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Tēnā koe s 9(2)(a)

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to Manatū Hauora (Ministry of Health) on 23 June 2022. You requested:

A document recently published on the Ministry website is referred to as being a "summary" prepared for Cabinet of a document called the "Strategic Framework for COVID-19 Variants of Concern."

I would like to request a copy of the actual Strategic Framework (i.e., not the summary).

The time frame for responding to your request was extended until 12 August 2022 under section 15A of the Act. Please find attached to this letter a copy of the document you requested titled 'Aotearoa New Zealand's Strategic Framework for COVID-19 Variants of Concern'.

Please note, some information has been withheld under section 9(2)(g)(i) of the Act, in order to maintain the effective conduct of public affairs through the free and frank expression of opinions by or between or to Ministers and officers and employees of any public service agency. I have considered the countervailing public interest in release in making this decision and consider that it does not outweigh the need to withhold at this time.

I trust this information fulfils your request. Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: info@ombudsman.parliament.nz or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests.

Nāku noa, nā

Steve Waldegrave
**Acting Deputy Director-General
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COVID-19

Aotearoa New Zealand's Strategic Framework for COVID-19 Variants of Concern

Effective June 8 2022

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Engagement on the plan	
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I. Glossary

Term	Definition
Clinical severity	<p>The severity at which the disease manifests clinically. It may range from having no apparent symptoms (asymptomatic), to critical illness and death. Severe illness in respiratory disease is usually due to respiratory failure, septic shock or multiorgan failure.</p> <p>Severity of COVID-19 is usually measured by rates of hospitalisation, respiratory support, admission to intensive care, mechanical ventilation or death. Each measure has advantages and disadvantages.</p>
Frame-shift	<p>A genetic mutation that occurs due to either an insertion or deletion of a nucleotide bases in numbers that are not multiples of three, leading to a change in the open-reading frame.</p> <p>This results in significant changes in the protein downstream from the mutation. These mutations can alter the properties of the protein and change the manner in which the virus behaves.</p>
Immune escape	The ability of the virus to evade our body's immune response.
Immune response	The response of our immune system to an infection. It includes development of specific antibodies to the virus and cell-mediated responses (triggered by T cells).
Incubation period	The time interval between infection of a host and the appearance of the first sign or symptom of the disease.
Infectiousness	A characteristic that concerns the relative ease with which the disease/virus is transmitted to other hosts. An airborne spread virus for instance, is more infectious than one spread by direct contact. The characteristics of pathogen entry/exit to the host are thus also determinants of infectiousness. In addition, to the ability for the pathogen to survive/persist in the environment separate to the host can be viewed as an infectiousness trait.
Mutation	Small change made to the pattern of nucleotides that make up the virus. These occur as the virus spreads and replicates. Most mutations do not benefit the virus.
Mutability	The tendency or liability for mutations to occur. Most viruses have an underlying or base rate of mutation which remains relatively constant. However, with an increasing number of infections occurring, the opportunity for new mutations will increase due to the amount of virus circulating and not the underlying mutability of the virus.
R₀, Reproductive number	The reproductive number R ₀ (R-naught), is a measure of the contagiousness of a disease. It is the average number of people who catch a disease from an infected individual when there are no control measures in place lockdowns.
R_{eff}, Effective reproductive number	The 'effective R' (Reff) is the R observed when control measures are in place. Reff can therefore change depending on the control measures currently enacted in a particular population. In general, whenever R is less than 1, i.e., an infected person goes on to infect less than one person on average, then the prevalence of the disease would be expected to decrease.

Transmissibility	<p>The quality of a pathogen by which it is passed on from one person or organism to another. This can be conferred by several mechanisms (or a combination of these):</p> <ul style="list-style-type: none"> • Features of the infection such that each infected individual is likely to infect. For example, by: <ul style="list-style-type: none"> ○ the rate of virus shedding ○ the number of days where virus is shed (increasing duration of infectiousness), or ○ the number of days where someone is infectious but is unaware of it (increasing the asymptomatic but infectious period – the prodromal period or increasing the proportion of cases that are never symptomatic but are infectious). • The extent of immune escape, such that each infected individual is more likely to infect others. For example, by: <ul style="list-style-type: none"> ○ protection against infection with (and onward transmission of) a new variant is not conferred as well by vaccination or previous infection as it is against infection with current variants. ○ a previously seen variant “re-emerges” due to waning of protection from vaccination or infection.
Variant	<p>Viruses with mutations are referred to as variants of the original virus. New variants of SARS-CoV-2 have been emerging as the virus has spread and evolved.</p>
Variant of Concern (VoC)	<p>WHO definition: A SARS-CoV-2 variant that meets the definition of a VOI (see below) and, through a comparative assessment, has been demonstrated to be associated with one or more of the following changes at a degree of global public health significance:</p> <ul style="list-style-type: none"> • increase in transmissibility or detrimental change in COVID-19 epidemiology, OR • increase in virulence or change in clinical disease presentation, OR • decrease in effectiveness of public health and social measures or available diagnostics, vaccines, therapeutics.
Variant of Interest (VOI)	<p>WHO definition: A SARS-CoV-2 variant:</p> <ul style="list-style-type: none"> • with genetic changes that are predicted or known to affect virus characteristics such as transmissibility, disease severity, immune escape, diagnostic or therapeutic escape; AND • identified to cause significant community transmission or multiple COVID-19 clusters, in multiple countries with increasing relative prevalence alongside increasing number of cases over time, or other apparent epidemiological impacts to suggest an emerging risk to global public health.
Variant under Investigation (VUI)	<p>UKHSA definition: SARS-CoV-2 variants, if considered to have concerning epidemiological, immunological or pathogenic properties, are raised for formal investigation. At this point they are designated Variant Under Investigation (VUI) with a year, month, and number. Following a risk assessment with the relevant expert committee, they may be designated VoC.</p>

II. Executive summary

Aotearoa New Zealand's Strategic Framework for COVID-19 Variants of Concern (the Strategic Framework) considers likely and potential scenarios to inform planning considerations and ensure that we are prepared to respond as required. While these scenarios are based on evidence and have been subject to review, it is important to note they are hypothetical.

The scenarios prepared as part of the Strategic Framework range from low transmissibility and low immune-evasion, essentially where the virus has enough transmissibility to create a high case load, but current effective immunity is protection enough. Other scenarios include a high transmissibility and high immune-evasion, where without significant intervention the pressure on the healthcare system would be immense and the number of COVID-19 related deaths would be likely to increase, particularly among the elderly. We have also accounted for the possible scenario of multiple co-circulating variants, however based on current evidence this is somewhat less likely.

In planning for future variants, we have the advantage of having systems and an evidence informed range of responses in place that can be applied to the scenario at hand. Currently, it is likely that responses to most potential variants are focussed on minimisation and protection. This means that the focus would be on:

- continuing the focus on minimising impacts with widespread transmission to reduce the effects on the population, particularly vulnerable communities,
- avoiding additional burdens on the healthcare system that could be caused by Influenza Like Illnesses; and
- long-term planning for recovery and ensuring the system can respond to Variants of Concern.

Our access to global insights and monitoring provides some lead time and indicators on Variants of Concern to inform preliminary health risk assessments. As an island nation we do have the advantage of increasing border surveillance, which can be enacted quickly when we are alerted to any serious new Variant(s) of Concern. By increasing surveillance at the border, we should be able to slow the spread of any new variants and buy time to stand up a response if it is required and consider options that support or increase our understanding of a new Variant.

In the plan we have identified our key response measures, as a combination of baseline measures and extra measures that would be used with more severe Variants of Concern. The baseline measures include:

- ongoing border and community surveillance
- RAT based testing except for PCR where required for diagnostic or surveillance purposes, isolation requirements for current cases
- infection prevention controls including mask use
- vaccination and therapeutics
- border measures, including pre-departure testing and post-arrival testing
- the ongoing use of Care in the Community networks.

Further reserve measures that can be called on for more severe Variants of Concern, noting the measures will be very context specific:

- Increased use of testing through targeted interventions
- Contact tracing

- Capacity limits
- stronger border measures, including self-isolation for arrivals, MIQ or border closures, and
- Regional and national lock-downs.

By completing this preparedness process now, we have the advantage of being able to identify what future responses may look like and work on preparedness measures to strengthen our response. This will not only make it easier to activate the response more rapidly, but also make the responses more effective. An example of this is the development of potential seroprevalence surveys which will provide information on the level of immunity in the community and inform measures that may be required as part of a response.

We know that in using these measures there will be trade-offs that will need to be made between the health impacts and impacts on social and economic wellbeing. Work is currently underway to develop a detailed understanding of the impacts of these measures and will be used to inform future decision making.

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III. Purpose

Aotearoa New Zealand's Strategic Framework for COVID-19 Variants of Concern (the Strategic Framework) provides an overview of preparedness and response considerations for the health system to new COVID-19 Variants of Concern. It takes a strategic approach to the continuous enhancement of future responses, including the improvement of current tools and measures. Future responses will consider the best available evidence at the time and balance a range of other considerations, including equity, impact of vulnerable groups, health system capacity as well as economic and social impacts.

While there is a high likelihood of new Variants of Concern emerging, the timeframe, characteristics, clinical impacts, and the context in which they may emerge, is not clear. Given this uncertainty, and to assist preparedness and response planning, the Strategic Framework considers five plausible scenarios that reflect the likely characteristics of new variants. Approaches for each scenario are considered, as well as the likely risk-assessment considerations.

The scenarios and approaches provide a common framework for agencies, iwi and businesses to individually and collectively consider the tools and resources likely required for an effective response – whether this be simply a scaling up of existing activity, such as changing our testing approach, or reactivation of tools, such as maintaining pre-departure testing.

The focus of the Strategic Framework is at the national-level health response. New Variants of Concern will have a broader impact across regions, communities and sectors. Further planning for regions, communities and sectors will follow as part of All-of-Government work.

The Strategic Framework does not commit the Government to any measures, and does not constrain government, regional or local planning in advance.

The scope of the Strategic Framework is outlined below:

In scope
• Details on the current evidence base.
• Information on global approaches.
• Peer reviewed scenarios.
• Information on how this Strategic Framework works with other plans and strategic plans.
• The proposed public health response for each scenario.
• Enablers to support the health response should they be required.
• How the Strategic Framework will support long term planning.
• The principles of Te Tiriti o Waitangi and how it has been embedded in the Strategic Framework.
• How equity has been embedded in the Strategic Framework.
Not in scope
• An All-of Government approach – the Strategic Framework will support all of government planning.
• A plan for regions and communities – the Strategic Framework will support this planning.
• Analysis of alignment to global responses – the Strategic Framework does provide an initial assessment.
• A plan that will be implemented in response to a new variant - the Strategic Framework will inform a plan when a new variant emerges.

IV. Context

Aotearoa New Zealand has been successful in preventing the worst impacts of COVID-19. We have achieved this by basing our response on strong scientific and public health advice, and by our willingness to learn and adapt our response to the evolving nature of the virus.

Since the outset of the pandemic, we have learned a lot about what does and does not work. We must embed these lessons and use them as a base to drive improved pandemic preparedness and response.

Throughout the course of the last two years particularly, Aotearoa New Zealand has been guided by our international science, epidemiological, public health and intelligence counterparts and by the collective construct the World Health Organization provides in relation to strategic planning and preparedness in response to acute global pandemics.

In this context we are using the following definitions for preparedness and response:

Preparedness: This is defined by the United Nations International Strategy on Disaster Reduction as 'the knowledge and capacities developed by governments, professional response and recovery organizations, communities and individuals to effectively anticipate, respond to, and recover from, the impacts of likely, imminent or current hazard events or conditions.' In this context, this is the planning process and the resulting work enable an effective response to a new Variant of Concern.

Response: these are the measures that will be applied (or continue to be applied) should a new Variant of Concern emerge, that will be supported and enabled through preparedness measures.

What we know about Variants of Concern

The development pattern of new variants is incremental change to the dominant variant. The emergence and rapid spread of the Omicron Variant of Concern towards the end of 2021 precipitated an acceleration of COVID-19 transmission worldwide, at an intensity the world had not seen.

As observed with Omicron, it is possible that another new variant will emerge that has many significant mutations. These mutations can result in major differences in either transmissibility, immune evasion, and/or clinical severity. It is currently unknown whether a frameshift occurs once every 1-2 years or once a decade [1].

Trait	Description
Infectiousness	New variants need to be more infectious than previous variants to be able to gain a foothold.
Probability of a 'frameshift'	It has been estimated that there is approximately a 30% chance of a frameshift occurring (like Omicron) in the next 12-months, but this estimate decreases the longer the time observed between frameshift events.
Severity	They may cause more or less severe disease. Severity is determined by the intrinsic severity of the variant and the immunity to severe disease in the

	population. Note, that the immunity to infection and immunity to severe disease may vary for different variants.
Speed of transmission	<p>A new successful variant that arises from incremental changes to the dominant variant is likely to be more transmissible than the existing predominant variant. A "frame shift" variant may be able to spread by not having to compete with dominant variants due to substantial immune evasion and changes to the mode of infection (to date all variants have entered cells through the ACE receptor in the nose or throat).</p> <p>A new variant may spread so quickly and be so transmissible that there is no option of buying time, by keeping it out, as it may already be in New Zealand. As we have seen with Omicron, the speed at which a new variant can replace old variants can be very swift. Omicron is estimated to have infected approximately 50% of the US population in about 10 weeks.</p> <p>On the other hand, a new variant may spread relatively slowly, on its way to becoming the dominant variant. For example, BA.4 and .5 have an approximately 10-20% transmission advantage over BA.2, which means that one or both are destined to become the dominant variant (all else being equal) but it may be a relatively slow burn, over a period of a few months.</p>

The situation has changed from March 2020

Since the initial outbreak in New Zealand in March 2020 much has changed and much has been learned about the virus and how best to respond to the pandemic. Time has allowed us to learn from the experience of other countries, as well as reflect on our own, and to consider the vast amount of scientific knowledge about the nature of the virus and how best to protect the health and wellbeing of our communities.

Nationally and internationally, there is better surveillance than in 2020

Global surveillance means that we will most likely receive early warning (within days of a sample being analysed) of a new threat before it is detected in New Zealand. This could include an understanding of the potential level of immune escape of the new variant as there is a better knowledge of which mutations are associated with this. Within weeks there may be early evidence of immune escape and changes in transmissibility. What will not be immediately known however, is the severity of a new variant as it takes 1-2 months for the data to be gathered and analysed.

It is possible that a new variant may already be circulating within the community by the time we are alerted of its emergence internationally. In this situation, rapid identification to inform a strong health response can still be effective (as those tactics were in March 2020), particularly if the new variant has a modest transmission advantage over the prevalent variant.

Some level of protection will already exist

The immunity (infection or vaccine related) that New Zealanders have built over the last two years will likely provide some continued level of protection against severe disease, as the mRNA vaccines did for Omicron. However, vulnerabilities due to waning immunity, unvaccinated and immunocompromised individuals should be considered, as there will be a significant proportion of the population who remain highly vulnerable to severe disease.

SARS-CoV-2 vaccines may be developed at greater speed

The first COVID-19 vaccines were developed in just 11 months. As mRNA technology evolves further, new vaccines can be developed within an even shorter timeframe – potentially within a few months to respond to new variants. However, global demand and manufacturing constraints may mean that it could take several months before there is sufficient supply for distribution. It will also remain important that the regulatory assessment is robust and Ministerial approvals processes are thorough.

As with the current situation with the influenza vaccine, some prediction based on best evidence and modelling is involved, but there is no guarantee of a good match between the vaccine in development and the actual variant that occurs during the season.

It is unknown at this point whether new COVID-19 vaccines will be updated annually, similar to the seasonal Influenza vaccine, or less frequently. As noted, the new variant may be sufficiently similar that a new vaccine is not required. Rather, a further dose of existing vaccines may be protective.

Higher transmissibility may mean fewer public health measures are effective

The degree of infectiousness of a new variant may be so great that some public health and social measures (PHSM) may not be effective.

During Delta, PHSMs including Managed Isolation and Quarantine (MIQ) bought time to reach high levels of population immunity through vaccination programmes (above 90% percent). MIQ and other border measures were effective in stopping the introduction of the Delta variant into the community for an extended time from May to August 2021.

The most effective way of protecting communities at greater risk is to strengthen layers of protection to reduce the levels of community transmission. Once Omicron became the dominant variant, effective vaccines were available but substantial protection against severe disease was only provided by three doses. The 7-day MIQ requirements and other border restrictions were still in place at the time slowed the introduction of Omicron into the community and bought us time until a sufficient proportion of the population (particularly older people) could receive three doses.

Erosion of social licence

To date, the success of our response to the COVID-19 pandemic has relied on an outstanding level of community support, adherence to the public health measures and participation in vaccination programmes. Understandably, as the pandemic has extended for over two years, some parts of the community have become less willing to cooperate with some public health measures. As such, there may be fewer public health levers available, and/or the interventions that are still available may be less effective.

Effective and engaging messaging is likely to be required to gain broad population support if restrictive public health measures were to be introduced once again.

Throughout the pandemic, research has monitored and assessed community attitudes. There will be an ongoing need for such research to ensure public health messaging remains effective and to act as a barometer of social licence.

V. The COVID-19 Strategic Approach

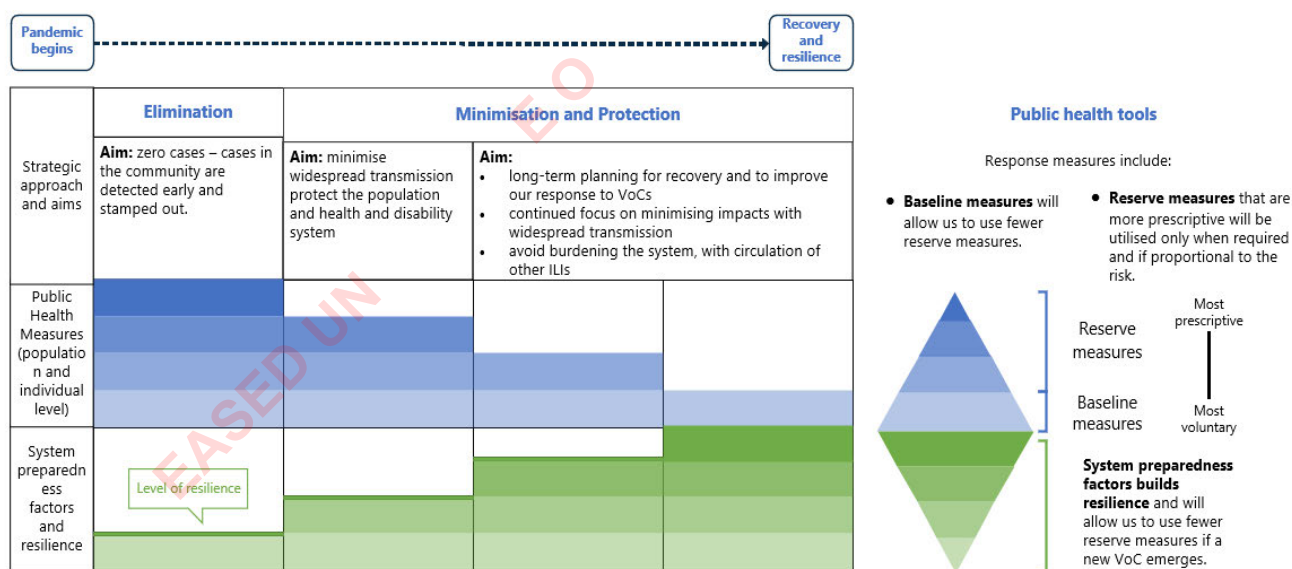
As the COVID-19 pandemic moves into its third year, Aotearoa New Zealand’s health response has continually evolved as both the virus and our ability to manage it has changed. From our initial elimination strategy we have shifted to one of minimisation and protection. We have continued to refine our response from the earlier Alert Level settings to the current COVID-19 Protection Framework.

As we look to shift to an environment where COVID-19 is endemic in Aotearoa New Zealand and globally, the potential for new Variants of Concern needs to be carefully considered as part of any future planning as changes are made in the post-peak Omicron environment, and to inform planning.

As we work to create a system that is resilient to new Variants of Concern, we need to carefully consider the role of preparedness measures to support an effective response. We are working to optimise the effectiveness of relevant measures and to minimise the need for more restrictive measures where possible.

This is highlighted in Figure 1 below which shows how the use of measures has progressed throughout our response to the pandemic, to the current state where in the minimisation and protection phase we are looking to use baseline measures where possible, although there are reserve measures that can be used if required. The green parts of the diagram show the enhanced system resilience through preparedness, that support more effective baseline measures- for example, improved through testing and surveillance technology.

Figure 1. The role of the public health response and preparedness factors



As such, the Strategic Framework sits within a wider strategic context which includes:

- the development of a strategy for the COVID-19 health response over the medium to long-term, focused on recovery and building resilience. It will provide strategic guidance for the health system and wider All-of-Government COVID-19 response and will inform the operating context in which we respond to new variants.
- revising the current surveillance and testing strategies to reflect the updated and more nuanced responses to different variant scenarios.

- informing the development of the Health Border Strategy and the interim and enduring arrangements for the health presence at the border.
- ensuring that responding to new Variants of Concern is supported in consideration of the future legal framework.
- advice and recommendations from World Health Organization (WHO), and other peak bodies and the potential impact of amendments to the International Health Regulations 2005 and proposals for a pandemic treaty.
- development of a COVID-19 vaccine strategy that will consider measures to maintain vaccine effectiveness and support agility to enable vaccines to respond new Variants of Concern as and when required.

The Ministry of Health continues to work with Department of Prime Minister and Cabinet (DPMC), Ministry of Business Innovation and Employment (MBIE), Ministry of Education, Ministry of Primary Industries, the New Zealand Customs Service and the Ministry of Foreign Affairs and Trade to progress broader planning for the All-of-Government response.

The scenario planning will also be available to inform broader strategic planning, with potential uses including the ongoing consideration of national quarantine capability and Treasury's work on resilience planning.

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VI. Scenarios to inform the Strategic Framework for new Variants of Concern

Five hypothetical COVID-19 variant scenarios have been developed to inform the Strategic Framework. Each scenario considers clinical severity, immune evasion, transmissibility, disease burden, and the availability of effective vaccines and antiviral therapeutics. The scenarios are:

- Scenario 1: High clinical severity, high immune escape
- Scenario 2: Low clinical severity, high immune escape
- Scenario 3: High clinical severity, low immune escape
- Scenario 4: Low clinical severity, low immune escape
- Scenario 5: Multiple co-circulating variants with different levels of severity and different levels of cross-protection.

All scenarios are compared to the Omicron BA2 variant which is the dominant variant in New Zealand at this time.

While there are clear uncertainties ahead, there are a number of expected assumptions based on science. A first assumption is that COVID-19 will continue to evolve with new Variants of Concern. Secondly it is assumed that in all scenarios the new variant has transmission advantage (increased R_0) and is able to out-compete Omicron BA2 (the current dominant in New Zealand).

We have also assumed that in all scenarios there is a degree of prior immunity from previous vaccination or infection. As such, the disease severity as discussed below refers to the severity observed in a population with an existing degree of prior immunity, rather than the 'intrinsic' severity associated with infection of an individual with no prior protection. For example, Omicron typically causes mild disease in vaccinated or previously infected populations but can be severe in unvaccinated individuals.

Disease characteristics and contextual factors

There are a range of factors that will need to be considered that could apply to all scenarios – which in turn will impact on the response approach. For example, evidence that the variant results in a longer infectious period or is resulting in chronic infections may lead to more severe impacts. These factors are outlined in the below:

Table 2: Factors that could be present in all scenarios

Changes to viral dynamics	Testing	Efficacy of therapeutics
<p>Longer incubation period: Longer time to develop symptoms may have benefits for contact tracing, but means that infected individuals would be infectious for longer, and unaware of their risk to others.</p> <p>Longer infectious period: Particularly if this is asymptomatic, could lead to more transmission.</p> <p>Chronic infections: If a variant can establish chronic infections in patients there is the potential for it to further adapt to evade the immune system and/or antivirals.</p> <p>New Variants of Concern: May be able to infect other animals and set up new reservoirs.</p>	<p>The efficacy (and sensitivity) of RATs to detect infection may change with the variant. Unlikely to impact on PCR assays which target conserved regions of the viral genome.</p> <p>Some testing procedures may be affected (e.g., S-gene dropout)¹.</p> <p>Future innovations in point-of-need, LAMP or CRISPR assays might have the capability to rapidly distinguish between some variants without the need for WGS.</p> <p>Wastewater testing may detect variants prior to detecting it in the community.</p> <p>Improved genome-based global surveillance systems may enable an effective early warning system for new variants.</p>	<p>Although selection pressure for treatment resistance is not yet high, Variants of Concern that evade immunity, may also evade antibody-based therapeutics.</p> <p>Resistance to antivirals will depend on the nature of the drug and how widely it is used. For example, drug resistance in HIV suggests that antiviral drug combinations may be required.</p>

Advice will also need to be considered against the following contextual questions, particularly if there are early indications of higher disease severity or transmissibility:

- How would the new variant affect communities at greater risk or those that experience inequitable health outcomes?
- How much pressure would a new Variant of Concern put on the health and disability system, including in the context of seasonal illnesses?
- Are the public health measures practical considering social license, and general support and compliance for measures where for a range of reasons (including COVID-19 related stress, anxiety or general 'fatigue' to the ongoing COVID-19 response)?
- Is the transmission advantage conferred by the new variant likely to be contained with measures that are acceptable to the public?
- Would response measures be consistent with the New Zealand Bill of Rights Act 1990?

There is also a need to balance the potential health impacts against social, environmental, and other economic impacts, noting that they are closely interrelated with the health impacts. They include the positive and negative economic, social and cultural (including social license) impacts

¹ S-gene dropout is when a mutation occurring in a specific part of the spike protein results in an inability of a particular test designed to test for the region with the mutation to produce a positive result. As multiple regions of the viral genome (usually three) are tested for, the failure to detect one of these genes while detecting the others is referred to as "gene dropout".

of the response, and the distributional impact of measures. Some of these impacts are currently directly addressed by the government through economic and social supports.

Co-circulating variants: the balance between transmissibility and immune escape

The potential for more than one circulating and co-existing variant is also considered, however given the limited evidence for this we have not planned for this or included it in modelling.

Co-circulating variants is when two or more variants have substantial immune escape from each other (e.g., immunity associated with infection with variant one does not provide protection from variant two, and vice versa) the more the two variants have distinct ecological niches and so are able to co-exist without being in direct competition.

The emergence of Omicron and other highly transmissible sub-variants has largely replaced previous lineages. It is not known if multiple variants with different severity, transmissibility and immune escape will be re-established, or if the pandemic will be dominated by a single highly transmissible variant². Appendix 1 contains further detail on this.

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² Although Delta does still circulate globally in very low numbers, and the implications of that are still unclear

VII. The response decision-making process

Throughout the COVID-19 pandemic we have continued to refine the decision-making process, and this has been enhanced by an improved evidence base.

To provide clarity of the response process, key decisions and the information we draw on, we have outlined the process in Appendix 3. This includes the stages of decision-making and the relevant information sources at each stage. It is important to note that this process focuses on the current role of the Ministry of Health, and once established on 1 July 2022, will change to include Health New Zealand and the Māori Health Authority.

The role of the Public Health Risk Assessment

Should a new Variant of Concern emerge, a Public Health Risk Assessment (PHRA) will remain an integral part of assessing the situation and providing considered public health advice at key decision points for Ministers. As outlined above, any response will vary depending on the contextual characteristics and the nature of the new Variant of Concern.

Connection to the All-of-Government Response

There is a process for an All-of-Government response as required where a response is critical, or decisions are required within 24 hours. The National Response Leadership Team³ would take the lead in providing advice and enacting a response through agreement from COVID-19 Ministers with Powers to Act. Ongoing responses would be supported by governance from the wider National Response Group.

Preparedness will need to factor in the absence of detailed information

A systematic approach will be taken to the assessment of the potential impact of the new variant(s) to determine which scenario is most likely. The Strategic Framework will include a process for rapid information gathering and management in the period before the scenario becomes clear. For each new variant, it will take time for researchers, data scientists, virologists, public health specialists and epidemiologists to determine the features and epidemiological characteristics of the virus, and therefore the threat that the new variant poses.

As an indication of timeframes, in the two-four weeks following initial detection of the Omicron variant offshore, anecdotal findings and early data gave indications on the transmissibility, immune evasion and severity characteristics of the Omicron variants. However, strong epidemiological and clinical data to support these findings only emerged in the one-two months following detection.

³ The NRLT consists of the Chief Executives or delegates of the Ministries of Health; Education; Business, Innovation and Employment; Social Development; Foreign Affairs and Trade; Transport; Justice; Housing and Urban Development; and Department of the Prime Minister and Cabinet; Treasury; Public Service Commission; Police; Customs and Te Arawhiti.

Table 2: Timeline for availability of data on Omicron relative to the first identification of it as a Variant of Concern (26 November 2021)

Property of the virus	Approximate timeframe
Mutations – which may give some initial data on potential immune escape, severity, and transmissibility . Also the quantity of mutations also may signify a ‘new’ virus that may not respond to current vaccines/therapeutics.	~ 1 week
Neutralisation studies – laboratory studies performed on samples taken from previously infected and/or vaccinated individuals, can give early data on the protection (or immune escape) conferred from vaccination and/or prior infection.	~1-2 weeks
Anecdotal clinical reports – reports of unusual features clinical cases can indicate a change in severity e.g., use of oxygen and other interventions, higher rates of admission to ICU. Any unusual/change in symptoms may be indicated.	1-2 weeks
Vaccine effectiveness (VE) – Note that neutralisation studies provide some earlier indication of VE. Reinfection rates also begin to be available.	~1 month
Epidemiological studies – By comparing cohorts in the data, conclusions can be drawn on vaccine efficacy and severity, transmission and many other features including incubation, secondary attack rate. Studies provide more solid data, adjusting for country-specific and other confounding factors, but take more time.	2-3 months
Testing data – whether a new variant can be identified with current testing modalities.	~1-3 weeks
Symptoms and severity – infection surveys can address whether the symptoms have changed and conform earlier anecdotal reports. Initial reports of hospitalisation and hospital data are available around the same time as VE.	~ 1 month
Secondary attack rates	~1 month
Growth rates estimates – The growth rate can be estimated as soon as the variant begins to become predominant in a country with a robust surveillance system, e.g., South Africa, United Kingdom, United States. Can depend on whether S-gene tests can identify the new variant or whether WGS is required.	1-2 weeks
Mortality rates	~1-2 months

Note: Primary sources use Omicron as a case study and are based on early reports from South African scientists and physicians, and the UKHSA Technical Briefings from 3 December 2021 onwards. Timeframes are approximate and depend on the speed of transmission relative to the dominant variant – higher levels of transmission mean more data is available sooner on immune escape, severity and growth advantage.

Previously, response measures included MIQ and border measures. This allowed us time to observe the epidemiological situation overseas and build this understanding into our response.

However, open borders will make it challenging to employ the same approach to waiting for further information. It is likely that a highly transmissible novel variant would rapidly enter our borders and potentially become established. The Strategic Framework and associated operational documents, explore the thresholds for the potential use of isolation and quarantine facilities or other border measures.

VIII. Responses to each of the scenarios

Strategic approach to new Variants of Concern

Planning for new Variants of Concern needs to occur at several levels, from global and national level responses to local and community-based responses. The intention is that this initial Strategic Framework is focussed on the national health response. Further local and community-based responses will then be developed and informed by this.

The overall objectives in response to COVID-19 Variants of Concern remain focussed on reducing and controlling the incidence of COVID-19 infections and to prevent, diagnose and treat COVID-19 to reduce mortality, morbidity, and long-term impact. It will also need to be aligned with a strategic context where we are increasingly going to be focussing on resilience and recovery, and a context in which there will be greater reliance on voluntary and non-prescriptive measures.

Any effective response will also need to consider how we support equity of outcomes and uphold Te Tiriti o Waitangi as part of an effective health response. This will mean tailoring responses and leveraging relationships with communities.

A response will also need to be cognisant of the broader impacts on social and economic wellbeing. It will also need to recognise that we are working as part of the All-of-Government response to identify and mitigate negative impacts of any public health measures so these can be factored into planning and decision making.

Determining the best approach

If a new Variant of Concern emerged that could lead to significant health, social and economic impacts, and it was feasible to keep the variant out of the country to buy time to develop a more effective response through domestic measures, the adoption of an elimination approach may be considered. However, the threshold for this is likely to be particularly high.

We note that an elimination approach is less likely to be used. This is due to the increased levels of population immunity that is likely to limit the severity of disease and the reduced social license for more stringent public health measures, including MIQ. It is also likely to be complicated by the likelihood of high transmissibility levels which makes eliminating any new variants particularly challenging. No country has successfully eliminated Omicron, which has a higher R value than preceding variants

Based on recent experience we know that the right combination of public health measures can minimise the spread and health and disability system impact of pandemics. This this may be preferable over an elimination approach.

An elimination approach is only likely to be proposed in a situation that contained a range of the following factors:

- if there were indications of very high clinical severity and likely high fatality rates (based on early evidence from overseas).
- transmissibility levels that could be managed with strong border measures, including MIQ.
- there are high levels of immune escape and current immunity is unlikely to be effective.
- there were clear benefits that could be realised in the time that an elimination approach could be sustained.

- where the health and disability system are already under pressure, or a new Variant of Concern is likely to place the health and disability system under extreme pressure.
- where at-risk communities are likely to be severely affected.

The use of 'prepare', 'contain' and 'manage'

We have developed the Strategic Framework to include three response stages:

- Prepare: System is alerted to new Variant of Concern - system readies to pivot and if needed to move to contain.
- Contain: First community case - system pivots to reduce transmission.
- Manage: Widespread community transmission - system pivots to preserving critical infrastructure and protecting communities at greater risk and priority populations.

Surveillance supports all stages. This involves the ongoing international and national monitoring of Variants of Concern to inform Public Health Risk Assessments and response decisions. Surveillance will also inform the effectiveness of any measures we have in place domestically.

The three response stages reflect the different context that we are operating in from March 2020 and in December 2021 when the COVID-19 Protection Framework was introduced. In our new context where the R value of the virus is likely to be higher, the likelihood of elimination and 'stamping it out' is much less viable. Additionally, the levels of immunity from COVID-19 vaccination or prior infection in the population is now higher and we have greater understanding of the effectiveness of domestic public health measures in reducing transmission.

Public health measures considered

Across key public health aspects of the response, certain measures will change through each phase of the response:

Government and community-led responses:

- Surveillance
- Testing
- Case investigation and contact tracing
- Isolation and quarantine
- Care in the community and broader health response.
- Vaccination and therapeutics
- Border measures
- Infection prevention and controls, including requirements for ongoing mask use.

Individual-led responses:

- Mask use
- Social distancing
- Isolation and appropriate use of sick leave

Decisions around the appropriate measures reflect likely contextual factors, including the impact of a Variant of Concern on health outcomes, and broader socio-economic outcomes. Decisions have also considered the expected pressure on the health and disability system.

Some measures, most notably mask use, have a wider value in preventing the spread of other respiratory illnesses as well as COVID-19. This additional value will be considered in future decisions, and as part of system preparedness we will need to consider how we can bolster ongoing mask use in some settings or circumstances.

The COVID-19 Protection Framework has a potential role in providing clear public health settings to support the response to different variants. The use of this tool is contextual and will need to be considered as part of planning any potential public health response.

This process set out above will still occur when functions from the Ministry of Health transfers to interim Health New Zealand. The Ministry (including the iPHA) and iHNZ have worked together to ensure that the functions will transfer in a way that maintains a strong response and mitigates any risk to the continuity of the response.

Appendix 4 presents the responses to each of the scenarios, across each of the phases from prepare, contain and manage.

Targeted approaches for particular areas and communities

We know particular communities and areas are at greater risk from new Variants of Concern, and this needs to be included in our planning processes. There is a concentration of risk in particular communities around South Auckland (and the broader Auckland region to an extent) due to the combination of proximity to the border and the number of communities at greater risk that live in the area. In other communities, e.g. parts of the Eastern Bay of Plenty, there are communities with high concentrations of social deprivation, high co-morbidities and limited access to health care which require their own targeted approaches. This should be a factor that informs prioritisation of targeted preparedness and response activities.

To this end we will be increasing using All-of-Government responses to provide integrated responses, including working with the Ministry of Social Development, Ministry of Housing and Urban Development, the health entities, iwi partners and Care in the Community networks to provide localised responses that are tailored to their needs.

Trade-offs

Economic, social and health outcomes are inextricably linked as the pandemic has demonstrated. Decisions on what measures to employ need to consider likely benefits, risks and trade-offs. Where possible, data should be gathered to measure these impacts across a range of outcomes.

We should be particularly mindful of the value that preparedness activities and our baseline measures present: for example, the more people we can get vaccinated and boosted, and provide with access to antivirals the less we should need to respond to protect the health system during peaks. Furthermore, the safer we can make being in the community through the use of face masks and public health communication to support good health behaviours, the more people can continue to participate in the economy.

Some public health and social measures such as contact tracing, quarantine (particularly when the criteria for who must quarantine includes close contacts) and isolation, provision of economic and social supports to enhance compliance with public health measures, border closures, and lockdowns are resource-intensive. Response measures are generally more costly than our baseline measures and preparedness activity.

Further work is underway as part of the All-of-Government response to better understand the detailed impacts.

IX. Preparedness factors

The ability for the response to be stood up quickly and be sustainable will be significantly influenced by careful consideration of enabling factors, including workforce planning, the legal framework, vaccine supply, ongoing effective data, contact tracing capacity, surveillance capacity and appropriate testing methodologies.

It will be important to ensure that these factors are able to be implemented rapidly and are continued to be optimised to minimise the need for more restrictive tools.

Measure	Description
Complete workforce planning for new Variants of Concern	<ul style="list-style-type: none"> Strengthening workforce capability beyond responding to COVID-19, alongside planning and prioritising capacity to respond to new Variants of Concern. Prioritising Māori public health workforce capacity and capability will also be essential to our obligations under Te Tiriti o Waitangi. Ensuring capacity within the relevant Ministry and Health New Zealand teams, ESR, and diagnostic laboratories to prepare for, and respond to, expected infectious disease incursions and outbreaks. Surge workforce planning is being considered.
Maintain an appropriate legal framework	<ul style="list-style-type: none"> Work is underway to ensure that responses to Variants of Concern will continue to be supported by an appropriate legal framework. While most public health measures are currently enabled through COVID-19 specific legislation, the ongoing role of the COVID-19 Public Health Response Act 2020 and the associated orders and secondary legislation will be reviewed.
Support ongoing vaccination efforts and prepare for future roll-out	<ul style="list-style-type: none"> Work continues to maximise vaccine coverage for key groups and developing a vaccine strategy that will support rapid supply and roll-out of any new vaccines. S9(2)(g)(i) [REDACTED] Lessons identified through evaluations of Māori influenza and measles vaccination programmes will inform how we deliver other vaccination programmes and health services to Māori in a more equitable way. Maximising vaccine coverage for key groups, including primary courses for 5-11 year age group and booster uptake in the 16-17-year age group S9(2) [REDACTED] Work is underway on the medium term COVID-19 Vaccine strategy that will account for the potential situation that a new vaccine is required.
Maintain testing infrastructure and supply	<ul style="list-style-type: none"> Ensure sufficient of supply rapid antigen tests to support widespread testing, and sufficient PCR and WGS capacity. Maintaining required laboratory capacity in the event of a new variant by completing new contracting arrangements with laboratories. Contracting arrangements need to consider the additional costs of ensuring border-related positive PCR test samples are routinely and quickly transferred to ESR to support whole-genome sequencing to support variant surveillance, and appropriate surge capacity. Continue to assess the potential application of new testing methodologies. Ensure pre-departure testing can be rapidly re-established.

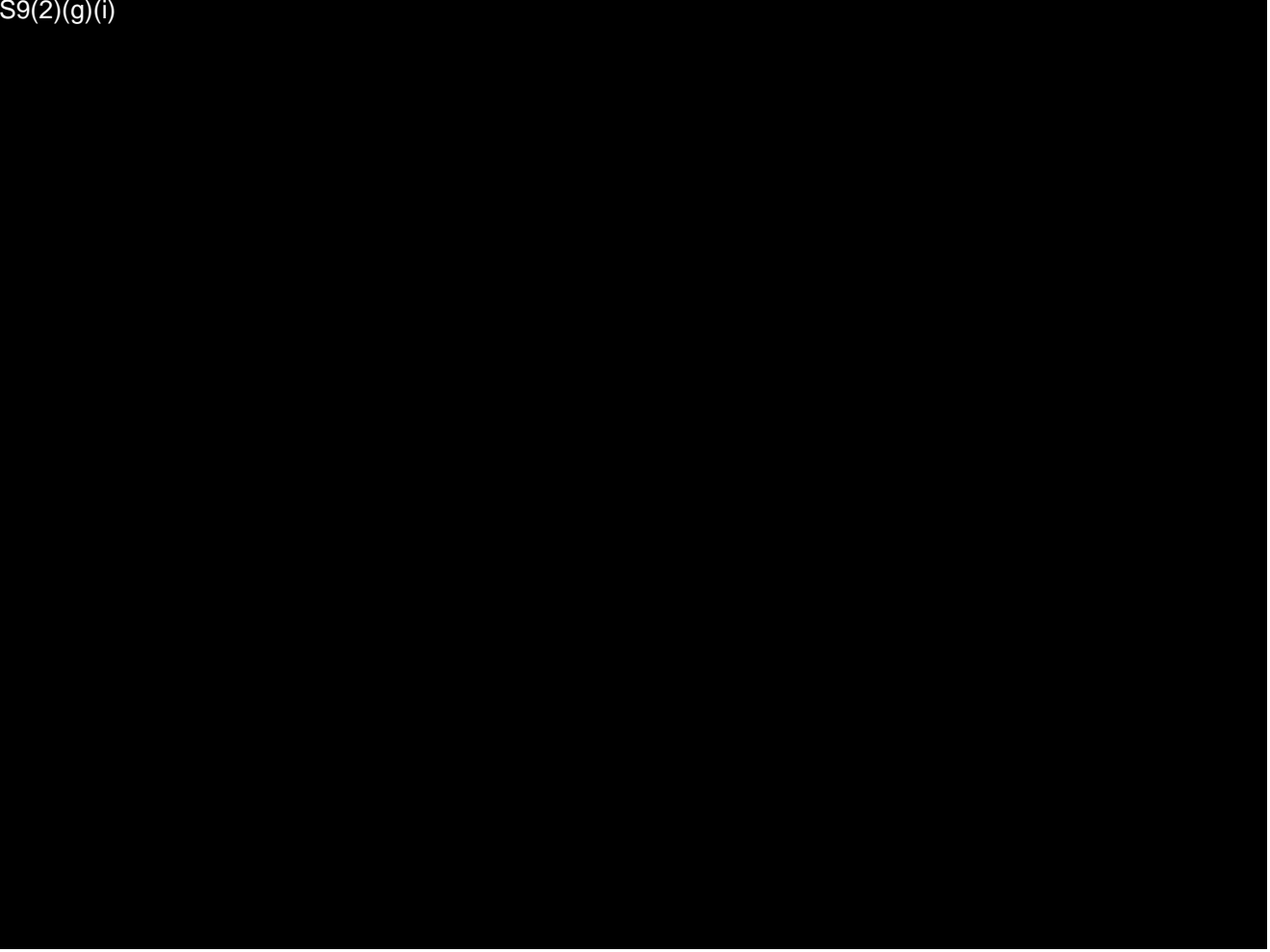
<p>Prepare communication plans, including targeted communication for communities</p>	<ul style="list-style-type: none"> Engaging with the public will be key in the success of responses to any future outbreaks or incursions. Targeted campaigns can assist the Ministry in fulfilling its Te Tiriti o Waitangi and equity obligations. Strong communications campaigns are needed to boost vaccination. Learning from the past e.g. a key lesson from the 2019 measles response was to bring the population onside to respond in an agile way.
<p>Improve data collection, reporting and analysis</p>	<ul style="list-style-type: none"> Continue to improve our disease and vaccination data collection, wastewater surveillance sequencing and analysis capabilities to immediately identify and detect new and emerging variants. Continue improvements to COVID-19 disease and vaccination data collection, wastewater surveillance, and virus sequencing capacity so we are better prepared to respond rapidly to emerging threats. Identify appropriate indicators to inform continuous monitoring and improvement.
<p>Leverage contact tracing</p>	<ul style="list-style-type: none"> In the early stages Public Health Unit-led contact tracing with national source tracking and case management may be deployed to provide New Zealand with some local and regional areas for targeted focus. In a high clinically vulnerable and high immune escape setting the value of contact tracing after the first and second identified case and contacts will need to be clear.
<p>Surge Response Plan</p>	<ul style="list-style-type: none"> S9(2)(g)(i) [REDACTED]
<p>Maintain surveillance capacity</p>	<ul style="list-style-type: none"> Surveillance testing will be used to identify when we have a new variant. We must ensure that we have sufficient capacity to undertake the surveillance required. The Surveillance Strategy provides information on the detailed response, including the relative importance of respective surveillance measures. Ongoing work to enhance the surveillance system to identify new cases and Variants of Concern at our border and in our communities. Working with the Institute of Environmental Science and Research (ESR) to increase Whole Genome Sequencing capacity. Wastewater surveillance is also important for understanding community cases, and we continue to enhance this including work with ESR on enabling surveillance to distinguish between variants. Enhance understanding of levels of immunity in the population to understand potential risk and inform responses. Consideration is being given to how to identify both natural immunity levels and vaccine-based immunity levels.
<p>Laboratory device review and Innovation framework</p>	<ul style="list-style-type: none"> A stocktake across the laboratory and hospital settings is being undertaken. It will help inform regions with variability to scale and target testing modalities and enable the right testing modality to the right presentation of contact or potential case. The Ministry, DPMC, and MBIE are establishing a Testing Innovation Framework across laboratory groups, networks and science and research institutes. It will inform the regulatory assessment processes and undertake horizon scanning for the latest in innovation and technologies to support our ongoing response to COVID-19 and other infectious disease.

<p>Contact tracing</p>	<ul style="list-style-type: none"> • Recognise that the value of contact tracing will be limited in the absence of restrictive policy settings at the border and in community. • In the short-term, it is likely that we could not scale contact tracing to the levels we have had previously, primarily because we could be contending with more than one variant at a time over the course of the coming months. • In the early stages of each phase across the responses, Public Health Units led contact tracing with national source tracking and case management will provide New Zealand with some local and regional areas for targeted focus. The value of contact tracing after the first and second identified case and contacts will need to be clear.
<p>Leveraging our COVID-19 Variant responses and play book</p>	<ul style="list-style-type: none"> • Developing a series of plans in coordination with suppliers and the health care system for delivery of updated vaccines, tests, and treatments. • These plans and processes suggest that vaccines, PPE, and tests can be deployed in days and weeks rather than months using the vaccine supply chain and logistics to sites, community testing centre and pop-ups, and the PPE portal.
<p>Leverage a proven COVID-19 surge Response Plan</p>	<ul style="list-style-type: none"> • S9(2)(g)(i) [Redacted]
<p>Regulatory review of variant-specific versions of vaccines and treatments</p>	<ul style="list-style-type: none"> • S9(2)(g)(i) [Redacted]
<p>Critical medical items supply</p>	<ul style="list-style-type: none"> • The Ministry currently maintains a national stockpile of at-home tests, PPE and critical medical supplies for use in surge events. • Pharmac is responsible for securing antiviral medications and are part of the all-of-government COVID-19 Vaccine Strategy. • Continue to assess the utility of therapeutics. • S9(2)(g)(i) [Redacted] • The Government will be ready to deploy supplies to the health and disability sector alongside clinically vulnerable and priority populations ensure adequate supply in times of surges, COVID-19 outbreaks, or new variants.

All-of-Government measures for consideration

S9(2)(g)(i) [Redacted]

S9(2)(g)(i)



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X. Te Tiriti o Waitangi and Equity commitments

Consistent with the principles underpinning the long-term COVID-19 Strategy, this Strategic Framework is underpinned by Te Tiriti o Waitangi obligations and support equity of outcomes.

Te Tiriti o Waitangi

Embedding the principles of Te Tiriti o Waitangi into our work is a key part of being responsive to, and providing a response for, Māori.

Meeting our obligations under Te Tiriti is necessary if we are to realise the overall aims of He Korowai Oranga - our Māori Health Strategy and to achieve outcomes for the health and disability system as a whole. This includes a desire to see all New Zealanders living longer, healthier, and more independent lives. These Tiriti obligations underpin Whakamaau: Māori Health Action Plan 2020 - 2025 which sets the Government's direction for Māori health advancement over this time.

The principles of Te Tiriti o Waitangi provide the framework for how we will meet our obligations under Te Tiriti in our day-to-day work. These are:

- Tino rangatiratanga
- Equity
- Active protection
- Options
- Partnership

The COVID-19 pandemic has seen Māori experience worse outcomes, compared to other ethnicities, which means Māori are at greater risk of worse outcomes should a new Variant of Concern emerge. It is therefore critical that the needs of Māori, and the commitments made in Te Tiriti o Waitangi, are integral to the health and disability response to COVID-19.

Changes to our COVID-19 response measures therefore need to continue to support iwi, hapū, whānau, and hāpori Māori to make decisions for themselves, regardless of legal settings, e.g. within the COVID-19 Protection Framework and relevant COVID-19 orders.

Working with Māori on design and delivery of services

The Crown's obligations to Māori under Te Tiriti o Waitangi require active protection of tāonga, and a commitment to partnership that includes good faith engagement and knowledge of the views of iwi and Māori communities. In the context of the COVID-19 response, this involves considering what will support a national response that is co-ordinated, orderly, and proportionate, considering the Crown's obligation to actively protect Māori health, interests and rangatiratanga.

Māori vaccination and booster rates remain lower than the rest of the population largely due to a slower rollout of the initial vaccination campaign to Māori communities. While in the week to 3 May 2022 1,900 Māori received a vaccination dose, trending up for the third consecutive week, first dose vaccinations for tamariki Māori aged between 5 and 11 are under 1,000 for the seventh consecutive week. This has been exacerbated by the high numbers of Māori recently infected with COVID-19 and the three-month interval between becoming a case and receiving a booster dose.

Locally-led responses continue to be relied upon particularly in Māori communities where local Māori providers and providers contracted by Whānau Ora commissioning agencies are mobilising to respond to the demands of their communities.

Across many of the measures in the Variants of Concern Strategic Framework, there are effective examples of equity-centred approaches informed by Te Tiriti o Waitangi. A testing action plan focused on advancing equitable access for Māori, Pacific, and disabled people has been developed and is currently being implemented. The COVID-19 Care in the Community framework has created opportunities for community-led responses, including working with iwi.

As part of the COVID-19 Māori Health Protection Plan, work is underway to build community resilience and increase vaccination uptake. These measures will be beneficial and support the principle of active protection in the event of a new variant.

Māori providers are becoming increasingly more concerned about the wider health and socioeconomic impacts of the pandemic on whānau, and in 'catching up' on health services (such as flu immunisations, childhood MMR, screening services) that have been deferred.

Ensuring Māori whānau have comprehensive and immediate supports through the Omicron outbreak will contribute to their resilience so they can leverage recovery opportunities, and these impacts and opportunities will need to be considered as part of wider planning.

Equity

In Aotearoa New Zealand, people have differences in health that are not only avoidable but unfair and unjust. Equity recognises that people with different levels of advantage require different approaches and resources to obtain equitable health outcomes.

To support this, and as per our minimisation and protection approach, the priority is to slow down transmission of the virus and protect our communities at greater risk. These communities include Māori, Pacific peoples, disabled people, rural and isolated populations, communities that experience barriers to engaging with the health and disability system. We also know that certain geographical factors that disadvantage particular groups, including proximity to the border for South Auckland communities.

There are also a range of underlying risk factors that may negatively impact equitable outcomes. These risk factors are intersectional and compound the effects of other risk factors on individuals and communities. Risk factors include vaccine status, age, sex/gender, ethnicity, pregnancy, co-morbidities, disability, mental health and addictions, material deprivation and poverty, occupation, household characteristics, high risk settings, inadequate access to health care.

An equitable approach to public health and outbreak management includes not only a focus on communities at greater risk. It also requires understanding the barriers faced by these communities, enabling public health participation, and promoting health and wellbeing. Community engagement strengthens relationship and build health literacy for the long term.

We will continue to learn from All-of-Government engagement with community leaders and technical experts to ensure that responses are tailored to the needs of communities, and proactively enables community-led responses.

Devolving power and resources to communities

Local communities have played an important communications role by supporting ongoing messaging to support various efforts of the COVID-19 response, such as supporting safe isolation and helping to increase vaccination uptake. We will continue to work through the networks established as part of caring for our communities and other local responses to support active partnership.

XI. Global Responses to Variants of Concern

Understanding the broader global context is an important principle that underpins our COVID-19 response. While recognising that New Zealand has its own unique situation and national COVID-19 response, it is important that we remain attuned to global developments, and that we meet our international obligations and contribute to the global response effort.

Global surveillance efforts

Global surveillance efforts will be vital to the early identification and response to new variants, and as a member of the World Health Organization, we are committed to strengthening these efforts, including working towards increased information sharing between members.

The International Health Regulations (2005) (IHR), administered by the WHO, sets out the international legal framework for preventing and controlling the spread of disease and other public health hazards between countries. Under the framework, member States are required to notify the WHO of any events which may constitute a public health emergency of international concern, as well as any health response measures implemented. This includes the notification of new Variants of Interest and Variants of Concern.

Our response will also be informed by other global surveillance efforts including:

- the Centre for Disease Control and Prevention's (CDC) system for monitoring all variants and classifying those requiring more attention and plans to continue this surveillance effort as the pandemic continues.
- the European Centre for Disease Prevention and Control (ECDC) variants dashboard, which is updated weekly providing an overview of new variants in EU/EEA member states.

The WHO has also reiterated that surveillance activities require coordination between the human and animal health sectors and more global attention on the detection of animal infections and possible reservoirs among domestic and wild animals. We expect that this will become worse with the effects of climate change.

International approaches to strategic planning

We have considered global approaches to our strategic planning, including the WHO's *Strategic Preparedness, Readiness and Response Plan to End the COVID-19 Emergency in 2022* (the WHO's Plan). The WHO's Plan outlines a global strategic response to COVID-19 based on scenarios that include new Variants of Concern, and a proposed roadmap to inform national and local planning. The report is built on six pillars, which have informed our thinking:

- Enabled and empowered communities
- Enhance surveillance, laboratory, and public health intelligence capacity
- Supported and protected public health and medical workforce
- Resilient health systems
- Emergency medical supply systems
- Research and innovation.

We are in regular contact with similar jurisdictions to inform our planning and to share our own lessons. We regularly meet with Chief Medical Officers from Australia, Canada, the United Kingdom (UK), and the United States, and are in regular contact with Singapore health officials. We have also received information on other countries' Variants of Concern planning, including South Africa and the Republic of Korea. These relationships are particularly valuable as those jurisdictions are currently developing their own approaches to potential new variants

International scenario planning

Global approaches were considered in the development of our scenarios and proposed responses. Our scenarios broadly align with the UK's Scientific Advisory Group for Emergencies (SAGE) scenarios regarding the emergence of new variants, and the WHO's Plan.

Both plans predict that:

- milder variants will have lower severity and that vaccines will remain effective
- worst-case scenarios will have high severity of disease and significant immune escape.

For comparison, the worst-case scenarios proposed by SAGE and the WHO are as follows:

UK's SAGE	<u>Reasonable worst-case</u> : global incidence, incomplete vaccination and animal reservoirs lead to repeated emergence of variants with some displaying significant immune escape. Severe disease, mortality and long-term impacts following infection are seen. Updated vaccines and annual, widespread rollouts are necessary. Protections will need to be enforced especially when new variants outpace vaccine updates.
WHO	<u>Worst-case</u> : Future variants are highly transmissible and able to evade vaccines and immunity requiring vaccine alteration and broader boosting.

In addition to the high-level alignment, our scenarios have considered the potential for chronic disease, the need for ongoing vaccinations, and potential for animal reservoirs to spread disease.

Supporting Pacific states - the Pacific Health Corridors work programmes

Consistent with information sharing and support provided as part of the Pacific Health Corridors work programme, we will share the scenarios and information on the planning process and responses with Tokelau, Cook Islands, Niue, Samoa, Tonga and Tuvalu.

XII. Next steps

This Strategic Framework is focussed on the preparedness and response measures in place to respond to the emergence of new Variants of Concern, with a particular focus on national level responses. Further detailed consideration of regional, local and community health responses is required with Health New Zealand, the Public Health Agency and Māori Health Authority.

A government wide planning process is underway to support detailed operational planning of response measures, informed by the information in this Strategic Framework.

The Strategic Framework is a living document that will continue to evolve based on regular scanning of emerging research and evidence, and experiences in other jurisdictions. The Ministry produces a bi-weekly monitoring document on Variants of Concern that will inform ongoing consideration of the Framework, and the potential need for responses.

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XIII. Appendices

Appendix 1: Evidence base for new variants, including information on co-circulating variants

SARS-CoV-2 has been characterised by the emergence of new Variants of Concern, with “successful” new variants rapidly becoming dominant strains worldwide. To date the Alpha, Delta and Omicron variants have sequentially emerged and dominated. The rapidity of the emergence and dominance of new variants is demonstrated by the replacement of Delta by BA.1 within about one month in New Zealand, and the subsequent replacement of BA.1 by BA.2 within a similar period. [ESR analysis] These variants have had a transmission advantage over previous variants. This pattern of enhanced transmission advantage with each new dominant variant is likely to continue, because increased transmissibility confers a substantial evolutionary advantage.[1]

New Omicron variants and subvariants are being reported frequently, with at least three Omicron subvariants, BA.4, BA.5 and BA.2.12.1, increasing in prevalence in many parts of the world including New Zealand.

Therefore, the identification of new Variants of Concern arriving in New Zealand will depend on three main variables: the prevalence of the Variants of Concern in the arrivals to New Zealand (which reflects prevalence overseas); the detection rate of cases arriving into New Zealand and the efficacy of the WGS surveillance of arrivals.

SARS-CoV-2, as with many viruses, has an intrinsic ability to mutate frequently. This, coupled with extensive global transmission, means SARS-CoV-2 has a large mutational potential, and therefore it is difficult to predict the emergence of future novel Variants of Concern.[2] The ability of SARS-CoV-2 to jump into other mammalian hosts further complicates predictions.

SARS-CoV-2 is a virus that is constantly undergoing mutation, which may or may not have a significant functional impact on the phenotype or ‘characteristics’ of the virus. A new variant is one that has marked phenotypic differences that impact on disease characteristics, primarily its intrinsic transmissibility, ability to evade immunity or disease characteristics such as severity. Concerning SARS-CoV-2 variants can be classified in several ways:

Variant of Interest (VOI): WHO defines a VOI as a SARS-CoV-2 variant with genetic changes that are predicted or known to affect virus characteristics such as intrinsic transmissibility, disease severity, immune escape, or may adversely impact diagnostics or treatments; and is identified to cause significant community transmission or multiple COVID-19 clusters, in multiple countries with increasing relative prevalence alongside increasing number of cases over time, or other apparent epidemiological impacts to suggest an emerging risk to global public health.[3]

Variant of Concern (VOC): WHO defines a VOC as a SARS-CoV-2 variant that meets the definition of a VOI and, through a comparative assessment, has been demonstrated to be associated with one or more of the following changes at a degree of global public health significance:

- Increase in transmission advantage or detrimental change in COVID-19 epidemiology; or
- Increase in virulence or change in clinical disease presentation; or
- Decrease in effectiveness of public health and social measures or available diagnostics, vaccines, treatments.

Variant of High Consequence (VOHC): The U.S. CDC defines a VOHC as a variant that has clear evidence that prevention measures or medical countermeasures have significantly reduced effectiveness relative to previously circulating variants.[4] This could include failure to be detected by diagnostic tests, a significant reduction in vaccine effectiveness, reduced susceptibility to treatments or more severe clinical disease. Currently, no SARS-CoV-2 variants are designated as VOHC.

It is also possible for variants of SARS-CoV-2 to undergo recombination, where two different variants infect the same host at the same time, exchange genetic material, and form a new 'combined' variant. For example, the XE subvariant of Omicron is a recombinant of BA.1 and BA.2. The likelihood of recombination events is increased when more than one variant is prevalent and there is extensive ongoing transmission.

Many Omicron mutations associated with the spike protein were unexpected and had not previously been seen in any previously circulating variants. Concerning, even though Omicron is thought to have branched off from the other variants in mid-2020, it went undetected by global surveillance systems until November 2021. The two most likely competing theories that explain how it was able to mutate extensively and go undetected for an extended period are:

- the variant evolved in an animal reservoir and then made the jump back into humans, or
- the variant evolved over a period of time within one or more immunocompromised individuals who were unable to clear the virus.

In addition, there are a range of other factors that can make the surveillance more challenging, e.g., the lower morbidity associated with Omicron makes the initial identification of the disease more difficult.

The probability of emergence of a new, concerning variant is difficult to estimate. There is some evidence that the likelihood of coronaviruses jumping the species barrier is increasing, given two new emergent coronaviruses in the last 20 years (including SARS in 2003 and MERS in 2012) in addition to SARS-CoV-2, against a backdrop of only four other endemic coronaviruses in total, and as human activity is increasingly encroaching on wildlife areas.[5] In a recent presentation to the FDA's Vaccines and Related Biological Products Advisory Committee, Dr Trevor Bedford estimated that an 'Omicron-like' event (i.e., substantial mutations associated with the spike protein) may occur every 1.5 to 10 years, with a probability of approximately 30% for one occurring in the next 12 months, based on the current speed of genetic change.[6] This probability will decrease and gain more precision as the observed time between 'Omicron-like' events increases. More likely (approximately 70%) was continued evolution within BA.2.

It is unknown why certain variants become predominant at different times, however we can infer from some general principles. Any 'successful' new variant will likely employ a variety of characteristics to spread in human and/or animal populations. These characteristics are outlined below.

Transmission advantage: Any 'successful' new variant would need to be more transmissible than the predominant variant, such as Omicron, which is already extremely well adapted. Enhanced transmissibility could be achieved either through increased:

Intrinsic transmissibility: Intrinsic features of the virus (e.g., higher viral load, greater environmental stability, easier aerosolisation, increased infectivity of cells in the upper airways, and ACE-receptor access/binding) may allow it to be transmitted more rapidly.[7] Transmission by asymptomatic cases has been a key feature of SARS-CoV-2, that has enabled extensive transmission.[1] The protection provided by vaccines against onward transmission tends to wane

quickly, however vaccines designed for the original strain of SARS-CoV-2 have continued to be remarkably effective, particularly against severe disease.

Immune escape: Increased immune evasion relative to the current effective immunity within the population (i.e., has many more ‘susceptible’ individuals available for it to infect) will also enhance transmission. In the current post-vaccination/post-infection era, even with waning of protection, it is likely that for a variant to be successful it will need access to a large pool of susceptible individuals from those with some, or no, prior immunity.[8]

Severity: A new Variant of Concern could be more or less severe than previous variants: disease severity does not necessarily create a selection advantage or disadvantage.[9, 10] For example if a virus kills a host quickly then the virus has less opportunity to transmit to others. Similarly if the disease is symptomatic and the symptoms develop soon after infection, causing the individual to stay home or go to the hospital, then less transmission in the community will tend to occur. However, the severity of disease caused in the host days or weeks after infection is less relevant to successful onward transmission of the SARS-CoV-2 compared to some other pathogens. This is because SARS-CoV-2 is able to be transmitted for several days following infection without causing severe disease, or even symptoms, in many or most people. Transmission from asymptomatic and pre-symptomatic individuals has been a key feature of the success of SARS-CoV-2. It is unclear if a new variant will be more or less severe, but greater intrinsic severity is certainly a possibility.[11] Severity would be selected ‘for’ if it also increases transmission, or it could be simply incidental to the transmission advantage. For example:

- Lower severity means that people who are infectious but remain asymptomatic or mildly symptomatic continue to socialise and infect more people than if disease were more severe and they stayed at home.
- A variant which results in more severe disease may also be associated with higher viral shedding (causally or incidentally) and therefore be more transmissible, as appears to have been the case with Delta.
- A variant associated with a higher likelihood of chronic infections (especially in immunocompromised patients) may generate further subvariants with unknown characteristics.

Caution should be used when describing some forms of COVID-19 as ‘mild’, for several reasons. If a variant is highly transmissible but relatively mild in a vaccinated individual, as we saw with Omicron, the overall disease burden on the healthcare system and the community can still be huge. Secondly, the disease may not be mild for many parts of our community, such as the elderly, Māori and Pacific Peoples, the immunocompromised, those with underlying risk factors and comorbidities, and those not up to date with their vaccinations; the disease associated with a variant may only be mild for those who are otherwise healthy with prior immunity (from vaccination or prior infection), i.e., the ‘intrinsic’ severity may not be mild. Finally, the disease burden of long COVID is still unknown, and preliminary data indicates that long COVID can follow a mild or a severe acute phase of the disease.

Nonetheless, in the long run, the most likely scenario is that the existing ‘layers of immunity’ from prior infection and vaccination will blunt the severity of disease caused by new variants. For example, even though Omicron was substantially different to Delta, with respect to mutations in the spike protein, population immunity conferred by vaccines and/or prior infection was effective in protecting against severe disease, albeit that a third dose was essential to deliver the bulk of that protection.

With regard to the responses triggered by particular scenarios, there is a raft of public health measures and surveillance that apply generally.[12] For example: continued surveillance of COVID-19

and new variants; accessible and timely treatments and ‘up to date’ vaccinations, particularly for communities at greater risk; ventilation improvements; sufficient sick leave in order to enable reduction in spread. Many of these measures are ‘pandemic preparedness’ measures that are either already in place or would have to be put in place in advance, such as treatments, vaccinations, ventilation and sick leave entitlements. If possible, other measures should be ready to be ‘stood up’ quickly when needed. However, if the new variant is substantially better at transmitting than the existing prevalent variant, then the speed of transmission may mean that some measures are unable to be implemented in time.

However, endemicity - in the sense of the pattern of spread of COVID-19 becoming more ‘predictable’ with potential seasonal variation - is not guaranteed in the short or medium term.[13] It is prudent to Document for less optimistic scenarios, as they still remain a possibility.[1]

Out of the scope of this document, but nonetheless a major long-term planning consideration, is the burden of long COVID. Research on long COVID is still emerging - although some case definitions have been proposed, the wider research community has not yet settled on the general description for the case definition of the syndrome, which is a necessary precursor to conducting most clinical research.[14] Nonetheless, given high transmissibility, if even a small percentage of individuals suffer disease burden in the long-term, then long COVID will shift to be a larger focus for the response to COVID-19. Other long-term planning considerations such as public health infrastructure and decision-making will also need to be considered.[15]

Co-circulating variants: the balance between transmissibility and immune escape

The potential for more than one circulating and co-existing variant is also considered, however we given the limited evidence for this we have not planned for this or included it in modelling.

Co-circulating variants is when two or more variants have substantial immune escape from each other (e.g., immunity associated with infection with variant one does not provide protection from variant two, and vice versa) the more the two variants have distinct ecological niches and so are able to co-exist without being in direct competition.

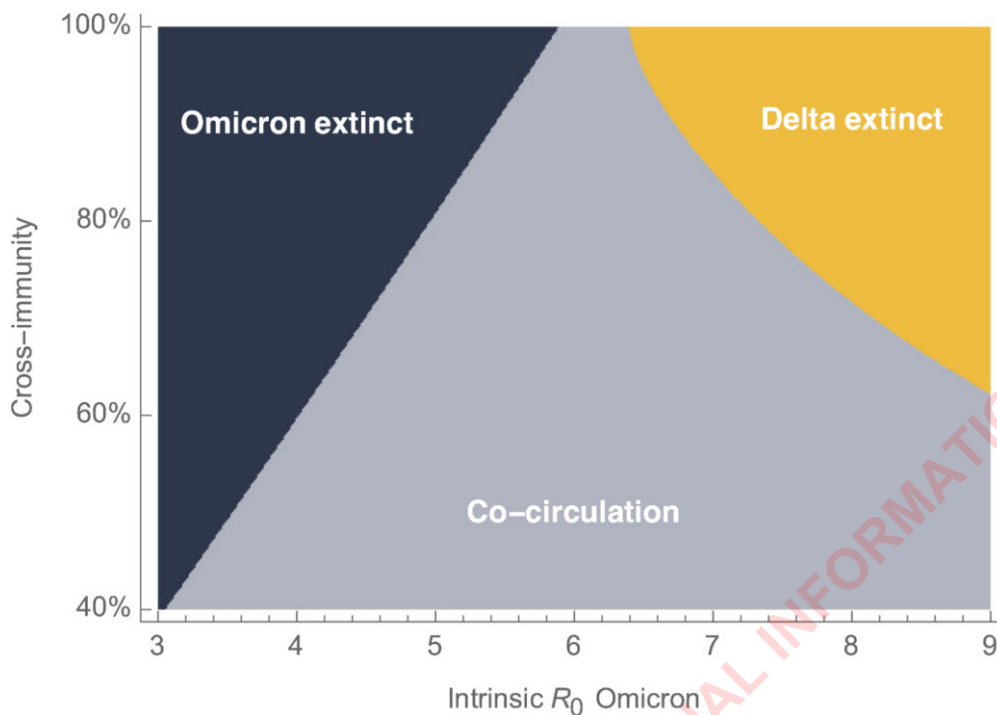
[5] This situation was common at the beginning of the pandemic with gradual replacement of the original SARS-CoV-2 variant with Beta in Africa, Gamma in South America, Alpha in Europe and Delta in India. The emergence of Omicron and other highly transmissible sub-variants has largely replaced previous lineages. It is not known if multiple variants with different severity, transmissibility and immune escape will be re-established, or if the pandemic will be dominated by a single highly transmissible variant⁴.

Figure 2 shows the relative balance between transmissibility (R_0) and immune escape that is needed for co-circulation to occur, i.e., if two variants have a similar R_0 and/or infection with one does not provide protection from the other, then the two variants have the potential to co-circulate. In the case of Figure 2, calculations were performed to help determine if Delta and Omicron may co-circulate. We now know that Omicron has a higher R_0 than Delta, and that

⁴ Although Delta does still circulate globally in very low numbers, and the implications of that are still unclear

Omicron and Delta did not provide much cross-protection from each other for unvaccinated individuals, but there was substantial cross protection when the individual was vaccinated.[3, 6]

Figure 2. Relative balance between transmissibility (R_0) and immune escape needed for co-circulation to occur.⁵



Co-circulation does occur between the other endemic coronaviruses that are associated with influenza. However, some coronaviruses have a similar peak each season whereas others appear to alternate as to how high the peak of infection is each year. This implies that some coronaviruses potentially confer some cross-protection with each other, and others do not. Figure 3 below illustrates how this has been observed in Scotland in recent years.

Co-circulating variants may or may not be a final state for SARS-CoV-2, and even if it is, the timing of when this will happen is unknown. It could be happening now, with BA.4, BA.5, and BA.2.12.1. BA.4 and BA.5 are increasing at the same time in United Kingdom and other countries, for example, or it may take a long time to settle into this pattern. Currently, there is evidence that BA.4 and BA.5 now have evolved to be better at reinfecting than BA.2, and that this is part of an overall trend of greater immune escape (from Delta to Omicron, and now between the successive successful sub-lineages of Omicron).

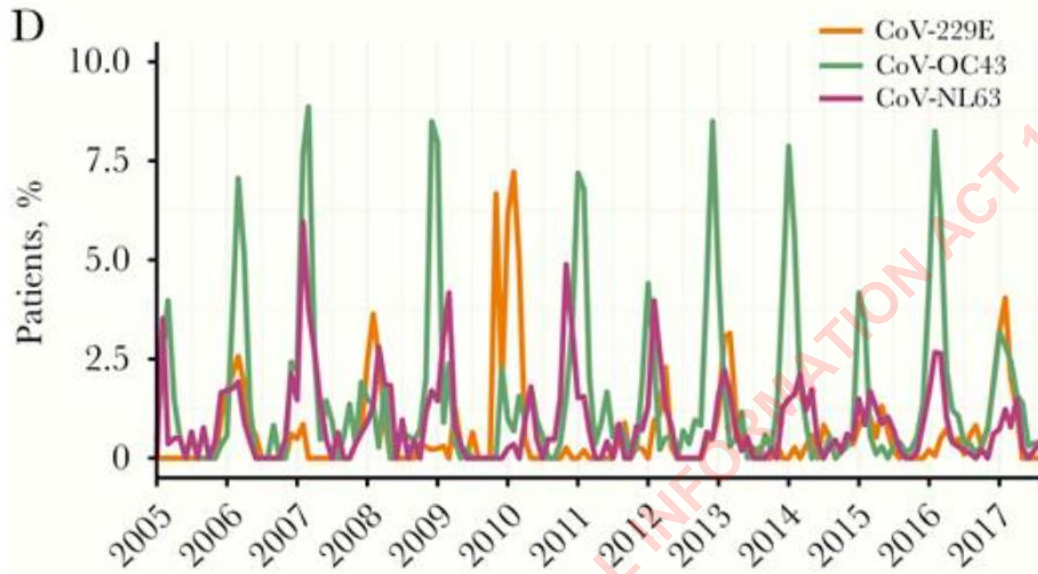
It is not yet known how SARS-CoV-2 will behave seasonally, and the extent of any cross-protection from future circulating coronaviruses.

It is possible to get two or more co-circulating variants of SARS-CoV-2, we may have more frequent COVID-19 waves each year, less so if there is some cross protection. Currently, even

⁵ Figure Error! Main Document Only. The combination of R_0 and cross-immunity from two variants that might be needed in order for two variants to co-circulate (labelled as Omicron and Delta). These two variants had the potential to co-circulate (grey region) if the cross-immunity was low or if Omicron's R_0 was similar to Delta's ($R_0=6$). If cross-immunity from Delta was high and Omicron's R_0 was relatively low compared to Delta's, then Omicron would become extinct (dark blue); conversely, if cross-immunity was high and Omicron's R_0 was high, then Delta was predicted to become extinct (yellow). This analysis was performed prior to Omicron becoming dominant. Link to figure: <https://twitter.com/trvrb/status/1470420216232374281>

without co-circulation. We are likely to see 3-4 pandemic waves a year for the short to medium term, due to evolution within Omicron and waning of protection, albeit 'mild' disease due to vaccines and prior immunity. Either way, this would still be a substantial increase in the overall burden of disease, even though the severity is lower compared to the start of the pandemic

Figure 1 Monthly prevalence of seasonal coronaviruses (sCoVs) detected among patients with respiratory illness virologically tested in NHS Greater Glasgow and Clyde, Scotland, United Kingdom, between January 2005 and September 2017. A, CoV-229E. B, CoV-OC43. C, CoV-NL63. D, Comparing all sCoV types.



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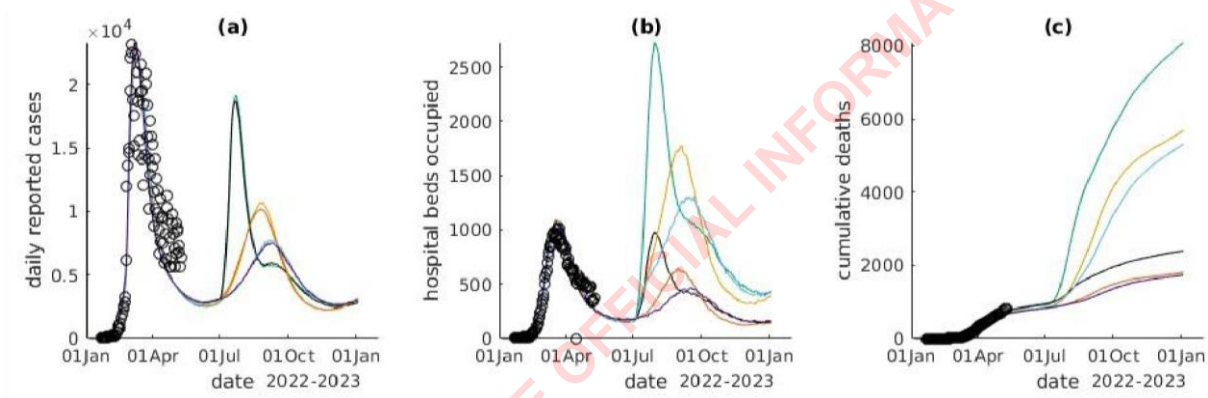
Appendix 2: Modelling on Variants of Concern

We have conducted modelling based on the scenarios and differing levels of clinical severity and immune escape to provide an indication of the range of potential health impacts. The modelling is included in Appendix 2. The key points from the modelling are:

- variants with a high degree of immune escape or high virulence are the most concerning ones; a variant with both would place very high loads on the hospital system.
- variants that reach the older population would place extremely high demands on hospital and treatment capacity, and in some cases, very high mortality.
- the least severe hypothetical variants that respond to current vaccines would have effects similar to the recent Omicron wave.

These are based on a purely hypothetical start date of 1 July.

Figure 3: Cases (a), hospital occupancy (b), and deaths (c) by variant scenario



Key	
Scenario 1: High clinical severity, high immune escape	
Scenario 2: Low clinical severity, high immune escape	
Scenario 3: High clinical severity, low immune escape	
Scenario 4: Low clinical severity, low immune escape	
Baseline- Omicron Severity:	

In these scenarios, the population response is enough to keep cases below the March 2022 peak. However, if we assume no or a muted change in PHSMs or voluntary behaviour change the numbers of cases, hospitalisations and deaths would be much higher.

The pattern for hospitalisations is different: most scenarios would see hospital occupancy above March 2022 Omicron levels. The reason is the higher virulence in most scenarios, and that the older population (who have higher case-hospitalisation and case-fatality rates) have the least

prior immunity. Additionally, they may be eligible for antivirals which may reduce their hospitalisation rate (assuming antivirals are effective against a new variant).

After the initial peak, each scenario has a pattern of rebound and/or second wave. The timing of these would be uncertain; they are due to the population relaxing social controls, and then to waning immunity.

We noted that in some of the scenarios, hospital capacity is clearly exceeded; however the model does not include any excess mortality or additional response if this were to happen.

The hospital workload in a normal winter is about the same as in the recent COVID-19 peak. DHB's winter planning work indicates that over 1,000 beds are needed for respiratory conditions in peak winter months, 400 more than summer levels. An RSV outbreak could need another 900 beds over one month. This demand would be at the same time as any beds needed for COVID-19 patients.

Assumptions that underpin the modelling

Each scenario assumes that the new Variant of Concern reaches New Zealand on July 2022. A variant that arrives later could have less effect if more people experience prior infection before the introduction of a new variant; but could also have larger effects if population immunity has waned significantly. Current evidence is that immunity wanes noticeably over a period of several months.

The scenarios have been based on the effects of the Delta and Omicron variants. In general, Delta has been used as the model for a variant with greater severity than Omicron, while transmission and immune escape are relative to Omicron.

We also note that the fifth planning scenario is for SARS-CoV-2 co-circulating with other infectious diseases is not considered in these modelling scenarios.

The model is based on a number of hypothetical assumptions. Firstly it assumes that the population would respond to news of a severe variant by reducing social mixing and increasing social distancing even before any official change in the Community Protection Framework. This response likely represents a mixture of public health interventions, such as the "Red" setting, and spontaneous behaviour change in response to perceived risk. Examples include using masks, working from home, and adopting the levels of precautionary behaviour seen in February 2022. Whether the response is as effective as during February 2022 in flattening the curve is uncertain.

Table 3: Model settings for variant scenarios

Parameter	Variant 1	Variant 2	Variant 3	Variant 4	Variant 5
Intrinsic transmissibility (R₀)	Omicron	Omicron	Omicron	Omicron	Omicron
Severity of new variant					
Probability of hospitalisation	Delta	Omicron	Delta	Omicron	Delta
Probability of death	Delta	Omicron	Delta	Omicron	Delta

Vaccine effectiveness against new variant					
Infection	60% relative to Omicron*	60% relative to Omicron*	Omicron	Omicron	Omicron
Severe disease	90% relative to Omicron*	90% relative to Omicron*	Omicron	Omicron	Omicron
Mortality	90% relative to Omicron*	90% relative to Omicron*	Omicron	Omicron	Omicron

Cross immunity to new variant from prior infection with Omicron					
Infection	50%**	50%**	80%***	80%***	Omicron
Severe disease	94%**	94%**	100%***	100%***	Omicron
Mortality	94%**	94%**	100%***	100%***	Omicron

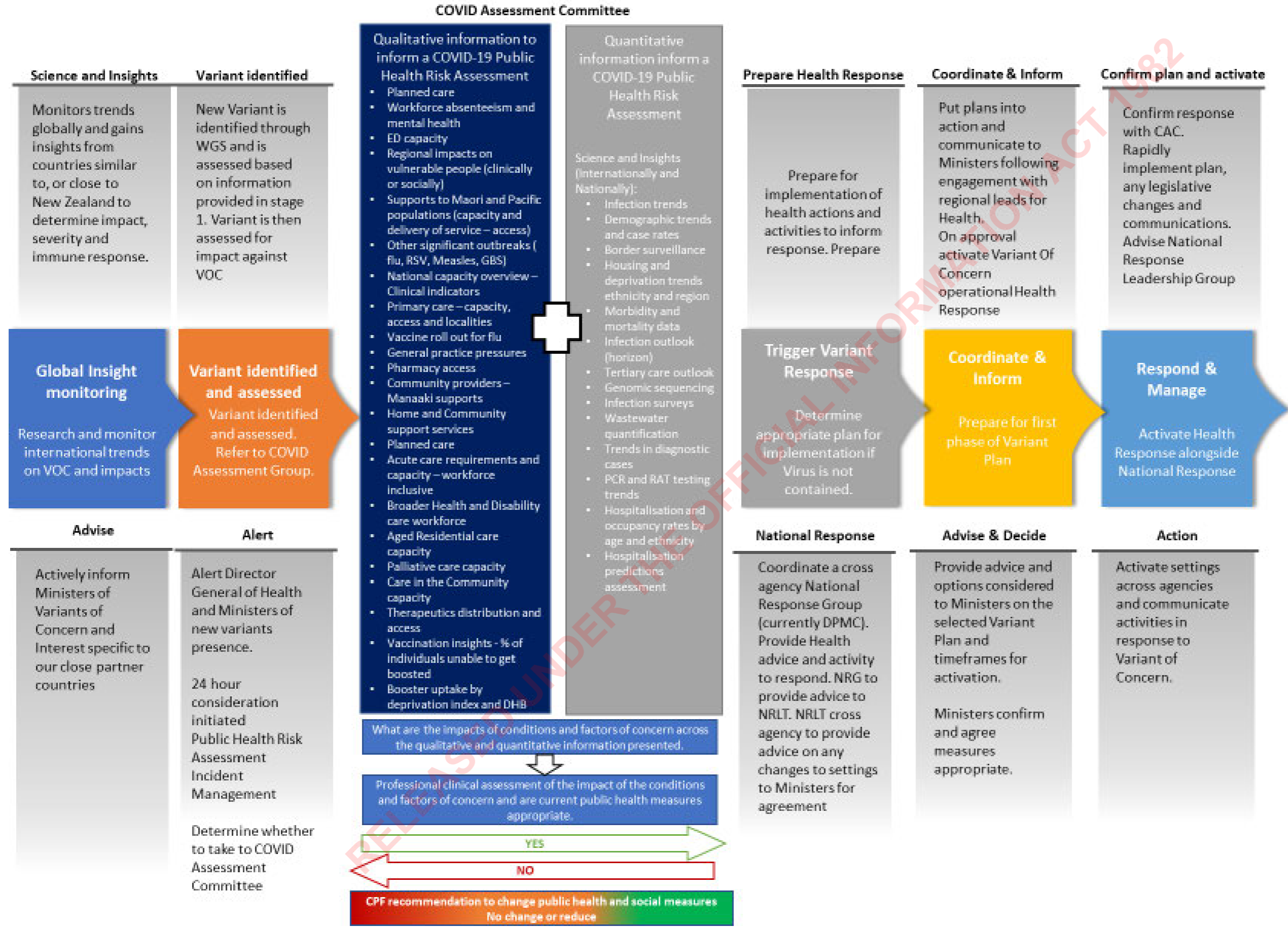
* Multipliers of the VE (vaccine effectiveness) parameters used for Omicron

** Immunity wanes rapidly

*** with faster reduction in immunity

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Appendix 3: Process for Identifying New Variants of Concern



Appendix 4: Proposed response to scenarios

Note: This appendix did not eventuate. As such, there is no further information.

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