, page 138).

Medsafe (New Zealand's medicines regulator) was aware of the potential risk, as several of its 58 provisional approval conditions related to manufacturing contamination, e.g. condition 7.5

"7. Provide the reassessment of the active substance specification for the DNA template purity and impurities. Due date: July 2021."

The synthetic DNA contamination meets the definition of a new organism under the Hazardous Substances and New Organisms Act 1996, which has been brought to the attention of the Environmental Protection Authority (EPA) – no action has been taken.<sup>6</sup>

In June 2025, Mr McKernan appeared before New Zealand's Royal Commission Phase Two. He has re-recorded his presentation he gave.<sup>7</sup>

# Important Questions for the Commissioners to Ask — and of Whom:

#### Chris James, Medsafe:

- Did Medsafe review Pfizer's Process 2 manufacturing data and assess the DNA levels?
- Did Medsafe consider the impact of DNA being encapsulated in lipid nanoparticles?
- Did Medsafe consider the potential for DNA integration into human genomes?
- What actions has Medsafe taken since learning about the SV40 promoter enhancer in the Pfizer vials?

#### EPA:

 You have been advised of the risks of DNA contamination, including evidence found in a child's dose batch sent to New Zealand. Why have you not taken action?

- <sup>1</sup> Kevin McKernan Evidence to the FDA <a href="https://x.com/TheChiefNerd/status/1669443898547003399">https://x.com/TheChiefNerd/status/1669443898547003399</a> and presentation slides <a href="https://anandamide.substack.com/p/">https://anandamide.substack.com/p/</a>
- ${}^2 \underline{\ \ } \underline{\ \ \ } \underline{\ \ } \underline{\ \ \ \ } \underline{\ \ \ } \underline{\ \ \ } \underline{\ \ \ } \underline{\ \ \ \ } \underline{\ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ } \underline{\ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ \ } \underline{\ \ \ \ \ } \underline{\ \ \ \ \ } \underline{\ \ \ \ \ } \underline{\ \ \ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ } \underline{\ \ \ } \underline{\ \ \ } \underline{\ \ \ \ } \underline{\ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ } \underline{\ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ } \underline{\ \ \ } \underline{\ \ \ \ } \underline{\ \ \ } \underline{\ \ \ \ \ } \underline{\ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ } \underline{\ \ \ \ \$
- Kevin McKernan's expert report in the Australian GMO case https://drive.google.com/file/d/1mA7k3QtEc1BukCkX7UScLm0iQYD2v5jc/view?usp=sharing
- 4 https://www.who.int/news-room/questions-and-answers/item/contaminated-medicines-affecting-children#:~:text=Contami
- Medsafe's 58 provisional approval conditions (many related to contamination): https://medsafe.govt.nz/COVID-19/Comirnaty-Gazette.pdf
- Letters to Medsafe and EPA re DNA contamination: 13 September 2023, 3 October 2023, 24 September 2024 Letter to EPA 3 October 2024
- Mr McKernan replicated the evidence he gave to NZ's Royal Commission Phase 2: https://x.com/kevin\_McKernan/status/1931351886310834369



# 1.4 DNA CONTAMINATION

RC Term - Vaccine Approval - International
B. Change in manufacturing process

Kevin McKernan

#### Why this issue is relevant:

Pfizer altered its manufacturing process to upscale production - this is known as Process 2.

Process 2 uses synthetic DNA, which was not adequately filtered out leaving excessive levels of DNA contaminating the vaccines.

Process 1 was used in the larger trials. Process 2 was tested on only a few hundred people and was never subjected to large-scale randomised controlled trials (RCTs).

Despite this, New Zealanders received Process 2.

The original Pfizer trial used Process 1, a manufacturing method that produced a 'clean' product, free from DNA contamination.<sup>1</sup>

However, the mass vaccine rollout in New Zealand used Process 2, which had only been tested on a few hundred individuals. This second process is the source of the DNA contamination.<sup>1</sup>

Both Pfizer and Moderna upscaled their production to Process 2 to meet demand for the vaccines. Neither filtered out the DNA contamination, which remains in the vaccine vials – even in more recently produced booster doses. To date, 13,588,280 COVID-19 doses have been administered to the New Zealand population², the vast majority being Pfizer. The DNA contamination is encapsulated in lipid nanoparticles (LNPs), which distribute it throughout the body and into human cells (see issue 1.9, page 168).

#### **Details:**

In October 2020, the protocol for the pivotal Pfizer/BioNTech Comirnaty trial (C4591001) was amended. It showed that nearly all doses used in the clinical trial were from Process 1 — 'clinical batches' made using in vitro transcription. See Figure below.<sup>1</sup>

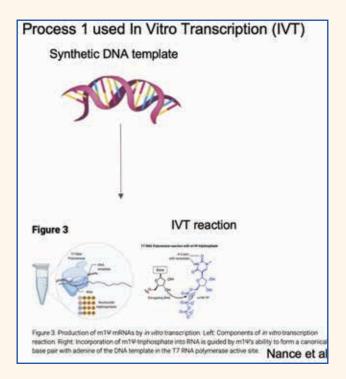
For large-scale emergency supply post-authorisation, Process 2 was developed. See Figure right.<sup>1</sup>

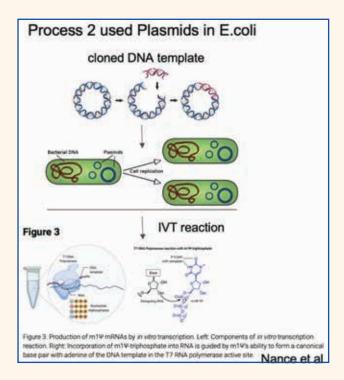
#### Key differences included:

- · Changes to the DNA template used to transcribe RNA.
- · Changes in the purification phase.
- Alterations to the lipid nanoparticle manufacturing process.

Process 2 batches were shown to have substantially lower mRNA integrity.3

The DNA contamination in Process 2 should have been filtered out - but was not.





### Important Questions for the Commissioners to Ask — and of Whom:

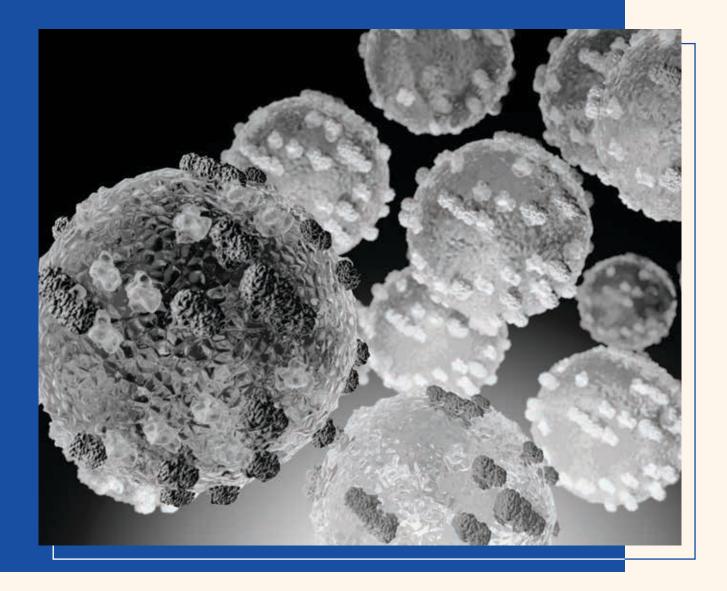
#### Chris James, Medsafe:

- Did Medsafe consider the possibility of DNA integration from contamination?
- Were any of Medsafe's conditions related to the potential for DNA contamination?
- What action has Medsafe taken since learning of the DNA contamination?

#### Medsafe and the EPA:

- You have been advised of the risk of DNA contamination, including evidence in a child's dose batch sent to New Zealand.
- · Why have you not acted on this?

- <sup>1</sup> Kevin McKernan's presentation (See Issue 1.4.A footnotes 1 and 7)
- New Zealand vaccine doses: https://www.tewhatuora.govt.nz/for-health-professionals/data-and-statistics/covid-19-data/vaccine
- OVID-19: Researchers face wait for patient-level data from Pfizer and Moderna vaccine trials, Guetzkow J, BMJ, 13 May 2023: https://www.bmj.com/content/378/bmj.o1731/rr-2



# 1.4 DNA CONTAMINATION

RC Term - Vaccine Approval - International C. SV40 promoter-enhancer

Kevin McKernan

#### Why this issue is relevant:

The SV40 promoter-enhancer is a genetic sequence derived from Simian Virus 40, known for its ability to initiate gene expression in a variety of cell types.

This sequence has been associated with cancer development and was not disclosed to regulators by Pfizer, but has been discovered in Pfizer vials of COVID-19 vaccines.

The Moderna vaccine has not tested positive to this genetic sequence.

#### Details:

Scientist Kevin McKernan discovered DNA fragments containing SV40 promoter sequences in Pfizer vaccine vials. Pfizer did not inform the regulators of the adulteration of its vaccines with the SV40 enhancer promoter.

Australia's Therapeutic Goods Administration (medicines regulator) has admitted that the SV40 enhancer/promoter may facilitate nuclear transport of DNA.<sup>2</sup>

Presence of both DNA contamination and SV40 promoter in Pfizer vials has also been confirmed in peer-reviewed study Kammerer, U (2024) BioNTech RNA-Based COVID-19 Injections Contain Large Amounts Of Residual DNA Including An SV40 Promoter/Enhancer Sequence.<sup>3</sup>

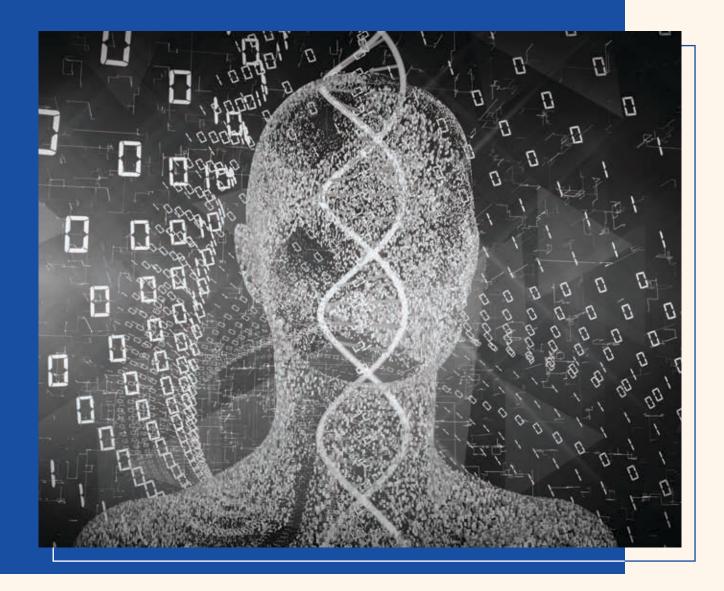
These SV40 DNA fragments can potentially integrate into the human genome, raising serious concerns about insertional mutagenesis and oncogenesis (the development of cancer).<sup>4</sup>

## Important Questions for the Commissioners to Ask — and of Whom:

#### Chris James, Medsafe:

 What action has Medsafe taken since learning of the SV40 promoter-enhancer being found in the Pfizer vials?

- https://www.researchgate.net/publication/375065939\_DNA\_fragments\_detected\_in\_monovalent\_and\_bivalent\_PfizerBioN
- https://news.rebekahbarnett.com.au/p/bombshell-australian-drug-regulator?open=false#%C2%A7sv-enhancer-re
- ${}^{3} \underline{\quad https://publichealthpolicyjournal.com/biontech-rna-based-covid-19-injections-contain-large-amounts-of-residual-dna-in}}$
- <sup>4</sup> See Vilchez, R (2004) Emergent Human Pathogen Simian Virus 40 and Its Role in Cancer https://pmc.ncbi.nlm.nih.gov/articles/PMC452549/



# 1.4 DNA CONTAMINATION

RC Term - Vaccine Approval - International
D. Synthetic DNA contamination including Pfizer's
SV40 promoter confirmed in tumour and blood

Kevin McKernan

#### Why this issue is relevant:

Synthetic DNA contamination is now being detected in people post-vaccination (in blood and tumour samples), suggesting it is self-replicating or persisting long-term, potentially altering biological processes in the body.

#### **Details:**

Synthetic DNA has been identified in:

A tumour biopsy, one year after vaccination1

The blood samples of 75 South Australians, all of whom had received only Pfizer or Moderna vaccines.<sup>2</sup>

These findings indicate that vaccine-derived DNA may be integrating into the human genome, raising concerns about its long-term presence and potential effects on human health.

Research in this area has only just begun, much is self funded.

#### South Australian Blood Study: 2:

In a cohort of 102 participants, synthetic DNA contamination was found in 75 individuals.

All participants had received only Pfizer or Moderna vaccines.

# Important Questions for the Commissioners to Ask — and of Whom:

#### Chris James, Medsafe:

- Has Medsafe been made aware of findings showing vaccine-derived synthetic DNA in human tumour and blood samples?
- Did Medsafe evaluate the risk of long-term DNA integration or persistence in the body during the approval process?
- What steps has Medsafe taken since learning of these findings?

#### Ministry of Health:

- Has the Ministry initiated or commissioned any investigation into the presence of synthetic DNA in vaccinated individuals?
- What ongoing monitoring, if any, is being undertaken regarding potential genomic integration or related adverse effects?

#### Environmental Protection Authority (EPA):

 Given that synthetic DNA qualifies as a genetically modified organism under New Zealand law, what is the EPA's response to its detection in human tissue and blood?

#### References:

- https://anandamide.substack.com/p/sv40-origin-of-replication-in-mammalian?utm\_source=publication-search
- South Australian Blood Study https://pmc.ncbi.nlm.nih.gov/articles/PMC9935276/

https://anandamide.substack.com/p/chakraborty-open-review

https://anandahilde.substack.com/p/chakidborty-open-review

 $\underline{https://anandamide.substack.com/p/bloody-hell?utm\_source=publication-search}$ 

See also Issue 1.1.6.C for further detail on the SV40 promoter-enhancer's role in cancer.



# 1.4 DNA CONTAMINATION

RC Term - Vaccine Approval - International

E. Testing of vials by independent labs with vials sourced from eight countries confirms excessive DNA contamination

Kevin McKernan

#### Why this issue is relevant:

Independent laboratories have tested mRNA vaccine vials sourced from numerous countries.

The testing has confirmed excessive DNA contamination in the majority of the vials and detected the SV40 enhancer-promoter sequence in Pfizer vials.

This shows that the issue is not regional, it is a global problem.

#### Details:

Since the initial discovery of DNA contamination, further independent testing of vials from across the globe has confirmed the same contamination issues.

- Vials from 8 countries (U.S., Canada, Germany, Japan, France, Australia, Slovakia, Ireland) tested positive for excess DNA contamination.<sup>1</sup>
- In Australia, Pfizer and Moderna vials (including a child's batch that was also shipped to New Zealand) was tested under chain-of-custody and cold-storage protocols and found to be contaminated. This is recorded in the Prosecution Brief.<sup>2</sup>
- In the United States, FDA scientists supervised testing and confirmed excessive contamination in multiple samples.<sup>3</sup>
- In Slovakia, Dr. Peter Kotlar MP<sup>4</sup> was appointed by the Slovakian government with full authority to investigate their pandemic response. He coordinated chain-of-custody testing of:
  - 85 Moderna vials from 17 lots.
  - 35 Pfizer vials from 7 lots.
  - All vials were stored correctly and were in date. Results showed DNA contamination ranging from:
    - 0.2-160 ng/dose (Moderna).
    - 1-100 ng/dose (Pfizer).
- In Ireland, testing of Pfizer's more recent XBB.1.5 booster and the JN.1 booster doses found DNA levels exceeding the regulatory limit by more than 8 times, indicating no improvements in Pfizer's later batches.<sup>5</sup>

# Important Questions for the Commissioners to Ask — and of Whom:

#### Chris James, Medsafe:

- Were Medsafe and New Zealand health authorities informed of international findings confirming DNA contamination?
- Has Medsafe tested New Zealand-held vials for DNA contamination or requested testing by independent laboratories?

#### Ministry of Health:

 Given Australia's Prosecution Brief confirmed contamination in a child's batch also delivered to NZ, what action has been taken to investigate this?

#### **Environmental Protection Authority (EPA):**

- Are you aware that confirmed DNA contamination constitutes a genetically modified organism under NZ law?
- What steps, if any, have you taken in response to this global confirmation of DNA contamination?

#### References:

- https://docs.google.com/spreadsheets/d/lgJj3GSrM-UJR9c6Lrcn1k8\_buQkQznuUVSKuMR8\_2lU/edit?gid=0#gid=0
- <sup>2</sup> https://porthedlandmotion.info/wp-content/uploads/2024/10/240909-D-Speicher-Report.pdf and

#### Prosecution brief:

https://drive.google.com/drive/folders/11gHVWNMcE09nKJWITE-J2c-IZap\_XQeG?usp=share\_link

- 3 https://jhss.scholasticahq.com/article/127890-a-rapid-detection-method-of-replication-competent-plas and https://anandamide.substack.com/p/fda-white-oak-lab-finds-6x-to-470x
- https://anandamide.substack.com/p/once-again-dna-contamination-is-found and https://www.facebook.com/watch/?mibextid=wwXlfr&v=2130634934039562&rdid=ByAX2YugCkNOy5pi
- https://www.courageoustruth.davidspeicher.com/p/pfizer-comirnaty-in1-booster-contains



# 1.4 DNA CONTAMINATION

RC Term - Vaccine Approval - International
F. Regulators efforts to downplay the importance of this issue

Kevin McKernan

#### Why this issue is relevant:

Regulators globally have failed to protect the public from the potential risks of DNA contamination and the SV40 enhancer/promoter sequence.

While acknowledging some issues privately or internally, regulators have publicly downplayed concerns, describing them as 'misleading information', despite growing scientific evidence to the contrary.

#### **Details:**

Regulators including Health Canada, the U.S. FDA, and Australia's TGA have vacillated in their responses to concerns about DNA contamination and the SV40 enhancer/promoter sequence in mRNA COVID-19 vaccines.

#### These regulators1 assert2 that:

- Plasmid DNA contamination cannot integrate into the genome.
- Contaminant DNA will be naturally destroyed by the body before entering cells.
- Even if DNA reaches a cell, it cannot enter the nucleus (where genomic integration would occur).

#### However, emerging evidence contradicts<sup>2</sup> these claims:

- Moderna's own patents and FDA industry guidance acknowledge the potential for genomic integration.
- Internal TGA emails (obtained via FOI) reveal that TGA officials were aware their public claims lacked evidential support.<sup>3</sup>
- Neither the U.S. CDC nor the TGA hold any evidence that COVID-19 vaccines do not alter DNA, despite repeated public assurances to that effect.<sup>4</sup>

## In 2025, a group of scientists and professionals submitted a Citizens' Petition to the FDA<sup>5</sup>, stating:

- mRNA products meet the FDA's definition of gene therapy and should not have been classified as vaccines.
- Pfizer and Moderna were granted categorical exclusions from Environmental Assessments (EAs), thereby avoiding review by the Cellular, Tissue, and Gene Therapies Advisory Committee.
- This misclassification prevented public disclosure and informed consent, which would be legally required for gene therapies.
- The petition calls for revocation or suspension of the Biologics License Applications (BLAs) for Comirnaty and Spikevax.

#### The petition also asserts:

- Synthetic DNA contamination has been found in mRNA products.
- This contamination may pose risks of genomic integration and cancer development.

### Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe:

- Has Medsafe tested any COVID-19 vaccine vials held in New Zealand for DNA contamination?
- If not, why has this not been initiated, particularly in light of global confirmations and known batch overlaps?

#### Ministry of Health or Medsafe:

 Has New Zealand independently reviewed claims of regulatory misclassification of mRNA vaccines as traditional vaccines rather than gene therapies?

- <sup>1</sup> TGA's media release describing DNA contamination concerns as "misinformation" https://www.tga.gov.au/news/media-releases/addressing-misinformation-about-excessive-dna-mrna-vaccines
- Rebuttal to the TGA's misinformation claim https://news.rebekahbarnett.com.au/p/addressing-allegations-that-dna-contamination
- Internal TGA emails revealing withheld concerns<sup>2</sup> https://news.rebekahbarnett.com.au/p/bombshell-australian-drug-regulator
- <sup>4</sup> TGA states it holds no evidence that vaccines don't alter DNA<sup>3</sup> https://news.rebekahbarnett.com.au/p/cdc-holds-no-evidence-for-claim-that
- FDA Citizens' Petition (2025)

  https://childrenshealthdefense.org/wp-content/uploads/FDA-2025-P-0335-0001\_attachment\_1.pdf 5



# 1.5 GENE TECHNOLOGY BILL

RC Term - Vaccine Approval - New Zealand Gene Technology Bill and timing

Katie Ashby-Koppens

#### Why this issue is relevant:

The Gene Technology Bill is scheduled to be passed by the end of 2025, three months before the Royal Commission's Phase Two report is due in February 2026. Phase Two of the Royal Commission explicitly includes a review of the COVID-19 vaccines, which are gene technology and would have been regulated by this proposed legislation if it were in place. Passing legislation ahead of the Royal Commission Phase Two final report risks preempting the Commission's findings and undermining its purpose.

The National-led government has introduced the Gene Technology Bill, which has passed its first reading. This is the first legislation of its kind in New Zealand and would enable the use of genetically modified organisms (GMOs) outside of laboratory settings. COVID-19 mRNA-LNP vaccines, such as those produced by Pfizer and Moderna, are gene therapies. The Royal Commission is actively examining the use of these technologies. However, the proposed Bill - if passed before the Commission's report - is likely to sidestep important scrutiny and public consultation.

#### Details:

The Pfizer and Moderna COVID-19 vaccines are gene therapies. In some countries they satisfy the definition of genetically modified organisms. ACT's technology spokesperson said about the Bill:

"I remember standing up as an opposition MP in 2019 laying out a proposal that is effectively replicated in the bill now before Parliament today. Back then, I was advised to use the euphemism "biotechnology" instead of genetic modification to avoid a fearful knee-jerk reaction. How far we have come."

#### Emphasis added.

The Royal Commission Phase Two is tasked with evaluating biotech COVID-19 vaccines, including mRNA-based gene therapies. Its final report is due in February 2026.<sup>2</sup>

Despite this, the Gene Technology Bill is scheduled for passage by the end of 2025, including the establishment of a new regulatory body.

A particularly concerning provision is found in Clause 50 of the Bill, which allows for:

"Mandatory medical activity authorisations for a human medicine that is or contains gene technology that has been approved by at least two recognised overseas gene technology regulators." <sup>3</sup>

This clause effectively bypasses any detailed local regulatory or investigative process, outsourcing decision-making to foreign regulators. This mirrors the approach taken during the COVID-19 vaccine rollout, when approvals by the U.S. FDA and UK MHRA were relied upon, despite differences in variants, disease and timeframe impacting New Zealand.

### Important Questions for the Commissioners to Ask — and of Whom:

## Minister for Research, Science and Innovation and the Bill's drafters:

 Why is the Government investing millions in a Royal Commission report on "lessons learned" if the Gene Technology Bill is allowed to pass beforehand, potentially rendering the Commission's findings irrelevant or inconsequential?

# Ministry of Business, Innovation and Employment (MBIE) and relevant Parliamentary committees:

 Who determined the Bill's timeline, and was consideration given to the Royal Commission's reporting schedule?

## Medsafe and the proposed Gene Technology Regulator:

 What protections exist to ensure local context is considered before adopting overseas regulatory decisions—particularly in light of past experience with COVID-19 vaccines?

- https://www.act.org.nz/nz\_a\_step\_closer\_to\_being\_a\_superpower\_in\_agricultural\_genetics
- <sup>2</sup> https://www.covid19lessons.royalcommission.nz/about-us/phases-of-the-royal-commission/
- https://www.dentons.co.nz/en/insights/articles/2024/october/24/end-to-gene-technology-ban-announced



# 1.6 THE CONTRACTS

RC Term - Vaccine Approval - New Zealand
A. Procurement Agreement Terms

Katie Ashby-Koppens

#### Why this issue is relevant:

Medsafe shielded Pfizer's commercial interests while millions of New Zealanders were injected with a product still under investigation, withholding critical safety data and undermining the public's right to informed consent.

The New Zealand Government entered into multiple procurement contracts with Pfizer and other manufacturers for the supply of COVID-19 vaccines. These contracts have not been publicly disclosed. Given the vaccines were taxpayer-funded - and in many cases mandated - the public has a right to know the terms under which they were procured: commercial in confidence is not a valid excuse.

If the New Zealand contracts resemble those released in other jurisdictions, significant concerns arise about the promotion of the vaccines as unequivocally "safe" and "effective."

#### Key concerns from international agreements include:

- The vaccines were described as "aspirational" a term suggesting experimental status.
- The manufacturer was granted full indemnity, transferring all liability to the purchaser (the government).
- Contracts acknowledged the rapid development process, absence of long-term safety data, potential adverse effects, and uncertain efficacy.
- Vaccine doses were not serialised, compromising traceability.
   In light of these factors, full disclosure of the contracts is not just in the public interest, it is essential for maintaining trust and accountability.

New Zealand's Ombudsman<sup>2</sup> has refused to grant disclosure of the contracts, but did require Ministry of Health to supply a statement summarising the same.<sup>3</sup>

#### Details:

South Africa made public the terms of its procurement agreement with Pfizer. Terms include:

2 Agreement to Supply

(b) Purchaser acknowledges and agrees that (i) Pfizer's efforts to develop and manufacture the Product are aspirational in nature and subject to significant risks and uncertainties, and (ii) the fact that any other drug or vaccine to prevent, treat or cure COVID-19 infection is successfully developed or granted Authorisation earlier than the granting of Authorisation for the Product shall not change the current situation of urgent needs for prevention of the spread of the COVID-19 infection that poses serious threats to and harmful effects on the lives and health of the general public.

#### 5.5 Purchaser Acknowledgement.

Purchaser acknowledges that the Vaccine and materials

related to the Vaccine, and their components and constituent materials are being rapidly developed due to the emergency circumstances of the COVID-19 pandemic and will continue to be studied after provision of the Vaccine to Purchaser under this Agreement. Purchaser further acknowledges that the long-term effects and efficacy of the Vaccine are not currently known and that there may be adverse effects of the Vaccine that are not currently known. Further, to the extent applicable, Purchaser acknowledges that the Product shall not be serialized.

#### 8. INDEMNIFICATION.

Indemnification by Purchaser. Purchaser hereby agrees to indemnify, defend and hold harmless Pfizer, BioNTech, each of their Affiliates, contractors, sub-contractors, licensors, licensees, sub-licensees, distributors, contract manufacturers, services providers, clinical trial researchers, third parties to whom Pfizer or BioNTech or any of their respective Affiliates may directly or indirectly owe an indemnity based on the research, development, manufacture, distribution, commercialization or use of the Vaccine, and each of the officers, directors, employees and other agents and representatives, and the respective predecessors, successors and assigns of any of the foregoing ("Indemnitees"), from and against any and all suits, claims, actions, demands, losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' and other counsels' fees and other expenses of an investigation or litigation), whether sounding in contract, tort (delict), intellectual property, or any other theory, and whether legal, statutory, equitable or otherwise by any natural or legal person (collectively, "Losses") caused by, arising out of, relating to, or resulting from the Vaccine, including but not limited to any stage of design, development, investigation, formulation, testing, clinical testing, manufacture, labelling, packaging, transport, storage, distribution, marketing, promotion, sale, purchase, licensing, donation, dispensing, prescribing, administration, provision, or use of the Vaccine, any information, instructions, advice or guidance provided by Pfizer, or BioNTech or any of their respective Affiliates and relating to the use of the Vaccine, or any processing or transfer of anyone's personal information processed and transferred by Purchaser to the Indemnitees ("Covered Activities").

#### **Emphasis added**



# Important Questions for the Commissioners to Ask — and of Whom:

# Ministry of Health and Signatories of the Pfizer Supply Agreements:

#### **Contract Transparency and Public Interest**

- Why were the full terms of the vaccine agreements not proactively disclosed, especially given that the vaccines were taxpayer-funded and mandated?
- Will the Ministry commit to releasing these agreements in full, with minimal redactions, to uphold transparency and accountability?

#### Acknowledged Risks and Experimental Nature

- The agreements describe Pfizer's efforts as "aspirational" and note unknown long-term effects. On what basis did the Ministry promote the vaccines as "safe and effective"?
- Was the public informed that the government had acknowledged the vaccines' experimental nature and unknown risks?
- Was this information shared with healthcare providers, schools, and employers enforcing mandates?

#### **Indemnification and Liability**

- What legal or ethical analysis supported accepting such broad indemnity provisions?
- In the event of injury or long-term harm, who within the NZ Government is accountable for compensation, given Pfizer's protection?
- Were elected officials and the public made aware of the indemnity terms before the rollout?

#### Serialisation and Traceability

- Why was the lack of dose serialisation accepted, given it impedes investigation of manufacturing or batch-related safety concerns?
- What steps were taken to mitigate this risk?

#### **Decision-Making Process**

- Who signed the Pfizer supply agreements on behalf of the Government did they have necessary authority?
- What roles did Cabinet, legal advisors, or independent experts play in the approval process?
- Did Medsafe or other regulators review the terms, especially those related to safety, liability, and traceability?
- Has any post-agreement legal or ethical review been conducted to assess the contracts' alignment with NZ law, informed consent principles, or the Bill of Rights?

- 1 SA Pfizer Agreement: https://drive.google.com/file/d/14PUbCml4UPpOlLK1IEdWcxi9bMo2JPdE/view?usp=share\_link
- Ombudsman Decision on Pfizer Agreement Release: https://www.ombudsman.parliament.nz/resources/chief-ombudsmans-opinion-oia-complaints-about-refusal-covid-19-vac
- <sup>3</sup> NZ MOH Summary statement of New Zealand COVID-19 vaccine procurement process and contracts with suppliers: https://www.health.govt.nz/information-releases/summary-statement-of-new-zealand-covid-19-vaccine-procurement





# 1.6 8 DOSES / PERSON

RC Term - Vaccine Approval - New Zealand
B. 8 doses / person procured

Katie Ashby-Koppens

#### Why this issue is relevant:

New Zealand secured a minimum of eight vaccine doses per person, reflecting an expectation of continued booster requirements well beyond the initial two-dose protocol.

In 2020, New Zealand had procured at least 4.3 doses per person

By 2022, New Zealand had procured at least 8 doses per person.

#### Details:

	Date	Doses total	Adult doses	Paediatric doses
Plizer	22-Dec-20	1,500,525	1,500,525	
	5-Mar-21	8,500,635	8,500,635	
	12-May-21	100,620	100,620	print.
	7-Sep-21	274,950	274,950	
	10-Sep-21	500,760	500,760	0.4
	22-Oct-21	4,701,060	3,447,060	1,254,000
	28-Jun-22	3,000,000	2,500,000	500,000
Janssen	22-Dec-20	2,000,000	0	
Novavax	15-Dec-20	10,720,000	V. V	
AstraZeneca	15-Dec-20	7,600,000	10	

# Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health:

Procurement Volumes and Booster Planning

- New Zealand procured enough doses for roughly 8 per person. When did the Ministry anticipate the need for ongoing boosters?
- If this was known early, why was the public told that two doses would "complete" the vaccination process?



# 1.7 NZ PROVISIONAL CONSENT

AND THE EROSION OF SAFEGUARDS

The story of how New Zealand approved and distributed the Pfizer COVID-19 vaccine is not simply one of urgent action in a crisis – it is a case study in how legal safeguards, expert guidance, and public trust can be quietly eroded when political imperatives take precedence over process. At the centre of this issue is the use – and subsequent redefinition – of provisional consent, a regulatory mechanism designed for restricted use in exceptional circumstances, not for the mass administration of a novel gene-based product to an entire population.

Under the Medicines Act, provisional consent was intended to allow limited access to experimental treatments for seriously ill patients – those with no other options. It exempted applicants from meeting the full evidentiary standards required for ordinary approval, including proof of safety, quality, and efficacy. Yet this lower threshold was used to justify a nationwide rollout of a still-trialled vaccine with just two months of clinical data. Despite its provisional status, the product was promoted as "safe and effective" – a phrase that misrepresented both the science and the law.

When the High Court found this use of provisional consent to be unlawful, the government did not reflect or adjust. Instead, it amended the law the very next day - rushing through all three readings in Parliament without public input, removing the clause that had triggered the ruling. Expert advisory groups, such as CV TAG, raised serious concerns - particularly about myocarditis risks in young people - but their recommendations were often sidelined, ignored, or quietly reversed. Internal documents reveal

deliberate efforts to strip this safety advice from public messaging, underscoring the extent to which key decisions were politically, rather than medically, motivated.

The misuse of provisional consent to serve political objectives meant that the usual safety checks were bypassed. Expert warnings were sidelined, legal limitations were removed without public consultation, and the provisional status was obscured by public messaging that promoted certainty where none existed. The result was a deeply compromised process in which regulatory standards, medical ethics, and informed consent were subordinated to the urgency of policy goals. Sponsors' data and information was favoured and often not rigorously scrutinised, despite the nation's health resting in the hands of politicians and regulators. These actions not only jeopardised public trust and safety at the time, but also set a dangerous precedent for how experimental medical products might be approved and promoted in the future.

#### In this section

- A. Provisional Consent versus Ordinary Consent in NZ
- **B.** Court Decision and change of Medicines Act around provisional consent limitations
- C. Medsafe's 58 Conditions on Pfizer
- D. Medsafe Technical Datasheets
- E. Use of Vaccine in pregnancy
- F. Timeline and approvals 12-18 year olds



# 1.7 PROVISIONAL CONSENT

RC Term - Vaccine Approval - New Zealand
A. Provisional Consent versus Ordinary Consent

Sue Grey and Dr Alison Goodwin

#### Why this issue is relevant:

The use of provisional consent allowed a novel and inadequately tested gene therapy (mRNA COVID-19 vaccine) to be approved and administered to the majority of New Zealanders. Provisional consent was originally designed to allow access to potentially life-saving treatments for terminally ill or seriously unwell individuals. Provisional consent was never intended as a vehicle for mass population rollouts of medicines. The regulatory pathways were misused by the government.

Provisional consent under New Zealand law was meant to provide early access to experimental medicines for a limited number of patients in urgent need, not to replace the rigorous standards of full regulatory approval. The mRNA COVID-19 vaccine had just two months of safety data before being granted provisional consent, despite still being in an active clinical trial. Unlike full consent (under s20 of the Medicines Act 1981), provisional consent (under s23) does not require the submission of evidence on a product's safety, quality, or efficacy – a critical regulatory safeguard. Yet, despite this, the government promoted the vaccine as "safe and effective" to the general population, including healthy individuals and teenagers at minimal risk from COVID-19.

This raises serious legal and ethical questions, especially when viewed in light of the New Zealand Bill of Rights Act 1990 (BORA), which protects individuals from non-consensual medical experimentation. The vaccine rollout, undertaken in tandem with the ongoing clinical trial, was not properly assessed under sections 10 (protection from medical experimentation) and 11 (informed consent) of BORA.

#### Details:

#### Provisional vs Full Consent Requirements: 1

- Under the Medicines Act 1981, provisional consent (s23) applications must provide information as per s21(2)(a-h) only.
- Sections s21(2)(i)-(k) which require documentation of safety, quality, and efficacy - are only required for full consent under s20.

#### Ongoing Clinical Trial:

The Pfizer vaccine was granted provisional consent with only two months of trial data. The clinical trial was not complete at the time the rollout commenced until February 2023 by which time the vast majority of New Zealanders had been injected well beyond initial administration.

#### Misleading Public Messaging:

Despite lacking full safety and efficacy evidence, government campaigns claimed the treatment was "safe and effective" - a contradiction of the regulatory status and a potential breach of public trust. The advertising for the vaccines also appears to be in breach of the Medicines Act.

# Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health / Medsafe:

- Why did the NZ Government promote the mRNA product as "safe and effective" when Medsafe deemed the evidence insufficient for full consent under s20?
- Who authorised or approved the public messaging strategy?

#### Crown Law / Legal Advisors:

 Section 20(3) of the Medicines Act explicitly states that full consent does not constitute a warranty of safety or efficacy. Was it legally and ethically appropriate to promote a provisionally approved treatment with this level of uncertainty?

# Government Decision-Makers / Human Rights Commission:

- Given that the product had only provisional consent and the trial was ongoing, why was the rollout not assessed under both s10 (medical experimentation) and s11 (informed consent) of the New Zealand Bill of Rights Act?
- Why were healthy individuals, including children and teenagers, not protected under these rights, especially considering their low risk from COVID-19?

https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html#DLM55061



# 1.7 PROVISIONAL CONSENT

RC Term - Vaccine Approval - New Zealand

B. Court Case and Subsequent Change to Medicines Act around provisional consent limitations

Sue Grey and Dr Alison Goodwin

#### Why this issue is relevant:

This case highlights a critical moment where legal safeguards around medicine approvals, designed to protect public safety, were swiftly removed through extraordinary legislative action. The High Court found that the government's use of provisional consent for a nationwide vaccine rollout was unlawful under existing legislation. Rather than address the court's concerns, the government amended the law the very next day, without public consultation, to remove the constraint that had triggered the ruling. This raises serious concerns about regulatory integrity, the erosion of democratic processes, and the potential for future use of provisional approvals without adequate evidence of safety, quality, or efficacy.

In May 2021, a High Court ruling found that the government's use of provisional consent under the Medicines Act was unlawful, as it was intended only for restricted use in a limited number of patients – not for a population–wide vaccine rollout. Rather than reconsider its approach, the government amended the Act the very next day to remove the limiting clause.

The Bill passed all three readings in a single day, an extremely rare move, without public consultation. This bypass of legal safeguards paved the way for the mass use of provisionally approved medicines without the usual evidence of safety, quality, or efficacy, setting a concerning precedent for future public health decisions.

#### **Details:**

Provisional consent under s23 of the Medicines Act 1981 originally allowed medicines to be approved "on a restricted basis for the treatment of a limited number of patients." This clause was a critical safeguard to prevent unproven medications from being widely distributed (September 2020 version).

On 18 May 2021, the High Court ruled in Nga Kaitiaki Tuku Iho Medical Action Society Inc v Minister of Health that **the use of provisional consent to justify a population-wide rollout of the Pfizer vaccine was inconsistent with the law.**<sup>2</sup>

Instead of revisiting the legality or ethics of the rollout, the government introduced a Bill the very next day (19 May) to delete the limiting phrase from the Medicines Act. The Bill passed all three readings in one day, an extremely rare event, without public consultation. It received Royal Assent on 24 May 2021.

From that point forward, provisional consent could legally authorise mass use of medicines, despite safety, quality, and efficacy data lacking.

### Important Questions for the Commissioners to Ask — and of Whom:

#### Minister of Health / Parliamentarians:

- Why was there no opportunity for public input into such a significant and far-reaching amendment to the Medicines Act?
- What precedent does this set for future legislation or regulation of new or experimental medicines?

#### Medsafe / Ministry of Health:

- What protections now exist to prevent the mass use of provisionally consented products with no submitted evidence of safety, quality, or efficacy?
- Was the rapid amendment process consistent with principles of democratic accountability, transparency, and informed public health policy?

- https://www.legislation.govt.nz/act/public/1981/0118/81.0/DLM53790.html
- <sup>2</sup> https://jade.io/article/1021982
- https://www.legislation.govt.nz/act/public/1981/0118/84.0/DLM53790.html



# 1.7 PROVISIONAL CONSENT

RC Term - Vaccine Approval - New Zealand
C. Medsafe's 58 Conditions on Pfizer provisional consent limitations

Dr Alison Goodwin

#### Why this issue is relevant:

In February 2021, Medsafe granted provisional consent for Pfizer's Comirnaty vaccine, subject to 58 significant (not insignificant) conditions. These included the provision of critical safety, efficacy, manufacturing, and quality control data after rollout began.

Despite this, New Zealand proceeded with a mass vaccination campaign in parallel with the vaccine clinical trial. When official requests were made to view Pfizer's data submitted in response to the 58 conditions, Medsafe withheld the information, citing commercial sensitivity.

#### This raises serious concerns about:

- · Public safety
- Public transparency
- · Regulatory oversight
- · Informed consent
- Protection of patient rights

Medsafe approved Comirnaty on a provisional basis for 9 months with 58 post–approval conditions.<sup>1</sup>

These conditions involved outstanding clinical trial data, manufacturing validation, safety monitoring, information to confirm manufacturing and purity (see Issue 1.4A, page 130).

The vaccine was rolled out nationally before Pfizer met these requirements.

Medsafe later extended deadlines for Pfizer to comply with the 58 conditions and ultimately refused to release Pfizer's response data, citing commercial sensitivity.

This lack of transparency compromised the public's ability to give informed consent.

#### **Details:**

#### Key Points from the 58 Conditions

- Safety Data: Full 12-month safety data from Pfizer's pivotal trial C4591001 was still pending at the time of rollout.
- Manufacturing Process & Consistency: The vaccine used in mass rollout (Process 2) differed from the product used in clinical trials (Process 1) (see Issue 1.4B, page 132). Pfizer was required to validate the comparability between these two processes — data that was not available at the time of public use.
- Product Characterisation & Impurities: Pfizer was required to evaluate the presence of truncated and modified mRNA species and unintended protein translation (with potential autoimmune/genotoxic implications) and to provide detailed data on impurities in the lipid nanoparticles (ALC-0315 and ALC-0159), including elemental impurities and solvent residues.
- Pharmacovigilance: Pfizer was obligated to submit Periodic Safety Update Reports (PSURs) and maintain an evolving Risk Management Plan (RMP).
- **Labelling:** New Zealand-specific packaging and labelling was required, with clarity on the provisional nature of approval.
- Subpopulations: There was no requirement to demonstrate efficacy in key vulnerable groups (e.g. Māori, Pacific peoples, pregnant women, immunocompromised).

## Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe unless otherwise specified:

#### On Provisional Approval and Timelines

- Why was provisional consent granted before key safety and efficacy data were available?
- Were the 58 conditions ever fulfilled by Pfizer? If so, when? If not, why did vaccination continue?
- What were the outcomes of the 58 conditions?
- Were any timelines extended beyond those published in the original Gazette? On what basis?

#### On Safety Monitoring and Oversight

- Were Pfizer's required Periodic Safety Update Reports (PSURs) submitted? If so, what followup actions were taken?
- Was an independent safety monitoring system (external to Pfizer) established to track adverse events?
- Was the Risk Management Plan (RMP) updated as real-world data emerged? What changes were made?

#### On Informed Consent and At-Risk Populations

- Were healthcare professionals and the public explicitly informed that:
- The vaccine was only provisionally approved?
- Key safety and efficacy data were still pending?
- The product had not been specifically tested in vulnerable subgroups?

#### On Transparency, Manufacturing, & Consistency

- Why was Pfizer permitted to supply vaccines manufactured using a different process (Process 2) than the one used in clinical trials (Process 1), before providing data validating product comparability?
- What oversight was in place to confirm the safety, efficacy, and consistency of Process 2-manufactured vaccine batches?
- Were any changes in manufacturing process or formulation disclosed to the public during rollout, including the shift from Process 1 to Process 2 or changes in excipient buffers (e.g. PBS to Tris)?

#### On Impurities and Genotoxic Risk

- What concerns existed about truncated mRNA, unintended protein expression, and potential autoimmune or genotoxic effects?
- Were impurity profiles (including elemental and solvent residues in LNPs ALC-0315 and ALC-0159) fully assessed and publicly disclosed?

#### Ministry of Health / Cabinet:

 Given the known "missing information" for several subgroups (e.g. pregnant women, Māori, immunocompromised), why were these populations specifically prioritised in public vaccination campaigns?

#### References:

https://www.medsafe.govt.nz/COVID-19/Comirnaty-Gazette.pdf



# 1.7 PROVISIONAL CONSENT

RC Term - Vaccine Approval - New Zealand
D. Medsafe Technical Data Sheets

Lynda Wharton

#### Why this issue is relevant:

The original Medsafe technical data sheet for Pfizer's Comirnaty mRNA vaccine (Feb 2021) clearly indicated numerous gaps in safety and efficacy data, which is at odds with the public message "safe and effective". These had not been rectified in subsequent versions of the Medsafe datasheet.

Further, the uncertainties were not disclosed during the informed consent process.

#### This raises serious concerns about:

- Public safety
- Public transparency
- · Regulatory oversight
- · Informed consent
- Protection of patient rights

The February 2021 Comirnaty Data Sheet issued by Medsafe listed significant unknowns: no data on genotoxicity or carcinogenicity, unassessed efficacy and safety in immunocompromised individuals, unknown duration of protection, and only limited data in pregnancy and lactation.

Despite these caveats, New Zealand's vaccine rollout and mandates proceeded without communicating this uncertainty. Pregnant women, immunocompromised patients, and even individuals who had experienced anaphylaxis were encouraged or required to take the vaccine, often without a full disclosure of known risks and unknowns. The "safe and effective" slogan was not aligned with Medsafe's own documentation, calling into question the transparency of public health messaging and the ethical integrity of the informed consent process.

#### Details

Excerpts from the original Medsafe Comirnaty Data Sheet (Feb 2021)<sup>1</sup>:

- Anaphylaxis: Incidence cannot be estimated from available data (pg. 6). A second dose should not be given to individuals who experienced anaphylaxis (pg. 3).
- Immunocompromised: Safety and efficacy not assessed in this group. Efficacy may be lower (pg. 3).
- Duration of Protection: Unknown; still under investigation (pg
   3).
- · Pregnancy & Lactation:
  - Pregnancy: Limited experience. Should only be given if benefits outweigh risks (pg. 4).
  - · Lactation: Unknown if excreted in breast milk (pg. 4).
- Genotoxicity/Carcinogenicity: No studies performed. Components not expected to be genotoxic (pg. 9).

#### Rollout context vs. data sheet content:

- May 2021: Border workers, including pregnant/breastfeeding women, were mandated. Medsafe had not approved for use in pregnancy until July 2021.
- Immunocompromised individuals were among the first vaccinated without disclosure of unassessed safety/efficacy.
- Anaphylaxis patients were instructed to take the second dose in hospital settings (with a crash cart present).
- Frail elderly were targeted early, often in residential care settings, without documented individual risk/benefit assessments.
- Pregnant women were encouraged to vaccinate from July 2021, even as the data sheet continued to state "limited experience."
- Further versions of the data sheet were issued in December 2022<sup>2</sup> and January 2025<sup>3</sup>

# Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe:

- Given the significant gaps in safety and efficacy data noted in Medsafe's own technical data sheet, what evidence justified the public messaging of "safe and effective"?
- What criteria did Medsafe use to support the vaccination of immunocompromised individuals, given the absence of safety and efficacy data for this group?
- What risk/benefit assessments were conducted to justify recommending the vaccine to pregnant and breastfeeding women prior to July 2021? Was this consistent with Medsafe's stated caution in the data sheet?
- What specific guidance or training did Medsafe provide to vaccinators and healthcare providers to ensure patients were properly informed of the unknowns and cautions listed in the data sheet?
- How did Medsafe expect medical professionals to assess the risks for pregnant women when clinical data were lacking and the risk from COVID-19 to this demographic remained uncertain?

#### **Medical Council of New Zealand:**

 If doctors were instructed to only use provaccine messaging, how were they expected to meet their ethical obligation to provide full informed consent—including disclosing known risks and documented unknowns?

- <sup>1</sup> Feb 2021
  - https://drive.google.com/file/d/18086yafxnxQ60pgyWHNuNWv9ccRAf2de/view?usp=sharing
- Dec 2022 https://web.archive.org/web/20230219022700/https://www.medsafe.govt.nz/profs/datasheet/c/ComirnatyOriginalOmicron
- <sup>3</sup> Jan 2025 https://www.medsafe.govt.nz/profs/datasheet/c/ComirnatyOriginalOmicronBA4-5inj.pdf



# 1.7 PROVISIONAL CONSENT

# RC Term - Vaccine Approval - NZ E. Use of vaccine in pregnancy

Katie Ashby-Koppens

#### Why this issue is relevant:

Medsafe's internal safety assessment of the Pfizer COVID-19 vaccine raised important uncertainties about its use in pregnancy. Yet, public health authorities promoted it as "safe and effective" for pregnant and breastfeeding women. This contradiction had major implications for informed consent and public trust.

#### Pregnant women were vaccinated:

- · Without full disclosure of known risks
- Without adequate trial data or a transparent riskbenefit assessment
- In some cases, under pressure or mandates to comply



Billboard in New Zealand

Pregnant women are typically excluded from clinical trials due to ethical and scientific concerns. Nevertheless, the Pfizer COVID-19 vaccine was recommended for pregnant women in New Zealand in June 2021.

Medsafe's **Non-Clinical Assessment** (January 2021)<sup>1</sup> identified critical uncertainties:

- Lipid nanoparticles (LNPs) did not remain at the injection site but instead distributed systemically, accumulating in various organs, including the ovaries (see issue 1.9, page 168).
- · The assessment stated:

"Although not directly addressable from the non-clinical data, there may be a basis in the current circumstances for concluding the risk of vaccination during pregnancy is outweighed by the potential benefits of immunity particularly for specific subpopulations at heightened risk."

· The proposed data sheet cautioned that:

"Administration of Comirnaty in pregnancy should only be considered when the potential benefits outweigh any potential risks for mother and fetus."

When requested under the Official Information Act, **Medsafe** withheld 52 of 57 pages of the Non-Clinical Assessment, significantly limiting public and professional scrutiny.

Despite these limitations, from 10 June 2021, New Zealand public health messaging strongly promoted the vaccine for use at any stage of pregnancy, with no public release of a formal risk-benefit analysis.<sup>2,3</sup> This was despite acknowledgement menstrual cycles were being affected.

The Medical Council of New Zealand (see Issue 15.A) issued directives forbidding doctors from discussing vaccine risks or offering alternatives, coercing them into breaching informed consent principles. These actions may not only constitute serious violations of medical ethics but also breaches of the Medicines Act 1981 and the New Zealand Bill of Rights Act 1990, with potentially far-reaching legal and ethical consequences.

## Important Questions for the Commissioners to Ask — and of Whom:

Obtain a full unredacted version of the Medsafe's Non-Clinical Assessment (January 2021)

#### Chris James, Medsafe Group Manager:

- Why did Medsafe withhold 52 of 57 pages of the Non-Clinical Assessment under the OIA?
- Given the biodistribution data showing systemic spread of LNPs, including accumulation in reproductive organs, why was this not communicated publicly or included in consent processes?
- How do you justify the statement that LNP distribution is not concerning, despite it differing significantly from traditional vaccine behaviour?
- Why was no public risk-benefit analysis released prior to the June 2021 decision to recommend Comirnaty for all stages of pregnancy?

#### Ministry of Health Officials:

- On what evidence was the "safe and effective" claim for pregnant women based?
- Why was the public messaging so unequivocal despite Medsafe's own cautionary language?
- Were alternative options (e.g. deferral of vaccination or non-mRNA alternatives) discussed internally, and if so, why were they not offered to the public?

- Medsafe Non-Clinical Assessment Jan 2021 Redacted https://drive.google.com/file/d/18086yafxnxQ60pqyWHNuNWv9ccRAf2de/view?usp=sharing
- Messaging for pregnant women in June 2021: https://www.auckland.ac.nz/en/news/2021/06/10/research-backs-offering-pregnant-women-covid-vaccine.html
- Medsafe's Safety Assessment of the Pfizer Vaccine for Pregnant Women <a href="https://www.medsafe.govt.nz/safety/Alerts/covid-19-vaccination-in-pregnancy.asp#:~:text=Medsafe%20and%20the%20">https://www.medsafe.govt.nz/safety/Alerts/covid-19-vaccination-in-pregnancy.asp#:~:text=Medsafe%20and%20the%20</a>
- <sup>4</sup> Messaging for periods being affected but nothing to worry about https://theconversation.com/could-the-covid-vaccines-affect-your-period-we-dont-know-yet-but-theres-no-cause-for-



# 1.7 PROVISIONAL CONSENT

RC Term - Vaccine Approval - New Zealand F. Timeline and approvals - 12 to 18-year-olds

Katie Ashby-Koppens

#### Why this issue is relevant:

The government's decision to provisionally approve the adult dose of Pfizer Comirnaty for 12–18 year olds disregarded the government's own expert technical advice intended to reduce risks, particularly the risk of myocarditis (through a single dose and/or longer dosing interval).

Internal government documents revealed a deliberate effort to suppress public communication about these safety measures, suggesting that the decisions to approve the vaccine for this age group were politically, rather than health, motivated.

The government provisionally approved the adult dose of Pfizer Comirnaty for 12–18 year olds, ignoring advice from its technical experts to reduce known risks, namely:

- Single dose recommendation permitting under-18s to receive only one dose for the purpose of workplace mandates.
- Extended interval increasing the interval between the first and second dose from three weeks to at least eight weeks in under 30s to reduce myocarditis risk.

Government documents reveal a deliberate intention to remove public messaging referencing longer dosing intervals as a protective measure against myocarditis.

#### Details

#### Early-Mid 2021: Initial Vaccine Considerations

- 1 June 2021: Medsafe provisionally approves the Pfizer vaccine for 12 to 15-year-olds.<sup>1</sup>
- 22 June 2021: CV TAG advises against vaccinating this group due to myocarditis risk.<sup>2</sup>
- 20 July 2021: CV TAG again advises deferral but considers high-risk groups.<sup>2</sup>
- 21 July 2021: CV TAG recommends extending the dose interval to at least eight weeks for 16–29 year olds.<sup>3</sup>
- 3 August 2021: CV TAG supports vaccination only for high-risk 12–15-year-olds.<sup>4</sup>
- 4 August 2021: Memo confirms CV TAG's recommendation.<sup>4</sup>

#### August 2021: Sudden Policy Shift & Lockdown

- 12 August 2021: CV TAG reverses its position, recommending vaccination for all 12 to 15-year-olds.<sup>1</sup>
- 12-13 August 2021: CV TAG recommends full rollout via email, citing Delta urgency - no supporting evidence included in the memo.<sup>4</sup>
- 16 August 2021: Cabinet discusses vaccinating all 12-15 year olds.<sup>4</sup>
- August 2021: NZ enters Level 4 lockdown after Delta detection.
- CV TAG's July 21 myocarditis advice is excluded from public messaging - claimed to be due to "insufficient evidence."<sup>5</sup>
- 19 August 19, 2021: PM Ardern announces vaccine approval for all 12 to 15-year-olds, citing expert advice.<sup>6</sup>

#### Late 2021: Dose Interval Controversies & Risk Communication

 12 August 2021: Government announces a six-week interval between doses but removes references to myocarditis risk in public messaging.<sup>7</sup>  6 September 6, 2021: Dr Helen Petousis-Harris (member of CV TAG and IIAG) raises concern via email about the exclusion of myocarditis in informed consent materials and after-care sheets, asking:

"Is someone on the email able to explain why we are not including myocarditis in the informed consent process or on the after-care sheet? Seems to me important to highlight the very small risk, symptoms to be aware of and what to do should they arise, like we do with routine rotavirus vaccine and intussusception."<sup>17</sup>

Her concern is acknowledged by MoH, and a response on September 8 says updated materials are in "final stages of approval."

However, days later, she indicates she had not heard back from the Quality and Safety team and raised concern that vaccinators be well-informed and confident in discussing myocarditis risk.<sup>17</sup>

- 21 September 2021: CV TAG expresses doubts about the full rollout to 12 to 15-year-olds.<sup>4</sup>
- 15 October 2021: CV TAG reportedly agrees to reduce the dose interval back to 3 weeks, despite concerns in their September 21 minutes about increasing use of short intervals and unresolved questions about safety in under-30s.8
- 6 October 2021: Government abruptly reverts back to a three-week dose interval, contradicting CV TAG's safety recommendations. At a press conference, Dr McElnay claims there were "no safety concerns" with the 3-week interval despite CV TAG minutes from the previous day expressing a desire for more data on interval-related side-effects.<sup>9</sup>

#### Late 2021 - Early 2022: Mandates & Paediatric Rollout

- 11 November 2021: CV TAG recommends under-18s receive only one dose for mandates.10
- 9 December 2021: CV TAG formalises this recommendation.<sup>10</sup>
- 15 December 2021: CV TAG recommends 8-week interval for 5–11-year-olds, consistent with Australia and Canada.<sup>11</sup>
- 16 February 16, 2022: CV TAG reconfirms this in a safety review.<sup>12</sup>

#### 2023: Post-Facto Justification

 February 2023: Ministry of Health states it cannot comment on why CV TAG advice was or wasn't adopted.<sup>13</sup>

#### See Cranmer's Substack:

- Part 1: PM's "No. 1 priority is medical advice" claim scrutinised. 14
- Part 2: "Two Shots for Summer" contradicted health advice. 15
- Part 3: MoH says it cannot explain deviations from expert advice.<sup>16</sup>

## Important Questions for the Commissioners to Ask — and of Whom:

#### CV TAG / Dr Ian Town:

- What new data prompted CV TAG to reverse its August 3 recommendation by email on August 122
- Why was this done outside scheduled meetings without supporting evidence?
- Did CV TAG re-assess the risk-benefit profile for healthy 12 to 15-year-olds, given myocarditis risks?
- Why didn't CV TAG insist its 8-week interval advice be retained when govt reverted to 3 weeks?
- Was CV TAG asked to validate a political decision rather than being consulted for safety advice?
- Who instructed the removal of public references to interval length and myocarditis risk?
- Did CV TAG object to this omission?
- Was CV TAG satisfied that informed consent was truly possible without clear public messaging?
- Why did CV TAG's single-dose advice for under-18s not result in policy change?
- Did CV TAG review how its advice was presented to Cabinet and the public?

#### **Helen Petousis-Harris:**

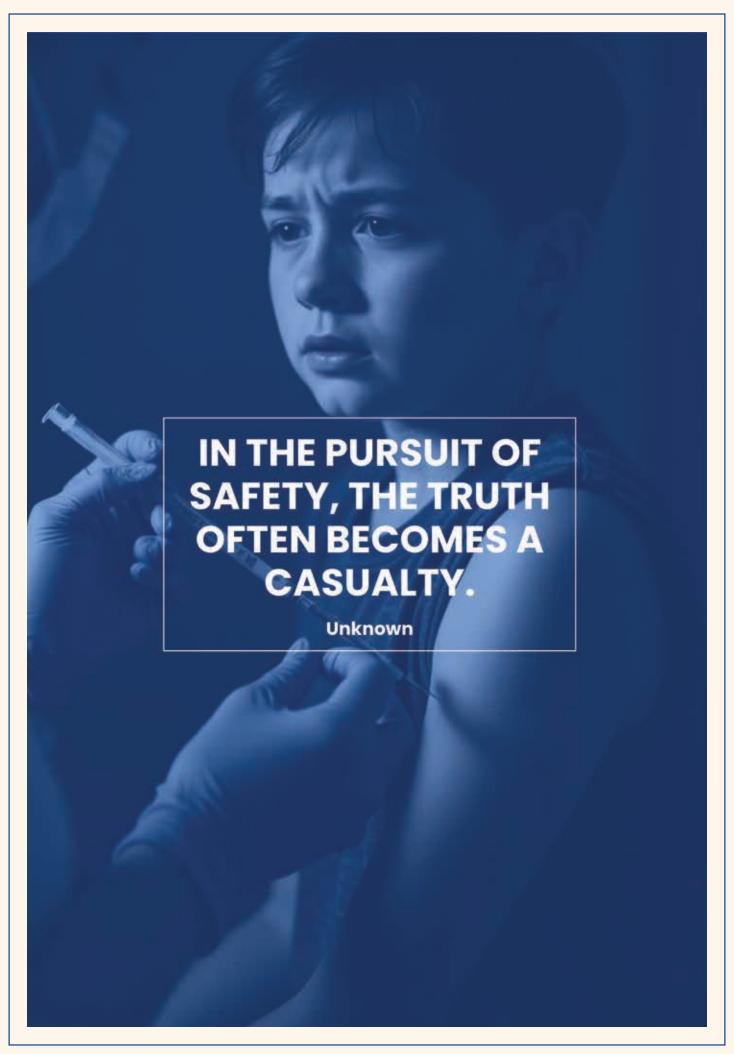
Your email to the COVID-19 Immunisation Implementation Advisory Group on 6 September 2021 raised a key issue:

- "Why are we not including myocarditis in the informed consent process or on the after-care sheet?"
- Were you satisfied with the Ministry of Health's response and the follow-through on this issue?
- Do you believe the risk of myocarditis was ultimately communicated clearly and consistently to the public and to vaccinators?
- Was there any internal resistance to your request, and was this risk ever downplayed or suppressed in communications against your advice?

#### **Director-General of Health:**

- What changed between CV TAG's advice on August 20 and the policy decision on August 23?
- Were there MoH-PMO or MoH-Cabinet communications influencing the shift?
- How were risks/benefits for healthy teens evaluated, especially with myocarditis concerns?
- Why was a phased or targeted rollout not considered as advised?
- What steps were taken to ensure adequate informed consent?
- Can the Ministry provide all communications from August 15–23, 2021?
- Does the Ministry still believe overriding CV TAG's recommendation was justified?

- Cabinet paper: decision to use the COVID-19 Pfizer vaccine for children aged 12 to 15 years <a href="https://web.archive.org/web/20230115180046/https://www.">https://web.archive.org/web/20230115180046/https://www.</a>
- <sup>2</sup> CV TAG recommendations June 24, 2021 https://web.archive.org/web/20220528063514/https://www.
- 3 CV TAG myocarditis interval advice July 21, 2021 https://web.archive.org/web/20221003112843/https://www.
- CV TAG priority group memo August 4, 2021 https://web.archive.org/web/20230115180058/https://www.
- Medsafe safety alert Comirnaty and myocarditis https://www.medsafe.govt.nz/safety/Alerts/comirnaty-myo
- 6 PM Ardern press release August 19, 2021 https://web.archive.org/web/20210820003212/https://www.
- Oovernment extends dose interval August 12, 2021 https://web.archive.org/web/20220124194040/https://
- Parliamentary written question Chris Bishop to Minister for COVID-19 Response <a href="https://www.parliament.nz/en/pb/order-paper-questions/">https://www.parliament.nz/en/pb/order-paper-questions/</a>
- 9 NewsHub Changing advice on vaccine dose intervals https://www.newshub.co.nz/home/politics/2021/10/three-
- OV TAG stance on mandating vaccinations for under-18s December, 9 2021 https://web.archive.org/web/20230116181651/https://www.
- CV TAG recommendation on 5-11-year-old Pfizer dose interval December 15, 2021 https://web.archive.org/web/20221003110304/https://www.
- CV TAG reconfirms 8-week interval for 5-1ls February 16, 2022 https://web.archive.org/web/20230116181625/https://www.
- Cranmer Substack COVID and our Kiwi Kids: The Ministry https://cranmer.substack.com/p/covid-and-our-kiwi-kids
- Cranmer Substack COVID and our Kiwi Kids: Part 1 https://cranmer.substack.com/p/covid-and-our-kiwi-kids-
- 15 Cranmer Substack COVID and our Kiwi Kids: Part 2 https://cranmer.substack.com/p/covid-and-our-kiwi-kids-
- 16 Cranmer Substack COVID and our Kiwi Kids: Part 3 https://cranmer.substack.com/p/covid-and-our-kiwi-kids-
- <sup>17</sup> University of Auckland OIA Response Helen Petousis-Harris myocarditis email (PDF, OIA 2024-OIA-0033-KatieAK)





# 1.8 EPA APPROVAL

RC Term - Vaccine Approval - New Zealand
Environmental Protection Agency's (EPA) Gene Therapy review

Jodie Bruning and Elvira Dommisse

#### Why this issue is relevant:

The EPA adopted a narrow and technical interpretation of "organism" and relied solely on Pfizer's data to approve the mRNA vaccine without proper risk assessments. This bypassed safety reviews required under the Hazardous Substances New Organisms (HSNO) Act 1996 and ignored known concerns about DNA integration, environmental impact, and cumulative effects of mRNA technology. The persons tasked with the review were not sufficiently qualified and their review relied on information supplied from Pfizer.

In early 2021, the EPA determined that Pfizer's mRNA vaccine (Comirnaty/BNT162b2) was not a genetically modified organism (GMO) under the HSNO Act. It applied a narrow, technical definition of "organism" and did not consider whether the modified genetic material posed health or environmental risks. The EPA claimed the vaccine did not qualify as a GMO because it used synthetic mRNA that did not self-replicate or form a complete organism. This classification meant the vaccine avoided GMO-related safety and environmental risk assessments required under the HSNO Act: EPA Staff Assessment Report; and Application & Documents (EPA database).

#### Key concerns include:

- Lack of independent review: The EPA relied entirely on Pfizer's application data without consulting external or peerreviewed sources.
- Absence of relevant expertise: The decision was made by Dr Kerry Laing, an environmental scientist, and Dr Julie Everett-Hincks, an animal scientist - no genomics, molecular biology, or virology experts were involved.
- Ignored scientific uncertainty: The EPA did not assess potential mRNA integration into the human genome, spike protein toxicity, or cumulative effects from boosters.
- Failure to apply the precautionary principle: Required under s7 of the HSNO Act, this was notably absent from the EPA's report.
- Fast-tracked approval: Pfizer's application was approved within four business days, coinciding with Medsafe's provisional consent.

#### Relevant sections of the HSNO Act 1996:

- Section 2 Defines GMOs as organisms modified by in vitro techniques or inheriting modified genes.
- Section 4 Mandates protection of public and environmental health.
- Section 7 Requires precaution where scientific uncertainty
   ovicts
- Section 26 Basis of EPA's determination (Pfizer's application).<sup>3</sup> By not classifying mRNA vaccines as GMOs, the EPA avoided required oversight and set a precedent for ignoring the possible long-term health and environmental consequences of novel gene technologies.

#### Citizens' Petition to the FDA (2024):4

See also the open Citizens' Petition to the FDA which alleges Pfizer and Moderna misclassified their mRNA products as vaccines instead of gene therapy products, enabling the companies to avoid legally required FDA environmental assessments.<sup>4</sup>

#### References:

- https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP204176/
- <sup>2</sup> https://www.epa.govt.nz/database-search/hsno-applicatio
- 3 https://www.legislation.govt.nz/act/public/1996/0030/latest/
- 4 https://childrenshealthdefense.org/wp-content/uploads/

Further commentary – Jodie Bruning article: https://jrbruning.substack.com/p/how-did-our-nzepa-fail-to-

## Important Questions for the Commissioners to Ask — and of Whom:

# Regulatory Interpretation and Legal Compliance (EPA)

- Why did the EPA adopt a narrow definition of "organism" that required self-replication, instead of applying the broader definition of a genetically modified organism (GMO) as outlined in section 2 of the HSNO Act?
- Given the HSNO Act includes organisms modified by in vitro techniques, on what basis did the EPA exclude synthetic mRNA from being classified as a GMO?
- Did the EPA apply or consult any internal policy guidelines or legal advice relating to the precautionary principle under section 7 of the HSNO Act when assessing Pfizer's application?

#### Scientific Basis and Risk Assessment (EPA)

- What independent scientific or peer-reviewed evidence did the EPA review regarding the potential for mRNA integration into the human genome, and why were concerns raised in the literature not addressed in the assessment?
- Did the EPA assess the potential cumulative risks associated with repeated booster doses of the vaccine, particularly with regard to genetic integration and immune system burden?

#### Scientific Basis and Risk Assessment (EPA)

- How did the EPA ensure that the four-day review period for Pfizer's Section 26 application was sufficient to assess the genetic and safety implications of a novel gene-based technology?
- Who drafted the EPA's Assessment Report, and were any external peer reviewers or independent experts in molecular biology, genomics, or virology consulted during the process?

# Accountability and Broader Oversight (EPA, Ministry for the Environment)

- By determining that the mRNA vaccine was not a GMO, did the EPA circumvent its legal responsibility to conduct safety and environmental risk assessments under the HSNO Act?
- What systems are in place within the EPA to detect and correct potential misclassifications of new biotechnologies, and has the EPA revisited its 2021 decision in light of new scientific developments?
- Has the Ministry for the Environment provided oversight or reviewed the EPA's handling of gene-based technologies, particularly in fasttracked or high-impact applications?



# 1.9 - BIODISTRIBUTION

#### RC Term - Vaccine Approval - New Zealand

Associate Professor Byram Bridle

#### Why this issue is relevant:

From the start of the COVID-19 vaccine rollout, public health officials and pharmaceutical companies assured the public that the Pfizer mRNA vaccine functioned like traditional vaccines – remained at the injection site and induced an immune response only in local draining lymph nodes. Pfizer and the regulators knew it did not. Pfizer's own biodistributions study submitted to regulators confirmed that the LNPs travelled systemically and persisted in the body beyond the short 48-hour study window, and confirmed what had been reported on the lipid nanoparticle (LNP) technology in the previous decade. A deliberate effort was made to withhold critical safety data from the public.

In May 2021, a biodistribution study submitted by Pfizer to Japanese health authorities was brought to the public's attention by Associate Professor Byram Bridle (Japanese Study). The study revealed that the LNPs carrying the mRNA did not remain at the injection site as claimed. Instead, most of the dose rapidly spread throughout the body, accumulating in critical organs such as the liver, spleen, adrenal glands, and – most concerningly – the ovaries. The study found that LNP concentrations peaked in some organs within 48 hours, but due to the study's limited timeframe (48 hours), the full duration of persistence was never properly assessed. This raises serious questions about long-term exposure and safety risks. Despite these alarming findings, public health agencies failed to disclose this critical information, and officials continued to insist that the vaccine components remained localised at the injection site.

In March 2022, a more complete version of Pfizer's biodistribution study became publicly available after a U.S. court order forced the FDA to release documents it had used to authorise the vaccine (U.S. Study). Pfizer/FDA sought a 75-year moratorium on disclosure.

The biodistribution study also revealed that Pfizer had originally tested a higher dose, which resulted in significant toxicity in animal trials, including death – yet rather than reconsidering the safety profile, the company simply lowered the dose and moved forward. Further, the FDA's version of the biodistribution study revealed that the study report submitted to New Zealand's regulator was confounded by combining data from males and females to give the incorrect impression that LNP accumulation had plateaued in most tissues. Parsing out the data from the FDA's version of the report showed that LNP concentrations were still increasing, in some cases nearly exponentially, in almost all female tissues at the termination of the study.

The U.S. Study when placed alongside the Japanese Study showed that the U.S. Study had cropped images and redacted data to facilitate publishing of incorrect conclusions about biodistribution and duration of persistence of mRNA in the body.

#### Details:

The LNP-encapsulated mRNA spread throughout the body, accumulating in critical organs such as the liver, spleen, adrenal glands, and, most concerningly, the ovaries which raises significant concerns because each of these organs plays a crucial role in maintaining homeostasis, immunological functions, hormonal balance, and reproductive health.

The unintended accumulation of LNPs and subsequent spike protein production in these organs could have serious, long-term health implications.

#### 1. Liver (Hepatic Accumulation & Toxicity Risks)

The highest concentration outside the injection site was found in the liver. Male rats: 27.916  $\mu$ g lipid/g (21.5% of dose). Female rats: 30.411  $\mu$ g lipid/g (18.4% of dose).

Maximum concentration in the liver was observed at 8 hours post-dose in males and 48 hours in females, contradicting claims that biodistribution was minimal.

#### 2. Spleen (Immune System Concerns)

The highest concentration in the spleen was: Males: 24.434  $\mu g$  lipid/g.

Females: 27.155 µg lipid/g (1.1% of dose).

Peak spleen concentration appeared at 8 hours post-dose in males and 48 hours post-dose in females.

### 3. Blood and Lymph Nodes Throughout the Body (Systemic Dissemination Via Blood)

LNPs were found in the blood. They were also found in every lymph node that was examined. Each lymph node drains fluids from solid tissues in a discrete anatomical location. So, finding LNPs in lymph nodes throughout the body is indicative of solid tissues throughout the body getting seeded with the LNPs. Also, the spleen, to which the LNPs get distributed, is designed to filter particulates from blood. Combined, the data from blood, spleen, and lymph nodes is a clear indication of systemic biodistribution of LNPs via the circulatory system.

#### 4. Adrenal Glands (Hormonal Disruption)

The highest concentration in the adrenal glands was: Males:  $21.476 \ \mu g \ lipid/g$ .

Females: 14.942 µg lipid/g (0.1% of dose).

Accumulation peaked at 48 hours post-dose.

#### 5. Ovaries (Reproductive Health & Fertility Concerns)

The highest concentration in the ovaries was:

Females: 12.261 µg lipid/g (0.1% of dose)

Accumulation in ovaries was still rising at the end of the study, suggesting a continued increase beyond 48 hours, which was never studied further.

## Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe and former DG Health:

- When did NZ receive all versions of Pfizer's biodistribution study?
- What information did the government base its messaging on that the vaccine stayed in the arm.?

#### References:

See Associate Professor Byram Bridle's expert reports filed in The Kiwi Kids' Case:

Second report:

https://thehoodnz.com/storage/app/media/Kids%20Case/BridleFurther2.pdf

Third report

https://thehoodnz.com/storage/app/media/Kids%20Case/BridleReply2.pdf

(For context First report:)

https://thehoodnz.com/storage/app/media/Kids%20Case/Bridle\_Affadavit2.pdf



# 1.10 LIPID NANOPARTICLES

RC Term - Vaccine Safety
Scientific Studies Timeline LNPs and safety
concerns in mRNA COVID-19 vaccines

Hilary Butler

#### Why this issue is relevant:

Lipid nanoparticles (LNPs) are used to deliver mRNA in COVID-19 vaccines, such as Pfizer's Comirnaty and Moderna's Spikevax. While granted "Generally Recognized As Safe" (GRAS) status by regulators, there were longstanding concerns about LNP safety prior to the COVID-19 vaccine rollout, particularly relating to immune system activation and hypersensitivity. Post-rollout research has only deepened these concerns. These issues raise urgent questions about the adequacy of pre-approval safety assessments and ongoing regulatory oversight.

- The risks of LNP technology listed above have been known for over 40 years.
- Despite this, regulators did not review or reassess these risks during the Emergency Use Authorization approval process.
- Post-rollout animal studies in 2022 and 2024 confirmed that mRNA-LNPs can profoundly disrupt both adaptive and innate immune functions, cause inflammation, anaphylaxis-like reactions, autoimmunity, and suppress mRNA translation, and have additive effects with the mRNA of spike toxaemia, multi-organ toxicity, immune dysfunction, neuropathies, coagulopathies, and more complex autoimmunity.
- These findings collectively challenge the original GRAS classification of LNPs and call for urgent regulatory reassessment.

Chronological Timeline of Key Findings & Concerns:

Pre-2020 – Existing Knowledge on PEGylated Lipids & Immunological Reactions

#### Known Risks:

- Evidence of PEG-related anaphylactoid reaction listing hypotension, cardiac output reduction, thromboxane release, IL-6 release, fever and death.<sup>1</sup>
- These haemodynamic changes were confirmed and termed Complement Activation-Related Pseudoallergy (CARPA). These reactions after PEGylated lipids used in nanoparticleformulated drugs are not mediated by IgE but are triggered by all four complement cascades. Dr. János Szebeni has for 40 years highlighted anaphylaxis-like responses and non-target effects after administration of PEGylated drugs, especially in persons who already have anti-PEG antibodies.<sup>2</sup>
- In more than 200 unvaccinated persons, 97% had anti-PEGylated antibodies, with around 3% with enormous levels of IgM and IgG.<sup>3</sup>
- Repeated exposure to PEGylated liposomes can lead to anti-PEG antibodies which reduce drug efficacy, which raised the risk of adverse reactions upon subsequent exposures to any future liposome drug.<sup>4</sup>

#### 2020-2021 - LNP Use in COVID-19 Vaccine Rollout

- Regulatory bodies like EMA granted Emergency Use Authorization for mRNA COVID-19 vaccines based on limited clinical trial data, despite three decades of medical literature highlighting immunological risks from PEGylated lipids.
- GRAS status for LNPs was maintained without any confirmation
  of the presumed structure of vaccine LNPs, toxic effects, or
  exploration of long-term negative impact on the immune
  system.

2022 – First In Vivo Evidence of Long-Term Immunological Impact

- Study showed that pre-exposure to mRNA-LNPs or LNPs alone suppressed adaptive immune responses for extended periods.<sup>6</sup> The study also documented:
  - · Altered innate immune fitness.
  - Increased resistance to influenza but decreased resistance to fungal infections.
  - · Inheritance of immune changes by offspring.

#### 2024 – Inflammatory Effects and Translational Shutdown

- Research<sup>7</sup> demonstrated that LNPs, once injected, cause:
  - · Strong innate immune activation.
  - · Cell death in immune tissues.
  - Inflammation via cytokines IL-1ß and IL-6.
  - Suppression of mRNA translation, contradicting the idea of LNPs as immunologically inert carriers.

#### 2025 - Expert Perspective on Platform-Wide Risk

 14 February 2025 Dr Szebeni the primary pioneer in LNP safety research, presentation<sup>5</sup> - cited the consequences

- of LNPs as intense immunogenicity, transfection, multiorgan distribution, inflammatory reactions, autoimmune phenomena and somatic hypermutation.
- Dr Szebani considers the many off-target immunological drawbacks a fundamental barrier to the mRNA platform in general - particularly for any LNP/mRNA vaccine development. He warns that these effects are not vaccine-specific but platform-wide, raising serious questions about the viability of this technology for COVID-19 and future applications.

For the full technical details, see the accompanying Expert Annex:  $\ensuremath{^8}$ 

## Important Questions for the Commissioners to Ask — and of Whom:

#### Regulatory Agencies (e.g. Medsafe, EMA):

- What specific data were evaluated by Medsafe to grant GRAS status to the LNPs in mRNA vaccines?
- Have there been any initiatives to re-evaluate the safety profile of both PEGylated drugs and vaccine LNPs in light of emerging evidence of hypersensitivity, anti-PEG antibodies, and autoimmunity indicating potential long-term immunological effects?

#### **Clinical Trial Sponsors and Researchers:**

- Have clinical trials been designed to monitor for potential long-term effects of LNP exposure on adaptive and innate immune responses?
- Is there evidence of altered vaccine efficacy or increased adverse events in individuals with prior exposure to LNP-based formulations?

#### **Public Health Authorities:**

- What guidelines are in place to monitor and manage individuals who develop anti-PEG antibodies due to repeated exposure to PEGylated products?
- Are there strategies to identify and mitigate risks associated with CARPA in populations receiving mRNA vaccines?

- https://pubmed.ncbi.nlm.nih.gov/6704423/
- https://pubmed.ncbi.nlm.nih.gov/10226097/
- 3 https://pmc.ncbi.nlm.nih.gov/articles/PMC10239905/
- 4 https://pubmed.ncbi.nlm.nih.gov/31275462/
- https://odysee.com/@Corona-Investigative-Committee:5/ (Start time: 3.20.03)
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# 1.11 ADVERSE EVENTS

The COVID-19 vaccination campaign was launched in a climate of urgency, trust, and collective responsibility. But as with any medical intervention – especially one rapidly rolled out under emergency provisions – transparency, caution, and responsiveness to emerging safety signals were essential. Instead, the public conversation was tightly controlled, early warnings were downplayed, and adverse reactions – some severe, some fatal – were too often minimised, ignored, or silenced.

This section reflects on what happened when adverse events began to be reported and what the data indicated when it began to accumulate. It highlights the serious, sometimes permanent harm that individuals experienced, and the systemic failures that allowed those harms to be overlooked. Reports of myocarditis, pericarditis, neurological complications, reproductive disruptions, and even death emerged both internationally and in New Zealand (remember New Zealand was 6 months behind the rest of the world). These red flag signals were neither rare nor weak – and yet, the public was not adequately informed, the medical profession was not consistently updated, and existing pharmacovigilance systems were not scaled to meet the moment.

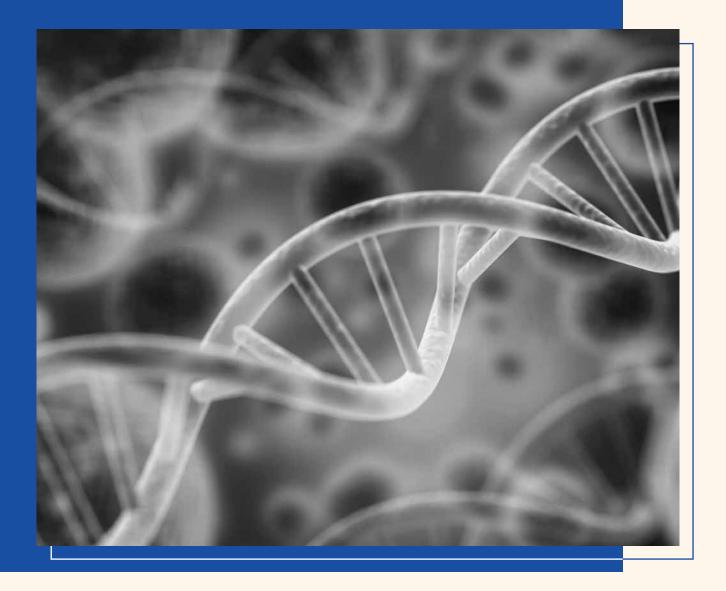
Even the Prime Minister's personal Facebook post encouraging vaccination in late 2021 – intended to reassure the public – unintentionally became a forum for thousands of New Zealanders to share reports of harm and loss following vaccination.

Rather than being treated as valuable signals demanding urgent investigation, many of these comments were reportedly deleted in real time. No changes were made to public messaging. This erasure, symbolic of a broader unwillingness to listen, deepened the public's sense of being unheard and dismissed.

Adverse events are not just numbers; they are lived experiences. Each report represents a person, a family, a life changed. The erosion of informed consent, the lack of tailored risk assessments, and the absence of meaningful follow-up for the injured, mark a sobering chapter in our public health history. This section seeks not only to document what occurred, but to honour those who were affected – and to ask the necessary questions that were not asked when it mattered most.

#### In this section

- A. MRNZ Platform
- **B.** Dangers of the Platform
- C. Myocaditis timeline scientific studies
- D. Myocarditis report, delayed and damning Adverse Events Reports
- E. U.S. VAERS
- F. NZ CARM Adverse Events
- G. NZ CARM Death Reports
- H. Jacinda's Facebook



# 1.11 ADVERSE EVENTS

RC Term: Vaccine Safety

A. mRNA Platform—A view from the inventor

Katie Ashby-Koppens of Dr Malone's evidence he gave in the Kiwi Kids' Case

#### Why this issue is relevant:

The mRNA vaccine technology, central to the COVID-19 response, was originally developed by Dr Robert Malone. His concerns over its rushed deployment, inadequate safety testing, and the suppression of scientific debate challenge the mainstream narrative. Understanding the platform's origins through its inventor's eyes is critical for assessing the integrity of its application and the legitimacy of its continued use.

Dr. Robert Malone played a key role in inventing mRNA vaccine technology in the 1980s and expressed serious reservations about how the platform was used in the COVID-19 pandemic. He highlighted concerns regarding safety, inadequate testing, and authoritarian suppression of dissent. He asserts that key scientific principles were disregarded in the rush to deploy mRNA vaccines under emergency authorisation.

Despite his foundational role, Malone has faced censorship and reputational attacks for voicing these warnings. His perspective challenges the portrayal of mRNA vaccines as settled science, calling for rigorous and open debate based on first principles and risk-benefit analysis.

#### **Details:**

Dr Malone gave the following evidence to the New Zealand government during the Kiwi Kids Case<sup>1</sup>:

- Origin of the mRNA platform: Dr. Malone was the first
  to demonstrate that mRNA could be delivered into cells
  using lipid carriers, enabling protein expression in vivo, a
  foundational step in the development of mRNA vaccines. He
  co-authored key scientific publications and filed patents on
  the technology, marking him as a central figure in its creation.
- Emergency Use and Bypassed Protocols: Malone criticises the use of Emergency Use Authorisation (EUA) to deploy mRNA vaccines without full testing, especially in healthy individuals. He asserts this violated established norms in drug and vaccine development, including toxicology, reproductive testing, and pharmacokinetics.
- Concerns over Safety and Monitoring: He argues that critical safety signals were ignored or suppressed. These include biodistribution of lipid nanoparticles, spike protein toxicity, myocarditis, and reproductive toxicity. Postmarket surveillance, he believes, has been inadequate and manipulated.
- · Medical Concerns with the mRNA Platform:
  - Biodistribution and Spike Protein Toxicity: Malone explains that, contrary to original assurances, the lipid nanoparticles used to deliver mRNA do not stay at the injection site. Instead, they travel throughout the body and accumulate in various organs, particularly the liver, spleen, bone marrow, adrenal glands, and ovaries. This systemic distribution raises serious concerns about off-target effects. Moreover, the mRNA induces cells to produce the SARS-CoV-2 spike protein, which Malone describes as biologically active and cytotoxic, capable of directly damaging blood vessels and organs.
  - Myocarditis and Pericarditis: He notes that young males have experienced significant rates of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the heart's outer lining) following vaccination. These risks, in his view, were downplayed by public health authorities and not properly weighed in risk-benefit analyses, especially for low-risk populations.
  - Reproductive and Fertility Risks: Malone highlights concerns about the accumulation of lipid nanoparticles in reproductive organs and their potential impacts on fertility. He criticises the lack of long-term reproductive toxicology studies, especially given that the technology was administered to pregnant women without adequate safety data, a move he calls "medically indefensible."

- Immunological and Autoimmune Reactions: He warns
  that repeated exposure to spike protein via boosters
  may provoke immune tolerance, antibody-dependent
  enhancement (ADE), or trigger autoimmune conditions.
   The presence of PEG (polyethylene glycol) in the lipid
  nanoparticles is also flagged as a known allergen with the
  potential to cause anaphylaxis.
- Neurological Symptoms: Reports of dizziness, tinnitus, paralysis, seizures, and other neurological issues postvaccination are discussed as possible indicators of neuroinflammatory or autoimmune reactions, which Malone says were not sufficiently investigated.
- Suppressed Early Warning Systems: Malone accuses authorities of ignoring or downplaying safety signals from vaccine injury databases, such as VAERS (U.S.), EudraVigilance (EU), and Yellow Card (UK), as well as suppressing independent physician reports.
- Regulatory Breaches and Absence of Long-Term Data: Malone asserts that basic toxicology, genotoxicity, carcinogenicity, and reproductive safety testing were bypassed due to the EUA framework. He believes regulators failed in their duty of care by authorising the mass deployment of a novel gene therapy platform under pandemic pressure, without adequate long-term data.
- Suppression of Dissent and Informed Consent Violations:
   Malone documents professional retaliation and censorship faced by himself and other scientists who raised alarms. He argues the public was misled into believing the vaccines were "safe and effective" without being provided the information necessary for informed consent, a fundamental principle of medical ethics.

Dr Malone also gave the following presentations, which were played to the Phase 2 Royal Commission:

https://www.dropbox.com/scl/fo/tjqleklzmqlfrbiqcv4kr/AL

# Important Questions for the Commissioners to Ask — and of Whom:

#### Chris James (Medsafe), Ministry of Health:

- The mRNA vaccine platform is described as the creator of the platform as a form of gene therapy. Why did regulators choose to classify these products as vaccines rather than gene therapies, and what implications did that have for safety testing and public perception?
- What standard preclinical studies (toxicology, genotoxicity, reproductive effects) were skipped in the rush to authorise mRNA vaccines under provision consent, and who made that call?



# 1.11 ADVERSE EVENTS

### **INCLUDING A REAL RISK OF MYOCARDITIS**

RC Term: Vaccine Safety
B. Dangers of the Platform

Katie Ashby-Koppens summarising Dr McCullough's evidence given to the Phase Two Royal Commission

#### Why this issue is relevant:

Dr Peter McCullough is one of the most qualified medical experts globally, with board certification in internal medicine and cardiology, over 1,000 peer-reviewed publications, and extensive leadership in clinical trials and pharmacovigilance. He provided expert evidence in the judicial review challenging New Zealand's provisional approval of Pfizer's vaccine for children aged 5–11 years, raising urgent concerns about its necessity, efficacy, and safety. His credibility is further enhanced by the fact that he consistently raised red flags before vaccine rollout, during implementation, and after harm became apparent.

His warnings, which should not have been ignored, were not made in hindsight, but rather reflect consistent, science-based foresight.

Dr McCullough's timeline shows a remarkable consistency in expert warnings:

- Before vaccine rollout (August 2020 The Hill)
- During early rollout (August 2021 VFF)
- As part of sworn expert evidence (2022 NZ judicial review)
- After government data confirmed harms (May 2025 U.S. Senate)

He is not merely a commentator — he is a world-leading expert who stood virtually alone in raising early warnings that have now been tragically confirmed. His opinions are founded in science, clinical ethics, and the duty to protect public health, especially the health of children.

Dr McCullough gave unambiguous expert opinion evidence that:

- Children faced negligible risk from COVID-19.
- · Natural immunity offered robust and durable protection.
- The vaccines were losing efficacy and were mismatched to circulating variants (especially Omicron).
- The Pfizer vaccine posed unacceptable and inadequately studied risks to healthy children, especially myocarditis.
- Key vaccine trials excluded individuals who had recovered from COVID-19 and lacked proper long-term safety protocols.
- Mass vaccination of children with these novel genetic platforms violated basic clinical and ethical principles.

#### Details:

- 1. August 2020: Warning the World in The Hill<sup>1</sup>
- Dr McCullough criticised the unprecedented speed and lack of long-term safety data in Operation Warp Speed.
- Warned of potential for immune enhancement, autoimmune conditions, and unforeseen risks, especially in children.
- Called the accelerated programme "the largest gamble in human vaccine history."
- This was prior to any vaccine approval a clear, sciencebased early warning.
- August 2021: Viral Interview with Voices for Freedom (VFF, New Zealand)<sup>2</sup>
- Dr McCullough spoke out during New Zealand's vaccine rollout. This was a direct public warning to New Zealanders during rollout — at the time the rollout for healthy teenagers was approved (despite the government's own expert advice) and well before the judicial challenge for Kiwi Kids aged 5-12.
- Warned about myocarditis in young males, the lack of early treatment protocols, and mRNA vaccine risks.
- Emphasised that natural immunity was being ignored and that mass vaccination in children was unjustified.
- 3. 2022: Dr McCullough's Expert Affidavit filed in New Zealand's High Court in Judicial Review Proceedings challenging the provisional approval for 5–11 Year Olds<sup>3</sup>

In his affidavit for Kiwi Kids' Case, Dr McCullough stated that:

- Children faced negligible risk from COVID-19.
- · Natural immunity was robust and long-lasting.
- Vaccines were mismatched to new variants (e.g. Omicron) and rapidly losing efficacy.

- Pfizer's vaccine posed unacceptable myocarditis risks, especially in healthy boys.
- The trials excluded individuals who had recovered from COVID-19, lacked long-term safety protocols, and failed to meet basic ethical standards.
- This was sworn expert evidence based on current data and longstanding concerns.

# 4. May 2025: U.S. Senate Testimony Confirms Suppression of Myocarditis Data<sup>4</sup>

- Hearing: "The Corruption of Science and Federal Health Agencies"
- Senate Homeland Security and Governmental Affairs, Permanent Subcommittee on Investigations
- Dr McCullough's key testimony:
  - Federal agencies knew by February-March 2021 that myocarditis was elevated in young people, but delayed public warnings.
  - Myocarditis rates post-mRNA vaccine far exceeded baseline in adolescent males.
  - He stated the public was denied informed consent due to the CDC and FDA suppression of safety signals.
  - Affirmed that his 2020 warnings had been tragically vindicated.
  - This confirms that the harms were predictable and known to regulators, but were ignored.

## Important Questions for the Commissioners to Ask — and of Whom:

### Ministry of Health and Director General of Health:

- Were internationally credible voices like Dr McCullough, who publicly raised concerns about myocarditis and inadequate safety protocols, included in New Zealand's vaccine advisory process, in particular after his August 2021 interview addressing our national rollout and its risks to children?
- What ethical justification was used to approve mass vaccination of healthy 5–11 year olds, who faced negligible COVID-19 risk, despite emerging myocarditis data and the exclusion of COVID-recovered children from trials? Was meaningful informed consent ever possible under these conditions?
- When did the Ministry first become aware of elevated myocarditis risk in young males postmRNA vaccination, and why did it proceed with approving vaccines for children on 3 December 2021, despite mounting international warnings, including Dr McCullough's detailed reporting of this risk throughout 2021?

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# 1.11 ADVERSE EVENTS

**RC Term: Vaccine Safety** 

C. Scientific Studies Timeline Myocarditis

Lynda Wharton

#### Why this issue is relevant:

Vaccine-induced myocarditis was recognised as a risk as early as April 2021, particularly in young males. Evidence mounted throughout 2021, yet the Ministry of Health did not begin informing the public until December 2021 - after most of the population, including adolescents (a group at higher risk of myocarditis), had already received two doses.

While serious safety signals were emerging internationally and domestically, New Zealand authorities delayed informing the public. Meanwhile, the country's most aggressive vaccination campaign continued at full pace, undermining informed consent.

### Timeline of Key Scientific Findings and Regulatory Responses:

- January 2021 EMA presents Israeli myocarditis surveillance data.<sup>1</sup>
- April 2021 CDC begins internal investigation; VAERS records growing myocarditis reports.<sup>2</sup>
- 29 April 2021 NZ ISMB discusses a local case of myocarditis after Pfizer vaccination.<sup>3</sup>
- 28 May 2021 CDC publicly warns of myocarditis risk.4
- Early June 2021 Medsafe states "no signal" for myocarditis.<sup>5</sup>
- 9 June 2021 Medsafe sends limited communication to healthcare providers.<sup>6</sup>
- 11 June 2021 WHO Global Advisory Committee identifies a "strong signal".<sup>7</sup>
- 25 June 2021 U.S. FDA updates EUA factsheet to include myocarditis warning.<sup>8</sup>
- 29 June 2021 NZ COVID-19 Vaccine Technical Advisory Group recommends public disclosure.9
- 21 July 2021 Medsafe issues first public alert on its website.10
- 28 July 2021 Medsafe updates Consumer Medicine Information datasheet, omitting myocarditis from summary.<sup>11</sup>
- Sept 2021 U.S. study: Myocarditis in children aged 12–17 postmRNA vaccination.<sup>12</sup>
- Sept 2021 Leaked health data from the Wellington Region showed a significant rise in myocarditis cases during 2021. Between 1 January and 30 September 2021, there were 444 more cases of myocarditis compared to the same period in 2020. The increases by age group were as follows: 20–29 years (+13%), 30–39 (+15%), 40–49 (+11%), 50–59 (+14%), and 60+ (+19%). The rate of myocarditis was estimated at 127 cases per 100,000 vaccine recipients—42x higher than the figure of 3 per 100,000 referenced by Director-General of Health Dr Ashley Bloomfield in a December 2021 letter. 128
- Sept 2021 Internal concerns about informed consent raised:
  Helen Petousis-Harris, a government advisor and vaccine expert, emailed members of the COVID-19 Immunisation Implementation Advisory Group with the subject line "Question about informed consent." She asked why myocarditis was not being included in the informed consent process or in aftercare information, noting:

"Seems to me important to highlight the very small risk, symptoms to be aware of and what to do should they arise, like we do with routine rotavirus vaccine and intussusception."

This internal concern was not publicly communicated by Petousis-Harris at the time.

- Oct 2021 Israeli study confirms myocarditis risk in young males.<sup>13</sup>
- Dec 2021 Dr Bloomfield's letter to DHBs: "Myocarditis and pericarditis have been established as very rare but serious adverse events associated with the Comirnaty vaccine. In New Zealand, the true incidence of vaccine-associated myocarditis is unknown, as the onset of symptoms occurs in the first few days after vaccination and is potentially under-reported. However, the overall rate of this event in New Zealand is reported to be around 3 per 100,000 vaccinations."
- Dec 2021 HP-H email informed consent

 Sept 2024 – NZ study confirms persistent cardiac injury postvaccination.<sup>14</sup>

#### **Executive Summary**

#### Proven Cardiac Risk After Pfizer Vaccination

Serious cardiac adverse events - especially myocarditis and pericarditis - have been confirmed following Pfizer mRNA vaccination, particularly in young males after the second dose.

Despite CDC (April/May 2021) and WHO (June 2021) alerts, Medsafe was slow to notify either vaccinators or the public.

- NZ ISMB case (29 April 2021).15
- CDC warning (28 May 2021).<sup>16</sup>
- Medsafe alert to doctors (9 June 2021)<sup>17</sup>

#### Delayed Acknowledgement and Informed Consent Failures

- Medsafe maintained "no signal" position in early June 2021.<sup>18</sup>
- First public warning issued 21 July 2021.19
- Datasheet update on 28 July 2021 still excluded myocarditis from the summary.<sup>20</sup>

#### Evidence from NZ: Long-Term Cardiac Harm

 A New Zealand study found lasting cardiac abnormalities at 3-month follow-up among adolescents with vaccineassociated myocarditis.<sup>21</sup>

#### Subclinical Myocarditis and Sudden Death Risk

No active screening in NZ has been implemented, despite clear international findings:

- Thai study: 3.5% subclinical myocarditis/pericarditis in adolescents.<sup>22</sup>
- Swiss study: 2.8% troponin elevation indicating myocardial injury in adults.<sup>23</sup>

#### Double Risk: Infection + Vaccine

The narrative that "infection causes more myocarditis than vaccination" is challenged by studies showing:

- Increased infection risk following multiple vaccine doses.
- Higher total spike exposure from repeated vaccination.

#### Examples:24

- UK Data: Myocarditis Only in Vaccinated Children<sup>25</sup>
   The UK OpenSAFELY study (1.2 million children aged 5-15) found:
- Zero myocarditis cases from infection
- All myocarditis occurred in vaccinated children

#### Underdiagnosis and Lack of Surveillance

- Chest pain is one of the most reported adverse events postvaccination
- Myocarditis often requires contrast MRI, not routinely used in N7
- No active programme to detect subclinical cases
- FDA Follow-Up Shows Persistent Cardiac Injury<sup>26</sup>

U.S. adolescents with vaccine-associated myocarditis showed persistent damage at 3-month MRI follow-up, even with mild initial symptoms

#### No Personalised Risk-Benefit Assessment

- Young, healthy adults at minimal COVID risk were not offered tailored risk assessments.
- Vaccine mandates often overrode legitimate medical exemptions—even after myocarditis diagnosis.

### Important Questions for the Commissioners to Ask — and of Whom:

#### Chris James (Medsafe), CV TAG, Ministry of Health:

- Why were New Zealanders not informed of the potential risk of myocarditis from the Pfizer mRNA vaccine as early as April 2021, when international data (CDC, Israel) and domestic cases were already under discussion?
- Why did the Ministry of Health and Medsafe continue to state "no signal" into June 2021, despite the NZ ISMB discussing a myocarditis case on 29 April 2021 and despite CDC warnings issued on 28 May 2021?
- Why did a formal public alert only appear on 21 July 2021, and why was the Consumer Medicine Information Sheet not updated to reflect myocarditis risk in the summary?

#### NZ Study Showing Long-Term Cardiac Injury After Myocarditis

- Following the publication of the New Zealand myocarditis and pericarditis study (with 3-month follow-up), which documented ongoing cardiac symptoms in a significant number of patients, what official alerts or clinical guidance updates were issued to:
  - · Vaccinators?
  - General practitioners?
  - The New Zealand public?
- What long-term monitoring or follow-up has been planned for those affected by myocarditis post-vaccination, beyond the 3-month window?

- Will the Ministry of Health or study authors provide access to anonymised "free text" questionnaire responses from affected participants to the Royal Commission of Inquiry or future public health reviews?
- Why was an OIA request for this anonymised data refused, despite its relevance to assessing ongoing harm and informing future consent processes?

#### Subclinical Myocarditis and Undiagnosed Risk

- Given international studies (Thai and U.S.-based) have shown rates of 2.5–3.5% subclinical myocarditis in actively screened adolescents and young adults post-Pfizer vaccination, why has no active surveillance or screening programme been implemented in New Zealand?
- What assessment has been made of the potential population-scale risk of undiagnosed subclinical myocarditis, especially considering its association with sudden cardiac death?

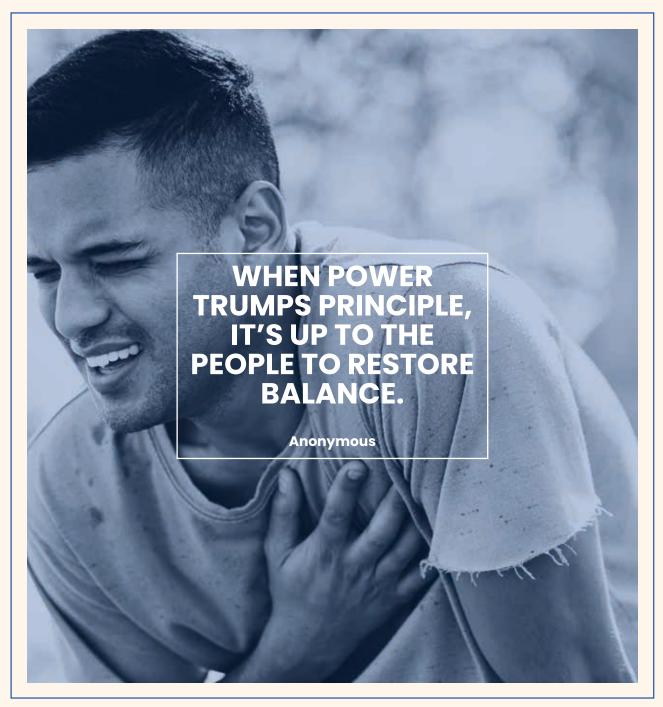
### Changing Evidence on Infection and Myocarditis

- Medsafe and MOH have consistently stated that "the risk of myocarditis is greater from COVID infection than vaccination." However, there are now multiple peer-reviewed studies showing that individuals receiving more doses of mRNA vaccines have a higher risk of infection over time.
- Will Medsafe and the Ministry now reassess or update this public message, given the dual risk of myocarditis from both:
- Vaccination itself, and
- The increased likelihood of breakthrough infection following multiple doses?

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# 1.11 ADVERSE EVENTS

RC Term: Vaccine Safety

D. High incidence of Adverse Event Reports for Pfizer Comirnaty

Lynda Wharton

#### Why this issue is relevant:

The Pfizer COVID-19 vaccine was a novel product using a new delivery system that had only received Provisional Consent because it was supported only by short-term safety data produced early and significant safety signals (or red flags). Instead of prompting caution, the vaccine was approved for use in younger and healthier cohorts.

Adverse event reporting rates for COVID-19 vaccines in New Zealand are significantly higher than for non-COVID vaccines

 11x higher for general events and 6x higher for serious events. Despite clear early safety signals, the vaccine was approved and promoted for broad use, including among low-risk groups. The data raises serious questions about the safety claims made and the robustness of the monitoring systems in place.

#### Details:

#### 1. Pfizer's Own Post-Marketing Surveillance (First 90 Days)

Pfizer's report to the U.S. FDA, covering the first 90 days of global vaccine use (to 28 February 2021), included:

- 42,086 adverse event reports comprising 158,893 individual events.
- 1,223 deaths reported internationally (Table 1).
- 11,361 individuals not recovered at the time of reporting.
- 1,200 Adverse Events of Special Interest (Schedule 1).

#### Full report 1

#### 2. New Zealand Adverse Event Data - Medsafe (to Nov 2022):2

- 64,829 adverse event reports following COVID-19 vaccination.
- 3,688 classified as serious (hospitalisation, permanent harm, or life-threatening).

• 184 deaths reported post-vaccination.

#### SMARS Dashboard (to Feb 2025)3 (includes variant vaccines):

- 67,028 adverse event reports.
- 186 deaths reported post-vaccination.

#### 3. Serious Adverse Events in Pfizer Trial Data<sup>4</sup>

- An independent peer-reviewed reanalysis of Pfizer and Moderna trial data published in vaccine found:
- 1 serious adverse event per 800 doses.

# 4. Comparison – COVID vs Non-COVID Vaccine Reporting in NZ (2022) $^{\scriptscriptstyle 5}$

#### Non-COVID Vaccines (2022):

- 2,377,469 doses administered.
- 1,136 adverse event reports (1 per 2,092 doses).
- 125 serious reports (11% of reports; 1 per 19,019 doses).

#### COVID-19 Vaccines (to November 2022):6

- 11,888,254 doses administered.
- 1 adverse event report per 183.3 doses.
- 1 serious adverse event per 3,223.4 doses.

## 5. Underreporting Acknowledged by Medsafe Medsafe notes that:

"It is generally accepted that only a small proportion (not more than 5%) of all adverse reactions are reported."

Prescriber Update (October 2001), page 24.7

# Important Questions for the Commissioners to Ask — and of Whom:

#### Chris James (Medsafe), CV TAG, Ministry of Health:

#### 1. Safety Claims vs Early Data

- On what basis did Medsafe and the MoH promote the Pfizer vaccine as "safe and effective" when over 1,000 deaths had been reported internationally in the first 90 days?
- Why was this early safety data not disclosed to the New Zealand public before rollout began?
- Were any steps taken by Medsafe to reassess safety once post-marketing surveillance data revealed serious and fatal outcomes?

#### 2. Informed Consent and Risk Disclosure

- How can informed consent be considered valid when known risks, including death and serious adverse events, were not fully disclosed to the public?
- Why were vaccinators, doctors and pharmacists not required by the MoH to share updated safety data as part of their professional duty of care?

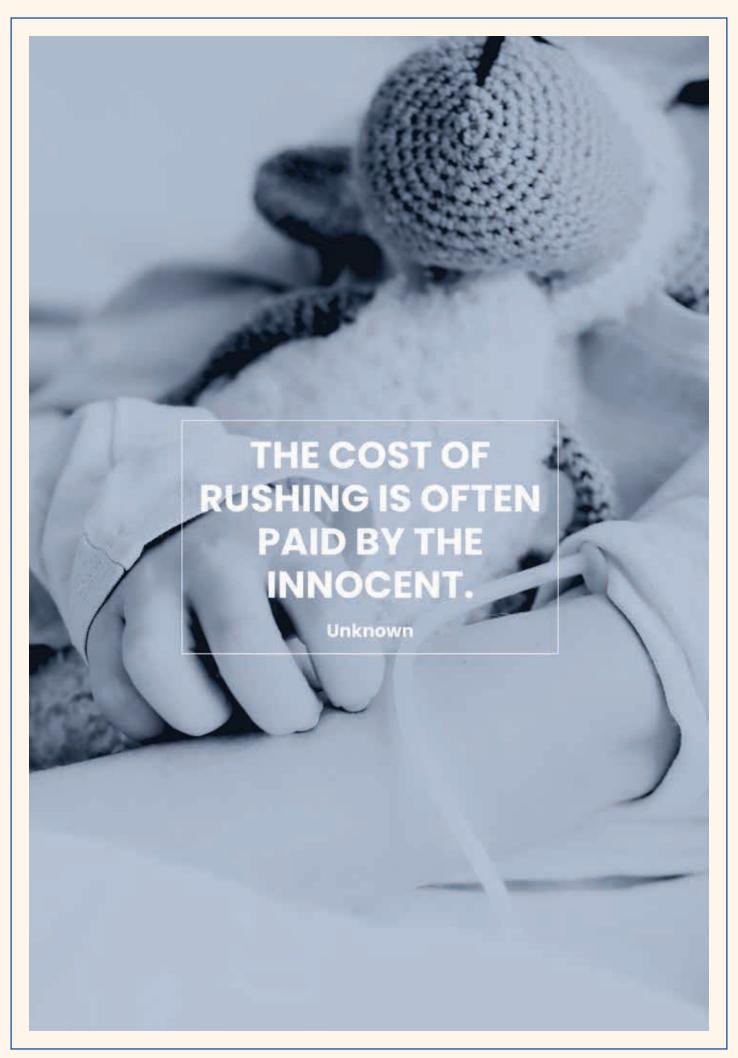
#### 3. Adverse Event Reporting Systems

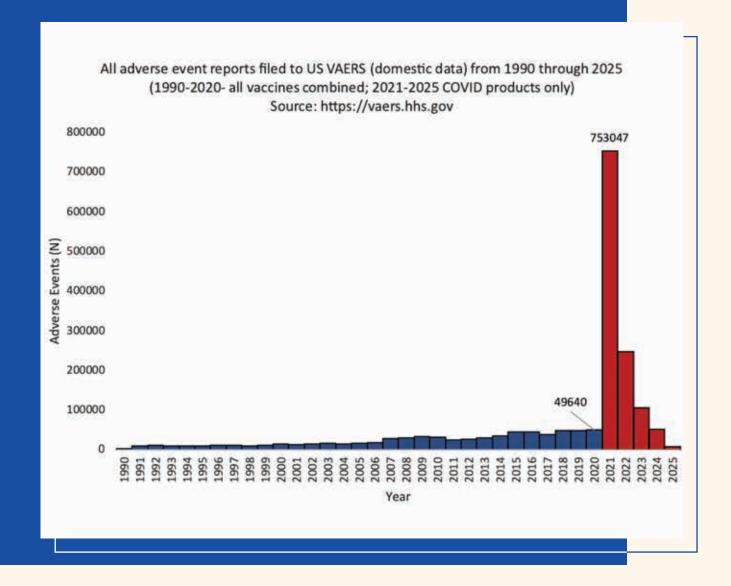
- Why did Medsafe and the MoH fail to establish a proactive, well-funded programme to promote adverse event reporting for COVID-19 vaccines?
- Given Medsafe's own admission that underreporting is common (less than 5%), why was passive surveillance considered sufficient?
- What systems were in place to ensure adverse event reports were being captured, reviewed, and followed up?

#### 4. Oversight of Safety Signals

- Why was there no investigation or public explanation from Medsafe regarding the significantly higher adverse event reporting rates for COVID-19 vaccines compared to other vaccines?
- Why weren't these safety signals treated as red flags requiring enhanced pharmacovigilance and public transparency?

- https://www.pro-memoria.info/wp/wp-content/uploads/Eventi-avversi-al-28-02-2021\_-Report-5.3.6-post-marketing-expe
- <sup>2</sup> https://www.medsafe.govt.nz/COVID-19/safety-report-46.asp
- 3 https://www.medsafe.govt.nz/SMARS/Default
- 4 https://www.sciencedirect.com/science/article/pii/S0264410X22010283
- <sup>5</sup> https://www.medsafe.govt.nz/safety/reports-and-promotion/ADRStatistics/2022.asp
- 6 https://www.medsafe.govt.nz/COVID-19/safety-report-46.asp
- https://www.medsafe.govt.nz/profs/PUarticles/PDF/Prescriber%20Update\_Oct01.pdf (see page 24)





# 1.11 ADVERSE EVENTS

**RC Term: Vaccine Safety** 

E. U.S: VAERS (Vaccine Adverse Event Reporting System)

Jessica Rose

#### Why this issue is relevant:

The U.S. rollout of COVID-19 vaccines began on 14 December 2020—two months ahead of New Zealand (February 2021). The U.S. VAERS database, a critical early warning safety signal system, detected a marked increase in serious adverse events following vaccination.

Given the novel mRNA technology and the Emergency Use Authorization (EUA) under which the vaccines were deployed (a process that bypassed standard long-term trials due to time constraints), it was essential for New Zealand to closely monitor safety data from countries further ahead in the rollout.

### 1. Sharp Increase in Adverse Events and Deaths Reported to VAFRS<sup>1</sup>

- In 2021, following COVID-19 vaccine rollout, reported deaths in VAERS increased by 6,000% compared to the previous decade's annual average.
- Overall, adverse events rose by 1,500% above the ten-year average.
- A close eye should be kept, especially at the early juncture of vaccine-related deaths surpassing deaths from COVID-19.

#### 2. Underreporting of Adverse Events

- VAERS is a passive system relying on voluntary reports, leading to underreporting.
- Estimates suggest an Underreporting Factor (URF) of 31, implying actual adverse events are significantly higher than recorded.

#### 3. Temporal Patterns Indicate Causation

- Many serious adverse events, including deaths, occur within 48 hours of vaccination.
- According to the Bradford Hill Criteria, a framework used in epidemiology to assess causation, the clustering of adverse events suggests a causal relationship with the vaccine.<sup>2</sup>
- Conditions with strong temporal associations included myocarditis, anaphylaxis, reproductive issues, and blindness.

#### 4. Myocarditis Risk in Young Males

- Young males, especially under 40, were at significantly higher risk of myocarditis from the vaccine than from COVID-19 infection.
- A dose-response relationship was observed, with higher rates after the second dose.
- Children aged 12–15 experienced myocarditis at 19x the expected rate.

#### 5. Reproductive and Infant Outcomes

- Increases in reports of spontaneous abortion and reproductive complications were recorded.
- Some adverse events were reported in infants via breast milk, including seven deaths in the 0–2 year age group.

#### 6. Neurological and Immunological Disorders

- Sharp rises in neurological, cardiovascular, and immunological events were observed.
- Blindness was reported in many cases after the first dose.
- Skin disorders became one of the most commonly reported issues.

#### 7. Vaccine Failure (Breakthrough Infections)

- Over 30,000 breakthrough COVID-19 infections were recorded in vaccinated individuals.
- Data indicated the vaccine did not reliably prevent infection or transmission.
- In Israel, over 80% of hospitalised COVID-19 patients were double-vaccinated.

#### 8. Safety Signals Warranted Urgent Investigation

- The volume and severity of adverse events were sufficient to justify immediate regulatory scrutiny.
- Continuing mass vaccination especially among younger cohorts - should have been reconsidered pending investigation.

Full report: Rose, J. A Report on the U.S. Vaccine Adverse Events Reporting System (VAERS) of the COVID-19 Messenger Ribonucleic Acid (mRNA) Biologicals. Science, Public Health Policy and the Law. 2021 May; v2.2019–2024.3

## Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe and the Ministry of Health:

- What monitoring of adverse event data from overseas jurisdictions, including VAERS, was undertaken by Medsafe and the Ministry of Health?
- What specific safety signals, such as increases in myocarditis, reproductive harm, or neurological issues, were noted by officials, and how were they evaluated?
- Was the Bradford Hill Criteria or any other formal causation framework applied to assess the clustering of adverse events?
- What action, if any, was taken in response to the large volume of VAERS-reported deaths and severe adverse events?
- Were overseas data trends considered before expanding vaccine approvals to children and young people in New Zealand?

- VAERS:
  - https://vaers.hhs.gov/
- $^{2} \quad \underline{\text{https://jessicar.substack.com/p/the-bradford-hill-criteria}}$
- 3 https://publichealthpolicyjournal.com/a-report-on-the-u-s-vaccine-adverse-events-reporting-system-vaers-of-the-covid



# 1.11 ADVERSE EVENTS

**RC Term: Vaccine Safety** 

F. NZ - CARM (Centre for Adverse Reactions Monitoring)

Katie Ashby-Koppens

#### Why this issue is relevant:

Medsafe had access to information indicating a significant increase in adverse event reporting, including serious reactions and death, before approving the Pfizer vaccine for adolescents and children.

CARM (Centre for Adverse Reactions Monitoring) is New Zealand's national system for collecting reports of adverse reactions to medicines and vaccines. It is a voluntary reporting system known to suffer from significant underreporting estimated at 95% – yet the spike in adverse event reports following the COVID-19 vaccine rollout was substantial.

From February to December 2021, the number of daily reports rose from an historical average of 2.6 per day to 137 per day – a 5,207% increase. Reported deaths also surged, from 3 (over five years pre-COVID) to 158 in just over a year post-rollout. These figures came despite CARM's known data limitations and reporting gaps.

The rate of serious adverse events more than doubled compared to pre-COVID vaccines, and a noticeable spike in serious cases occurred in December 2021 - just before Medsafe approved the Pfizer vaccine for 5 to 11-year-olds.

Myocarditis cases were particularly elevated in young males aged 12–29, with incidence more than 4x the expected background rate. New Zealand also reported significantly higher rates of adverse events per 10,000 doses than Australia.

These findings point to concerning patterns of harm and raise critical questions about regulatory oversight, especially given Medsafe's decision to expand the vaccine rollout to children while such data was already available.

#### Details:

#### Increase in Adverse Event Reports

- Pre-COVID vaccines (2005-2009):
  - ~2.6 reports/day for all vaccines (Primary Affidavit, p.10).
  - 6.8 adverse events per 10,000 doses (Reply Affidavit, 2 p.3).
- COVID vaccine period (Feb-Dec 2021):
  - 137 reports/day (Primary Affidavit, p.2).
  - 51.7 adverse events per 10,000 doses (Reply Affidavit, 2 p.3).
- By March 2022: Over 60,935 adverse events reported (Primary Affidavit, p.15).
- Adjusted for dosage volume: 660% increase in adverse events.

#### Deaths Reported to CARM

- 2005–2009: 3 deaths over five years (Primary Affidavit, p.12).
- Pfizer vaccine (Feb 2021 Mar 2022): 158 deaths reported (Primary Affidavit, p.19).
- 3 deemed "likely" due to vaccine-induced myocarditis.
- $\,$  50 could not be assessed due to insufficient information.

#### **Underreporting Issues**

- Global data suggests only 5–10% of adverse events are reported (Primary Affidavit<sup>1</sup>, p.7).
- Actual adverse event numbers may be significantly higher.

#### Serious Adverse Events

- Pre-COVID: 3.6% of reports were serious.
- Post-rollout: 8.1% serious (Reply Affidavit, 2 p.5).
- Spike in serious events noted in December 2021, prior to approval for 5–11-year-olds (Reply Affidavit, 2 p.5–6).

#### Comparison with Australia

 NZ reported 3x more adverse events per 10,000 doses than Australia (Reply Affidavit,<sup>2</sup> p.5).

#### Myocarditis

- Incidence in 2021 >4x higher than expected background rate (Reply Affidavit,<sup>2</sup> p.7-8).
- Highest rates in males aged 12–29 (Reply Affidavit,<sup>2</sup> p.8–9).

#### Sources

Lisa Mitchell Affidavits (Primary¹ and Reply²) filed in the Kiwi Kids' Case.

# Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe and the Ministry of Health:

- Why did Medsafe proceed with authorisation of the Pfizer vaccine for children despite the spike in serious adverse events in 2021?
- What consideration was given to the myocarditis data, particularly the elevated rates in young males, before extending vaccine approvals to adolescents and children?
- How does Medsafe account for the 660% increase in adverse event reporting after adjusting for vaccine volume?

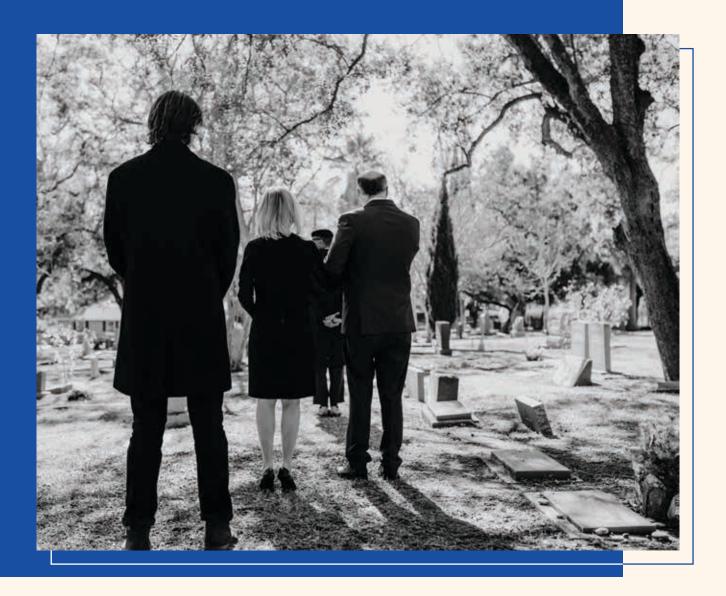
# CARM (or those involved in its oversight and data cleansing):

- What internal processes exist for handling high volumes of reports, and how were these applied during the COVID-19 vaccine rollout?
- How does CARM address the well-documented issue of underreporting, and were any steps taken to improve reporting completeness during the pandemic?

# The Commissioners may wish to explore the following:

- What measures, if any, were put in place to independently review and respond to the reported deaths and serious adverse events?
- Were New Zealand's rates of adverse events and deaths considered in light of international comparisons, such as with Australia? If not, why not?

- https://drive.google.com/file/d/1q2onCjx5RWR-aRtBddlcn3FZy5J9ePEO/view
- <sup>2</sup> https://drive.google.com/file/d/1i0Yam8rvwgrh8c-jrFRPYsFYYaFFO3Wn/view?usp=share\_link



# 1.11 ADVERSE EVENTS

RC Term: Vaccine Safety
G. CARM Death reports

Lynda Wharton

#### Why this issue is relevant:

The number of death reports submitted to CARM following COVID-19 vaccination was exceptionally high compared to usual reporting rates for all other vaccines in New Zealand. This occurred despite the absence of mandatory reporting or any public campaigns to encourage reporting.

As of Safety Report 46,<sup>1</sup> 183 deaths were reported to CARM following administration of the original Pfizer mRNA COVID-19 vaccine (Tozinameran). Additional reports include:

- One death following the BA.4/5 variant
- One death following the XBB.1.5 variant
- One death following the JN.1 variant

These 183 deaths followed the administration of 11.88 million COVID-19 vaccine doses.

By contrast, in 2022,3 there were 2,377,469 non-COVID vaccine doses administered. Fewer than six deaths were reported following those vaccines (the exact number withheld to protect privacy). Even assuming five deaths, this equates to one death per 475,493 doses for non-COVID vaccines.

In comparison, for the COVID vaccine, the rate was one death reported per 64,963 doses—an increase of over 7x the non-COVID rate.

The Ministry of Health has confirmed five deaths in New Zealand as causally linked to the Pfizer mRNA vaccine. However, many of the reported deaths were not investigated via autopsy (see Issue 1.12.D), and no elderly deaths in care homes were investigated following vaccination.

Of note, Pfizer's own Post-Marketing Safety Surveillance Report - covering the first 90 days of global use - documented 1,223 deaths reported worldwide during that period (See Issue 1.2.E).

#### **Details:**

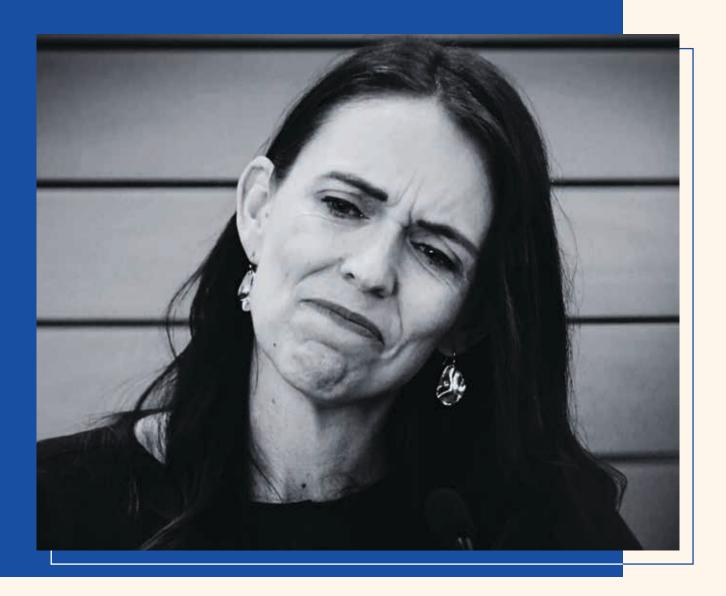
- Medsafe Safety Report 46 (183 deaths).1
- SMARS database (deaths post-Nov 2022).2
- Non-COVID vaccine dose data for 2022.3
- Non-COVID vaccine death figures via OIA (Ref H2024045275).4
- Pfizer Post-Marketing Safety Report (first 90 days).<sup>5</sup>

# Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe and the Ministry of Health:

- Why were New Zealanders not informed that Pfizer received 1,223 death reports globally in the first 90 days of the vaccine's use?
- Why was a post-mortem not performed on every death reported in close proximity to receipt of a COVID-19 vaccine dose?
- Why were elderly care home deaths not investigated, given the vulnerability of this group?
- Why was the unprecedented rate of postvaccine death not treated as a potential safety signal warranting immediate review or intervention?

- https://www.medsafe.govt.nz/COVID-19/safety-report-46.asp
- <sup>2</sup> <a href="https://www.medsafe.govt.nz/SMARS/Default">https://www.medsafe.govt.nz/SMARS/Default</a>
- <sup>3</sup> https://www.medsafe.govt.nz/safety/reports-and-promotion/ADRStatistics/2022.asp
- 4 https://drive.google.com/file/d/ITZIAW8nNnV8tVnLhmsG8\_o3XIXwVyUnI/view?usp=share\_link
- <sup>5</sup> https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf



# 1.11 ADVERSE EVENTS

**RC Term: Vaccine Safety** 

H. Jacinda Ardern Facebook Social Media "side-effects" post 26 September 2021

Lynda Wharton

#### Why this issue is relevant:

On 26 September 2021, then-Prime Minister Jacinda Ardern made a Facebook post about receiving the Pfizer COVID-19 vaccine and her experience with side-effects. The post received tens of thousands of comments in a matter of days, many of which described serious adverse effects or deaths reportedly occurring after vaccination. Instead of prompting further investigation or changes to vaccine messaging, many of these comments were deleted, some within minutes. The post itself was later removed from Facebook.

Jacinda Ardern posted on Facebook in September 2021:

"I was reading some research today, on why some people have chosen not to be vaccinated to protect them against COVID-19 yet. One of the most common is that they're worried about the side-effects. So let's talk about that! Like all medicines, you might experience some mild side-effects 1–2 days after getting your vaccination. That is totally normal, and also a sign that your body is learning to fight the virus. Most side-effects don't last long. For me, I had a sore arm after my first dose (it reminded me of the tetanus jab) and I felt a bit weary after the second one, but not for long!"

She concluded by encouraging people to speak to someone they trust or their GP, and linked to the government's COVID-19 website.

The post generated around 30,000 comments within days. Many of these comments reported serious adverse reactions, including the deaths of friends and family members allegedly following vaccination.

A team from The Health Forum NZ monitored the post and documented comments in real time, capturing screenshots before they were deleted. These records show a significant volume of adverse event reporting.

Despite this public response, there was no apparent adjustment to public health messaging or the informed consent process. In late 2024, the original post was removed from Jacinda Ardern's Facebook page. An archived post remains <sup>1</sup>

Supporting material includes screenshots and comment compilations, which will be provided by The Health Forum NZ upon request.

# Important Questions for the Commissioners to Ask — and of Whom:

Jacinda Ardern, Medsafe, and the Ministry of Health:

- Given the volume of reported serious harm in response to the post, was any formal review of the Pfizer mRNA vaccine rollout undertaken?
- Why were comments reporting harm removed in real time—often within minutes?
- Who was responsible for moderating the post and deleting comments: Ardern's social media team or Facebook?

https://www.facebook.com/jacindaardern/posts/pfbid02yqqAjXNGHnZAcr3aQjTVxlJzJbf57isCjqbtN9YwLeJ7KTv3hS



# 1.12 MORTALITY

Understanding the true impact of New Zealand's COVID-19 response requires confronting the most irreversible of outcomes: death. Mortality data offers a stark, unambiguous signal – one that should have prompted rigorous inquiry when patterns shifted in unexpected and concerning ways. They were not. Instead data was manipulated.

In New Zealand, all cause mortality figures began climbing in mid-2021 and remained elevated throughout 2022 and beyond. This rise did not correlate with early waves of COVID-19, nor was it confined to those infected. Instead, it closely followed the introduction of the COVID-19 vaccination campaign, including the widespread rollout of primary doses and, later, boosters.

Early official commentary framed New Zealand as a global success story, pointing to "low excess deaths" as proof that the public health strategy had worked. But closer analysis tells a different story. A key insight from Professor John Gibson and others, is that official mortality figures were significantly understated due to a basic methodological error: death projections failed to adjust for the sudden drop in population growth caused by border closures and stalled immigration. Once corrected, excess deaths from early 2021 onward were more than double the government's figures – over 3,200 deaths by mid-2023.

This revised lens casts serious doubt on the claimed safety of the vaccination programme. If vaccines had been overwhelmingly protective, a decline in all-cause mortality would be expected. Instead, mortality increased – first following the initial vaccine rollout and then more sharply during the booster phase. Age-specific data shows the greatest rise in death rates among boosted populations, while unboosted age groups saw no similar spike. Statistically, the association between boosters and mortality is difficult to ignore.

Yet, investigation has lagged. Adverse event reports, including hundreds of post-vaccination deaths recorded by CARM, were frequently marked with "insufficient information." Pathologists were not routinely instructed to investigate vaccination status, coroners lacked timely access to medical data, and changes to the Coroners Act further reduced scrutiny - effectively making it easier to not investigate deaths by unexplainable natural causes. These systemic oversights may have concealed key safety signals, including from deaths that appeared sudden or unexplained.

Let us put it plainly: had the unvaccinated been dying in large numbers, we would have heard about it. It would have been headline news. Their deaths would have been cited as justification for every mandate, every restriction, and every dose. Instead, the pattern of rising mortality has been quietly swept aside - minimised, dismissed or ignored - because it is inconvenient to the official narrative.

#### In this section

- A. Excess all cause mortality
- B. NZ's misleading claim of low excess mortality
- C. Booster and excess mortality
- D. Pathology Autopsies
- E. Changes to the Coroner's Act



# 1.12 MORTALITY

RC Term: Vaccine Safety

A. All-cause mortality

Dr Simon Thornley

#### Why this issue is relevant:

All-cause mortality refers to the total number of deaths in a country each year, regardless of cause. New Zealand's all-cause mortality increased by approximately 5% in early 2022 following the rollout of the COVID-19 vaccines.<sup>1</sup>

A substantial increase in all-cause mortality was observed in New Zealand from mid-2022 until present, following the introduction of COVID-19 vaccine mandates in late 2021 and a major vaccine drive, including the "Vaxathon" event.

Similar patterns have been reported in other countries, such as Australia. Despite scientific studies raising concerns, the New Zealand government has not appeared to investigate the potential role of the COVID-19 vaccines, or if they have, they have not communicated this with the public.<sup>2</sup>

#### **Details:**

- The Ministry of Health's reporting for 2022 showed that allcause mortality in New Zealand was approximately 35% above seasonally adjusted historical trends in late August 2022 (see Figure 1 below).
- In the last week of August 2022, there were 246 more deaths than the long-term average, totalling 946 deaths that week, a 35% increase from the peak in the year before.
- Professor John Gibson of Waikato University found nearly 3,000 excess deaths in an eight-month period during 2023, representing an 8% increase. This is at odds with claims of other public health commentators that claim our excess death rate may be explained away by a lower-than-expected death rate in 2020 (See Issue 1.12.B, page 198).

COVID-19 deaths alone do not account for this rise. Health authorities should consider whether COVID-19 vaccines played

a role in the recent pattern of raised excess deaths in this country. While health authorities often argue the vaccines have a net beneficial effect on mortality, other experts are expressing concern:

- The vaccines do not prevent infection.3
- Many countries experienced increased excess mortality following vaccine rollouts.<sup>4</sup>
- If the vaccines reduced COVID-19 deaths with minimal adverse effects, a decline in all-cause mortality would be expected. Instead, a rise has occurred in many European countries, for example.<sup>5</sup>
- This observation is consistent with a re-analysis of Pfizer and other vaccine trial data showing more serious adverse events in the vaccinated group than in the placebo.<sup>6</sup>

#### **Additional context:**

- Some U.S. states are **moving to ban COVID-19 vaccines** due to growing concerns about adverse effects.
- Over 3,500 case series of serious side-effects have been published.<sup>7</sup>
- As of 11 August 2023, the U.S. VAERS system recorded 35,911 post-vaccine deaths, triple the total reported for all other vaccines combined since 1990s.
- New Zealand has paid unprecedented levels of compensation for vaccine-related injuries<sup>9</sup>.

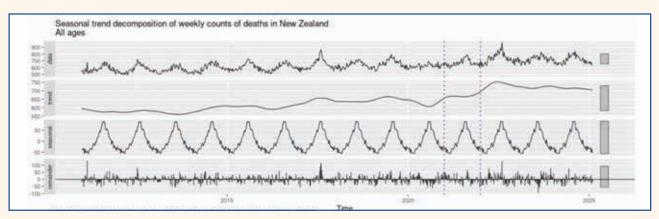


Figure 1. Seasonal trend decomposition of weekly counts of all-cause death in New Zealand. Vertical purple dashed lines represent the start and end of 2021. The de-seasonalised long-term trend is shown in the 'trend' plot, whereas the raw weekly counts are shown in the 'data' plot. 10,11

# Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health and Medsafe:

 Have you investigated the cause of the sharp rise in all-cause mortality in New Zealand in mid-2022?

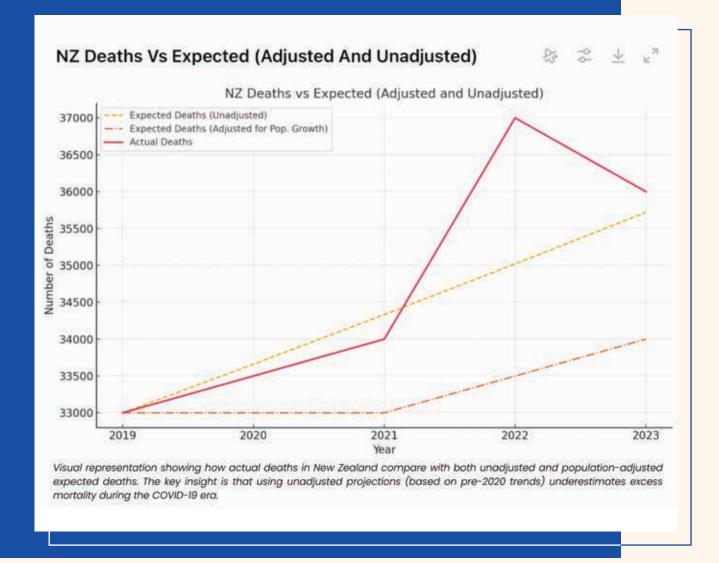
## International health authorities and comparative data analysts:

 Have you investigated the cause of the sharp rise in all-cause mortality in New Zealand in mid-2022?

# New Zealand Government and relevant advisory bodies (e.g. CV TAG, IMAC):

 Has New Zealand critically reviewed the vaccine programme in light of substantial adverse event data and historic levels of compensation?

- 1 https://www.tandfonline.com/doi/full/10.1080/00779954.2024.
- <sup>2</sup> https://www.apjhs.com/index.php/apjhs/article/
- 3 https://doi.org/10.1093/ofid/ofad209
- 4 https://bmjpublichealth.bmj.com/content/2/1/e000282
- https://www.apjhs.com/index.php/apjhs/article/
- 6 https://pubmed.ncbi.nlm.nih.gov/36055877/
- <sup>7</sup> https://react19.org/science
- 8 https://doi.org/10.1016/j.prp.2023.155030
- As of September 2024, ACC have paid out over \$11,429,594 in damages (as of Sept 2024) (Official Information Act request, reference: GOV-035284)
  - https://drive.google.com/file/d/1pmO6se3oan\_9VIXV
- https://mpidr.shinyapps.io/stmortality/
- https://sithor.shinyapps.io/time\_series\_change\_point/



# 1.12 MORTALITY

**RC Term: Vaccine Safety** 

B. NZ's claims of low excess mortality to justify vaccination were based on statistical flaws

Katie Ashby-Koppens based on Professor John Gibson's research

#### Why this issue is relevant:

New Zealand's excess death figures during COVID-19 were significantly understated due to a basic statistical flaw: officials failed to adjust for the sharp drop in population growth caused by closed borders and halted immigration.

#### New Zealand was uniquely positioned to succeed:

- Vaccines before the virus: The population was vaccinated before Omicron arrived (29 Dec 2021).
- Border control: The country had a near-zero-COVID environment throughout 2020–2021.
- 80%+ of the population double-vaccinated before community spread began.

New Zealand's health officials have repeatedly pointed to low excess mortality to justify the COVID-19 response, including lockdowns, mandates, and one of the world's most aggressive vaccine rollouts. But that claim does not hold up under scrutiny.

## A recent peer-reviewed study shows that excess death calculations were methodologically flawed:

- Population growth collapsed in 2020–2021 due to closed borders and halted immigration.
- Yet baseline death projections continued to assume 2% annual growth, inflating the "expected" deaths.
- This made actual deaths appear low masking the true scale of excess mortality.

When corrected for population changes, New Zealand had over 3,200 excess deaths from Jan 2020 to mid-2023 — more than double the official figures.<sup>1</sup>

#### **Details:**

Omicron was first found in New Zealand on 29 December 2021, when over 80% of the population 5+ had received two doses.<sup>2</sup>

#### 1. Misleading Baselines

Statistics NZ and global trackers (e.g. Our World in Data, The Economist) used historical population growth to project expected deaths. But during 2020–2021, population growth slowed dramatically due to border closures.

"Using historical growth rates (2015–2019) overestimates expected deaths by 1.3 to 2.5%".

#### 2. Revised Excess Deaths

Correcting for population growth, the authors estimate 3,203 excess deaths from Jan 2020 to Jun 2023 — significantly higher than the 1,250–1,430 often cited.

"Our corrected estimates show that excess deaths were nearly twice the official tally over this period." (p. 6)

#### 3. Temporal Patterns

The largest increase occurred in 2022, after the vaccine rollout and amid the Omicron outbreak.

"The excess mortality peaked after widespread vaccination and coincided with COVID-19's largest waves." (p. 7)

#### 4. Policy Implications

The study suggests official mortality statistics may have downplayed real harms and that current methods used by MoH and global organisations need revision.<sup>3</sup>

If the vaccines reduced COVID-19 deaths with minimal adverse effects, a decline in all-cause mortality would be expected. Instead, a rise has occurred in many jurisdictions.

This observation is consistent with a re-analysis of Pfizer and other vaccine trial data showing more serious adverse events in the vaccine groups than in placebo groups.<sup>4</sup>

# Important Questions for the Commissioners to Ask — and of Whom:

#### Statistics NZ and Ministry of Health:

#### On Mortality Data Integrity

 Have you investigated the cause of the sharp rise in all-cause mortality in New Zealand in mid-2022?

#### Ministry of Health and Medsafe:

#### On Vaccine Safety and Timing

- What investigations have been undertaken to explore the temporal correlation between mass vaccination in 2022 and the spike in excess deaths that same year?
- How many of the 3,000+ excess deaths between 2020–2023 have been officially reviewed for potential vaccine-related causality?

# Department of the Prime Minister and Cabinet (DPMC) and COVID-19 advisory groups:

#### On Transparency and Public Trust

- Why were academics and analysts who raised early concerns about excess mortality excluded from official advisory panels or public debate?
- Does the government acknowledge that overstating 'low excess deaths' gave a misleading impression of the success of the COVID-19 response?

#### Ministry of Health and Cabinet:

#### **On Policy Implications**

- What mechanisms exist to correct or update public health data when significant methodological flaws are identified post hoc?
- How will this revised mortality data inform future pandemic planning or vaccination policy?

- https://www.tandfonline.com/doi/full/10.1080/00779954.2024.2314770
- <sup>2</sup> https://en.wikipedia.org/wiki/COVID-19\_pandemic\_in\_New\_Zealand
- https://www.covid19lessons.royalcommission.nz/reports-lessons-learned/main-report/part-two/7-3-our-assessment/
- 4 https://pubmed.ncbi.nlm.nih.gov/36055877/.



# 1.12 MORTALITY

RC Term: Vaccine Safety

C. The Rollout of COVID-19 Booster Vaccines is

Associated With Rising Excess Mortality in New Zealand

Katie Ashby-Koppens based on Professor John Gibson's research

#### **Summary:**

An economic paper by Professor John Gibson analysed NZ mortality and vaccine rollout data and found a statistical association between excess deaths and the booster phase of the programme.

#### Why this issue is relevant:

The rollout of COVID-19 booster doses in New Zealand was statistically associated with rising excess mortality, particularly among age groups eligible for boosters, while no such increase is seen in younger, mostly unboosted age groups.

- Excess mortality rose sharply after December 2021, aligning with the booster rollout.
- No comparable rise was observed during the initial two-dose (original protocol) vaccine rollout.
- An estimated 16 excess deaths per 100,000 booster doses (via instrumental variables method).
- This equates to over 400 excess deaths in New Zealand.
- Valued using a statistical life measure, these deaths represent a cost of over NZD \$1.6 billion.

#### Details:

A June 2022 reported study showed a close relationship between the Pfizer vaccine booster rollout and rising excess mortality. This correlation was not seen with the rollout of the first two doses.

The paper suggested 400 excess deaths from the booster rollout in New Zealand, or 16 excess deaths for every 100,000 doses given. The age groups most likely to be boosted had 7–10 percentage point rises in excess mortality rates. The age group too young for boosters saw no such rise in excess mortality.

Increased risk appeared to be associated with dose, i.e. the more COVID-19 vaccinations received, the higher the risk of adverse events and mortality.

"Here, dose-dependent adverse events may explain why booster rollout is associated with rising excess deaths while rollout of original protocol doses is not. Secondary analysis of serious adverse events reported in the mRNA vaccine RCTs shows higher risks with Moderna than with Pfizer, perhaps from dosage differences (100mg for Moderna versus 30mg for Pfizer). The use of the Pfizer booster raises the accumulated dosage, which may then make these vaccine adverse events more likely".

The data used was weekly deaths in New Zealand from 2011 through to the end of March 2022 to calculate excess mortality during the rollout of the Pfizer injection.

The paper noted that all-cause deaths used to calculate excess mortality are not reported in real time. The lag means that few people would be aware in real time of the risk of increased mortality from the booster.<sup>1</sup>

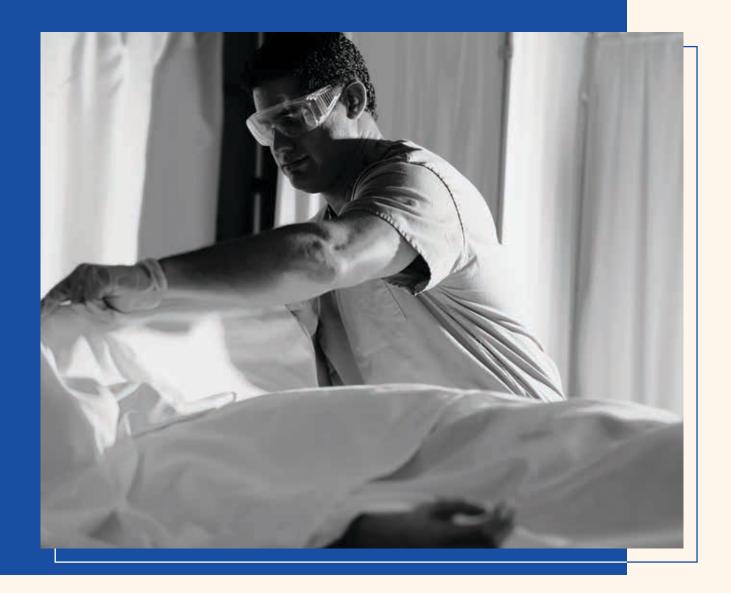
# Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health:

 Having provisionally consented to booster requirements, what monitoring did you introduce to detect any increase in adverse events or all-cause mortality?

#### References:

https://repec.its.waikato.ac.nz/wai/econwp/2211.pdf



# 1.12 MORTALITY

**RC Term: Vaccine Safety** 

D. Coroners not requesting pathology (no autopsies)

Dr Alison Goodwin

#### **Summary:**

Post-mortem and coronial investigation processes in New Zealand did not adequately scrutinise sudden or unexplained deaths during and after the COVID-19 vaccine rollout. This occurred alongside changes to the Coroners Act, which made it easier to determine 'natural causes' and forgo investigation. This may have contributed to missed opportunities for detecting adverse vaccine reactions or understanding excess mortality trends.

In New Zealand, generally a post-mortem is conducted by a pathologist if directed by a coroner.\(^1\) This gatekeeping role is critical in identifying the cause of death in 'reportable deaths' — including cases linked to novel medical interventions like the provisionally consented COVID-19 vaccines.

Despite reports of sudden and unexplained deaths post-vaccination, there is limited evidence that coroners or pathologists systematically investigated to confirm vaccination status, test for spike protein, or request detailed autopsies. Questions also remain about political influence, delays, and systemic gaps in New Zealand's passive adverse event reporting system. See changes to the Coroners Act (Issue 1.12E, page 206).

#### **Evidence and Key Details:**

#### 1. Coronial Access to Vaccine Data

As of August 2021, the Coronial Service may not have had timely access to individuals' COVID-19 vaccination status when investigating deaths.

The Memorandum of Understanding (MOU) between the Chief Coroner and the Director-General of Health, intended to facilitate such access, appears to have lacked clarity or efficiency.<sup>2</sup>

#### 2. Coronial Delays

The average time to close a coronial case in 2021 was reportedly 455 days, with inquests taking nearly four years.

Such delays may hinder the timely identification of vaccinerelated safety signals.<sup>3</sup>

#### 3. Post-Mortem Protocol Gaps

- No clarity on whether pathologists systematically reviewed vaccination status.
- Testing for spike protein or lipid nanoparticles does not appear to have been routine.
- Some coronial post-mortem requests may have been denied or expedited without full assessment.

#### 4. CARM Data Red Flags

As of mid-2022, New Zealand's passive surveillance system (CARM) had recorded 160 post-vaccination deaths, 48 of which were marked "insufficient information".<sup>3</sup> This raises questions about the adequacy of passive reporting and whether active surveillance was warranted.

#### 5. Known Conditions Detectable by Post-Mortem<sup>4, 5, 6</sup>

- Thrombosis: Potential link between spike protein and blood clotting.
- Myocarditis: Four vaccine-related deaths officially acknowledged by Medsafe.
- Cancer: Concerns about accelerated cancers possibly due to p53 or BRCA suppression.
- Pregnancy Outcomes: Original trials excluded pregnant women; anecdotal reports suggest increased stillbirths and miscarriages.
- Autoimmune Conditions: Guillain-Barré syndrome, transverse myelitis, immune thrombocytopenia.

#### 6. Limited Safety Data

The Pfizer vaccine was approved with only two months of safety data per participant. The phase 3 trials continued until February 2023.<sup>7</sup> As there was limited safety data available, active monitoring and review should have continued after vaccination commenced.

#### 7. Early Awareness of Potential Harms

A February 2021 OIA<sup>9</sup> revealed that officials anticipated that up to 1.1% of vaccine recipients may suffer serious adverse events requiring time off work.

A Pfizer report - released after a U.S. court order - documented 1,223 deaths in the first 90 days post-rollout (see isue 1.2E, page 122).10

#### 8. Influence on Coronial Objectivity

- Public officials made statements dismissing vaccine involvement in deaths before coronial findings were available.
- NZDSOS noted that verbal acknowledgements of vaccine involvement by coroners were sometimes omitted from written reports.
- Questions arise about coronial independence and political pressure on reporting.

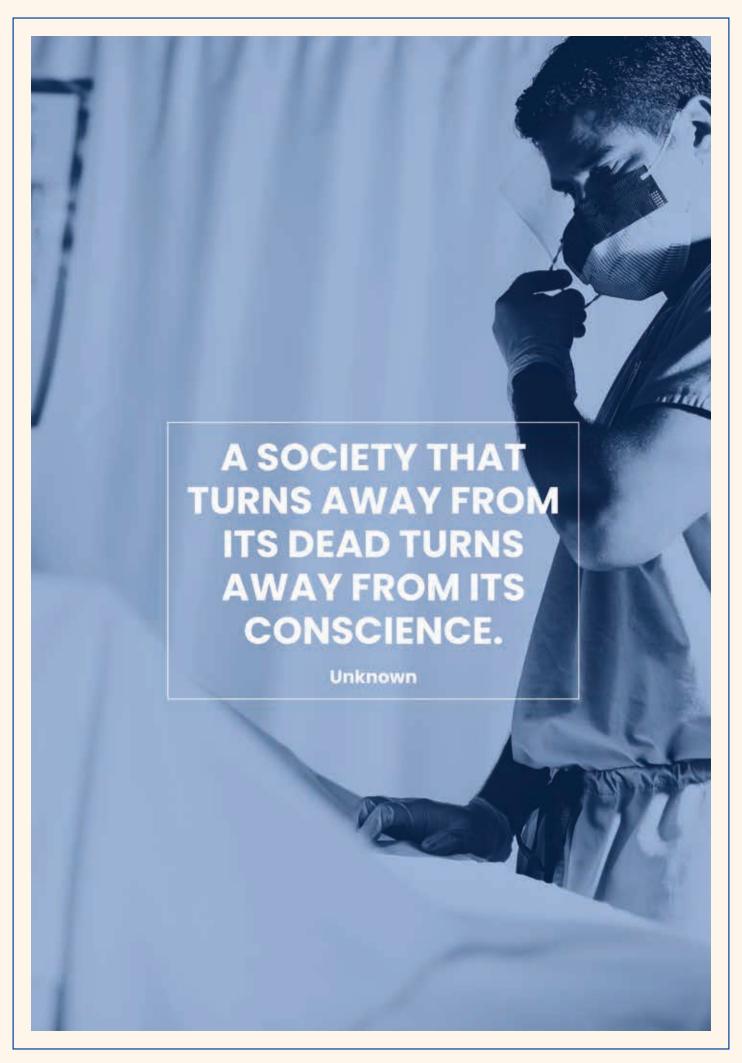
# Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health:

- Why was COVID-19 vaccination status not routinely recorded and reviewed in all sudden, unexpected, or unexplained deaths after the rollout of a novel provisionally approved vaccine?
- What instructions, if any, were issued to coroners or pathologists regarding the inclusion of vaccination status in autopsy protocols and reports?
- Has the Ministry since implemented systematic procedures to ensure this information is collected in all reportable deaths?
- Is testing for spike protein or lipid nanoparticles conducted in any post-mortem examinations in New Zealand? If not, why not?
- Why has New Zealand not adopted immunohistochemical staining for spike protein, given that such analysis is available overseas and can help identify vaccinerelated pathology?

- What internal or external reviews have been conducted to assess the adequacy of current post-mortem protocols in detecting vaccinerelated harm?
- What specific pathological features would indicate a possible vaccine-related death? For instance, is histological analysis of inflamed tissue around a ruptured aorta routinely undertaken to assess spike protein presence or immune infiltration?
- Under standard pharmacovigilance procedures, what actions would typically follow a report of death after a medical intervention such as vaccination?
- What criteria are used to determine whether a death reported to CARM requires further investigation or referral for independent review?

- Guidelines for Verifying Death
  <a href="https://www.tewhatuora.govt.nz/assets/Publications/Death/Guidelines-for-Verifying-Death.pdf">https://www.tewhatuora.govt.nz/assets/Publications/Death/Guidelines-for-Verifying-Death.pdf</a>
- Memorandum of Understanding https://drive.google.com/file/d/IGyWrOyUbFOnVwcCA4rLxxyjLun-QywkD/view?usp=share\_link
- 3 https://www.nzherald.co.nz/northern-advocate/news/kaitaia-family-desperately-seeking-answers-about-crash-face-coroni
- Medsafe Safety Report #43 (mid-2022): https://www.medsafe.govt.nz/COVID-19/safety-report-43.asp
- Medsafe PDF on Myocarditis: www.medsafe.govt.nz/safety/Alerts/comirnaty-myocarditis-alert.htm
- <sup>6</sup> Comirnaty (Pfizer) Data Sheet: https://drive.google.com/file/d/lopKzwQzSVi5BzpBjLy2p\_EJbPN9OGBtj/view?usp=share\_link
- Pfizer Phase 3 Clinical Trial Record (NCT04368728): https://clinicaltrials.gov/study/NCT04368728
- NEJM Original Study on Pfizer mRNA vaccine: https://www.nejm.org/doi/full/10.1056/nejmoa2034577
- NZDSOS OIA Maximising Vaccine Uptake in Tier 1 Border Workers: https://nzdsos.com/2022/06/03/nzdsos-court-case-2022-review/
- Pfizer 3-Month Post-Marketing Safety Report (PHMPT): https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf
- In the case of Isabella Alexander
  <a href="https://www.nzherald.co.nz/nz/covid-19-delta-outbreak-coroner-says-death-of-teen-not-linked-to-vaccine/OEEJATMBMBPX">https://www.nzherald.co.nz/nz/covid-19-delta-outbreak-coroner-says-death-of-teen-not-linked-to-vaccine/OEEJATMBMBPX</a>
  In the case of Sean Wainui
  <a href="https://www.nzherald.co.nz/nz/rugby-star-sean-wainuis-death-coroner-confirms-investigation-into-suspected-suicide/">https://www.nzherald.co.nz/nz/rugby-star-sean-wainuis-death-coroner-confirms-investigation-into-suspected-suicide/</a>





# 1.12 MORTALITY

RC Term: Vaccine Safety
E. Changes to the Coroners Act

Katie Ashby-Koppens

#### Why this issue is relevant:

The Coroners Act was amended during a period of unprecedented excess mortality. The amendments introduced an assistant coroner role and removed the requirement for coroners to investigate deaths that appeared natural but remained unexplained.

Many adverse events associated with the COVID-19 vaccines present as natural causes of death. The amendment reduced even further the likelihood that such deaths would be properly investigated as potential vaccine-related.

In August 2022, the Coroners Amendment Bill (Government Bill 157-1)<sup>1</sup> was introduced and later passed, amending the Coroners Act 2006.<sup>2</sup> The changes came into effect on 5 April 2023.

#### The stated rationale for the amendments:

"The coronial system is currently under considerable pressure. Coroners are struggling to keep pace with the number of cases being accepted into the coronial jurisdiction, which has resulted in an increasing active caseload and an increase in the average time taken to conclude coronial investigations."

See: All Cause Mortality Issue 1.12A, page 196; and Pfizer's 6 Month Adverse event report - where most of the adverse events are unexplained natural causes, Issue 1.2F, page 124.

## Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health:

- Given the rise in deaths in New Zealand following the mass rollout of a novel vaccine one for which manufacturers were indemnified and which carried documented risks—why was legislation introduced that reduced the likelihood of coronial investigation into unexplained deaths?
- Are there unintended consequences of changing the Coroners Act in 2023, i.e. now easier to determine 'natural causes' and not investigate thoroughly?

- Coroner's Amendment Bill 2022 https://legislation.govt.nz/bill/government/2022/0157/14.0/whole.html
- <sup>2</sup> https://www.legislation.govt.nz/act/public/2006/0038/125.0/DLM377057.html



# 1.13 MANDATES

New Zealanders were assured that COVID-19 vaccination would remain a personal choice. Yet over time, that promise gave way to an expanding web of mandates, restrictions, and indirect pressures that left many with no meaningful alternative. What began with limited border worker requirements quickly extended to wide sectors of society - including children as young as 12 - who were locked out of work, education, and community life.

Government messaging and policy blurred the line between consent and coercion. Private employers were enlisted to enforce compliance through tools like the Vaccination Assessment Tool. Meanwhile, vaccine passes became de facto mandates, and public campaigns promoted the Pfizer vaccine with exaggerated certainty – raising legal and ethical concerns about government endorsement and the erosion of informed consent.

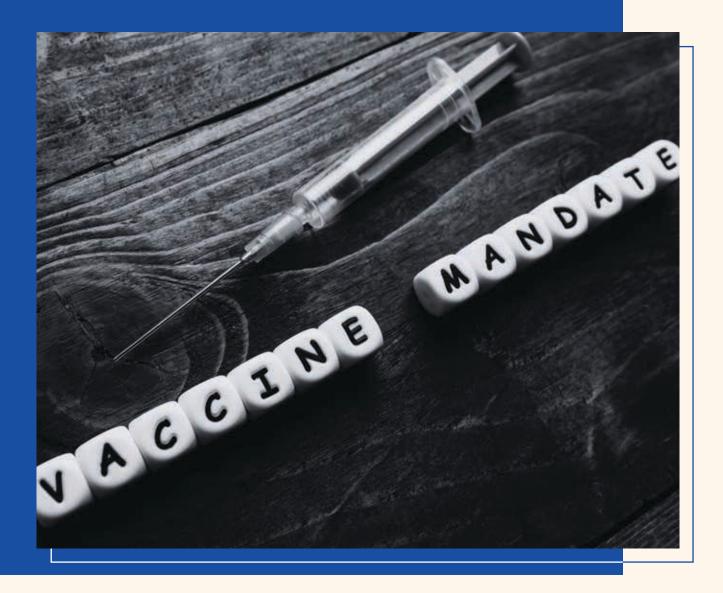
AUT's independent legal and ethical review later found the mandates unjustified in both principle and practice. They disproportionately impacted marginalised communities, strained public trust, and lacked transparency around evidence and necessity.

In February 2022, tens of thousands gathered peacefully on Parliament's lawns to protest the mandates and broader overreach of emergency powers. Their calls for dialogue were ignored. Their presence was mischaracterised. Yet their message was clear: the government had gone too far.

This section traces how public health powers were used to normalise unprecedented control over personal medical decisions, and the societal cost of doing so.

#### In this section

- A. Coercion the mandate creep
- B. Mandates not warrented cost benefit analysis
- C. Mandates not legally or ethically justified
- **D**. Government Pressure
- E. Parliament Protest



# 1.13 MANDATES

RC Term: Vaccine Safety

A. The mandate creep

Katie Ashby-Koppens

#### Why this issue is relevant:

New Zealanders were repeatedly assured that vaccination was a "choice". The Prime Minister also assured the population that vaccinations would not be mandated.

Yet those who declined were systematically excluded from work, education, and everyday life. What began as limited mandates for border workers quickly evolved into mechanisms that pressured private employers to comply, culminating in sweeping coercive measures that forced even 12-year-olds to be vaccinated simply to re-enter and participate in society. The vaccine pass was a vaccine mandate.

The COVID-19 response in New Zealand saw the steady expansion of government powers through a series of Vaccination Orders and regulatory tools. Initially limited to highrisk border and healthcare roles, mandates soon expanded to encompass wide sectors of society, including health, education, corrections, police, and eventually the general workforce (via their employers).

Where the government did not directly mandate vaccines, it enabled and pressured private entities to do so, through tools like the Vaccination Assessment Tool for emplyers to easily justify vaccine policies. These policies culminated in the Traffic Light System, effectively locking unvaccinated individuals (aged 12+) out of daily life.

This slow but deliberate mandate creep reveals how "public health" justifications were used to normalise unprecedented control over personal medical decisions, often with unclear or changing legal justifications.

#### **Details:**

## Late 2020 - Early 2021 - The government states that New Zealanders would not be mandated:

"I see no reason to do that", Jacinda Ardern (Sept 22, 2020).1

"The government is not making COVID-19 or any other vaccines compulsory", Chris Hipkins (3 Sept 2020).2

"The government's made it clear that the vaccine won't be mandatory in New Zealand, and I think that's the case in just about every country around the world", Ashley Bloomfield (4 Feb 2021).3

#### April - December 2021 - Vaccination Mandates

- 30 April 2021 COVID-19 Public Health Response (Vaccinations)
   Order 2021 began with border workers.
- October-November 2021 Expanded to:
  - Healthcare and disability sector.
  - Education sector (teachers and support staff).
  - Prison workers (Corrections staff).

- December 2021 The government introduces the Vaccination Assessment Tool. Provided legal basis for employers to implement vaccine policies independently under health and safety grounds, without having to conduct a full and proper health and safety assessment for the workplace.<sup>5</sup>
- December 2021 Police and Defence Force Vaccination Order.<sup>6</sup>
- Required all NZ Police and NZDF staff to be vaccinated.

## Nov 2021 - The government would not force all New Zealanders to be vaccinated

Jacinda Ardern stated that it was always her view that the government would not force all New Zealanders to be vaccinated, and that view had not changed.

She emphasised that vaccination requirements were applied to certain workforces and workplaces, based on assessments of duty of care to protect the most vulnerable. Ardern also clarified that vaccine certificates would not be required to access essential services such as health care, food or government support.<sup>7</sup>

## Dec 2021 - Sept 2022 - Vaccine Passes - The Traffic Light System<sup>8</sup>

- Instituted vaccine pass requirements for anyone 12 years and older to access basic aspects of public life:
  - Hospitality, gyms, events, gatherings, travel, sitting driver's licence, even education-related activities.
  - Created a tiered system of restrictions based on regional "risk level", but in all cases, vaccine passes were central.
  - Businesses and services that didn't comply risked penalties, while individuals were effectively locked out of society.

#### Mar 2022 - Permanent Residents were not allowed home9

 Only vaccinated permanent residents were allowed to return to NZ without quranantine.



## Important Questions for the Commissioners to Ask — and of Whom:

# Ministry of Health, COVID-19 Response Minister, and Relevant Agencies:

#### On Government Assurances vs. Actions

- In 2020 and again in late 2021, Prime
   Minister Jacinda Ardern publicly stated that
   vaccination would not be mandated for all
   New Zealanders.
- What legal or ethical framework justified the subsequent expansion of mandates to wide sectors of society, including indirect enforcement through private employers and restrictions on children aged 12+?
- How does the government reconcile its public assurance that vaccine passes would not be required to access essential services with the reality that people were excluded from accessing driver licence testing, educational activities, and even some health services?

#### On the Use of the Vaccination Assessment Tool

- What risk-benefit analysis or health and safety review was conducted prior to introducing the Vaccination Assessment Tool in December 2021?
- To what extent did the government consult with WorkSafe NZ, unions, or civil liberties experts before releasing a tool that enabled employers to implement vaccine mandates without a full workplace-specific assessment?

 Was any monitoring conducted to evaluate the appropriateness or impact of employer-led mandates introduced via this tool, particularly in low-risk or remote work environments?

#### On the Legal Foundation of Mandates

- What were the specific legal criteria or thresholds used to determine which sectors required direct mandates (e.g. police, teachers, corrections)?
- Why did the government consider it lawful to mandate vaccination for 12-year-olds to access social and educational participation under the Traffic Light system, given their comparatively low risk profile?
- Were any internal legal reviews conducted that raised concerns about the proportionality or legality of these mandates? If so, will those reviews be made publicly available?

## On the Traffic Light System and Societal Exclusion

- What evidence informed the decision to apply the Traffic Light System to children aged 12+, effectively making vaccination a condition for normal societal participation?
- Did the Ministry model or anticipate the social, psychological, and educational harm of excluding unvaccinated individuals (including minors) from basic community life? If so, what were the findings?
- What redress, if any, will be provided to individuals, especially young people, who were coerced, harmed, or excluded as a result of these policies?

- https://www.stuff.co.nz/politics/350546399/coronavirus-jacinda-ardern-confident-enough-kiwis-will-get-covid-19-vaccine-
- <sup>2</sup> https://www.lnews.co.nz/2020/09/03/health-minister-takes-aim-at-deliberate-misinformation-claiming-potential
- ${}^{3} \underline{\quad \text{https://www.rnz.co.nz/news/national/435777/new-zealand-preparing-in-case-of-early-pfizer-covid-19-vaccine-delivery.} \\$
- See full amendment history https://www.legislation.govt.nz/regulation/public/2021/0094/latest/LMS487853.html
- https://www.legislation.govt.nz/regulation/public/2021/0418/latest/LMS616557.html
- 6 https://www.legislation.govt.nz/regulation/public/2021/0415/latest/whole.html
- <sup>7</sup> https://www.rnz.co.nz/news/political/454836/pm-jacinda-ardern-we-have-not-taken-lightly-the-decision-for-some-areas-
- 8 https://www.legislation.govt.nz/regulation/public/2021/0386/latest/LMS563461.html
- 9 https://www.covid19lessons.royalcommission.nz/reports-lessons-learned/main-report/part-two/4-2-what-happened/





# 1.13 MANDATES

RC Term: Vaccine Safety

B. November 2021 - Mandates Not
Warranted on a Cost-Benefit Analysis

Dr Martin Lally

#### Why this issue is relevant:

Vaccine mandates for COVID-19 have been among the most controversial policies adopted during the pandemic. In November 2021, when the Vaccination Order was introduced for healthcare, education, and prison workers, vaccine mandates for the general population were not warranted on a cost-benefit basis.

Even under extremely conservative assumptions, such as only a 4% per year reduction in the quality of life for 2.5 years for those objecting to vaccination, the costs of the policy (in the form of QALY losses for those who opposed vaccination) exceeded the benefits (in the form of lives saved in QALY terms) by at least 32 times. Even for health workers, the costs exceeded the benefits but to a much lesser degree because of their frequent and close contact with vulnerable individuals. This conclusion applies even more so to education workers, who primarily interact with people at low risk of contracting COVID-19.

#### **Details:**

- Opposition to vaccination is rational for healthy individuals under 30, whose increased risk of death from covid due to not being vaccinated was so low that it was less than the risk of death (plus serious vaccine side-effects in equivalent QALY terms).<sup>1</sup>
- In late 2021, when the principal vaccination mandates were introduced, the vaccination rate for the 12+ group was already about 80%, and it subsequently reached about 90%. So, between 10% and 20% of the 12+ New Zealand population were vaccine objectors. At 20%, this is 840,000 New Zealanders.
- If these individuals experienced on average only a 4% annual QALY loss over 2.5 years, the total cost is 84,000 QALYs.
- Research by Professor Michael Plank and cited in the earlier Royal Commission report was that the vaccination program saved 6,650 lives. This involved raising the vaccination rate from zero to the 90% rate achieved, with the last 10% (80% to 90%) estimated to have saved 625 lives.
- With 20% of the 12+ population objecting to vaccination, the effect of the mandates was to raise the vaccination rate from 80% to 90% and therefore to save 625 lives. This is about 2,600 QALYs.
- The cost of the mandates (84,000 QALYs) then exceeds the benefit (2,500 QALYs) by 32 times.
- As the proportion of the 12+ population objecting to vaccination falls, and therefore the costs of the mandates fall, the benefit falls even faster and therefore the costs exceed the benefits even more strongly.
- Even for **health workers**, who may disproportionately contribute to transmission to high-risk patients, the costs of the mandates exceeded the benefits, but to a lesser degree.
- This conclusion applies even more strongly to education workers, whose occupational exposure does not involve vulnerable groups.

## Important Questions for the Commissioners to Ask — and of Whom:

#### The Government:

- Has the New Zealand Government conducted any formal cost-benefit analysis to justify vaccine mandates?
- Was the impact on vaccine objectors' quality of life, including mental health and employment loss, ever quantified?
- What was the government's estimate for the number of lives saved by mandating the vaccine?
- Why were education workers included in mandates, despite no evidence they posed significant risk to vulnerable populations?
- Does the government accept that Medsafe's public assertions that "the protective benefits of the vaccination against covid-19 far outweigh the potential risks" is not true for most healthy people, and especially those under 30.
- Will the government now review its policies in light of this analysis and the emerging data on vaccine risk-benefit ratios by age and health?



# Vaccine pass required for entry

# 1.13 MANDATES

RC Term: Vaccine Safety

C. Mandates not ethically or legally justified

Katie Ashby-Koppens summarising AUT Report. Workforce vaccine mandates: The effect on vaccine uptake and healthcare workers' labour market outcomes.

#### Why this issue is relevant:

Vaccine mandates fundamentally altered the rights of New Zealanders during the COVID-19 pandemic, affecting employment, education, movement, and social cohesion. AUT'S NZ Public Research Institute undertook a comprehensive legal and ethical review and found (in their view) that mandates of the type and extent adopted in New Zealand were not ethically or legally justified overall.

AUT's independent report<sup>1</sup> critically evaluates New Zealand's vaccine mandate policies from legal, ethical, and public health standpoints. The authors conclude:

"In our view, mandates of the type and extent adopted in New Zealand were not ethically or legally justified overall."

#### Key points:

- · Ethical justifications were weak and inconsistently applied.
- Mandates created division and discrimination, particularly affecting already marginalised groups.
- Public health benefits were overstated, while risks and social costs were downplayed.
- The government failed to provide transparent evidence that mandates were proportionate or necessary.

The report calls for robust legal frameworks, greater accountability, and more honest risk communication from public institutions going forward.

#### Details from AUT's report:1

- Mandates lacked strong ethical foundations and disproportionately affected certain groups without sufficient evidence they were necessary (pg 4).
- The government applied mandates not only to frontline health and border workers but also extended them to education and private sector employment, impacting a far larger group than initially anticipated (pg 7–8).
- The absence of legal precedent and the vague justification under the COVID-19 Public Health Response Act raised significant rule-of-law concerns (pg 10-11).
- Ethical frameworks for mandates (e.g. proportionality, necessity, reciprocity) were poorly adhered to. For example, no system existed to fairly compensate those harmed by mandates or to accommodate those with good-faith objections (pg 12–14).
- There was little to no space for public or professional dissent.
   Those who questioned mandates were stigmatised or silenced. This contradicts democratic values and the ideal of open scientific debate (pg 17–19).
- Evidence of real-world vaccine effectiveness was shifting rapidly by late 2021 and early 2022, yet mandates remained rigid. The mandates did not reflect the emerging reality that vaccines had limited transmission-blocking capability (pg 21–23).
- Māori and vulnerable communities were disproportionately

affected by coercive policies, undermining trust and violating the principle of equity (pg 25–26).

 The authors recommend future pandemic responses be grounded in genuine public dialogue, transparency, and respect for human rights, rather than coercion and institutional control (pg 28).

## Important Questions for the Commissioners to Ask — and of Whom:

#### The Government:

- What specific evidence did the government rely on to justify the scale and duration of mandates — especially when transmissionblocking benefits were known to be marginal?
- Why was there no independent legal review of the mandates at their peak, despite widespread public concern and clear impacts on civil liberties?
- Why were ethical principles like compensation, informed consent, and the right to conscientious objection not consistently upheld?
- Why did the government not publicly share the risk-benefit assessments that underpinned the mandate policy decisions?
- What steps has the government taken to repair the social damage and loss of trust caused by the mandates, especially among marginalised and vaccine-injured communities?
- How will the government ensure future pandemic responses uphold individual rights, scientific integrity, and public trust?



# 1.13 MANDATES

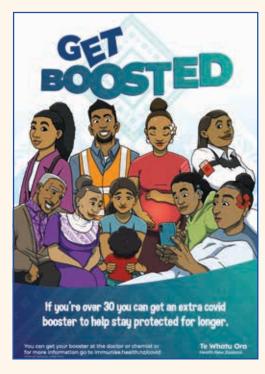
RC Term: Vaccine Safety

D. Government Pressure - Advertising - Government Advertising and Promotion of COVID-19 Vaccines

Voices for Freedom Research Team

#### Why this issue is relevant:

During the COVID-19 vaccine rollout, the New Zealand Government and Ministry of Health engaged in extensive promotional advertising campaigns that presented the Pfizer-BioNTech (Comirnaty) vaccine in ways that may have misled the public. Some campaigns appeared to breach the Medicines Act 1981, which prohibits government endorsement of therapeutic products, as well as advertising standards around balance, accuracy, and informed consent. This issue raises concerns about public trust, the integrity of public health messaging, and whether proper legal and ethical boundaries were maintained.



Te Whatu Ora A3 downloadable poster

Between 2021 and 2022, the Government used taxpayer-funded campaigns to promote the COVID-19 vaccine across television, print, digital, social media, and in-person events. This included the Unite Against COVID-19 Campaign and the Vaccine Campaign, held by DPMC, where \$87,657,993 was spent between 1 March 2020 and 31 December 2021.

Advertising slogans such as "Protect them for life. Immunise." and "Don't wait, vaccinate." were widely used. Government logos, including those of the Ministry of Health and New Zealand Government, were prominently displayed on material promoting a specific vaccine.

#### These advertisements:

- Suggested official government endorsement of a commercial product, potentially in breach of the Medicines Act 1981, s58(1) (b).<sup>2</sup>
- Used exaggerated claims about vaccine safety and efficacy, including in vulnerable groups such as pregnant women and children.
- Appeared to omit key risk information required for informed consent
- Used emotional and psychological pressure tactics, particularly in M\u00e4ori and Pasifika communities.
- Were rolled out with high-intensity, high-budget saturation, leaving little room for counter-narratives or informed debate.

The use of public funds to aggressively market a provisionally approved medicine, while presenting it as fully safe, effective, and the only acceptable option, is a matter warranting close scrutiny by the Inquiry.

#### Details:

## 1. Legal concerns: government endorsement of therapeutic products

Section 58(1)(b) of the Medicines Act 1981 prohibits advertisements that "claim, indicate, or suggest that the product has been recommended or approved by any government agency." Despite this, official government branding was featured on promotional materials for the Pfizer-BioNTech (Comirnaty) COVID-19 vaccine.

#### 2. Misleading or exaggerated claims

Government-funded ads included definitive statements about vaccine safety and efficacy that exceeded the available evidence at the time. Examples included:

- "Protect them for life. Immunise." implying lifelong protection for children, which the Advertising Standard Authority upheld complaints against ruling it was misleading.<sup>3,6</sup>
- "The Pfizer vaccine will not affect your fertility or your baby's genes or DNA." — stated without reference to the lack of longterm reproductive safety data in humans.3
- "Getting vaccinated is the best way to protect yourself and your baby." — asserted without acknowledging risk-benefit variability or emerging safety signals.<sup>3</sup>
- "95% protection" a figure drawn from early clinical trial data measuring relative risk reduction, not absolute risk reduction, which was far lower. This distinction was not explained in public communications, giving the impression of nearcomplete protection and omitting important context around statistical framing, real-world effectiveness, and waning immunity.<sup>2</sup>

#### 3. Psychological pressure and emotional manipulation

Campaigns such as "Super Saturday" and "Shot Cuzz" employed emotionally charged or identity-driven messaging. Imagery of heroic action, collective duty, and social belonging was used to encourage compliance, especially among young people and Māori.<sup>3,4</sup>

#### 4. Promotion to vulnerable populations

Targeted outreach campaigns used mobile buses, celebrity endorsements, and culturally tailored messaging to promote vaccination in Māori, Pasifika, and low-income communities. These efforts emphasised urgency and unity but frequently omitted key information about side-effects, clinical trial limitations, or the vaccine's provisional approval status.<sup>35</sup>

#### 5. Use of public funds for vaccine marketing

Over \$85 million in taxpayer money was committed to COVID-19 vaccine advertising. The government used multiple media channels and contracted PR agencies and influencers to encourage uptake. Critics argued this created an environment of social coercion rather than informed medical decision-making.<sup>1</sup>

#### 6. Advertising Standards Authority complaint upheld

A government vaccine advertisement was the subject of a successful complaint to the Advertising Standards Authority (ASA), which ruled it misleading. This established that government communications did not always meet basic advertising standards.<sup>6</sup>

# Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health and COVID-19 Response Unit:

- Were the legal requirements of the Medicines Act 1981, including Section 58, reviewed before launching promotional campaigns?
- Who approved the wording of vaccine-related ads, particularly claims like "Protect them for life" and "95% effective"?
- Why were risks, side-effects, and provisional approval status not clearly disclosed in all advertising material?

#### Advertising Standards Authority (ASA):

- How many complaints were made about government vaccine advertising, and how many were upheld?
- Was the government held to the same standards as commercial advertisers?

# Department of the Prime Minister and Cabinet (DPMC):

 What was the involvement of central government communications staff in developing, approving, and coordinating vaccine promotional content?

#### Māori and Pasifika health providers:

- Were they consulted on how culturally tailored advertising would be perceived?
- Were informed consent protocols adapted for these targeted communities?

#### Medsafe and the Ministry of Health:

• Did Medsafe review the accuracy of claims made in public health advertisements?

#### References:

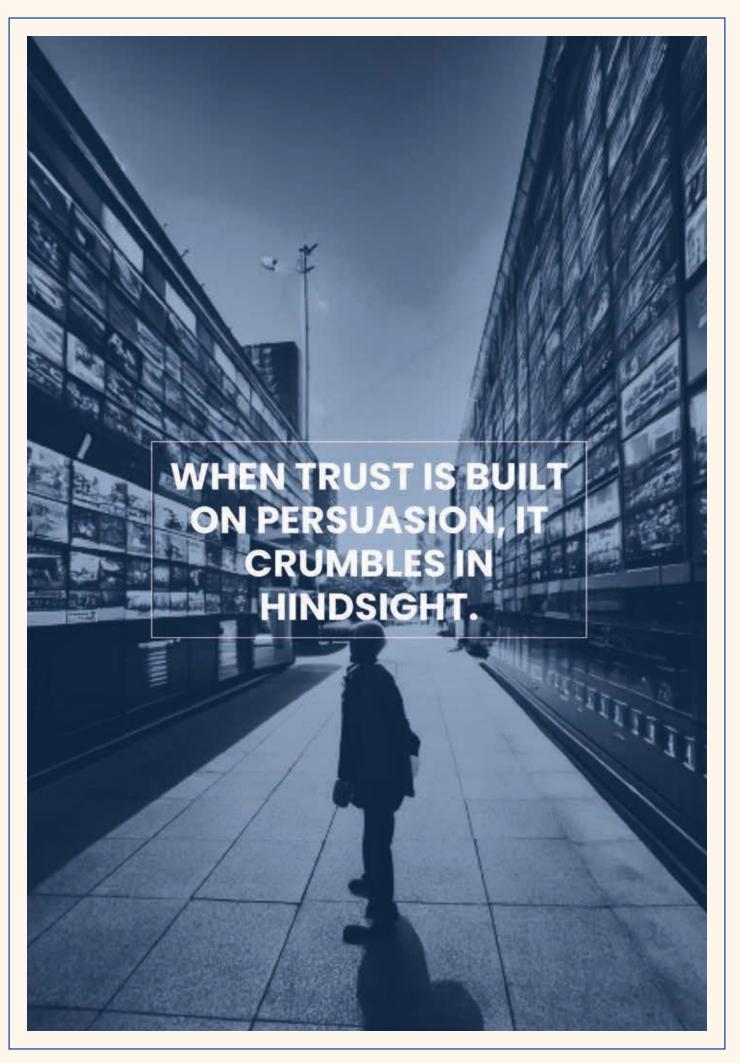
https://www.dpmc.govt.nz/sites/default/files/2022-05/dpmc-roia-0ia-2021-22-0735-costs-of-covid-19-public-information-

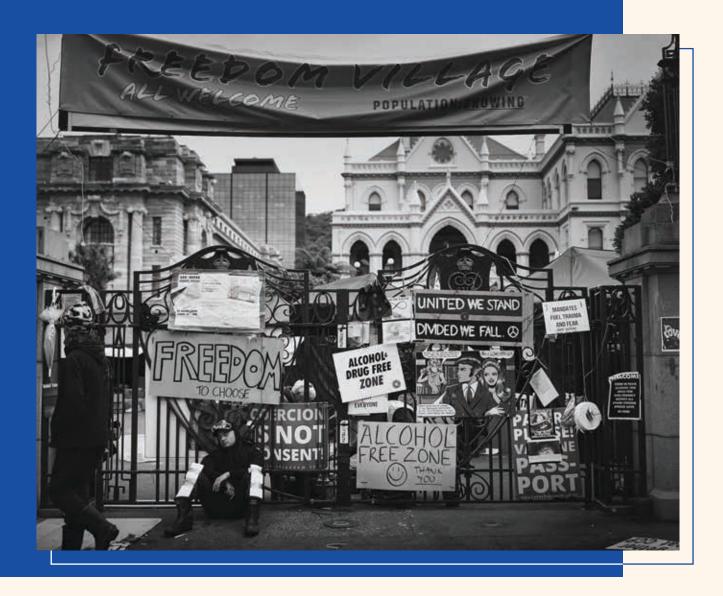
lNews: Govt's COVID advertising tips past \$35m in last year alone (27 March 2022): https://www.lnews.co.nz/2022/03/27/govts-covid-advertising-tips-past-35m-in-last-year-alone/

Department of the Prime Minister and Cabinet (DPMC) OIA response: COVID-19 Vaccine Advertising Costs, Ref: OIA-2021/22-0988 (19 April 2022):

https://www.dpmc.govt.nz/sites/default/files/2022-05/dpmc-roia-oia-2021-22-0988-covid-19-vaccine-advertising-costs.PDF

- Medicines Act 1981, Section 58(1)(b): https://www.legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html
- <sup>3</sup> COVID-19 Advertising Materials (OIA 1115 Appendix 7, Ministry of Health): https://drive.google.com/file/d/1\_VCiH2IN3QBwXMmiOXS30ginXZUsWMD7/view?usp=share\_link
- 4 "Super Saturday" and "Shot Cuzz" Māori TV campaign example: https://www.youtube.com/watch?v=6xpzOccAAaA
  - https://www.facebook.com/watch/?v=2959849197599442
- <sup>5</sup> Pacific Peoples COVID-19 Vaccination Research Report, Ministry of Health (2021): https://www.health.govt.nz/system/files/2021-09/pacific\_peoples\_covid-19\_vaccination\_research\_report\_proactive\_release.pdf
- 6 Advertising Standards Authority Complaint 22/197: https://drive.google.com/file/d/1K3LwkgdayNGowAyfh2aq03vS6XyypS3b/view?usp=share\_link





# 1.13 MANDATES

**RC Term: Vaccine Safety** 

E. Parliament Protest 2022 - A People's Stand Against COVID-19 Mandates

Alia Bland

#### Why this issue is relevant:

In February 2022, almost two years to the date of the first lockdown, thousands of New Zealanders descended on Parliament grounds to protest against mandates and government overreach to the COVID-19 response. The Parliament Protest was one of the largest and most sustained acts of civil disobedience in New Zealand's modern history. Thousands of New Zealanders gathered. Protestors from diverse backgrounds voiced their concerns over job losses, segregation, and loss of rights — peacefully and lawfully. Despite this, they were misrepresented by the media and dismissed by politicians. The government's refusal to engage set a dangerous precedent for democracy.

From mid-February to early March 2022, protestors, supported by Voices for Freedom and allied groups, occupied the grounds around Parliament to demand an end to vaccine mandates and the COVID-19 Public Health Response Act. Despite sustained peaceful protest and repeated calls for dialogue, the government and all political parties refused to meet with protestors.

The Speaker of the House and police engaged in increasingly aggressive tactics, while public officials and media issued repeated misrepresentations about the nature of the protest.

At the heart of the protest was a call for the restoration of democratic values: freedom of speech, informed consent, bodily autonomy, and non-discrimination. Participants spanned ethnicities, age groups, political affiliations, and vaccination status. Over 1.2 million New Zealanders reportedly supported the protest.

The protest also highlighted serious concerns about police conduct, misinformation by officials, and government refusal to uphold human rights principles.

Despite this, Voices for Freedom and others maintained a commitment to peaceful protest and legal advocacy, including substantial legal support for protestors wrongfully arrested.

#### Details:

- Protestors included vaccinated and unvaccinated individuals, with 27% Māori and 45% reporting they voted Labour or Green in 2020.<sup>1</sup>
- Groups represented included Voices for Freedom, Convoy 2022 NZ, NZDSOS, Freedom Alliance, Outdoors & Freedom Movement, The Freedom and Rights Coalition, and The Hood NZ.<sup>2</sup>

- The protest remained peaceful despite provocations, misleading information, and political hostility. Independent footage later debunked claims that protestors peppersprayed police — it was shown to be accidental police "friendly fire".<sup>7</sup>
- Multiple offers for mediated dialogue were ignored by the government. Winston Peters noted this was the first time in living memory that all parties refused to meet with a parliamentary protest.<sup>2</sup>
- Protestors proactively worked with Police to manage traffic and safety and consistently condemned violence or aggression on-site.<sup>2</sup>
- Protest organisers accused Police of PR manipulation e.g. raising unsubstantiated claims of sexual assault, refusing to identify known agitators, and threatening to block portaloos from being serviced.<sup>27</sup>
- The Human Rights Commission hosted a hui with VFF and allied groups, allowing impacted individuals and experts to share personal testimony and scientific data.<sup>4</sup>
- VFF's legal team supported over 90 protestors with legal aid;
   79% had charges withdrawn or accepted diversion, and none had been convicted as of September 2022.<sup>5</sup>
- Nearly 2,000 complaints were submitted to the Independent Police Conduct Authority (IPCA) regarding Police conduct at the protest.<sup>5,3</sup>
- · Mandates for teachers were lifted a month following.

# Important Questions for the Commissioners to Ask — and of Whom:

#### Former Prime Minister Jacinda Ardern:

- Why did you and your Cabinet refuse to meet with peaceful protestors, even when a qualified mediator was offered?
- Given your public admission that mandates created a two-tier society, why were mandates not removed sooner when Omicron was declared "mild and moderate for most people"?<sup>6</sup>
- Why did you not correct false information about protestor behaviour — including the pepper spray incident — when evidence disproved the claims?<sup>7</sup>

#### **New Zealand Police Commissioner:**

- Why did police raise unsubstantiated claims (e.g. sexual assault risk, presence of dangerous individuals) with media before alerting protest organisers? <sup>2,7</sup>
- Why were known agitators and offenders not removed from the site, and why was footage of such individuals withheld from protest security teams?<sup>7</sup>
- Have any police officers or communication staff been held accountable for the misrepresentations and disinformation spread during the protest?

# All Parliamentary political parties (2020 Parliament):

- Why did every party refuse to engage with protestors, setting a precedent of mass political disengagement from public dissent on Parliament grounds?
- What safeguards will be introduced to prevent future governments from using emergency legislation to override human rights without proportionality or public accountability?

- The Platform / Horizon Research, "Parliamentary Protest Poll Results," February 2022.
  - https://web.archive.org/web/20220221115658/https://theplatform.kiwi/opinions/parliamentary-protest-poll-results-february-2022
- Voices for Freedom press releases and protest communications: Press Releases:
  - https://www.voicesforfreedom.co.nz/press-releases/
  - Facebook protest page archive:
  - https://www.facebook.com/NZParliamentProtest2022/
- Independent Police Conduct Authority (IPCA), Terms of Reference and information on the 2022 Parliament Protest Inquiry: Website:
  - https://www.ipca.govt.nz/Site/parliament-protest/
- <sup>4</sup> Statements by Chief Human Rights Commissioner Paul Hunt and coverage of the Human Rights Commission hui, as referenced in VFF press releases and media (Feb 2022).
- https://www.voicesforfreedom.co.nz/blog/vff-meets-with-human-rights-commission/
- Voices For Freedom blog post, "Your Voices Matter" by Katie, Head of Legal, published 15 September 2022.
  Full link:
  - https://www.voicesforfreedom.co.nz/blog/your-voices-matter
- Public statements by Dr Bryan Betty, Chair of the General Practitioners Council, on Omicron and public health prioritisation quoted in VFF press releases and media coverage (Feb 2022).
  <a href="https://www.voicesforfreedom.co.nz/blog/vff-meets-with-human-rights-commission/">https://www.voicesforfreedom.co.nz/blog/vff-meets-with-human-rights-commission/</a>
- Video footage and protestor accounts cited in press releases regarding pepper spray incident and other events at Parliament.
  Source archives maintained via Facebook:
  - https://www.facebook.com/NZParliamentProtest2022/





# 1.14 GASLIGHTING

### Medical Grounds Were Ignored—and Injuries Dismissed

This section addresses two critical yet often overlooked aspects of New Zealand's COVID-19 response: the withdrawal and abrupt overhaul of medical exemptions, and the systemic failure to support the vaccine-injured through the Accident Compensation Corporation (ACC). Together, these issues reveal a troubling pattern – where those most in need of protection were instead left without options, recourse, or recognition.

Initially, medical exemptions were permitted based on the clinical judgement of qualified health practitioners. That changed in November 2021, when responsibility was shifted to the Director–General of Health and criteria were narrowed so dramatically that even those with documented contraindications – such as previous anaphylaxis (including to an earlier COVID–19 vaccine), myocarditis, or pre–existing heart conditions – were routinely denied. The result was a centralised, opaque system that sidelined treating doctors and failed those with legitimate medical risks. Consequently, people had to receive their doses at the hospital, near crash carts.

For those who did proceed with vaccination and suffered injury, the government pointed to ACC as a safety net. But it was a net riddled with holes. Despite early internal projections of a serious injury rate as high as 1.1%, over half of the 4,300 vaccine-related claims were declined. Even in cases involving death or neurological injury with clear temporal links to vaccination, claimants were left to navigate an impersonal and inconsistent process - one that too often defaulted to denial.

These failures are not just bureaucratic missteps. They represent a deeper abandonment of New Zealanders who did what they were told, took one for the team, and trusted that the system would look after them if things went wrong. Instead, the government overrode clinical judgement, marginalised the injured, and breached its duty of care to those it had urged into compliance.

#### In this section

- A. Exemption changes
- B. ACC



# 1.14 GASLIGHTING

**RC Term: Vaccine Safety** 

A. Mandates: Exemption Changes and Exemptions

Lynda Wharton and Katie Ashby-Koppens

#### Why this issue is relevant:

The mandatory vaccine order was changed to make it very difficult to obtain recognised vaccine exemptions from a person's GP. Decision-making was handed to the Director-General of Health. Very few medical exemptions were granted after this change, denying access to people who were genuinely entitled to one.

Despite this, 11,005 exemptions were granted to healthcare workers to avoid significant service disruption.

Medical exemptions were initially readily accessible from a person's GP under the Vaccinations Order. Shortly after the Order was broadened to include prison, education, and healthcare workers, the exemption clause was repealed and replaced with a new clause allowing personal exemptions only through the Director–General's office.

This severely restricted access to exemptions and denied many people protection despite legitimate medical grounds.

Separate from the individual medical exemptions on offer, exemptions were available to avoid disruption of services. The Minister granted over 11,000 exemptions to avoid disruption of services in the health care setting.

#### **Details:**

July 2021: The second version of the COVID-19 Public Health Response (Vaccinations) Order 2021 was introduced, relating to workers at managed quarantine facilities.<sup>1</sup>

- Clause 7A provided an accessible exemption where:
  - "the affected person has particular physical or other needs a suitably qualified health practitioner (in the course of examining the person) determines would make it inappropriate for the person to be vaccinated"
- Employers were required to note such exemptions on a register.
- A service disruption exemption could be granted by a CEO of a business (Clause 9).
- **25 October 2021:** The fifth version of the Order extended mandatory vaccination requirements to prison workers (by 6 November) and education and health workers (by 15 November).<sup>2</sup>
- This amendment retained Clause 7A and 9 exemptions referred to above and introduced a new Ministerial exemption to avoid service or supply chain disruptions (clause 12A).

#### **Exemption requirements:**

- Exemptions had to be issued by a "suitably qualified health practitioner," defined under s5 of the Health Practitioners Competence Assurance Act 2003.<sup>3</sup>
- The practitioner had to determine, in the course of examination, that vaccination was inappropriate for the individual.
- The term "inappropriate" was undefined, allowing for clinical discretion.

6 November 2021: A new version of the Order introduced the Director-General exemption (Clause 9A).<sup>4</sup>

- 7 November 2021: Another amendment revoked Clause 7A and introduced a second Director-General exemption (Clause 9B).
- The CEO and minister service disruption exemptions remained available, (Clause 9, 12A).<sup>5</sup>

#### Director-General exemption process:

- Applications had to be submitted by a suitably qualified health practitioner.
- Patients had to meet strict criteria outlined in the Gazetted COVID-19 Vaccination Exemption Criteria, first published on 12 November 2021.<sup>6</sup>

#### Examples of denied exemptions included:

- Pre-existing PEG allergy (a known Pfizer contraindication).
- Serious adverse events after a previous dose, including heart attack, myocarditis, pericarditis, and autoimmune conditions.
- Pregnancy or lactation.

#### Exemption application data:

- January 2022:
  - 1,411 applications for Temporary Medical Exemption (TME).
  - 490 granted (351 clinical trial participants, 51 prior COVID-19 infections).
- · November 2021 September 2023:
  - 8,259 applications.
  - 6,410 granted (5,684 COVID-19 infections, 414 clinical trial participants).<sup>8</sup>

#### Specific examples:

- Myocarditis: 119 applications → 43 accepted.
- Serious adverse event to previous dose: 215 applications → 48 accepted.
- Pre-existing inflammatory cardiac disease: 102 applications
   → 23 accepted.
- Acute decompensated heart failure: 53 applications
   → 5 accepted.
- Anaphylaxis to previous dose: 125 applications → 11 accepted.

#### Significant Service Disruption Exemption

From 13 November 2021 to 26 September 2022, a total of 478 applications for Significant Service Disruption exemption (SSD) were received. The Minister granted 103 applications, covering approximately 11,005 health related workers.<sup>9</sup>

# Important Questions for the Commissioners to Ask — and of Whom:

# Director-General of Health and the Ministry of Health:

- Why was Clause 7A, the health practitioner exemption, revoked only one day after the <u>Director-General</u> exemption was introduced?
- What criteria were used to override the clinical judgement of treating doctors?
- Were risk-benefit assessments made on an individual basis, or applied as a standardised policy?
- Why were exemptions denied to individuals with documented contraindications, such as PEG allergy or severe adverse reactions?
- Why were pregnancy and lactation never considered valid grounds for exemption, despite Medsafe's own data sheets noting "missing data"?
- Were any steps taken to protect medical independence during the exemption and mandate process?

#### Medsafe and ethics review bodies:

- Was there any formal ethical review of how vaccine mandates and exemption restrictions would impact vulnerable individuals?
- Did the policy uphold the principle of informed consent?

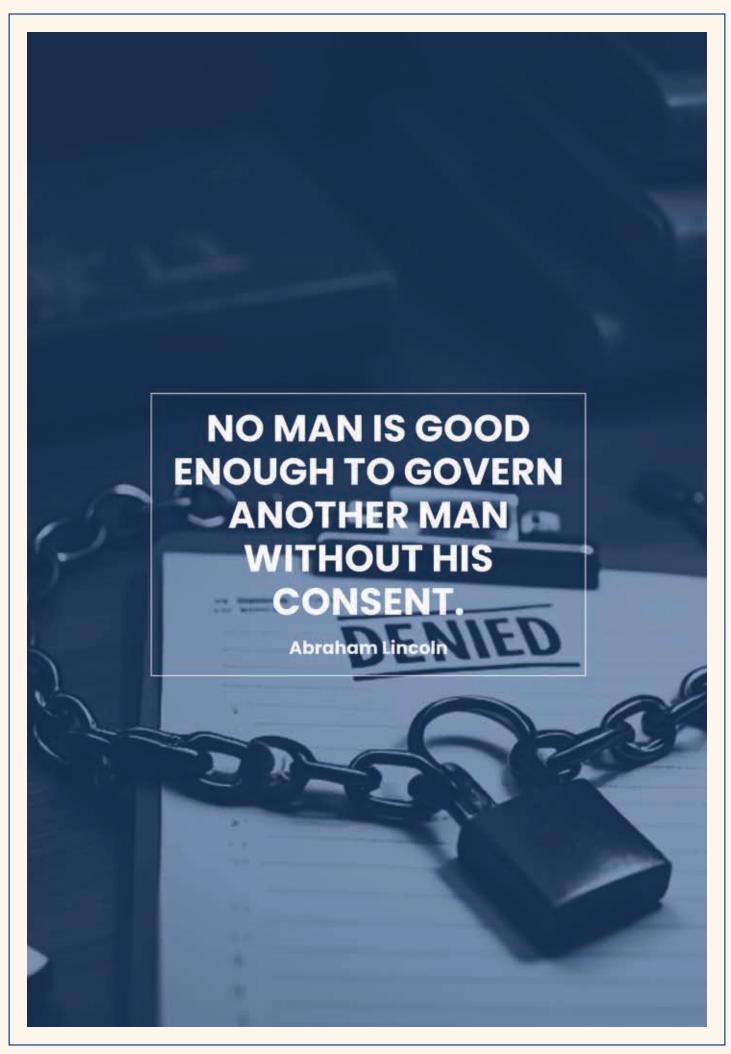
#### Professional health bodies:

 Were doctors discouraged, penalised, or investigated for issuing exemptions under Clauses 7/7A before those clauses were revoked?

#### All relevant authorities:

- How was the public health goal of high vaccination rates balanced with the rights of individuals with complex medical needs?
- Were legal protections and human rights frameworks adequately considered when designing the exemption process?
- Have there been any long-term health consequences for those denied exemptions despite medical justification?

- COVID-19 Public Health Response (Vaccinations) Order 2021 (Version as at 14 July 2021): <a href="https://www.legislation.govt.nz/regulation/public/2021/0094/21.0/LMS487853.html">https://www.legislation.govt.nz/regulation/public/2021/0094/21.0/LMS487853.html</a>
- OVID-19 Public Health Response (Vaccinations) Order 2021 (Version as at 25 October 2021): https://www.legislation.govt.nz/regulation/public/2021/0094/33.0/whole.html#LMS487894
- <sup>3</sup> Health Practitioners Competence Assurance Act 2003 Responsible Authorities: https://www.health.govt.nz/regulation-legislation/health-practitioners/responsible-authorities
- 4 COVID-19 Public Health Response (Vaccinations) Order 2021 (Version as at 6 November 2021): https://www.legislation.govt.nz/regulation/public/2021/0094/36.0/LMS487853.html
- OVID-19 Public Health Response (Vaccinations) Order 2021 (Version as at 7 November 2021): https://www.legislation.govt.nz/regulation/public/2021/0094/39.0/LMS487853.html
- 6 COVID-19 Vaccination Exemption Criteria (Gazetted 12 November 2021): https://gazette.govt.nz/notice/id/2021-go4910
- Official Information Act request H202200128 https://drive.google.com/file/d/195mR5BITzv9hRuYmEHu\_7qoJKHfYYEmt/view?usp=sharing
- Official Information Act request HNZ00028251 https://drive.google.com/file/d/1qoEh4d\_8mAQEv6OTMx2HA8sXvXRT51zt/view?usp=sharing\_
- Official Information Act Requests OIA HNZ00023978, OIA HNZ00027972 https://fyi.org.nz/request/23284/response/88679/attach/html/4/HNZ00023978%20Response%20Letter.pdf.html and
  - https://fyi.org.nz/request/23781/response/91380/attach/html/3/HNZ00027972%20Response.pdf.html





# 1.14 GASLIGHTING

RC Term: Vaccine Safety
B. Accident Compensation

Dr Alison Goodwin

#### Why this issue is relevant:

New Zealand undertook a government-led COVID-19 vaccination campaign under assurances of collective safety and individual protection, backed by its no-fault ACC injury compensation system. However, many of those who suffered serious vaccine injuries have been left without support. There are critical failures in ACC's processes highlighting the gap between government obligations and promises.

Despite official forecasts in February 2021 that serious vaccine injuries could affect up to 1.1% (in excess of 1 in 100) of recipients, this risk was not communicated to the public. Instead, the government relied on its no-fault accident compensation scheme (ACC) to reassure the public that any injuries would be supported.

Between 2021 and 2025, over 4,300 COVID-19 vaccine-related injury claims have been made to ACC, yet more than half were declined. Serious cases, including death and neurological injury, have been rejected, even with clear temporal links to vaccination. These denials reflect a systemic failure to uphold New Zealand's duty of care to vaccine-injured individuals and a deeper issue with the fairness, consistency, and transparency of ACC's decision-making processes.

#### Details:

## Government Acknowledgement of Risk - But No Public Disclosure

- In a February 2021 advisory titled "Advice on maximising uptake of COVID-19 vaccines in Tier 1", officials projected a serious injury rate of up to 1.1% from vaccination.
- This level of risk potentially affecting tens of thousands was not conveyed to the public.
- Instead, New Zealanders were encouraged to vaccinate with 'safe and effective' medicines and if, on the rare occasion, they were injured ACC would accept their injury.

#### ACC's Claim Data - A System That Did Not Support the Injured

- From February 2021 to January 2025, 4,318 COVID-19 vaccinerelated injury claims were lodged.
  - · 1,740 were accepted
  - · 2,540 were declined
  - 38 were undecided as of January 2025 <sup>2</sup>
- The majority of claims were denied, despite ACC's no-fault design, suggesting an unreasonably high bar for evidence and inconsistencies in how causality was assessed.

#### Lives Disrupted or Lost, with No Recognition

- Jessica's Story: One week after her first vaccine, Jessica developed autoimmune encephalitis, a serious neurological condition. Despite the timing and expert opinion, ACC denied her claim.<sup>3</sup>
- Garrett's Case: Garrett died 25 days after receiving his first COVID-19 vaccine. Despite this fatal outcome and a plausible link, ACC rejected the claim, citing insufficient causality.

These are not isolated cases. They represent a broader **failure of process** where claimants are left to navigate a **rigid and opaque system**, often while grappling with life-altering health outcomes.

# Important Questions for the Commissioners to Ask — and of Whom:

# ACC (Accident Compensation Corporation)::

#### **Evidence Thresholds and Causality**

- What evidence is considered sufficient for ACC to accept that a vaccine caused an injury, particularly in the absence of robust clinical trial or post-marketing safety data?
- Has ACC established a specific causality assessment framework for COVID-19 vaccinerelated injuries? If so, is it publicly available, and how does it compare to the WHO's causality guidelines?
- Given the government-led nature of the COVID-19 vaccination campaign, why was the standard evidentiary threshold for claimants not adjusted to reflect the difficulty in proving causation?

#### **Data Discrepancies and Transparency**

- As of January 2025, why has ACC accepted five fatal COVID-19 vaccine injury claims while only four deaths have been officially attributed to the vaccine by Medsafe? What explains this discrepancy?
- How frequently does ACC review or revisit previously declined claims when new scientific evidence or case trends emerge?

#### Timeliness and Process Integrity

- What is the average processing time for COVID-19 vaccine injury claims from submission to resolution? How does this compare to other treatment injury claims?
- How many claimants have pursued external reviews or legal action to challenge denied COVID-19 vaccine injury claims?
- What interim support, financial, psychological, or otherwise, is provided to claimants during the assessment process, particularly in cases involving severe or life-altering injuries?

#### Support vs. Rejection Patterns

- Of the claims that were declined, what proportion involved severe outcomes such as neurological injury, cardiovascular events, or death?
- What were the most frequently cited reasons for declining these claims?
- What steps is ACC taking to ensure consistency in the assessment of similar cases, especially when clinical presentations and post-vaccine timelines are comparable?

- Page 12)
  https://nzdsos.com/wp-content/uploads/2022/04/OIA-re-Maximising-Vax-Uptake-in-Tier-1-Border-Workers-2021-2.pdf
- https://www.acc.co.nz/assets/oia-responses/covid-19-vaccination-claims-refresh-january-2025.pdf References (continued):
- https://nzdsos.com/2023/11/26/the-tangled-web-of-acc-jessicas-story-part-2/
- 4 https://nzdsos.com/2023/11/06/case-of-garrett-utting/



# 1.15 CENSORSHIP IN NZ

New Zealand's COVID-19 response was marked by a coordinated suppression of dissent - particularly around vaccine safety and public health policy. This censorship was most visible in three areas: professional regulation, the treatment of dissenting doctors, and restrictions on public messaging. This section is further to section 0.6, Starting at page 71.

In April 2021, the Medical Council of New Zealand issued guidance effectively banning doctors from expressing any "anti-vaccination" views, even when based on legitimate clinical concern. Though informed consent was still legally required, practitioners risked disciplinary action for raising known risks or uncertainties. Doctors who spoke out were investigated, suspended, or pressured into silence through coercive "voluntary undertakings."

This punitive environment extended beyond the clinic. The Advertising Standards Authority changed its own rules mid-pandemic, introducing a "higher-level approach" that allowed it to ban advocacy advertising - like Voices for Freedom flyers - that had previously been deemed compliant.

The new standard wasn't about truthfulness, but alignment with government messaging.

Together, these actions formed a system of institutional censorship that undermined informed consent, silenced experienced clinicians, and deprived the public of critical information – at precisely the time it was most needed.

#### In this section

- A. Medical Council Guidance Statements
- B. Treatment of Doctors who questioned
- C. Advertising Standards Authority



# 1.15 CENSORSHIP IN NZ

RC Term: Vaccine Safety

A. Medical Council Guidance Statements

Mark Pinkerton

#### Why this issue is relevant:

The Medical Council of New Zealand (MCNZ) sets the standards for medical practice. During the COVID-19 pandemic, its guidance significantly influenced what doctors could communicate about vaccines, directly impacting informed consent, professional autonomy, and public discourse. MCNZ's statements were central to disciplinary actions and legal disputes, making them a critical component of the pandemic response.

In April 2021, the Medical Council of New Zealand (MCNZ), in collaboration with the Dental Council, issued a guidance statement titled 'COVID-19 vaccine and your professional responsibility." The document emphasised that health practitioners have an ethical and professional obligation to protect and promote the health of patients and the public and to participate in broader community health efforts. It further stated that vaccination plays a critical role in protecting public health by reducing the risk of acquiring and transmitting COVID-19

The guidance acknowledged that patients are entitled to receive information that a reasonable consumer, in that consumer's circumstances, would expect to receive, referencing Right 6 of the Code of Health and Disability Services Consumers' Rights. However, it also stated that "there is no place for anti-vaccination messages in professional health practice," including on social media or advertising.

This created a tension between the legal obligation to ensure full informed consent and the Council's restriction on discussing what might be labelled "anti-vaccination claims", a term that, in practice, included communication about legitimate risks or uncertainties. This contradiction had significant implications for medical practitioners, limiting their ability to provide individualised advice and undermining key principles of medical ethics, professional autonomy, and open scientific discourse.

#### **Details:**

#### Key Quotes from MCNZ Guidance<sup>1</sup>

- "Vaccination is a crucial part of the New Zealand public health response to the COVID-19 pandemic."
- "Health practitioners can help to protect themselves, their patients, and the wider community by getting their COVID-19 vaccination."
- "The Dental and Medical Councils have an expectation that all dental and medical practitioners will take up the opportunity to be vaccinated—unless medically contraindicated."
- "You have an ethical and professional obligation to protect and promote the health of patients and the public, and to participate in broader based community health efforts."
- "Patients are entitled to information that a reasonable consumer, in that consumer's circumstances, would expect to receive (Right 6, Code of Health and Disability Services Consumers' Rights)."
- "As regulators we respect an individual's right to have their own opinions, but it is our view that there is no place for antivaccination messages in professional health practice, nor any promotion of anti-vaccination claims including on social media and advertising by health practitioners."

## Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health (MOH):

- What data or studies did the Ministry rely on when advising MCNZ about vaccine safety and efficacy, including adverse events and realworld effectiveness?
- How did the Pfizer vaccine's provisional approval status influence Ministry advice to regulators?
- Was a formal risk-benefit analysis conducted and shared with MCNZ?
- Were doctors or independent medical experts consulted before finalising public health messaging?
- Can the Ministry provide records of communications with MCNZ regarding expectations for practitioner messaging?
- How did the Ministry ensure doctors remained free to present vaccine risks, uncertainties, and patient-specific concerns as part of informed consent?

#### Medical Council of New Zealand (MCNZ):

- Who authored or approved the COVID-19 vaccine communication guidance for doctors?
- Was the guidance peer-reviewed, and were dissenting clinical views considered?
- How much of the content was based on MOH advice, and did MCNZ independently verify vaccine claims?
- What legal or ethical reviews were undertaken to assess whether the guidance complied with informed consent obligations under the Code?
- How did MCNZ define the boundary between promoting public confidence and suppressing valid scientific discussion?
- What protections were in place for practitioners who raised safety concerns in good faith?

- Medical Council of New Zealand & Dental Council NZ. Guidance statement: COVID-19 vaccine and your professional responsibility (April 2021).
  - https://drive.google.com/file/d/1L0MyQMEOEcWZRHqBF0XdPvDT5vR4nT0\_/view



# 1.15 CENSORSHIP IN NZ

**RC Term: Vaccine Safety** 

B. Treatment of doctors who raised questions

Dr Cindy de Villiers

#### Why this issue is relevant:

Doctors who raised legitimate concerns during COVID-19 were censored, silenced and professionally threatened. This undermined their expertise, patient relationships, and professional obligations. It breached rights and obligations, raising serious questions about medical ethics, democratic accountability, and institutional integrity.

During the COVID-19 pandemic, doctors in New Zealand who expressed concerns about vaccine safety, mandates, or public health messaging were subjected to unprecedented censorship and disciplinary action. These doctors were often investigated, suspended, or pressured into signing so-called "voluntary undertakings" not to speak publicly—actions that appear incompatible with both the principles of free speech and professional independence. In many cases, standard disclaimers and expressions of opinion, previously considered acceptable, were suddenly grounds for punitive action.

The Medical Council of New Zealand (MCNZ) relied heavily on an improvised "Guidance Statement" to justify these measures. Legal action is now underway to challenge the legitimacy of this approach. The disparity between the aggressive treatment of dissenting doctors and the relative leniency shown toward practitioners involved in patient harm raises serious concerns about the regulator's priorities and impartiality.

This climate of fear and reprisal has contributed to a significant loss of experienced clinicians; some have been de-registered, others have retired early or quietly exited the profession, further straining an already burdened healthcare system. Most alarmingly, New Zealanders may have been denied access to critical medical information and alternative viewpoints during a time of national crisis.

#### **Details:**

#### Targeted Investigations and Disciplinary Action

Doctors who raised legitimate concerns about COVID-19 policies or vaccine safety were subjected to investigations, threats of suspension, and public censure. These actions created a climate of fear, discouraging open professional discourse and suppressing dissent, regardless of the clinical merit of their concerns.

#### "Voluntary" Gag Orders

Some doctors were pressured into signing "voluntary undertakings" not to speak publicly; agreements that raise serious concerns about consent, coercion, and the erosion of democratic freedoms. These undertakings effectively silenced professionals acting in good faith and the public interest.

#### Use of Emergency Guidance

The Medical Council of New Zealand relied on a hastily developed COVID-19 "Guidance Statement" to justify disciplinary action. This document, issued without proper consultation or legal robustness, is now the subject of legal challenge due to its questionable authority and process.

#### Loss to the Profession

The censorship and punitive environment drove many experienced doctors to deregister, retire early, or leave the profession entirely. This exodus not only weakened the already strained health workforce but also diminished the range of expertise and viewpoints available to patients and policymakers.

#### Legal and Ethical Breaches

The suppression of medical dissent appears to contravene both the New Zealand Bill of Rights Act and longstanding ethical obligations to patient advocacy and professional integrity. Silencing doctors who act on conscience undermines the trust at the core of the doctor–patient relationship and the accountability of public health decision–making.

# Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health (MOH):

 What communications or directives were issued to the MCNZ regarding managing dissent or enforcing adherence to the government's COVID-19 messaging?

#### Medical Council of New Zealand (MCNZ):

- What role did international bodies such as the Federation of State Medical Boards (FSMB) or the International Association of Medical Regulatory Authorities (IAMRA) play in shaping your approach to regulating speech?
- On what legal basis can a doctor acting in their private capacity be stripped of their fundamental rights under the New Zealand Bill of Rights Act?
- Where is the legitimate forum for scientific debate when medical professionals are silenced?
- Has any formal assessment been conducted to determine whether the statements made by dissenting doctors were factually incorrect or clinically harmful?

#### Both:

 What responsibility does the media bear in amplifying one narrative while actively discrediting dissenting medical voices?

#### References:

https://nzdsos.com/2022/09/11/mcnz-alarming-evidence-of-subversion/https://nzdsos.com/2024/10/18/court-report-nzdsos-v-mcnz-part-1/https://nzdsos.com/2023/09/29/witch-hunts/



# 1.15 CENSORSHIP IN NZ

**RC Term: Vaccine Safety** 

C. Advertising Standards Authority (ASA)

- Unilateral Changes to Their Own Rules

Katie Ashby-Koppens

#### Why this issue is relevant:

The ASA is New Zealand's watchdog for upholding advertising standards. When VFF messaging on flyers was inconveniently found to be accurate and the complaints dismissed, the ASA unilaterally introduced special rules to support the government narrative. The new rules meant the ASA could uphold complaints on the same flyer - not because the facts had changed but seemingly because the outcome was politically inconvenient.

The ASA enforces the Advertising Standards Code (the Code), which aims to ensure that every advertisement is responsible. The Code is "based on the principles of social responsibility and truthful presentation." All advertising must be legal, decent, honest, truthful, and must respect fair competition to maintain public confidence in advertising.

During the pandemic, the ASA issued contradictory rulings on the same flyer about masks, dismissing the 2021 version compliant but later upholding complaints against a nearly identical 2022 version. Between these rulings, the ASA introduced new evaluative criteria. These changes were not legislated, publicly consulted on, or in the Code—they were implemented specifically to enable the ASA to reverse its earlier decision that was more favourable to the narrative.

#### **Details:**

#### July 2021 - ASA Complaint 21/318: Complaint Not Upheld

In July 2021, Voices for Freedom (VFF) distributed a flyer questioning the effectiveness of masks and mask mandates. The ASA found the six statements in the flyer were not misleading, as they were adequately substantiated within the context of advocacy advertising. The complaint was not upheld. <sup>1</sup>

#### February 2022 – Introduction of the "Higher-Level Approach"

The ASA introduced a new evaluative framework for advocacy advertising on COVID-19: the "higher-level approach." This allowed the ASA to assess not just factual accuracy but whether an advertisement aligned with public health messaging. As a result, information previously deemed truthful could now be considered "socially irresponsible" if it conflicted with government positions.

#### October 2022 - ASA Complaint 22/275: Complaint Upheld

In September 2022, VFF reissued a flyer similar to the 2021 version. Despite containing comparable content, the ASA upheld the complaint this time, ruling that the statements were misleading and not socially responsible. The decision effectively banned the flyer's further distribution. <sup>2</sup>

#### Inconsistent Approach to Government Advertising

Critics argue that if the "higher-level approach" were applied consistently, many government COVID-19 advertisements would fail to meet ASA standards due to overstated efficacy, minimisation of risk, or failure to reflect emerging evidence.

While the ASA did uphold complaints against two government COVID-19 advertisements, many others—arguably more egregious than the VFF flyers—were not upheld. This suggests an inconsistent and potentially biased application of standards.

# Important Questions for the Commissioners to Ask — and of Whom:

#### ASA:

- What was the justification for introducing the "higher-level approach" in 2022?
- Was any public consultation or external review undertaken before implementing this new standard?
- On what legal or procedural basis were these new criteria introduced?
- Why was the higher-level approach not applied to certain government advertisements?
- How does the ASA ensure impartiality when assessing advocacy advertising that challenges government narratives?

#### Ministry of Health (MOH):

- Did the Ministry of Health have any formal or informal communication with the ASA before or during the period the new rules were introduced?
- Did MOH raise concerns or lodge complaints about VFF materials or similar advertisements?

- 1 https://drive.google.com/file/d/leOHk6V9r9INdIN0-T8bzodoLTk9KucC-/view?usp=share\_link Flyer https://www.voicesforfreedom
- <sup>2</sup> https://drive.google.com/file/d/1JriRg3zxsk4SrJCBOVC2PbwlOAIKPYe6/view?usp=share\_link



# 2.0 TESTING, TRACING AND OTHER PUBLIC HEALTH TOOLS

The second part of this inquiry turns the spotlight on the suite of public health tools deployed, or in some cases, deliberately withheld, during New Zealand's COVID-19 response. These included diagnostic testing, contact tracing, vaccine passes, serological screening, masks, and social distancing policies. Each of these decisions affected the public not only in terms of health but also in access to education, movement, employment, and civil liberties.

Part 2 of the Royal Commission Phase 2's Terms is: Testing, tracing, and other public health tools, for example RAT tests and masks. The Terms of Reference ask whether key decisions were "sufficiently informed by advice on any social and economic disruption such decisions were likely to cause" and whether they struck a "reasonable balance" between managing COVID-19 and protecting New Zealanders' rights and wellbeing.

#### This section examines whether public health tools were:

- Based on solid scientific evidence.
- Ethically and proportionately applied.
- Regularly reviewed in light of emerging data.
- Used to inform and empower the public or to control and divide them.

#### We know that:

Rapid testing in early 2020 was obstructed. Offers of hundreds of thousands of FDA-approved RAT kits were ignored or actively blocked by Medsafe, despite no legal requirement to do so. This obstruction delayed decentralised detection and may have worsened early spread, especially when speed was critical.

**Serology testing was suppressed.** Despite the capability existing, the public was denied access to antibody testing that could have revealed natural immunity, informed vaccine decisions, and reduced unnecessary exposure to experimental products.

#### The vaccine pass system for adolescents was coercive.

Children as young as 12 were excluded from school, sports, and driver testing unless vaccinated with a provisionally approved product.

This occurred despite no clear evidence of benefit for transmission in this age group and a known risk of myocarditis.

Mask mandates lacked robust evidence. Cabinet decisions were based on observational studies rather than randomised controlled trials. Even the WHO initially cautioned against general public masking. Scientific reviews showed little benefit, especially with cloth masks, and potential harms were overlooked.

#### Social distancing rules had no scientific foundation.

The widely used 2-metre rule was adopted without peer-reviewed evidence and was later admitted by international experts to be arbitrary. This rule caused significant harm to children, small businesses, and mental health.

This section is not just a technical audit. It is a reckoning with how evidence was used, ignored, or manipulated and how New Zealanders were affected when public health tools became instruments of control rather than care.

Let this phase be the beginning of accountability and the restoration of trust.

#### In this section

- A. RAT testing February 2020
- B. Serology
- C. Tracing
- D. Masks the science
- E. Social Distancing



# 2.1 RAT TESTING

RC Term: Testing for COVID-19
2.1 RAT testing February 2020

Emma Hart

#### Why this issue is relevant:

In early 2020, during the most critical early months of the COVID-19 pandemic, rapid testing could have provided a fast, decentralised tool for managing outbreaks and safeguarding communities. The Government issued two threats against a medical importer of the tests. Yet the New Zealand government actively obstructed these efforts through regulatory bans, bureaucratic delays, and a dismissive stance towards offers of validated test kits – potentially worsening the crisis.

In early 2020, companies offered New Zealand access to hundreds of thousands of rapid COVID-19 tests - many of which were FDA-approved or used in other developed nations. Rather than embracing these opportunities, New Zealand authorities created legal and administrative barriers to prevent their use.

A Medsafe notice in April 2020 banned point-of-care tests tests, including Rapid Antigen Tests (RATS), under the Medicines Act unless specifically approved by Medsafe – this is despite Medsafe admitting it had no technical evaluation capacity and that approval was not required for such devices under existing rules. This ban was extended through 2023.

Meanwhile, internal government communications show that offers of free or logistically viable test imports were sidelined, ignored, or passed endlessly between agencies. As communities pleaded for tools to protect themselves and reopen safely, the government prioritised central lab testing systems and control over the public health narrative rather than acting swiftly to increase national testing capacity.

#### Details:

- March 2020: Offers were made to supply over 500,000 rapid COVID-19 tests, including IgM/IgG antibody-based tests with FDA approval and claimed 96-99% accuracy. Logistics were in place (including access to a Boeing 777) for delivery from China to New Zealand within 1.5 weeks.<sup>1</sup>
- 25–27 March 2020: Emma Hart (ReGen Cellular) engaged with NZ Police and Medsafe regarding the test kits and delivery. Medsafe confirmed that no pre-market approval was required, yet testing was still not permitted. The offer was circulated among the Ministry of Health (MOH), NZ Police, MBIE, and MFAT with no action taken.<sup>2</sup>
- 22 April 2020: Medsafe issued a Section 37 notice banning the import, manufacture, or use of POC COVID-19 tests unless individually approved—despite previous advice that approval was not required.<sup>3</sup>
- April 2021: The ban was extended under the COVID-19 Public Health Response Act, again requiring approval from the Director-General of Health.<sup>4</sup>
- April 2023: The ban was finally lifted—three years after the pandemic's onset—once RATs had become globally recognised as essential tools.<sup>5</sup>

## Important Questions for the Commissioners to Ask — and of Whom:

#### Medsafe:

- Why did Medsafe issue a blanket prohibition on tests it admitted it wasn't required to approve or assess?
- Who specifically decided to ignore or defer early test kit offers, and on what scientific or legal basis?
- What role did centralised control of public health messaging play in the delay of decentralised testing capacity?
- Why were test suppliers not given a clear pathway or checklist for rapid approval?
- How many community outbreaks, lockdown extensions, or missed early interventions could have been mitigated with widespread access to POC tests from March 2020 onwards?
- Who will be held accountable for the public health consequences of this obstruction?

- Hart, Emma. "RAT Testing Offers and Government Response", PDF (pp. 6–8, 11–12, 15–16): <a href="https://drive.google.com/file/d/1YQxshoionYN7zApqUknHWJWa4lAuTM4Y/view?usp=share\_link">https://drive.google.com/file/d/1YQxshoionYN7zApqUknHWJWa4lAuTM4Y/view?usp=share\_link</a>
- Ibid. Correspondence from 25–27 March 2020 with NZ Police and Medsafe. https://drive.google.com/file/d/IYQxshoionYN7zApqUknHWJWa4IAuTM4Y/view?usp=share\_link
- Medsafe COVID-19 Point of Care Tests Notice 22 April 2020: https://www.medsafe.govt.nz/COVID-19/point-of-care-tests.asp
- 4 COVID-19 Public Health Response (Point-of-Care Tests) Order 2021: https://legislation.govt.nz/regulation/public/2021/0066/latest/LMS451450.html?search=ts\_act%40bill%40regulation%40deeme
- MOH announcement: Removal of Point-of-Care Test Order April 2023: https://www.health.govt.nz/strategies-initiatives/programmes-and-initiatives/covid-19/legislation-and-orders/covid-19



# 2.2 SEROLOGY

RC Term: Testing for COVID-19

Dr Alison Goodwin

#### Why this issue is relevant:

Despite early evidence that serology could reveal prior exposure to COVID-19, New Zealanders were denied access to antibody testing, even privately, while the government relied heavily on vaccination as the singular metric of protection.

Serology testing detects antibodies in the blood from past or current infection. Such testing was not available to the New Zealand public outside of limited studies.

This type of testing would have identified if a person had natural immunity to COVID-19, which would have been helpful given the asymptomatic infection and before the mass vaccination campaigns.

#### **Details:**

Understanding population-level immunity could have informed more proportionate public health decisions. Natural immunity has long been recognised as a powerful and durable form of protection against infectious diseases.

For COVID-19, it quickly became clear that vaccine-induced immunity waned within months, requiring regular booster doses.

Early access to serology testing could have:

- Identified individuals with existing immunity.
- Allowed them to opt out of vaccination and associated risks.
- Supported a more ethical and individualised approach to pandemic management.
- Recognition of prior infection could have also been provided as an exemption.

This ongoing study investigates how many people had been infected and whether antibodies are linked to changes in cardiovascular health. Crucially, it shows that antibody testing was possible in New Zealand - but limited to researchers, not the public. This gatekeeping of information prevented individuals from making informed decisions about their personal health risks, especially regarding whether they needed vaccination or boosters.<sup>1</sup>

Professor Christopher Pemberton's report on this study is scheduled to be completed February 2026.

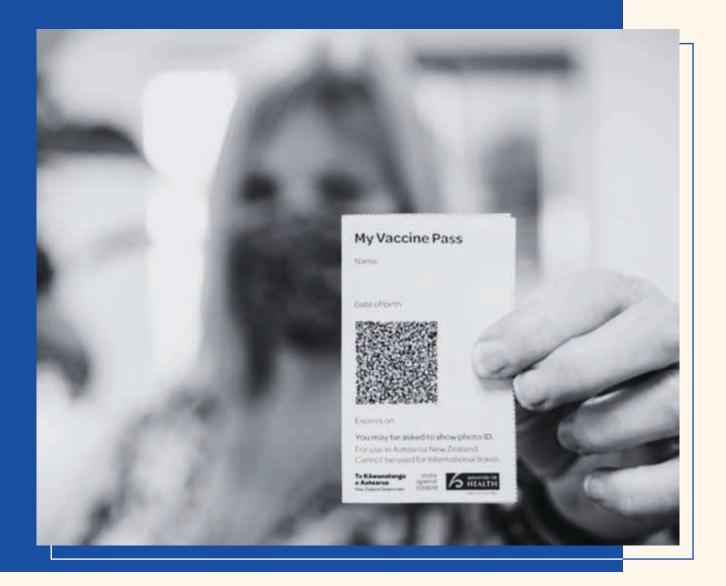
# Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health:

- Why was serology testing not made available to the general public, despite it being clearly used in academic studies like the University of Otago's antibody and heart health research?
- Given that the technology and capability existed, who made the decision to restrict antibody testing, and what was the rationale?
- Did the MOH consider the ethical and legal implications of denying the public access to information about their immune status especially in the context of vaccine mandates?
- Were public health policies, including the vaccine pass and mandate system, based on assumptions of zero or low natural immunity

   and if so, why was this not validated or updated using serology data?
- How many New Zealanders had detectable COVID-19 antibodies by mid-2021 and beyond, and why was this data not transparently communicated to the public?
- Why was natural immunity not recognised as an alternative to vaccination in public health policy, especially as international evidence mounted in its favour?
- Were any steps taken to assess the risk-benefit ratio of vaccinating those already immune from prior infection?
- Will the Ministry now commit to making antibody testing widely accessible and publicly report on seroprevalence data moving forward?

https://www.otago.ac.nz/news/newsroom/covid-19-antibodies-and-heart-health-focus-of-new-study



# 2.3 VACCINE PASSES

**RC Term: Tracing** 

Katie Ashby-Koppens and Dr Alison Goodwin

#### Why this issue is relevant:

In late 2021, New Zealand introduced the "My Vaccine Pass" system, which required individuals aged 12 and over to show proof of COVID-19 vaccination to access public venues, education, work, and community life

It was another form of mandate that redefined access to society as a conditional privilege rather than a fundamental right. It disproportionately impacted adolescents and young adults during key formative years.

The COVID Pass system was implemented with little public debate and no long-term safety data for the age group it targeted. It effectively coerced teenagers and young adults into receiving a novel mRNA product under threat of social and educational exclusion.

#### Key concerns include:

- Ethical breaches in consent, particularly for minors.
- Human rights violations stemming from discrimination based on vaccination status.
- Lack of transparent risk-benefit analysis for low-risk groups.
- Entrenchment of state-sanctioned segregation.
- The system created lasting harm: educational disruption, mental health deterioration, and community division, without proven impact on transmission in the Omicron era.

#### Details:

Age Threshold: Children aged 12 years and up were required to present a My Vaccine Pass for access to most public spaces under the COVID-19 Protection Framework.<sup>1</sup>

Informed Consent Failures: Teenagers and parents were not made fully aware that the vaccine had only provisional approval, meaning it was legally experimental.<sup>2</sup>

## Coercion in Education and Social Life: Teens unable or unwilling to be vaccinated were blocked from critical milestones:

- Driver licensing tests.<sup>3</sup>
- School events and sports: Many schools interpreted mandates strictly, excluding unvaccinated students from extracurricular and even curricular activities.<sup>4</sup>
- Applying for, attending, and graduating tertiary study.

#### Transmission Not Prevented:

 By early 2022, studies showed vaccinated individuals could still contract and transmit Omicron.<sup>5</sup>

#### Adverse Event Concerns Ignored:

 Myocarditis rates were highest in young males aged 12–17 following mRNA vaccination.<sup>6</sup>

#### Legal and Human Rights Conflicts:

- Discriminatory exclusion based on vaccine status likely contravened the NZ Bill of Rights Act:
  - Section 117 Right to refuse medical treatment.
  - Section 198 Freedom from discrimination.

#### International Outlier:

 New Zealand was one of the few countries to introduce pass systems for children as young as 12 during a period of low absolute risk to this group.<sup>9</sup>

## Important Questions for the Commissioners to Ask — and of Whom:

#### Ministry of Health:

- What evidence did the Ministry rely on to justify the vaccine pass requirement for healthy adolescents aged 12 and up?
- Why was no transparent, age-specific risk-benefit analysis published before implementation, particularly for 12–15 and 16–17-year-olds?
- Why did the Ministry fail to revise or rescind the pass system once evidence emerged that the vaccine did not prevent Omicron transmission?
- What monitoring did the Ministry undertake regarding pass-related harm, such as educational disruption or mental health impacts on adolescents?
- How did the Ministry reconcile this policy with known elevated risks of myocarditis in young males?

## Ministry of Education and Tertiary Institutions:

- What guidance did the Ministry provide to schools regarding vaccine pass enforcement?
- Was there any oversight of school-level exclusions from curricular activities (e.g. camps, NCEA assessments, driver testing)?
- How were universities and polytechnics instructed to handle vaccine pass requirements for enrolment, attendance, and graduation?
- What steps have been taken to identify and address educational disadvantage or trauma resulting from exclusion?

# Medical Council of New Zealand / Ethics Committees:

 How was the ethical principle of voluntary, informed consent upheld under the pressure of vaccine pass exclusion for adolescents?

#### Pharmac / Medsafe:

 What role did Pharmac or Medsafe play in assessing the implications of vaccine mandates or passes for young people?

#### **Cross-Agency Questions:**

- Were any alternative, less discriminatory public health tools considered before implementing a nationwide vaccine pass for adolescents?
- What reviews or reparations have been initiated (or are planned) for youth and families adversely affected by exclusionary policies?
- What safeguards have been introduced to prevent the future use of similar pass systems without full public consultation and legal review?

# Office of the Prime Minister and Cabinet (DPMC), including the COVID-19 Response Unit:

- What role did the DPMC play in coordinating or approving the My Vaccine Pass policy?
- Was a cost-benefit or social impact assessment undertaken before launching the pass system?
- Why was New Zealand an international outlier in mandating passes for children as young as 122

#### References:

- 1 https://en.wikipedia.org/wiki/My\_Vaccine\_Pass
- https://www.medsafe.govt.nz/COVID-19/status-of-applications.asp and

https://www.medsafe.govt.nz/COVID-19/vaccine

- $^{3} \quad \underline{\text{https://www.nzta.govt.nz/media-releases/vtnz-and-waka-kotahi-ready-for-surge-in-driver-licencing-tests-under-trafficed} \\$
- 4 https://www.schoolsportnz.org.nz/cms/news/enewsletter/6929?isNew=True
- <sup>5</sup> https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm

and

https://www.nejm.org/doi/full/10.1056/NEJMc2202542

- 6 https://www.cdc.gov/mmwr/volumes/70/wr/mm7035e5.htm and https://www.medsafe.govt.nz/COVID-19/vaccine-report-over
- https://www.legislation.govt.nz/act/public/1990/0109/latest/DLM225509.html
- 8 https://www.legislation.govt.nz/act/public/1990/0109/latest/DLM225540.html
- <sup>9</sup> https://en.wikipedia.org/wiki/Vaccine\_passports\_during\_the\_COVID-19\_pandemic





# **2.4 MASKS**

**RC Term: Masks** 

Katie Ashby-Koppens

#### Why this issue is relevant:

There was no robust scientific basis for the widespread or mandated use of face masks among the general public during the COVID-19 pandemic. WHO's initial evidence based recommendation was that mask-wearing was an "extreme measure" (see Issue 0.7A, page 82). Despite this, mask mandates were introduced in New Zealand with minimal reference to gold-standard scientific evidence and allowed for any item (e.g. fabric) to be used as a "mask," suggesting a psychological rather than medical basis.

- Cabinet decisions were based on observational studies, not RCTs
- Scientific studies show little to no evidence that typical maskwearing reduces infection.
- SARS-CoV-2 particles are small enough to pass through most masks.
- Masks may cause harm through hypoxia or immune suppression.
- Cloth masks are largely ineffective, allowing up to 98% of particles through.

# Chronological Summary of Key Scientific Findings November 2020 – Large RCT Finds No Statistically Significant Benefit of Masks

A Danish randomised-control trial found no statistically significant difference in coronavirus infection rates between mask-wearers and non-mask-wearers. The mask study was one of the largest of its kind ever completed.

# According to the study:

"The recommendation to wear surgical masks to supplement other public health measures did not reduce the SARS-CoV-2 infection rate among wearers by more than 50% in a community with modest infection rates, some degree of social distancing, and uncommon general mask use." <sup>1</sup>

## **Efficacy Concerns**

- A New Zealand cabinet paper notes that most evidence came from observational studies and epidemiological modelling rather than RCTs. It states:
  - "There are few RCTs on mask use in a pandemic context, largely due to ethical challenges." <sup>2</sup>
- SARS-CoV-2 particles are tiny and can pass through common mask fibres.
  - "The N95 filtering facepiece respirators may not provide the expected protection level against small virions. Some surgical masks may let a significant fraction of airborne viruses penetrate through their filters, providing very low protection against aerosolized infectious agents in the size range of 10 to 80 nm."<sup>3</sup>
- On N95 respirators vs surgical masks:
  - "The use of N95 respirators compared with surgical masks is not associated with a lower risk of laboratory-confirmed influenza." 4
  - "Among outpatient health care personnel, N95 respirators vs medical masks as worn by participants in this trial resulted in no significant difference in the incidence of laboratory-confirmed influenza."<sup>5</sup>

# Safety Concerns

- On the effect of N95 masks on oxygen levels in dialysis patients:
  - "Wearing an N95 mask for 4 hours during HD significantly reduced PaO2 (partial pressure of oxygen) and increased respiratory adverse effects in ESRD patients." 6
- · On immune function and hypoxia:
  - "Hypoxia inhibits the immune response in human cytotoxic T lymphocytes by limiting ATP generation, which leads to an impairment of effector functions."
- U.S. Occupational Safety and Health Administration (OSHA) quidance states:
  - "Human beings must breathe oxygen to survive, and begin to suffer adverse health effects when the oxygen level of their breathing air drops below [19.5 percent oxygen]. Below 19.5 percent oxygen, air is considered oxygen-deficient. At concentrations of 16 to 19.5 percent, workers engaged in any form of exertion can rapidly become symptomatic as their tissues fail to obtain the oxygen necessary to function properly." 8
- A study on 53 surgeons showed:
- "Considering our findings, pulse rates of the surgeons increase and SpO2 decrease after the first hour. This early change in SpO2 may be either due to the facial mask or the operational stress." 9

# Cloth Masks Are Highly Ineffective

- Penetration ranged from 40-98%, depending on fabric.10
- Marginal protection from particles smaller than 2.5  $\mu$ m.11

# Legal and Ethical Questions

The government acknowledged that high-quality evidence from RCTs was lacking due to ethical constraints yet proceeded to mandate mask-wearing across the entire population. If it is unethical to run controlled mask trials, is it ethical to apply these measures at national scale without robust evidence?

Mask exemptions existed for individuals with certain physical or mental conditions, suggesting an inconsistent application of the mandate.

# Important Questions for the Commissioners to Ask — and of Whom:

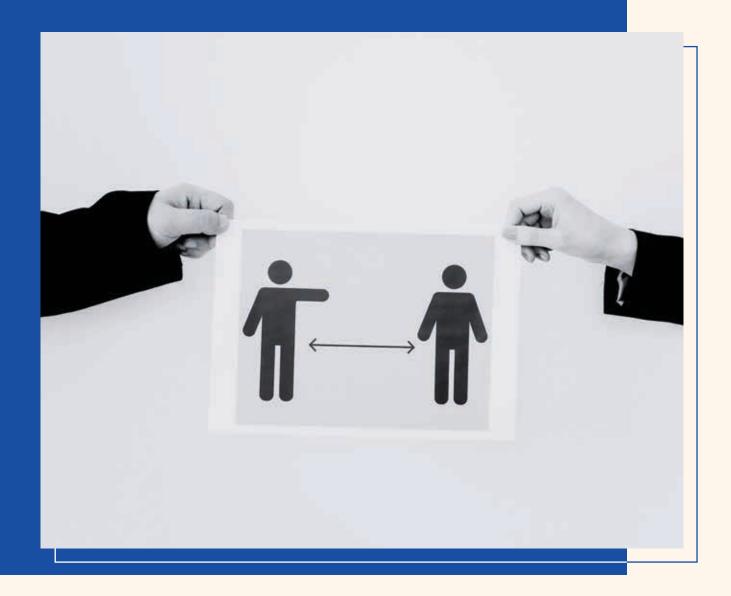
# **Director-General of Health:**

 Cabinet relied on your advice. If RCTs were considered ethically challenging, why was it ethical to mandate mask-wearing for millions of New Zealanders in the absence of such evidence?

# References:

- https://www.acpjournals.org/doi/10.7326/M20-6817
- https://www.dpmc.govt.nz/sites/default/files/2023-01/Paper-CP1-16112021-COVID-19-Resurgence-Improving-Public-Health
- https://pubmed.ncbi.nlm.nih.gov/16490606/
- 4 https://web.archive.org/web/20250221171634/https://onlinelibrary.wiley.com/doi/pdf/10.1111/jebm.12381
- https://pubmed.ncbi.nlm.nih.gov/31479137/
- 6 https://pubmed.ncbi.nlm.nih.gov/15340662/
- https://pubmed.ncbi.nlm.nih.gov/26179900/
- 8 https://www.osha.gov/laws-regs/standardinterpretations/2007-04-02-0
- 9 https://pubmed.ncbi.nlm.nih.gov/18500410/
- https://academic.oup.com/annweh/article/54/7/789/202744
- https://pubmed.ncbi.nlm.nih.gov/27531371/

See also the Cochrane report referred to in issue 0.7A, page 83, Footnote 4.



# 2.5 TESTING, TRACING AND OTHER PUBLIC HEALTH TOOLS

**RC Term: Social Distancing** 

Katie Ashby-Koppens

# Why this issue is relevant:

Social distancing was one of the most disruptive and far-reaching public health interventions during the COVID-19 pandemic. It affected schooling, business operations, travel, and human connection. Understanding where the six-foot rule (2 metres in NZ) came from, and whether it was based on science, is critical for future accountability and policymaking.

The six-foot social distancing rule was widely enforced across the globe during the COVID-19 pandemic as a central mitigation strategy. However, in recent U.S. Congressional testimony, Dr. Anthony Fauci admitted that this guidance "sort of just appeared" and was not backed by controlled trials or hard scientific evidence. The origins of the rule trace back to outdated, theoretical assumptions about droplet transmission with limited real-world validation. This calls into question the scientific integrity and justification for one of the most socially and economically damaging policies of the pandemic.

# **Details:**

- Fauci's 2024 Testimony (U.S. House Subcommittee):
  - Dr. Fauci stated that the six-foot distancing guideline "just sort of appeared," and acknowledged that the policy did not come from a specific scientific study. He attributed it to the CDC and others without confirming any underlying data basis. "It just sort of appeared... it was not based on data." — Dr. Fauci, Jan 2024 testimony to Congress.

# Historical Origin:

- The six-foot rule is believed to be based on a 1930s study
  of large respiratory droplets. However, later research shows
  that aerosol particles can remain suspended in the air and
  travel beyond six feet, making the distance arbitrary and
  ineffective in many indoor environments.
- Lack of Evidence for Effectiveness:
  - A March 2021 CDC study found no significant difference in infection rates between schools that enforced 3-feet versus 6-feet distancing among students.
  - A British Medical Journal (BMJ) article in 2020 warned that distancing rules were based on outdated science and called for re-evaluation.<sup>2</sup>

# Policy Impact:

- · Forced school closures and hybrid learning models.
- Small business and venue shutdowns due to spacing requirements.
- Social isolation, especially among the elderly and youth.
- Public transport and event restrictions.
- Long-term psychological and developmental effects in children and teenagers.

# Important Questions for the Commissioners to Ask — and of Whom:

# Ministry of Health:

- What evidence did national health authorities (e.g. NZ Ministry of Health) rely on when adopting and enforcing the 2-metre distancing rule?
- Why were real-world observational studies and aerosol science findings not integrated into public health guidance?
- Were the downstream harms of social distancing, particularly on mental health, child development, and social cohesion, ever formally assessed?
- What transparency and peer review processes were in place for such a significant public health recommendation?
- Should those who issued unvalidated mandates bear responsibility for their consequences?

# References:

- https://oversight.house.gov/release/covid-select-subcommittee-releases-dr-faucis-transcript-highlights-key-takeaways-in-
- <sup>2</sup> https://www.cdc.gov/mmwr/volumes/70/wr/mm7011e1.htm



# 3.0 LOCKDOWNS

We have not devoted much space here to recounting the lockdown experience in detail – not because it wasn't significant, but because the story of lockdowns belongs to the people who lived it. Every family separated, every child isolated from school, every shuttered business and cancelled milestone – these speak for themselves. That story will be told powerfully.

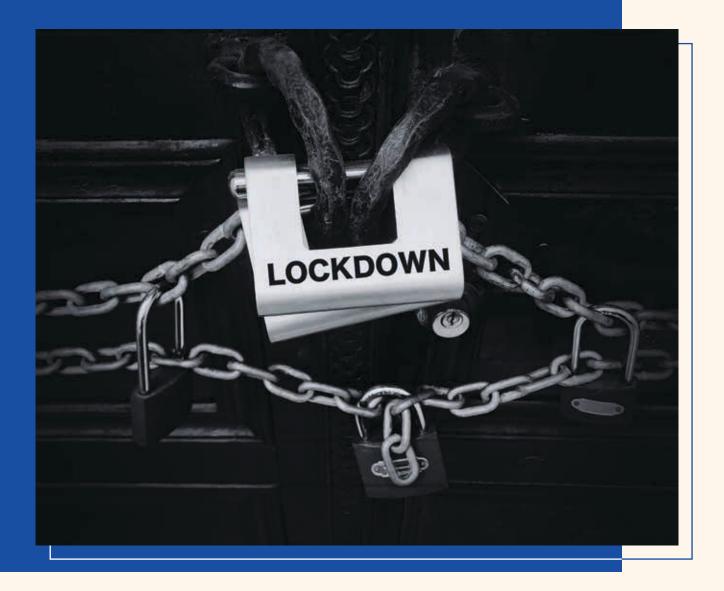
Part 3 of the Royal Commission Phase 2's Terms is: Lockdowns, especially the national lockdown in August and September 2021 and the Auckland/Northland extended lockdown late 2021.

This section focuses instead on what must be scrutinised at a systems level: whether the lockdowns, as a public health intervention, met the most basic tests of proportionality,

cost-effectiveness, and ethical justification. Available evidence shows they did not, the repercussions we continue to live with today indicates the costs dwarfed any benefit.

Even based on data available at the time, the decision to impose nationwide lockdowns failed standard cost-benefit thresholds used in health economics. New Zealand's own benchmarks for public spending on health were exceeded many times over, with consequences that were not just financial, but social, educational, psychological, and legal.

These trade-offs were neither transparently assessed nor honestly communicated. As the Commission reviews the decisions made in 2020, it must examine how such sweeping restrictions were imposed without rigorous analysis, and how we can ensure that never happens again.



# 3.1 FAILED COST BENEFIT

Lockdowns failed standard cost-benefit tests for public health interventions

Dr Martin Lally

# Why this issue is relevant:

New Zealand's COVID-19 lockdowns in 2020 were economically disproportionate and ethically questionable, even based on the data available at the time. Standard public health cost-benefit analyses showed that the lockdowns failed to meet the usual benchmarks for value, costing significantly more per life year saved than is typically considered acceptable.

Using data and estimates to the end of 2021, from which point the mass vaccination removed any argument for continued nation-wide lockdowns, analysis found that the cost per Quality Adjusted Life Year (QALY) saved by lockdowns rather than milder mitigation measures was at least 13x the New Zealand health system's accepted benchmark of \$62,000 per QALY. Compared to a mitigation strategy, the lockdowns incurred additional GDP losses of approximately \$17 billion. Even when applying worst-case death estimates, the cost per QALY saved far exceeded acceptable thresholds. Additional non-monetised harms — such as mental health deterioration, lost education, healthcare delays, and infringements on civil liberties — were significant. Retrospective analysis and transparent cost-benefit evaluations are essential for informing future public health responses.

# **Details:**

# Deaths Avoided vs. Cost Incurred

- Estimated deaths under mitigation strategy: 1,750 4,600.
- QALYs saved by lockdowns: up to 18,400, being 4,600 lives at
  most as above x five-year average residual life expectancy
  of COVID victims x 80% to reflect the lower than normal
  existing quality of life of these COVID victims.
- Benchmark value per QALY: \$62,000.
- Actual cost per QALY saved: At least \$826,000 (over \$1 million when including the psychological effects of unemployment on the additional unemployment due to the lockdowns).

# **Economic Cost**

- Estimated GDP loss due to lockdowns: \$17 billion.
- This represented approximately 40% of the total GDP loss due to the pandemic of \$43 billion.

# Other Social Costs (unquantified but substantial):

- Mental health decline.
- Lost education.
- Restrictions on civil liberties.
- Delays in healthcare access.

# **Future Lockdowns**

- Even less justifiable post-vaccination.
- Partial lockdowns may only be justified if affecting <10% of the population and not repeated.

# Important Questions for the Commissioners to Ask — and of Whom:

# Ministry of Health and Treasury:

- Did either agency conduct cost-benefit modelling of the 2020 lockdowns using QALYbased health economics standards?
- Were any less harmful mitigation strategies (e.g. targeted protections, Swedish or Floridastyle approaches) considered or modelled?
- Were the economic, psychological, and educational impacts of lockdowns factored into decision-making at any stage?

# Prime Minister (Jacinda Ardern at the time) and Director-General of Health (Dr Ashley Bloomfield):

- Did either agency conduct cost-benefit modelling of the 2020 lockdowns using QALYbased health economics standards?
- Were any less harmful mitigation strategies (e.g. targeted protections, Swedish or Floridastyle approaches) considered or modelled?
- Were the economic, psychological, and educational impacts of lockdowns factored into decision-making at any stage?

# Treasury (specifically Chief Economist):

- Has any retrospective cost-effectiveness evaluation been commissioned or completed?
- Will Treasury recommend that future pandemic responses include upfront costbenefit modelling using QALY or other economic frameworks?

# References



# 3.2 APRIL 2020 EXT.

April 2020 Lockdown five-day extension: delivered little benefit for immense cost

Katie Ashby-Koppens summarising the Productivity Commission's Cost Benefit Analysis authored by Dave Heatley

# Why this issue is relevant:

New Zealand's government imposed one of the world's strictest COVID-19 lockdowns, and extended it by five extra days in April 2020 (let alone the further lockdowns), claiming this would deliver "much greater long-term health and economic returns." It is unclear what this statement relies on.

New Zealand's own Productivity Commission identified in an early report that the five-day extension delivered little benefit for immense cost.

The Productivity Commission analysed whether adding five days to Alert Level 4 was worth it. While the government promised big gains, the analysis revealed the opposite: the extension likely saved only 239 QALYs (which includes the 30 deaths averted), yet it cost the country NZ\$749 million (equivalent to 22,700 QALYs lost) through economic harm, mental health deterioration, and delayed healthcare.

The net result was overwhelmingly negative, with the costs dwarfing the benefits. Even worse, the government's public claim of "greater long-term health and economic returns" appears to have been unsupported by any publicly available or peer-reviewed analysis, raising serious accountability concerns.

Note: Health benefits of an intervention are typically measured in quality-adjusted life years (QALYs). "Quality-adjusted" refers to the quality of life during the period lived, relative to that of an "average" healthy person of the same sex and age.

## **Details:**

The New Zealand Productivity Commission's May 2020 Report, a cost-benefit analysis of five extra days at COVID-19 alert level 4! found:

- · Purported health gains:
  - ~239 QALYs saved (based on optimistic assumptions), which included 30 COVID-19 deaths averted.
- · Massive costs imposed:
  - NZ\$489 million in direct GDP losses.
  - NZ\$245 million in slow economic recovery.
  - ~420 QALYs lost from heightened anxiety, depression.
  - Disruption to healthcare (-NZ\$1 million wasted on undelivered services).
- · Critical blind spots:
  - Early Italian data confirmed SARS-CoV-2 infects people of all ages, but morbidity (illness) and mortality (death) are highly concentrated in those with pre-existing health conditions and the elderly. The average age of people dying from COVID-19 in Italy is 79.5 (para 16).<sup>2</sup>
  - No clear evidence government evaluated the marginal cost-benefit trade-off before extending lockdown.
  - Author notes (para 3), no access to the analysis that supposedly justified the extension.
  - Benefits calculation relied on optimistic assumptions (e.g. Ref = 1).

 Final verdict: 239 QALYs gained (including the value of 30 COVID-19 deaths avoided). This benefit comes at a substantial cost: \$749 million (or equivalently, 22,692 QALYs lost). The extension delivered little benefit for an immense cost.

# Important Questions for the Commissioners to Ask — and of Whom:

# Government / Cabinet:

- Where is the documented cost-benefit analysis that justified extending Alert Level 4 by five days?
- How was it ethically justifiable to impose huge costs on the population without publicly available evidence?

# Ministry of Health:

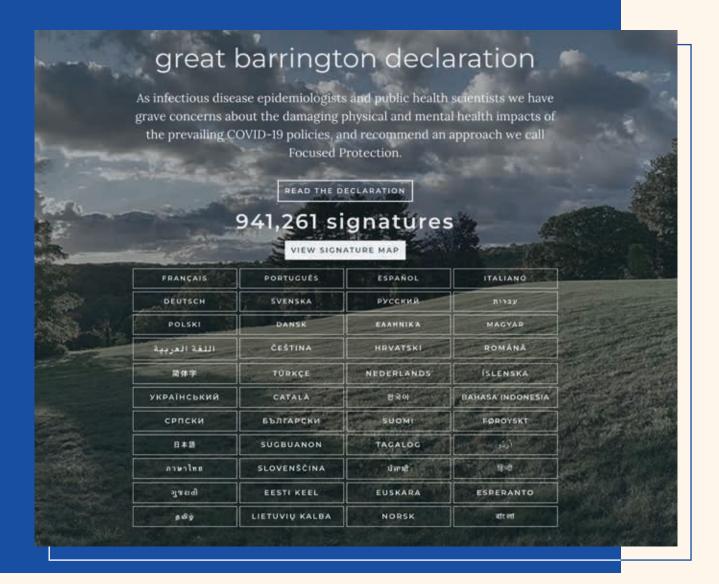
- Why were sweeping lockdown measures used when COVID-19 deaths were overwhelmingly among the frail elderly (79+)?
- How were mental health and non-COVID health harms factored into decision-making?

# Treasury:

- Should future crises require independent, published cost-benefit assessments before extreme restrictions are imposed?
- How can economic and health trade-offs be better modelled to avoid disproportionate harm?

# References:

- https://www.treasury.govt.nz/sites/default/files/2024-05/pc-rp-a-cost-benefit-analysis-of-5-extra-days-at-covid-19-at-alert-subsequently published in New Zealand Economic Papers, April 2022, Vol. 56 (1), pp. 41-48.
- <sup>2</sup> https://www.cebm.net/covid-19/global-covid-19-case-fatality-rates/



# 3.3 GREAT BARRINGTON

Great Barrington Declaration – World-Leading Experts Propose Focused Protection Policy Instead of Locking Down the Healthy

Katie Ashby-Koppens

# Why this issue is relevant:

The Great Barrington Declaration, published in October 2020 by globally respected epidemiologists and public health specialists, proposed an alternative strategy, Focused Protection, to safeguard the vulnerable while minimising social and economic harms.

If this was their expert advice at the time, it undermines the justification for New Zealand's August 2021 lockdown.

The Great Barrington Declaration was first published on 20 October 2020. It called for signatories and has now amassed close to one million signatures worldwide.

It argued that lockdown policies had caused significant collateral damage: deteriorating mental health, delayed medical care, economic hardship, and educational disruption—harms that disproportionately affected the working class and youth.

The Declaration proposed Focused Protection: allowing low-risk populations to live normally, thereby building herd immunity, while implementing targeted measures to shield the elderly and medically vulnerable. These recommendations were notably aligned with the World Health Organization's 2019 pandemic guidelines, prior to its 2020 policy reversal (see Issue 0.7.A, page 82).

The authors emphasised the stratified nature of COVID-19 risk, with older and frailer individuals at the greatest risk, and urged governments to balance infection control with minimising broader societal harm.

# Details

The Declaration was authored by three world-renowned experts:

 Dr Martin Kulldorff (Harvard – epidemiology and vaccine safety)

- Dr Sunetra Gupta (Oxford infectious disease modelling)
- Dr Jay Bhattacharya (Stanford public health and vulnerable populations)

# Key points:

- Lockdowns contributed to reduced childhood vaccination rates, poorer cardiovascular outcomes, fewer cancer screenings, and escalating mental health crises.
- COVID-19 mortality risk is 1,000 times higher in the elderly and infirm than in the young; for children, COVID-19 poses less risk than seasonal influenza.
- Herd immunity was considered inevitable, whether via natural infection or vaccination, so the objective should be to minimise mortality and societal harm during the transition.

# Recommended Focused Protection Measures:

- Employ immune or regularly tested staff in aged-care facilities.
- Minimise staff rotation and ensure grocery deliveries to the elderly.
- Permit low-risk individuals to resume normal life: open schools, universities, businesses, sports, and cultural events.
- Promote hygiene practices (e.g. handwashing, staying home when unwell) to lower the herd immunity threshold.

# The Great Barrington Declaration

The Great Barrington Declaration – As infectious disease epidemiologists and public health scientists we have grave concerns about the damaging physical and mental health impacts of the prevailing COVID-19 policies, and recommend an approach we call Focused Protection.

Coming from both the left and right, and around the world, we have devoted our careers to protecting people. Current lockdown policies are producing devastating effects on short and long-term public health. The results (to name a few) include lower childhood vaccination rates, worsening cardiovascular disease outcomes, fewer cancer screenings and deteriorating mental health – leading to greater excess mortality in years to come, with the working class and younger members of society carrying the heaviest burden. Keeping students out of school is a grave injustice.

Keeping these measures in place until a vaccine is available will cause irreparable damage, with the underprivileged disproportionately harmed.

Fortunately, our understanding of the virus is growing. We know that vulnerability to death from COVID-19 is more than a thousand-fold higher in the old and infirm than the young. Indeed, for children, COVID-19 is less dangerous than many other harms, including influenza.

As immunity builds in the population, the risk of infection to all – including the vulnerable – falls. We know that all populations will eventually reach herd immunity – i.e. the point at which the rate of new infections is stable – and that this can be assisted by (but is not dependent upon) a vaccine. Our goal should therefore be to minimize mortality and social harm until we reach herd immunity.

The most compassionate approach that balances the risks and benefits of reaching herd immunity, is to allow those who are at minimal risk of death to live their lives normally to build up immunity to the virus through natural infection, while better protecting those who are at highest risk. We call this Focused Protection.

Adopting measures to protect the vulnerable should be the central aim of public health responses to COVID-19. By way of example, nursing homes should use staff with acquired immunity and perform frequent testing of other staff and all visitors. Staff rotation should be minimized. Retired people living at home should have groceries and other essentials delivered to their home. When possible, they should meet family members outside rather than inside. A comprehensive and detailed list of measures, including approaches to multi-generational households, can be implemented, and is well within the scope and capability of public health professionals.

Those who are not vulnerable should immediately be allowed to resume life as normal. Simple hygiene measures, such as hand washing and staying home when sick should be practiced by everyone to reduce the herd immunity threshold. Schools and universities should be open for in-person teaching. Extracurricular activities, such as sports, should be resumed. Young low-risk adults should work normally, rather than from home. Restaurants and other businesses should open. Arts, music, sport and other cultural activities should resume. People who are more at risk may participate if they wish, while society as a whole enjoys the protection conferred upon the vulnerable by those who have built up herd immunity.

On October 4, 2020, this declaration was authored and signed in Great Barrington, United States, by:

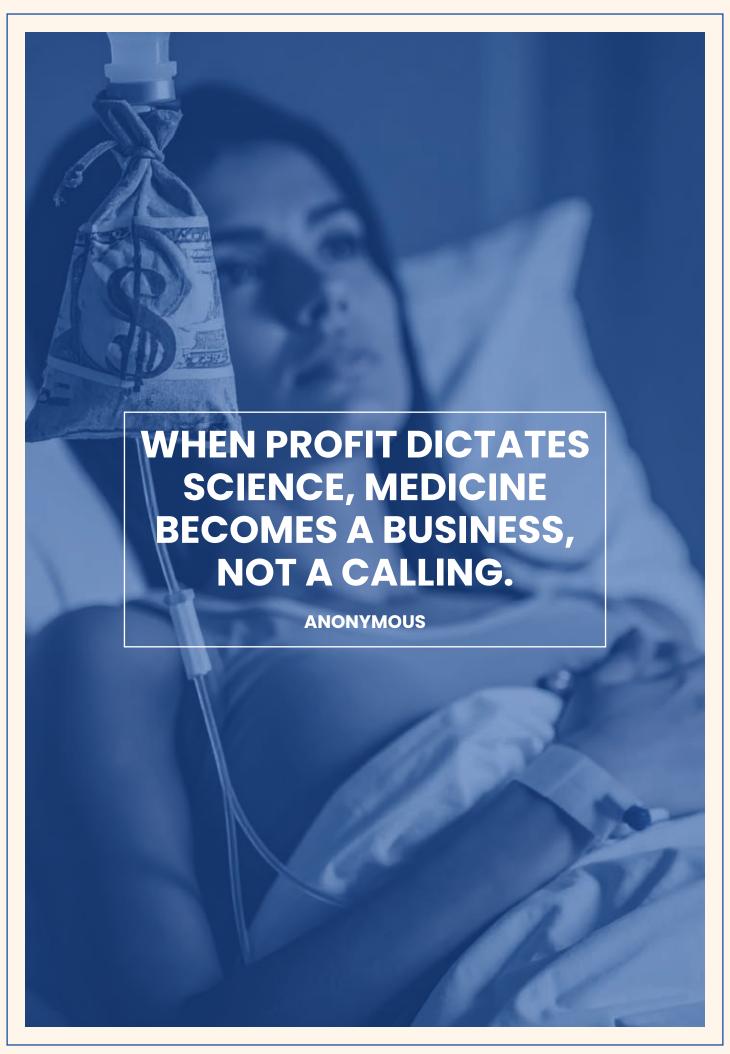
Dr. Martin Kulldorff, professor of medicine at Harvard University, a biostatistician, and epidemiologist with expertise in detecting and monitoring infectious disease outbreaks and vaccine safety evaluations. Dr. Sunetra Gupta, professor at Oxford University, an epidemiologist with expertise in immunology, vaccine development, and mathematical modeling of infectious diseases. Dr. Jay Bhattacharya, professor at Stanford University Medical School, a physician, epidemiologist, health economist, and public health policy expert focusing on infectious diseases and vulnerable populations.

# Important Questions for the Commissioners to Ask — and of Whom:

# NZ Ministry of Health and Former Director-General of Health:

- Why was the Focused Protection approach not considered or evaluated in New Zealand's COVID-19 response?
- Did the Ministry conduct a risk-benefit analysis comparing the costs of lockdowns (economic, health, social) versus their protective benefits?
- How were vulnerable populations specifically protected during the pandemic beyond general lockdowns?

- Was herd immunity modelling ever part of pandemic planning, and how did the Ministry estimate the role of natural immunity?
- Why were school closures extended, given the evidence on children's low risk and the harms of disrupted education?
- What measures are now in place to ensure that future public health responses minimise collateral damage and are proportionate to risk?



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# **DRAMATIS PERSONAE**



# Katie Ashby-Koppens

Katie has been a civil litigator for over 20 years, first in New Zealand and then in Australia. As a generalist civil litigator at first Katie cut her teeth in employment, medico-legal, regulatory dispute work before specialising in class actions and large matters.

Katie is head of legal for Voices for Freedom and Reality Check Radio. She is a lawyer in NSW and has been a part of many of the actions with respect to mandates and the COVID-19 vaccines.



# **Dr David Bell**

Public health physician and biotech consultant in global health. David is a former medical officer and scientist at the World Health Organization (WHO), Programme Head for malaria and febrile diseases at the Foundation for Innovative New Diagnostics (FIND) in Geneva, Switzerland, and Director of Global Health Technologies at Intellectual Ventures Global Good Fund in Bellevue, WA, USA.



# Alia Bland

Alia is a co-founder of Voices for Freedom and Reality Check Radio, grassroots organisations formed in response to New Zealand's COVID-19 policies. She has engaged with leading international experts in science and medicine and closely followed developments in health research, vaccine data, and public policy. With a background in education, Alia is skilled at making complex information accessible. Her perspective is shaped by direct engagement with hundreds of thousands of New Zealanders and navigating censorship, media exclusion, and government scrutiny during the COVID era.



# Associate Professor Byram Bridle

Associate Professor of Viral Immunology – Department of Pathobiology, University of Guelph, Ontario Veterinary College.

Prof Bridle is a viral immunologist who is passionate about improving life through two avenues of research. One arm of his research programme is dedicated to designing and optimising novel biotherapies for the treatment of cancers. The goal of his research team is to harness the natural power of a patient's immune system to eliminate their own cancer cells.



# **Professor Ian Brighthope**

Professor Ian Brighthope began his career in Agricultural Science before becoming a medical doctor in 1974, later dedicating his life to bridging the gaps he observed in traditional medical training. He pioneered Nutritional and Environmental Medicine in Australia, founding the Brighthope Clinics and the Australasian College of Nutritional and Environmental Medicine (ACNEM), where he served as president for over 26 years. A long-time advocate for complementary medicine and medicinal cannabis, he has held leadership roles in peak industry bodies and continues to lecture internationally. Professor Brighthope's enduring mission is to transform global healthcare by making nutrition and natural medicine foundational to medical practice and public health.



# **Simon Brown**

Simon Brown (PhD) is a graduate from the University of Otago (Chemistry, 1983) and a retired Senior Research Fellow and Principal Investigator with the Centre for Inflammation Research, University of Edinburgh (1998-2011); trained as a biochemist with expertise in molecular, cellular and animal models of inflammation with an emphasis on the innate immune response. Inflammation is typically a beneficial and self-resolving response to tissue injury and infection.



# **Jodie Bruning**

Jodie is a researcher whose work is grounded in legal, economic, and scientific principles aimed at safeguarding human and environmental health. With academic roots in agribusiness (Monash University) and public health research (University of Auckland), her focus has turned to the risks of chronic toxicity and poor nutrition, particularly in children, linked to weak chemical regulation and insufficient environmental monitoring. Her research critiques the failure of governance systems to adequately assess and prevent harm from diffuse pollutants, especially pesticides, due to underfunding and lack of cross-disciplinary expertise. In recognition of her advocacy, Jodie received the Robert Anderson Memorial Award from Amnesty International Tauranga Moana in 2019.



# **Hilary Butler**

Hilary began researching vaccines in 1981 after personal experiences eroded her trust in the medical system. She is the author of Just a Little Prick and From One Prick to Another, and has worked on over 20 vaccine injury and Shaken Baby Syndrome cases in New Zealand and overseas. Between 1986 and 2017, she assisted lawyers and doctors by analysing medical records alongside scientific literature. Hilary continues to research vaccine safety, with particular attention to concerns around the COVID-19 rollout.



# **David Charalambous**

David Charalambous is an expert in behavioural science with over 25 years of consulting experience, working with multinational clients and individuals from various backgrounds, including athletes and business leaders. As the founder of Reaching People, David has dedicated his career to improving communication and understanding among diverse groups. His unique approach integrates Behavioural Science, NLP, EFT, and other fields into practical systems that emphasise ethical influence and informed decision-making. Known for his engaging presentations and workshops, David has delivered insights globally, making complex psychological concepts accessible and actionable. Through his initiative, he aims to foster a more aware and resilient public, capable of making autonomous and informed choices in an increasingly complex world.



# Dr Cindy de Villiers

Cindy is an experienced General Practitioner who has worked in urban and rural hospitals and general practices in New Zealand and Australia for the past 30 years. Cindy graduated from Stellenbosch University, South Africa in 1990 and obtained her fellowship in General Practice in New Zealand in 2010.



# **Elvira Dommisse**

Dr Elvira Dommisse is a scientist with a background in Botany and Biochemistry, earning First Class Honours in Plant Physiology from Otago University. As a research scientist at DSIR (later Crop & Food Research), she pioneered genetic engineering techniques in onions, becoming the first in the world to publish on the subject. Her work raised early concerns about the safety and regulation of genetically modified crops, prompting her to leave the field in 1993 due to ethical concerns and dissatisfaction with the industry's lax oversight. Dr Dommisse has since been an advocate for greater scrutiny of transgenic crop development and its environmental implications.



# **Dr Alison Goodwin**

Dr Alison Goodwin, MBChB, FRNZCGP. GP by training. Terminated from position as a GP for making an informed decision not to receive COVID vaccine. Had APC suspended for 10 months in 2022 by MCNZ for questioning the COVID response, in particular lack of informed consent, displacement of medical ethics, first do no harm. Assisting New Zealanders with ACC claims and has read documentation (e.g. medical records, radiology and laboratory results, reports from pathologists and coroners) of vaccine injured and/or deceased New Zealanders.



# **Sue Grey**

Sue has law and science degrees, the latter majoring in microbiology and biochemistry. She also holds a Royal Society of Health Diploma. Sue was admitted to the bar in Auckland on 1 October 1990. After being a partner in MS Sullivan and Associates, she became a self-employed lawyer based in Nelson



# Emma Hart

Emma Hart is a global media strategist and board-level communications advisor with over 25 years' experience in journalism, reputation management, and executive counsel. From her early recognition at TVNZ to founding Europe's first broadcast media PR division at Edelman, she has shaped public narratives and advised C-suite leaders across major crises and global markets. Her clients include Microsoft, EY, HSBC, and the Bank of England. Now based in New Zealand, Emma leads Reputation Sync, providing elite crisis and governance communications for boards and leadership teams across Australasia.



# **Dr Martin Lally**

Dr Martin Lally is a former Associate Professor in Finance at Victoria University of Wellington and Director of Capital Financial Consultants, which provides financial economics advice to a wide range of clients in the public and private sectors in New Zealand and Australia. Dr Lally's primary work is advice on the cost of capital to government entities in New Zealand and Australia that are engaged in price or revenue capping natural monopolies. His principal expertise is cost benefit analysis.

Dr Lally was an expert in the Kiwi Kids' Case.



# **Kevin McKernan**

Kevin McKernan is a pioneering genomic scientist who played a key role in the Human Genome Project while leading R&D at the Whitehead Institute/MIT, where he secured several patents for nucleic acid purification. He later co-founded Agencourt Personal Genomics, driving a 100,000-fold reduction in the cost of sequencing a human genome, from \$300 million to just \$3,000, revolutionising the field. As CSO and Founder of Medicinal Genomics, Kevin has since turned his focus to the genomics of cannabis and hemp, creating platforms like Kannapedia.net and leveraging blockchain technologies to authenticate plant genetics and support cannabinoid research. His leadership in biotech also includes spearheading the acquisition of Ion Torrent for \$350 million, managing over 100 next-gen sequencing collaborations, and securing high-profile publications across Science Translational Medicine, Nature, and more.



# **Dr Mark Pinkerton**

Dr Mark Pinkerton BSc, BDS, DClinDent(Orth), MOrthRCSEd is a specialist orthodontist with a background in molecular biology and over 25 years of experience in the biological and clinical sciences. His research focused on gene expression in mechano-responsive periodontal ligament cells using real-time PCR, culminating in a thesis and several publications. Mark joined NZDSOS out of concern for the erosion of informed consent, human rights, and scientific integrity during the COVID-19 response. He was alarmed by the shift away from evidence-based practice toward reliance on obscure expert opinion, the societal division fostered by mandates, and the role of leadership and media in deepening that divide, compelling him to advocate for patient rights, ethical medical practice, and social cohesion.



## Jessica Rose

PhD (Computational Biology), MSc (Immunology), BSc (Applied Mathematics; Post doctoral degrees (Molecular Biology & Biochemistry).

Fellow at Brownstone Institute and Independent Medical Alliance.



# **Gary Sidley**

Gary Sidley worked within NHS mental health services for 33 years in a variety of nursing, psychological and managerial roles. In the 1980s he was employed as a psychiatric nurse at a large asylum in Manchester, commencing his clinical psychology training in 1987. Subsequently, he worked as a clinical psychologist in community mental health services, inpatient units and GP practices, as well as operating as a professional lead and a member of a Trust's senior management team. Gary opted for early retirement in 2013 and currently is a freelance writer and trainer with an interest in promoting alternatives to bio-medical psychiatry as ways of responding to human suffering.



# **Sinead Stringer**

Sinead Stringer holds a Masters in Behavioural Science from the London School of Economics, one of the leading institutions in this field globally. In 2021 she worked with PANDA to create a series of initiatives designed to promote conscious engagement. She is a change and transformation consultant who targets operational and behavioural risk and works primarily in regulatory and governance areas in financial institutions.



# **Dr Simon Thornley**

Dr. Simon Thornley is a public health physician and senior lecturer in epidemiology and biostatistics at the University of Auckland. His research encompasses cardiovascular disease risk estimation, the health impacts of sugar consumption, and infectious diseases such as scabies. During the COVID-19 pandemic, Dr. Thornley became known for his critical views on New Zealand's elimination strategy and vaccine mandates, contributing to public discourse through the 'COVID Plan B' group.



# Lynda Wharton

Lynda Wharton is a leading New Zealand holistic women's health specialist. She practices naturopathic medicine and traditional Chinese acupuncture. Lynda is a health researcher, writer and speaker.

Lynda set up the Health Forum shortly after the COVID-19 pandemic was declared. She has been an instrumental support to so many vaccine injured who were left feeling that they had nowhere to go.



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