Document 1

Briefing

Making better use of COVID Technologies

Date due to MO:	26 November 2021	**Action required by:**	10 December 2021
Security level:	IN CONFIDENCE	**Health Report number:**	20212432
To:	Hon Dr Ayesha Verrall, Associate Minister of Health		
Copy to:	Hon Dr Megan Woods, Minister of Research, Science and Innovation		

Contact for telephone discussion

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Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Document 1

Making better use of COVID Technologies

Security level:	IN CONFIDENCE	**Date:**	26 November 2021
To:	Hon Dr Ayesha Verrall, Associate Minister of Health		

Purpose of report

1. This briefing provides an update per your request on:
   a. the barriers relating to the introduction of new technologies into the health system that have been raised by MBIE in the context of the COVID-19 health response
   b. the medium-term priorities for the Ministry of Health (the Ministry)
   c. s 9(2)(b)(ii) [redacted]

Summary

2. In 2020, the Ministry for Business, Innovation and Employment (MBIE) set up the COVID Innovation Acceleration Fund (CIAF), which invested in a number of technologies that MBIE believed at the time had potential to support the government's COVID-19 response. This funding was directed to universities, independent researchers and private companies.
3. In bringing new technology to the public health system, there are three strategic overlapping barriers that are critical to determining whether the new technology will be successful. These are:
   a. Regulatory and accreditation
   b. Commercial and financial considerations
   c. Health system capacity and capability.
4. These barriers are common to many regulated industries. Issues specific to the public health system are understood through the work undertaken in the government's Health Research Strategy (2017), the Productivity Commission's work into Frontier Firms (2021) and the government's Industry Policy (2020).
5. The Ministry is working with the Health Reform Transition Unit in DPMC to develop a budget bid that would support the establishment of standing innovation capability and capacity in the health system. s 9(2)(b)(ii) [redacted]
6. In the longer term, the Ministry is working on the Therapeutic Products Bill, which will establish a comprehensive regulatory framework for medical devices and medicines to replace the Medicines Act.

7. In the short-term, there are some options that MBIE, the Ministry and the health system could offer to advance the investments made to date through CIAF, s 9(2)(b)(ii) [redacted] in the context of these technologies. These would specifically counter the barriers listed above

8. However, it needs to be noted that taking a direct approach to support individual technologies, has potential legal and media risks.

Recommendations

We recommend you:

a) **Note** that there are recognised barriers to new technology implementation in the public health system

b) **Note** that work is underway on medium- and longer-term solutions to these barriers

c) **Agree** to a meeting with officials to discuss the s 9(2)(b)(ii) proposal, a medium-term Ministry response to the identified barriers **Yes / No**

d) **Note** that there are options available for investments from the COVID Innovation Acceleration Fund, such as the s 9(2)(b)(ii) [redacted]

e) **Agree** that the Ministry of Health undertake an assessment of s 9(2)(b)(ii) [redacted] s 9(2)(b)(ii) [redacted] **Yes / No**

Shayne Hunter
Deputy Director-General
Data & Digital
Date: 2 December 2021

Hon Dr Ayesha Verrall
Associate Minister of Health
Date:

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Making better use of COVID Technologies

Background

1. In the response to the COVID pandemic, there has been rapid development and deployment of new technologies both in government, the community and in the health response. This is consistent with international responses and the response in New Zealand.

2. In early 2020, MBIE invested directly in a number of these new technologies through the CIAF. Given the timing of the investment arising from the pandemic, these technologies were at varying levels of readiness for production, had varying levels of applicability for the response, and were at varying levels of commercialisation.

3. The portfolio investment approach used for CIAF is a well-recognised model for investors to choose a large number investments, with the understanding that success is measured by the net return[1] of all the initiatives, rather than by the payback of each individual initiative. This is the approach used by private sector investment brokers, and the model used by most venture investment funds. On average, between 1% to 10% of investments are expected to make a return, with the assumption this return will cover the cost of the rest of the investments.

4. Ministers have been briefed previously by MBIE on the barriers facing a number of the CIAF initiatives so that they might understand opportunities to resolve some of these barriers. This analysis raises variously, a number of well-known and difficult to resolve issues in innovation and commercialisation, seen in New Zealand and internationally.

Barriers to implementing technology in health

5. With the introduction of technology to a health system, there are three broadly identified somewhat overlapping barriers, these are:

    a. Regulatory and accreditation

    b. Commercial and financial

    c. Health system capacity and capability.

Regulation and Accreditation

6. These barriers have been identified in the Health Research Strategy (2017), the Productivity Commission's work into Frontier Firms (2021) and the government's Industry Policy (2020). They were also recognised by an expert group convened to examine implementation opportunities for the Health Research Strategy.

7. The medical technology regulatory and accreditation position is one of interest to the Ministry of Health (the Ministry) as there is no comprehensive regulatory regime for this

[1] **This may include financial and non-financial returns as described in Treasury's Living Standards framework.**

https://www.treasury.govt.nz/information-and-services/nz-economy/higher-living-standards/our-living-standards-framework

Accessed: 29/1/2021

in New Zealand. Effectively a company (termed "sponsor"), simply needs to register a device with the Web-Assisted Notification of Devices (WAND) database managed by Medsafe.[2] There is no further action required.[3] The Director-General of Health has powers under the Medicines Act (1981) to request sponsors provide evidence of safety if they believe the device to be unsafe. If the Director-General is not satisfied with the evidence of safety, they are able to then apply sanctions including restriction of sale, a prison term not exceeding six months or a fine of $5,000 (Section 38 Medicines Act 1981).

8. This lack of comprehensive regulation has wider impacts than an inability to manage safety. There are issues with the lack of capability in New Zealand to advise businesses on international regulation requirements. This capability is often generated as overspill from a regulatory regime and also contributes to wider health system understanding of regulation. Further, a lack of regulation can mean the sector sets arbitrary or conflicting standards when choosing solutions. These risks were demonstrated in the example of "Bed Levers", a product designed to assist older people out of bed. The Coroner identified that a lack of standards for bed levers led to deaths in New Zealand and resulted in a recall action.[4]

Commercial and Financial

9. Commercial and financial barriers are common for new innovations. The health system generally operates with large deficits due to historic under funding. The incentive to operate more efficiently is missed due to benefits from innovation often falling outside the current financial year. A lack of targeted funding towards innovation or improvement as investments themselves are also a barrier as preference is given to new services in government Budgets. In addition, the Population-based Funding Formula and connection of this to existing purchasing frameworks means that it is a multi-year process to change what is purchased and for what amount, delaying the formal recognition of stated benefits. This means technology innovation, which necessarily takes time to deliver, needs to sustain itself over multiple financial years to first be implemented and then proved so that the costs can be matched to purchasing frameworks which can then be recognised and bought by DHBs and then described for reporting purposes. It is commonly understood that this is one of the key barriers to continued use of telehealth services, with one of the key interventions to support change in the past year being a suspension of purchase unit reporting compliance.

10. This commercial environment is further complicated by the role of Pharmac, who have since 2010 [5] been working to coordinate hospitals' purchasing of medical devices. This work was most recently surfaced to the public in 2019 with consultation on managing fairer access to hospital medical devices. Included in the feedback from a number of submitters were concerns about how Pharmac intended to proceed in the research and innovation space, this has not yet been resolved. A further issue for resolution is the

[2] **Testing Technology Regulatory requirements** https://www.medsafe.govt.nz/Medicines/policy-statements/COVID19/COVID19PointOfCareTestKits.asp **Accessed: 22/11/2021**

[3] **Consumers may also reasonably expect these meet consumer standards, such as with currently un-regulated beauty products.**

[4] **Recall notice issued relating to bed levers:** https://www.medsafe.govt.nz/hot/recalls/RecallDetail.asp?ID=23923 **Accessed 19/11/2021**

[5] **Pharmac 25 Year History** https://pharmac.govt.nz/assets/pharmac-25-year-history.pdf **Accessed 19/11/2021**

growing convergence of devices, consumable components and the digital and data integrations required to make new devices work. A current example is the introduction of new Troponin-T Point of Care tests being supported through a Health Research Council grant. There is no funding provided to support the cost of running the devices or any investment for the health system to integrate these into the various Emergency Departments that are a part of the study.

11. From the business side of the equation, the New Zealand market is extremely small when compared to Europe, the US, the UK and Australia, both in terms of health spending and the size of the wider market. This means many new businesses ultimately look at New Zealand as a steppingstone to export and a way to prove the technology is capable through the creation of a reference customer. With the lack of a regulatory regime, many local start-ups bypass New Zealand entirely to seek regulatory approval in their primary target export market. Start-ups are often cash-poor and rely on upfront payments to make progress, whereas public health systems including New Zealand generally pay in arrears as benefits are accrued. An alternative model to support these types of businesses that is often suggested is a "national contract" which in the past created competition and resilience issues in the health industry. This effect has been directly observable in the supply issues with Pharmac single supplier contracts. For businesses this may turn out to be unsatisfactory as well, where a single national contract means losing one contract results in the organisation leaving the market. An example of this is Cerner, one of the largest healthcare IT suppliers in the world who currently do not have a New Zealand office.

Health system capacity and capability

12. The third barrier to adoption is the capacity and capability of the health system itself to absorb the change and innovation associated with new technology. Many District Health Boards (DHBs) have a small staff who are focused on quality improvement activities driven from the Health Quality Safety Commission. This activity, often known as service improvement forms only one of three horizons of innovation as defined by McKinsey. [6] There is a lack of recognised groups doing work in horizon two and three in the health system with only two that have national identities (i3 in Waitemata and Via in Canterbury) and both have a bigger focus on service improvement. There are no direct funding streams for this activity in the health system, with the only continuity of roles, skills and experience coming from the next new project coming on stream at the right time.

13. From a capability perspective, a survey of 1200 health system workers undertaken by the Ministry in 2019 found that people were on average 20% less confident Innovating with Technology than with other digital literacy domains such as Digital Identity and Technical Proficiency.

14. Finally, there is little national visibility of innovation activity across the health system. The group in the Ministry accountable for understanding and developing policy to enable new technology for the health system, identifying and supporting innovators and

[6] **McKinsey Three Horizons** https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/enduring-ideas-the-three-horizons-of-growth **Accessed: 22/11/2021**

networks along with supporting this activity to occur across the health system, comprises just four staff.

Medium- and longer-term work to address these barriers

15. There is work under way in the Ministry to build a comprehensive regulatory framework for medical devices and medicines to replace the Medicines Act, called the Therapeutic Products Bill. This has yet to be introduced to the house and there remain issues relating to a number of aspects that challenge international regulators today including some of the complexity above and the convergence of key aspects of the technology.

s 9(2)(f)(iv) [redacted]

17. The government's investment in Hira also has a part to play. This has as a part of the scope, to consider how information when it is more integrated and available will support innovation and implementation of new solutions. This is being designed for many different users such as consumers, researchers, innovators and commercial providers.

Barriers for s 9(2)(b)(ii) [redacted]

18. You have asked for advice on how to build on the CIAF investment in s 9(2)(b)(ii) [redacted] and illustrates well the barriers faced by all technology providers entering the health market in New Zealand.

Accreditation

19. In a regulatory context, an organisation is required only to register with the WAND database in order to be able to sell a product in New Zealand. This registration is not sufficient to gain accreditation for use by accredited labs, and accreditation costs range upwards from $10,000.

20. Full international regulatory approval of a device could be considered in addition to WAND registration. s 9(2)(b)(ii) [redacted]

[7] s 9(2)(b)(ii) [redacted]

Commercial barriers

21. The health lab environment in New Zealand has changed significantly in the past 20 years, with a trend towards larger, more centralised, and longer-term contracts with commercial lab service providers (eg. APHG, SCLabs). District Health Boards have, in large part, divested their ownership and control of lab service provision to control costs through commercial negotiations and to remove many of the complicated risks associated with running a clinical and technical service. Many of the commercial competition issues described in previous sections were well explored in the Labtests vs Auckland DHBs Auditor General review in 2007. [8]

s 9(2)(b)(ii)

[redacted]

25. Taking the barriers described into account, the Ministry proposes the following next steps.

Recommended approach for s 9(2)(b)(ii)

s 9(2)(b)(ii)

[redacted]

[8] **Labtests Auditor General Review** https://oag.parliament.nz/2007/auckland-dhbs/part1.htm **Accessed 22/11/2021**

s 9(2)(b)(ii)

[redacted]

Equity

33. Investment in new technology for healthcare has the ability to increase and reduce inequity. It is important that all initiatives consider how they could be best implemented to reduce inequity. Data and Digital has recently established an Equity Lead role in order to drive this set of outcomes.

s 9(2)(b)(ii)

[redacted]

Next steps

35. The Ministry will undertake appropriate action, following your decisions on the recommendations in this briefing.

ENDS.

[99] **Government Procurement Principles** https://www.procurement.govt.nz/procurement/principles-charter-and-rules/government-procurement-principles/ **Accessed: 22/11/2021**

Document 2

Briefing

Transitioning the COVID-19 response functions to the new system structure in 2022

Date due to MO:	1 April 2022	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	20220241
To:	Hon Andrew Little, Minister of Health		
Copy to:	Rt Hon Jacinda Ardern, Prime Minister Hon Grant Robertson, Deputy Prime Minister Hon Chris Hipkins, Minister of COVID-19 Response Hon Dr Ayesha Verrall, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Te Tumu Whakarae mō te Hauora Director-General of Health	s 9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Document 2

Transitioning the COVID-19 response functions to the new system structure in 2022

Security level:	IN CONFIDENCE	**Date:**	1 April 2022
To:	Hon Andrew Little, Minister of Health		
Copy to:	Rt Hon Jacinda Ardern, Prime Minister Hon Grant Robertson, Deputy Prime Minister Hon Chris Hipkins, Minister of COVID-19 Response Hon Dr Ayesha Verrall, Associate Minister of Health		

Purpose of report

1. This briefing provides advice and seeks your feedback on the Ministry's proposed approach to the delivery of the COVID-19 response in 2022 and addresses the report-back in SWC-21-MIN-0223.

2. This report discloses all relevant information and implications.

Summary

3. To respond to the demands of COVID-19, the Ministry has built substantial new functions, including establishing the COVID-19 Health System Response Directorate.

4. The COVID-19 response has created a legacy of system enhancements within the public health system to manage current and future public health threats. The development of the future public health model is underpinned by the principles that have guided the system through the COVID-19 response.

5. Our approach to the response has evolved as we have dealt with the Omicron peak and commence planning for managing the post-peak phase. We now have a better understanding of the changing nature of the response functions and broadly where the different response functions will sit in the new health system.

6. The Ministry (including the interim Public Health Agency) and interim Health NZ will undertake a detailed mapping and planning exercise to ensure that the functions are transferred in a way that maintains a strong response and mitigates any risk to the continuity of the response. In the first instance, the existing functions need to be assessed to ensure they are still relevant and right-sized for the future, e.g. the nature and size of the border health function has changed significantly in recent weeks.

7. This exercise will include mapping out the day-to-day activities and requirements so that the receiving entities have a clear plan for delivering the functions being transferred on day one. This will include ensuring clarity on leadership, accountability, monitoring and

reporting (including to Ministers). This, together with the final FTE transfers and transfer plans, will be reported back by late-April.

8. Our assessment is that functions that are going to be transferred will be ready to do so in the next four to six weeks. We will continue to regularly update you on progress towards the transfer including any emerging risks or issues.

Recommendations

We recommend you:

a) **Note** that the COVID-19 response has created a legacy of system enhancements within the public health system and that the development of the future public health operating model (PHOM) is underpinned by the principles that have guided the system through the COVID-19 response. **Yes/No**

b) **Note** that we have broadly determined the appropriate location for the COVID-19 response functions in the new system, including those that will transfer to iHNZ and the iPHA, and the next step is to assess in detail the focus and size of each functions to ensure they are ready for the next phase in the response to the pandemic. **Yes/No**

c) **Note** that our assessment is that functions that are to transfer will be ready to do so in the next four to six weeks. **Yes/No**

d) **Note** that to ensure appropriate risk-management, the Director-General, the Chief Executive of iHNZ and the Chief Executive of the iMHA, will agree on the timing of the transfer of the COVID-19 functions. **Yes/No**

e) **Note** that we will also undertake a detailed mapping and planning exercise to ensure that the receiving entities are able to carry out key day-day response activities, requirements and critical decision-making processes from day one, including monitoring and reporting. **Yes/No**

f) **Note** that the Ministry will report back in mid-April on the final FTE transfer and transfer plan following the completion of functions mapping exercise. **Yes/No**

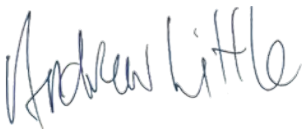
g) **Note** that should the status of the outbreak or nature of the virus change significantly, the Director-General and the Chief Executives of iHNZ and iMHA will make an assessment about whether the transfers continue as planned, and whether any alterations to timing or approach are needed to mitigate emergent risks. **Yes/No**

h) **Agree** to forward this briefing to the Prime Minister, Deputy Prime Minister, Minister of COVID-19 Response and Associate Minister of Health (Hon. Ayesha Verrall) **Yes/No**

Document 2

Dr Ashley Bloomfield
Te Tumu Whakarae mō te Hauora
Director-General of Health
Date: 01/04/2022

Fepulea'i Margie Apa
Chief Executive, Health New Zealand
Date:



Hon Andrew Little
Minister of Health
Date: 3/4/22

Document 2

Transitioning the COVID-19 response functions to the new system structure in 2022

Context

1. New Zealand has led a strong health response to COVID-19, promoting positive public health, equity, wellbeing, and economic outcomes through the phases of the pandemic.

2. To meet the operational demands of the response, the Ministry of Health (the Ministry) created a new operating model, standing up a new COVID-19 Health Response Directorate and adding new functions across other parts of the Ministry. This has been mirrored by additional operating capacity within DHBs both locally and regionally to support delivery responses and work with the Directorate in implementation.

3. The pandemic is ongoing, and we are still in an active response. As is happening across government, the Ministry is reviewing its current COVID-related functions to ensure they are still relevant, and the right sized for the overall approach now being taken with the borders open and the shift in the way testing and contact tracing are done.

4. Our response is evolving rapidly and will continue to evolve post-peak of the Omicron outbreak as the Government makes further decisions about key response settings, including shifts in the COVID-19 Protection Framework, future approach to COVID-19 vaccination, and changes in isolation settings for cases and household contacts.

5. Through the COVID-19 response, we have created knowledge and experience, new models of care, and a legacy of enhancements across public health and the wider health system. These functions have transformed and enhanced the capability, perception, and relevance of the public health system and will form the basis of our future public health operating model (PHOM).

6. In 2022, the COVID-19 response will evolve further as the COVID-19 pandemic continues to evolve, most likely towards an endemic disease, and parts of the response become embedded into the transformed health system.

7. Progressing with the transfer of the COVID-19 operational functions to Health New Zealand is consistent with the overall health and disability sector reforms. It will support the Ministry to strengthen its stewardship role and continue to provide national leadership and for Health New Zealand (Health NZ) to deliver integrated response and the Maori Health Authority to continuously improve responsiveness to Maori.

8. Within the transfer planning, it will be critical to ensure a stable handover of the current response while the pandemic continues and we have an active Omicron outbreak, with an expected ongoing level of diseases through winter and potential further peaks. In addition, functions transfer need to align with the future system public health operating model, the roles, and responsibilities for the system entities (including the Public Health Agency) and at a high-level view of how they cohesively fit together as part of the wider health system.

9. This briefing updates you on our agreed approach and timeframes for transferring the relevant COVID-19 response functions to the new health system entities and addresses the report-back requested in SWC-21-MIN-0223.

Current COVID-19 functions within the Ministry

10. To respond to the demands of COVID-19, the Ministry has built substantial new functions within the COVID-19 Health System Response Directorate in July 2020. This directorate pulls most of the Ministry's COVID-19 operational activity into a central place to provide consolidated pandemic stewardship, science, and public health advice to Ministers, and guide the sector to respond quickly and effectively.

11. Under the COVID-19 Response Directorate, we have developed several new functions including a national contact tracing and case investigation service, a new clinical management system and new testing modalities with national oversight. In addition, national approaches pre-existing functions were developed to deal with the extraordinary circumstances and the need for national consistency and certainty e.g. PPE supplies and logistics. These functions are a key part of the legacy that the COVID-19 response leaves for the health system.

12. Clear national leadership and an integrated approach has been critical at a time of complexity and ambiguity and has enabled the system to adapt quickly and efficiently to changing threat of the virus over the past two years.

13. Over the last 18 months, the COVID-19 Health Response Directorate's workload has increased as the response to the pandemic has evolved with significant increases in reporting requirements, additional support provided to the sector and increased support for teams managing borders, border exemptions, and MIQ activities.

14. The COVID-19 Directorate is also supported by many other parts of the Ministry, which have also pivoted from their 'business-as-usual' roles to support planning and response activities. We have also built significant work programmes and teams within the Health System Preparedness Programme, Care in the Community and the COVID-19 Vaccination and Immunisation Programme (CVIP).

COVID-19 Vaccination and Immunisation Programme

15. Operating alongside the COVID-19 response is the COVID-19 Vaccination and Immunisation Programme (now part of the National Immunisation Programme) that leads operational planning and guidance. The programme works closely with other parts of the Ministry, including:

    a. Policy and Strategy (sits within SSP): leading the strategy and policy advice to support the COVID-19 immunisation programme

    b. Purchasing (sits within SSP): management of COVID-19 vaccine portfolio, including Advanced Purchase Agreements and participation in COVAX.

16. The COVID-19 Vaccination and Immunisation programme was started with a view that, through the course of running the vaccine programme, the Ministry will take incremental steps to transition from a COVID-19 focused programme to a more strategic approach focussing on all immunisations more broadly [SWC-21-MIN-0223 refers].

17. The NIP is now planning for and ready to deliver a strengthened approach to all immunisation programmes (alongside the COVID-19 vaccine programme) that leverages

communications, analytics and other operational functions and lessons from the COVID-19 Vaccine and Immunisation Programme.

18. The NIP itself is a key public health programme that will be delivered by Health New Zealand, with some key service commissioning by the Maori Health Authority, and as such it will transfer to those organisations.

Leveraging the current operating model to strengthen the future public health system

19. The COVID-19 response has created a legacy of system enhancements within the public health system to manage current and future public health threats.

20. The development of the future public health model is underpinned by the principles that have guided the system through the COVID-19 response, as well as the goals of the health system reform. Critically, the aim in the future is to create a public health operating model (PHOM) that is nationally consistent and regionally responsive.

21. While the PHOM leverages the success of COVID-19, it also considers the challenges and opportunities within the current public health system. For this reason, the transfer of functions needs to be consistent with the new PHOM and the roles and responsibilities set out in the future model of public health.

22. Under the PHOM, the core COVID-19 response functions will be distributed according to how these fit within the roles and responsibilities of the new entities, as determined under the Pae Ora Bill:

    a. **Ministry of Health:** Act as the chief steward of the health system, including setting direction and expectations for the system and its entities, and the lead advisor to Government on matters relating to health, led by the Director-General of Health. The functions would involve a trio of policy; strategic public health; and chief science advice input

    b. **Public Health Agency**: Provide all public health and population health strategy, policy, regulatory, intelligence, surveillance and monitoring functions. The PHA will also work with Health NZ and Māori Health Authority to plan for public health promotion, prevention and protection programmes.

    c. **Health New Zealand**: Health NZ will support the capability of the health system, promote resilience within the system and ensure that the system is able to respond to surges in demand. As part of Health NZ The National Public Health Service (NPHS) will provide public health resources and leadership where required. HNZ will work closely with the Māori Health Authority to ensure responsiveness to Māori remains a core principle of all operations.

    d. **Māori Health Agency**: Work in partnership with the Ministry in shaping system policy and strategy to ensure performance for Māori. As co-commissioner ensure preparedness and development of Kaupapa Maori providers are capable to respond to communities. Partner with Health NZ to commission public health services across New Zealand and mitigate impact on clinical service delivery and equity of access, ensuring that the needs and expectations of Māori communities are also centred in design and delivery.

Transitioning from the immediate to a future state of the public health system

23. The current focus of the response is on managing ongoing impact of Omicron, reconnecting with the world, and planning for managing COVID-19 through the winter. Beyond this we are also working across Government to plan our future and longer-term approach to COVID-19.

24. Our approach to the response has evolved as we have dealt with the Omicron peak and commence planning for managing the post-peak phase. We now have a better understanding of the changing nature of the response functions and broadly where the different response functions will sit in the new health system.

25. Progressing with the transfer of the COVID-19 operational functions to Health New Zealand is consistent with the overall health and disability sector reforms. It will support the Ministry to strengthen its stewardship role and continue to provide national leadership and for Health New Zealand (Health NZ) to deliver integrated response and the Maori Health Authority to continuously improve responsiveness to Maori.

26. Within the transfer planning, it will be critical to ensure a stable handover of the current response while the pandemic continues and we have an active Omicron outbreak, with an expected ongoing level of diseases through winter and potential further peaks. In addition, functions transfer need to align with the future system public health operating model, the roles, and responsibilities for the system entities (including the Public Health Agency) and at a high-level view of how they cohesively fit together as part of the wider health system.

Transition and location of the COVID-19 Health Response Directorate's functions to new health entities

27. To date, we have carried out a series of hui with representatives from the Ministry, Health New Zealand (HNZ), and the Māori Health Authority (MHA) to develop a joint position on the location of functions and our approach to transferring them.

28. The agreed future locations for functions in the COVID-19 Response Directorate (the Directorate) are set out in **Table 1 below.**

29. The FTE numbers in Table 1 are the current numbers that have been provided to you to give a sense of the size of these current functions.

30. As is happening across government, many of the COVID-19 functions need to change for the next phase, including changes in the overall settings and approach. In particular, the number of FTEs will change and, in some cases, reduce considerably. A process of right sizing will need to occur as part of transfer exercises (more information below).

31. Equity is a critical cornerstone of the reformed health system. As we transfer the functions of the Directorate to respective entities, it is expected that equity as an outcome is embedded across the system.

Document 2

Table 1. Future of the COVID-19 Health Response Directorate Activities

Group (*current FTEs)*	**Emerging function**	**Receiving entity**
National Investigation and Tracing Centre (NITC) (~69 FTE)	NITC manage large national contact tracing service and a national case investigation service. The function has changed to support self-management of COVID-19.	**HNZ (NPHS)**
Public Health Operations Group (~ 12 FTE)	PHOG provides national public health leadership, coordination, and tactical direction for the management of case and contacts for COVID outbreaks.	**HNZ (NPHS):** Operations and tactics **PHA:** High level policy
Border Operations and MIQ (~36 FTE)	The team works on border operations, MIQ operational guidance, Health Order enforcements/exemption. Their processes and systems have been refreshed for reopened borders (incl. shifting focus on managing MIQ to supporting travellers to self-isolate). This team will need to be smaller and with a different focus in future.	**HNZ (NPHS):** Operational design **PHA:** Strategic approach to health at the border as part of Border Executive Board work programme
Testing and supply (~62 FTE)	Regulation and Accreditation: of approved COVID-19 test types, Testing Operations: Responsible for the operationalisation of testing strategy, procurement and contracting of private testing laboratories. Supply: Provide national coordination of supply chain of PPE/critical clinical supply. The systems for supply, procurement, distribution, and logistics is intended to be used beyond just testing kits. Project management: of critical and ongoing projects.	**PHA:** Regulation and accreditation **HNZ (NPHS):** Procurement and contracting of providers. Supply and project management
Science and insights (~51 FTE)	Public health intelligence and surveillance, expert technical and science advice, evidence-based insights to guide decision-making, secretariat for Technical Advisory Groups. Focus remains on providing daily reporting and insights to support our strategic response. In time, this would shift to include wider disease surveillance as is needed by the system.	**PHA:** Noting that there will be analytical and insights capability and capacity in HNZ (including the NPHS) and the MHA.
Response and coordination (~29 FTE)	Provides incident management, coordination of response activities, operational reporting, and monitoring and response to enquiries and requests for information about the response. Note this function will be smaller and have a different focus in future.	**HNZ:** Co-ordinates the national operational aspects of the response, working closely with the four regional response teams **MOH**: Part of AOG response and coordination of cross-government operational aspects of the ongoing response
COVID-10 Strategic Operations	Maintains strategic linkages across the Directorate teams and provide strategic operational and equity advice on implementation of the COVID-19 response.	**MOH:** Part of AOG response including ongoing Strategy and

(~29 FTE – including ODCE)	Note this function will be smaller and likely combine with the Response and Coordination function.	planning across government **HNZ (NPHS)**
Office of the DCE	Advisory and business support, privacy advice, operational planning and programme management	**HNZ (PHNZ)**: combined with strategic operations team **MOH**: privacy function will move to Health Legal team within Ministry.

COVID-19 Vaccination and Immunisation Programme

32. The COVID-19 vaccination programme has transitioned to an integrated National Immunisation Programme that focuses on immunisations broadly.

33. There has been in-principle agreement that the National Immunisation Programme roles will transfer to HNZ, with the final number and timing to be confirmed [DPMC-2021/22-1221].

34. The vaccine policy and strategy functions will transfer to the Public Health Agency.

35. There has been in-principle agreement to transfer responsibility of ongoing vaccine purchasing from the Ministry of Health to Pharmac [SWC-21-MIN-0223 refers]:

    a. It is timely to transition vaccine purchasing functions for COVID-19 to Pharmac alongside consideration of the wider Pharmac review and Health and Disability System reforms.

    b. It is crucial that with the transfer of vaccine purchasing functions that the outcomes focused approach and COVID-19 response are maintained as we continue to mitigate the impacts of COVID-19 on New Zealand and the health system.

36. Ministry of Health will report-back to Social Wellbeing Committee in May 2022 with further details on transferring the responsibility for the on-going management and purchase of COVID-19 Vaccines from the Ministry of Health to Pharmac, and the reallocation of the COVID-19 Vaccine and Immunisation Programme to the Public Health Service in Health New Zealand.

Transfer of related COVID-19 functions

37. The scope of the paper is limited to discussing the final location and timing of the transfer of functions within the COVID-19 Health Response Directorate. The details around the related functions which are scheduled to migrate will do so at their own specified times.

38. We have signalled below the location of the related functions that work closely with the COVID-19 response functions:

    a. **the Office of the Director of Public Health**: provide ongoing significant public health leaders and advice to the Ministry. The team will move to the Public Health Agency within the Ministry of Health and provide direct leadership to the national public health service in Health NZ (CAB-21-MIN-0092 refers).

    b. **Health System Preparedness and Care in the Community programme** (lead out of DHB performance and support directorate) was developed in 2021 as the

operational lead for supporting people to isolate and recover at home and provide support to sector to deal with increased demand. The team is still in active response mode; future need for and location of this work programme is still to be determined.

c. **System Strategy and Policy (SSP)**: the COVID-19 Policy and Strategy function sits within the SSP directorate and will remain within the Ministry to support the long-term strategic approach across government and the development of policy, legislation, and Orders.

d. **Data and Digital:** focused on the delivery of technology solutions and services which support the COVID-19 response, including contact tracing, border solutions COVID-19 tracer app and vaccine programme. This function will move to Health NZ (four of the nine teams have already shifted under Tranche 1 [DPMC-2021/22-1221]).

e. **Communications**: works to provide comprehensive public health campaigns that allowed populations to understand the measures in place. The function will shift to Health NZ as part of tranche 2 transfers.

f. **Global Health**: responsible for the vaccine roll outs to the Pacific and supporting Pacific health responses to COVID-19 as part of the Pacific Corridors. The function will remain in the Ministry.

Equity and Te Tiriti o Waitangi

39. As articulated by the Courts and the Waitangi Tribunal, equity is a principle of Te Tiriti, and one of the principles recommended by the 2019 Hauora report for the Health system is Equity.

40. Within this principle, it is critical to ensure that the any function transfer planning is developed and implemented with hauora Māori at the forefront is crucial for achieving positive health outcomes and meeting the Crown's obligations.

41. Planning of the future health system has been rigorous in positioning the Māori Health Authority and Health New Zealand to respond to the goals of the health reforms and the aspirations of te ao Māori.

42. The reforms aim to strengthen rangatiratanga Māori over hauora Māori, empower Māori to shape care provision, and give real effect to Te Tiriti o Waitangi. Initiatives throughout the COVID-19 response (such as Māori-led immunisation campaigns) have shown the massive impact Māori leadership can have on achieving equity.

43. Māori Health Authority, Health New Zealand, and the Ministry of Health will continue to build the relationship needed to work together in creating a joined-up system that is fair, equitable, and founded on Te Tiriti. For this, the entities must lead and model partnership across the sector to ensure equitable outcomes are enabled.

44. Specific to the proposal in this paper, it is also critical to ensure that we manage any risks the transfer may present in relation to hauora Māori and equitable outcomes for at-risk populations.

45. A devolved system needs to continue work together to uphold the integrity of the response functions and ensure that services are being delivered in a culturally competent manner to reduce additional health risks. It is thus recommended that the

proposed readiness assessment comprehensively evaluates the specific impact of any functions transfer on equity.

46. The entities are working together to ensure that te Tiriti and partnership with Māori is at the centre of design and delivery of the public health system – from strategy and policy to delivery and operations. There is also an explicit focus on embedding a population and equity centred approach for Māori, Pasifika, disabled peoples and other priority groups. The entities are also using the learnings and system enhancements from the continuing pandemic response and sector engagement to inform the continued development and implementation of the PHOM.

Timing and conditions for transitioning the COVID-19 response functions to new entities

47. Our planned approach to transferring functions is centred on ensuring that we transfer functions as soon as they are ready and the core elements are in place in the receiving agency, but also in such a way that ensures critical response functions continue without disrupting the response.

48. The following contextual factors have been considered while proposing the timing of the COVID-19 functions transfer to respective entities:

    a. **Operational readiness:** the key response functions are mapped out and understood, and an operating approach agreed to ensure the critical response functions continue without disruption.

    b. **Status of the response**: while the pandemic is still ongoing and response is ongoing, as the response evolves, many extant COVID-19 functions will either no longer be necessary in their current form, e.g. support for managed isolation and quarantine, or will be ready to become embedded in the wider health system as part of the long-term shift from crisis response to sustainable prevention and management of COVID-19.

49. The Ministry's assessment is that functions that are to be transferred will be ready to do so approximately four to six weeks from now. While some functions may be ready to transfer from 1 May 2022, the focus is on ensuring the functions are the right ones and the right size, and that everything is in place for a smooth transfer.

50. During this time, the Ministry and Health NZ will undertake a two-step process to prepare the functions for transition to the respective entities:

Step 1: Scoping of the functions

51. Officials from the Ministry and Health NZ will review the leadership, accountability and monitoring requirements for each function, and determine what is needed to deliver in the new system.

52. Through this exercise, we will also outline the functions that are new capabilities as compared to teams that have pivoted from 'business-as-usual' in order to deliver the COVID response.

53. Where relevant, we will retain the original purpose in the system, and maintain the appropriate capability to embed the legacy systems as part of the strengthening of the public health system. This will ensure entities are able to respond better to communicable diseases that are an ongoing challenge including sexually transmitted

diseases, foodborne illness, and vaccine preventable diseases, e.g. measles and pertussis, and/or represent a significant enhancement of previous functions, such as expanded contact tracing and improved logistics functions.

Step 2- Right-sizing process

54. The requirements of each function will then be used to determine the FTEs required to deliver the new system.

55. It can be expected that some functions likely to be much smaller, e.g. border management function), and/or are no longer needed at the same scale, e.g. those servicing the extensive reporting, while some will be 'new' functions in the wider system e.g. national contact tracing.

56. A change process will then be initiated with affected staff and timing for the functions to be transferred will be finalised.

Conditions for transferring the functions

57. To ensure appropriate risk management, the Director-General of Health, the Chief Executive of Health NZ, and the Chief Executive of Māori Health Authority, will make the final decision on the timing of the transfer of COVID-19 functions. The decision will be made using the following set of conditions:

    a. *Agencies are sufficiently ready to receive COVID-19 functions*: Director-General and the Chief Executives of Health NZ and Māori Health Authority agree structures, processes, leadership, capacity and capability to receive the COVID-19 functions and deliver the response are in place.

    b. *Risk management and monitoring***:** Director-General and the Chief Executives of Health NZ and Māori Health Authority agree risks associated with the transfer of the functions and a mitigation, the process for assessing trade-offs of mitigation actions is jointly agreed in the transfer including financial or delivery risks

    c. *Communication*: significant stakeholders agreed by the Director-General and the Chief Executives who are impacted by the transition have the necessary information to understand the changes, including the processes, systems, and associated accountabilities.

    d. *Oversight in place*: the Director-General and the Chief Executives agree the monitoring framework for assessing system performance approach and a framework in place to both monitor the reform activities and provide Ministers required information as part of ongoing oversight of Health NZ as a whole.

    e. *Equity embedded*: the Director-General and the Chief Executives agree priority areas for equity focus and work programmes in place to assure impact and engagement of those stakeholders are in place. We must also ensure monitoring forms part of how we ensure equity is being embedded in services.

58. The process will impact priority stakeholders, all of whom will be consulted as part of finalising the transfer process. This includes the relevant Ministers, DPMC as the lead on the AOG response, and (for the time being) District Health Boards.

59. It is also recommended that all the functions transfer on the same date unless there is merit in transferring a function earlier. A single transfer date will make it easier for staff to have clarity about when they're transferring and will make it easier for entities to receive the transferring functions.

60. Should the status or nature of the virus in the community change the Director-General and the Chief Executives of Health NZ and Maori Health Authority will make an assessment about whether the transfers continue as planned, and whether any alterations to timing or approach are needed to mitigate the risk.

Managing the risks associated with transferring functions

61. Transferring the functions across entities is not without risk, particularly at a time when the health sector is responding to multiple demands and pressures.

62. The due diligence process that we have followed for transfer decisions to date will surface any existing risks to performance of the function, along with risks that may emerge as a result of transfer. Where possible, functions are transferring with existing leadership and with teams as intact as possible to ensure continuity of the day-to-day work.

63. There are three key risks in transferring of response functions:

    a. The key risk with transferring of response functions while the response in underway is the potential loss of connections between different contributing elements of the response, and lack of clarity about how to join up different elements when devolved to different entities. Ongoing work to plan the operating approach to delivering the work in a devolved system is intended to mitigate this risk.

    b. There is also a risk that the nature of the virus in New Zealand changes between now and the transfer of functions, for example through the introduction of a new variant of concern, or there is a significant spike in infections and pressure on the health system as part of the current Omicron outbreak. Should either of these happen the Director-General and the Chief Executives will make an assessment about whether the transfers continue as planned, and whether any alterations to timing or approach are needed to mitigate the risk.

    c. The health sector has been actively responding to COVID-19 for more than two years now; this has taken a toll on the front-line workforce and as a result the sector may be less able engage in change and be ready for it. There are also some expectations that the system will transform from Day 1 rather than it being a transition date and the start of a process of transformation. This is being managed by clear agreement that stable transition is the primary goal and that we will utilise the new structures and partnerships to transform over a longer period.

64. Following tranche 1 of function transfers, the Ministry, jointly with the interim entities, conducted a 'lessons learned' exercise to identify risks as well as the opportunities to improve on planning approaches, processes and decision making. This will inform the way we undertake transfers of other functions, including those COVID-19 functions currently operating within the Ministry.

Next steps

Approach to finalising functions transfer

65. The Ministry and Health NZ will undertake the above-mentioned two-step change transfer process of scoping and right-sizing of the COVID-19 functions.

66. The Ministry is also creating a plan to ensure that equity considerations remain central through the transfer.

67. We will seek your approval on the final transfer plans by late-April, including leadership, accountability, and monitoring/reporting arrangements.

68. Further from this, officials will keep you updated regularly on progress towards the transfer including any emerging risks or issues.

Related report backs and work

69. There will be a separate report back from the Ministry and Transition Unit to the Minister of Health and Associate Ministers of Health (Hon Dr Ayesha Verrall and Hon Peeni Henare) in April 2022 on further progress in developing the PHOM and public health function transfer to the new public health entities.

70. The Ministry of Health will report-back to Social Wellbeing Committee in May 2022 with further details on transferring the responsibility for the on-going management and purchase of COVID-19 Vaccines from the Ministry of Health to Pharmac, and the reallocation of the COVID-19 Vaccine and Immunisation Programme to the Public Health Service in Health New Zealand.

71. Officials will also report back on the long-term trajectory and strategic direction for COVID-19, including our transition into living with COVID-19 as an endemic virus (joint Health and DPMC lead, reporting to Hon Chris Hipkins) by the end of April 2022.

72. The Ministry is currently planning a review of the New Zealand Influenza Pandemic Plan (NZ IPAP), which was last updated in 2017. The NZ IPAP was derived from past experience with influenza, however the plan needs to be revised significantly in light of COVID-19. Through the review, the Ministry will outline the tools and that are required to guide the system through future pandemics (not just influenza related ones) and respiratory illnesses more broadly.

Financial implications

73. Funding for COVID-19 response functions has been approved at different points and for different time periods due to the emerging nature of the pandemic and the required response to it. As a result, different areas of the response, such as testing, managed isolation and quarantine (MIQ) and Ministry resources, are all funded to different points in time.

74. The nature of the funding required for our ongoing response to COVID-19 is determined by the nature of the response and approach as we adapt our functions to address the current Omicron wave and then transition them into a response to COVID-19 as an endemic virus. The location of these functions across the transformed health system does not significantly impact on the resourcing required for these functions.

75. More details of the financial implications and requirements for the ongoing COVID-19 response are set out in the upcoming Cabinet paper detailing 'funding of the health system response to COVID-19 in 2022/23'. The paper includes information on the following areas, and further work continues to address the financial implications of the other areas of the response:

    a. Ongoing testing, tracing, isolation and quarantine

    b. Health system preparedness (including care in the community programme)

    c. Reconnecting New Zealanders

76. Confirmation of funding is also required to the National Immunisation Programme management currently in the Ministry of Health. All positions in the Programme are scheduled to end on 30 June 2022 due to uncertainty of on-going funding and where the Programme will be placed in the upcoming system reforms taking effect from 1 July 2022. Cabinet will be provided with a separate report in the next two weeks around decisions on 'funding of the National Immunisation Programme into 2022/21'.

Consultation

77. The briefing has been consulted across key partners in the transition process, including the Public Health Agency, interim Health NZ, interim Māori Health Authority and the Transition Unit.

78. The consultation discussions focused on the timing for transfers, the evolving nature of the functions and the process to land their eventual size, and the expression of the importance of equity in this work.

79. COVID-19 functions were always planned to be transferred through a process that was independent of other 'business-as-usual' health functions. This has allowed the process to have both the agility and the speed that is required in a time when the pandemic is still ongoing, and we are required to maintain a full-functioning response.

80. Further this agility is needed especially given the speed at which the Government's response to COVID-19 is evolving. As mentioned earlier, there is a cross-government process that is happening to determine the where key COVID-19 response functions and their leadership occur in future and the health COVID-19 functions transfer work needs to be seated within this context.

81. Seeking independent facilitation by PwC has created momentum around the COVID-19 functions transfer. We recommend maintaining this momentum and will come back shortly with the details outlined in the 'next steps' section.

ENDS.

Document 3

MINISTRY OF HEALTH
MANATŪ HAUORA

Briefing

Lifting importation and use restrictions on unapproved COVID-19 vaccines

Date due to MO:	6 April 2022	**Action required by:**	11 April 2022
Security level:	IN CONFIDENCE	**Health Report number:**	HR20220551
To:	Hon Chris Hipkins, Minister for COVID-19 Response Hon Andrew Little, Minister of Health		
Copy to:	Rt Hon Jacinda Ardern, Prime Minister Hon Grant Robertson, Minister of Finance Hon Nanaia Mahuta, Minister of Foreign Affairs Hon Aupito William Sio, Associate Minister of Health Hon Dr Ayesha Verrall, Associate Minister of Health Hon Peeni Henare, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Director-General of Health	S9(2)(a)
Maree Roberts	Deputy Director-General, System Strategy and Policy	S9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Document 3

Lifting importation and use restrictions on unapproved COVID-19 vaccines

Security level:	IN CONFIDENCE	**Date:**	11 April 2022
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Purpose of report

1. This report:
   a. provides advice on the current controls in place to manage the importation and use of COVID-19 vaccines not approved for use in New Zealand
   b. seeks your agreement not to continue the current prohibition on the importation and use of unapproved COVID-19 vaccines.

Summary

2. Access to safe and effective vaccines through the COVID-19 immunisation programme (the Programme), alongside other public health measures, remains a core part of our COVID-19 response.

3. COVID-19 vaccines are defined as 'medicines' under the Medicines Act 1981 (the Medicines Act). While the Medicines Act requires medicines to be approved first before general supply, there are some exemptions which can lead to vaccines being imported without having undergone an approval process to demonstrate their safety, quality, and efficacy for use in New Zealand.

4. In early 2021, when global and domestic COVID-19 vaccine supply was constrained, the Ministry was notified of increasing interest by s 6(a) [redacted] and the public to import and use unapproved vaccines in New Zealand. In April 2021, the Group Manager, Medsafe (under delegation from the Minister of Health) issued a Notice under section 37 of the Medicines Act to prohibit the importation and use of unapproved COVID-19 vaccines.

5. Over time, the national rollout of the COVID-19 immunisation programme and corresponding high rates of vaccine uptake, has reduced the interest in unapproved vaccines. There are also existing controls in the Medicines Act which officials consider will largely mitigate the current risk of the potential importation and use of unapproved vaccines.

6. The section 37 Notice expires on 27 April 2022, and officials recommend not extending the prohibition on the importation and use of unapproved COVID-19 vaccines.

We recommend you:

a) **Note** a Notice under section 37 of the Medicines Act is in force until 27 April 2022 to prohibit the importation, manufacture, packing, sale, possession, supply, administration or use of any vaccine for immunisation to prevent COVID-19.

b) **Note** the risks associated with unapproved vaccines and likelihood of their entry to New Zealand are low in the current context, given the mitigations under the Medicines Act 1981, restrictions on importers, and the successful rollout of the COVID-19 immunisation programme.

c) **Agree** not to extend the current prohibition on importing, manufacturing, packing, sale, possession, supply, administration or use of any vaccine for immunisation to prevent COVID-19. **Yes/No**

Hon Chris Hipkins

Minister for COVID-19 Response

10/4/22

Hon Andrew Little

Minister of Health

...../...../.....

Dr Ashley Bloomfield

Director-General of Health

5/4/22

Lifting importation and use restrictions on unapproved COVID-19 vaccines

Background

7. Access to safe and effective vaccines through the COVID-19 immunisation programme (the Programme), alongside other public health measures, remains a core part of our COVID-19 response.

8. COVID-19 vaccines purchased under our Vaccine Strategy [CAB-20-MIN-0229 refers] and administered through the COVID-19 Vaccine Immunisaton Programme (the Programme) have helped provide New Zealand's eligible population with protection against poor health outcomes from COVID-19. Every vaccine utilised in the Programme has been assessed by Medsafe for safety, quality, and efficacy prior to being made available.

9. In April 2021, the Ministry assessed the risks associated with the potential importation and use of COVID-19 vaccines not approved by Medsafe and purchased outside of the Vaccine Strategy as high. Subsequent action was taken to restrict importation of other COVID-19 vaccines to reduce this risk.

Existing regulation of COVID-19 vaccines and additional restrictions

All medicines require approval prior to use in New Zealand

10. Medsafe is the regulator of medicines and medical devices in New Zealand. It assesses the safety, efficacy and quality of medicines (including COVID-19 vaccines) before approving them, if appropriate for use in New Zealand. This process is comprehensive and follows international accepted guidance regarding the quality, safety, and effectiveness of medicines.

11. Companies wishing to supply a medicine in New Zealand must present extensive supporting information to demonstrate that its product is acceptable and meets all international standards and requirements under the Medicines Act. This prevents the New Zealand public from being exposed to poor quality, ineffective and counterfeit products.

12. There are exemptions under the Medicines Act which allow for the importation and use of unapproved medicines in limited circumstances. However, there are controls in the Medicines Act which apply to these exemptions. These controls reduce the risk of unsafe or low quality medicines being sourced outside of Medsafe approval and in this case, limit the likelihood of unapproved vaccines entering New Zealand. These controls include:

    a. limiting the importation and use of unapproved medicines by or for prescribers for administration to patients

    b. preventing the advertising of unapproved medicines to the public

    c. preventing the personal importation of unapproved medicines.

A section 37 Notice was introduced to completely prohibit the import, manufacture, packing, sale, possession, supply, administration or use of unapproved COVID-19 vaccines

13. In early 2021, when global and domestic COVID-19 vaccine supply was constrained, the Ministry was notified of increasing interest in the use of unapproved COVID-19 vaccines in New Zealand. The likelihood of importation and use by the public and s 6(a) s 6(a) n New Zealand was assessed as high.

14. Officials previously advised that despite the controls under the Medicines Act, there were considerable risks in allowing the importation and use of unapproved vaccines. The risks were outlined in advice to the Minister of Health [HR20210882], and are summarised below.

    a. **Safety risks:** COVID-19 vaccines not approved by Medsafe may expose people to poor quality, ineffective, unsafe and counterfeit products. Even if approved by other international regulators, they may not meet the safety assurance required for New Zealand. The import and use of unapproved vaccines may cause limited to no protection against COVID-19 and heightened risks of adverse events to unapproved vaccines.

    b. **Diversion of health resources:** to integrate unapproved vaccines into the Programme would negatively impact the roll out. This included the Programme's monitoring of recording of vaccinations, uptake, and national coverage. It would impact the safety training of practitioners and their rapid response to adverse vaccination events.

    c. **Other risks:** including risks to public confidence in the Programme, environmental concerns, and uncertainty on the liability for damages or injury. These concerns are detailed in the previous advice attached (see Appendix B).

15. The advice noted the existing regulatory controls were insufficient to ensure the safety or efficacy of vaccines sourced outside of Medsafe approval given the unprecedented demand for vaccines as a result of the pandemic [HR20210082 refers]. Certain benefits from the potential importation and use of unapproved medicines were recognised in previous advice, including the improved overall public and prescriber access to effective COVID-19 vaccines yet to be approved in New Zealand. However, on balance it was recommended that additional controls be implemented.

16. On 27 April 2021, a Notice was issued under section 37 of the Medicine Act to prohibit the importation, manufacture, packing, sale, possession, supply, administration or use of any vaccine for immunisation to prevent COVID-19 (see Appendix A).

17. The section 37 Notice can only be utilised once, for a specific time period not exceeding one year, and so will lapse on 27 April 2022. In order to extend the restrictions applied under the section 37 Notice, a section 11 Order under the COVID-19 Public Health Response Act 2020 would be required.

Proposal not to continue prohibition of COVID-19 vaccines

Officials are proposing that the Notice should be allowed to lapse with no extension to restrictions

18. The context around COVID-19 vaccines has changed and following the successful immunisation programme, demand for unapproved COVID-19 vaccines has reduced.

Officials consider that the controls in place without the section 37 Notice are sufficient to manage the potential risks in the current context.

The risk of importation of unapproved COVID-19 vaccines is much lower in 2022

19. The rollout of the Programme coordinated and directed a system wide response to meet public demand and need for COVID-19 vaccines. This has enabled a level of national immunisation coverage and protection against the impacts of COVID-19.

20. As a result, officials consider the likelihood of importation and use by the public to be much lower.

The current controls in place limit the remaining risks

21. As noted, the Medicines Act has provisions restricting the importation and use of unapproved medicines (including COVID-19 vaccines). The Act limits who can import and who can supply unapproved medicines. Organisations can only supply on the request of a medical practitioner for administration to a known patient under their care. Authorised prescribers can import for a patient under their care who is known to require the vaccine. In both instances, the Act limits importation or supply to health care professionals (either medical practitioners or authorised prescribers) who must ensure they provide healthcare of a professional standard and fully consider the risks and benefits of prescribing an unapproved vaccine.

22. The importation of COVID-19 vaccines is also very complex. The contractual and delivery requirements imposed by vaccine suppliers can be onerous. These include prerequisites for importation of meeting cost barriers, minimum dose delivery, cold chain management and complying with indemnity requirements.

23. Officials believe that in the current context, the provisions of the Medicines Act provide sufficient safeguards to manage the reduced demand for unapproved vaccines and their associated risks. Based on the this**, it is recommended that the current prohibition is not continued.**

Next steps

24. If you agree to our recommendation to not continue the prohibition on the importation, manufacture, packing, sale, possession, supply or use of COVID-19 vaccines then we will work with Medsafe and the Programme to manage the transition of the restriction and monitor for impacts on the vaccinations.

25. Officials note that the associated risks from the use of unapproved vaccines may change. The effectiveness of the above mitigations and constraints may change due to the evolving pandemic environment. Officials will continue to monitor the use of unapproved vaccines and advise whether a revised prohibition is required. If required, a future prohibition would likely be under a section 11 order under the COVID-19 Public Health and Response Act 2020.

ENDS.

Appendix A: Notice Under Section 37 of the Medicines Act 1981

Notice Under Section 37 of the Medicines Act 1981

Pursuant to section 37 of the Medicines Act 1981, the Minister of Health hereby prohibits the importation, manufacture, packing, sale, possession, supply, administration or use of any vaccine for immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 unless, in respect of a vaccine:

- the Minister of Health, or the Group Manager Medsafe (pursuant to delegation given by the Minister of Health) has given consent or provisional consent pursuant to sections 20 or 23 of the Medicines Act 1981; and
- the importation of the vaccine is made in accordance with all the conditions imposed by the Minister on giving consent or provisional consent and notified in the *New Zealand Gazette*.

The importation of the consented or provisional consented vaccine is, if relevant, subject to:

- the Director-General of Health, or the Group Manager Medsafe (pursuant to delegation given by the Minister of Health), giving their approval pursuant to section 24 of the Medicines Act 1981.

This notice does not apply to:

- a vaccine distributed for the purpose of obtaining clinical and scientific information with respect to its safety and efficacy approved pursuant to section 30 of the Medicines Act 1981.
- activities carried out by pharmacists in relation to packing, labelling and supply of the consented or provisional consented vaccine pursuant to section 26(1) of the Medicines Act 1981.
- a vaccine supplied in accordance with conditions that have been approved by the Group Manager, Medsafe, Ministry of Health under the Medicines Act 1981.

Note: This notice is valid for one year from the date of publication of this notice.

Dated this 27th day of April 2021.

DEREK FITZGERALD, Acting Group Manager, Ministry of Health (pursuant to delegation given by the Minister of Health on 11 September 2013).

Appendix B: HR20210882 - COVID-19 Vaccines – restricting importation and use outside the COVID-19 immunisation portfolio

Briefing

COVID-19 vaccines – restricting importation and use outside the COVID-19 Immunisation Programme

Date due to MO:	N/A	**Action required by:**	16 April 2021
Security level:	IN CONFIDENCE	**Health Report number:**	20210882
To:	Hon Andrew Little, Minister of Health		
Copy to:	Hon Chris Hipkins, Minister for COVID-19 Response Hon Ayesha Verrell, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General System Strategy and Policy	s 9(2)(a) [redacted]
Therese Egan	Principal Policy Analyst Public Health System Policy	
Chris James	Group Manager Medsafe	

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

COVID-19 vaccines

Restricting importation and use outside the COVID-19 Immunisation Programme

Security level:	IN CONFIDENCE	**Date:**	14 April 2021
To:	Hon Andrew Little, Minister of Health		
Copy to:	Hon Chris Hipkins, Minister for COVID-19 Response Hon Ayesha Verrell, Associate Minister of Health		

Purpose of report

1. This report provides the Ministry's risk assessment of the importation and use of COVID-19 vaccines that have not been approved by Medsafe and purchased by the Ministry; and action proposed to be taken to prohibit this importation and use except in tightly defined circumstances.

Summary

2. The Ministry has assessed the risks associated with importation and use of COVID-19 vaccines outside Medsafe approval, outside Ministry purchase and outside the national COVID-19 Immunisation Programme.
3. The likelihood of such importation and use is high – almost certain for small groups in New Zealand and probable for larger groups such as certain migrant communities.
4. The risks are considerable to the health and safety of people in New Zealand, to the effectiveness of the Immunisation Programme and to New Zealand's global role in promoting equitable access to vaccines and recovery from the pandemic.
5. The most effective and enforceable action to restrict importation and use is via a Gazette Notice issued under section 37 of the Medicines Act 1981. The Group Manager Medsafe has delegated authority from the Minister of Health to issue this notice. Based on the Ministry's risk assessment, planning is underway for such a notice be issued during April 2021.
6. This report provides the Ministry's risk assessment, reasons for added regulatory restriction and choice of regulatory mechanism, and plans for communication and dealing with issues that may arise. It invites any feedback you wish to provide by 16 April 2021.

Recommendations

We recommend you:

a) **Note** the Ministry's assessment that restrictions on importation and use of COVID-19 vaccines, outside those approved by Medsafe and purchased by the Ministry of Health, are necessary to support:

- health and safety of people in New Zealand
- immunisation programme effectiveness
- New Zealand's contribution to pandemic recovery.

b) **Note** that, based on this assessment, the Group Manager Medsafe is planning to issue a Gazette notice under section 37 the Medicines Act 1981 prohibiting importation, manufacture, possession, advertising, packing, sale, supply or use of COVID-19 vaccines under sections 25 and 29 of the Act, for one year.

c) **Provide** any feedback by 16 April 2021

Yes / No

I support the proposed course of action.

Maree Roberts
Deputy Director-General
System Strategy and Policy
Date: 12 April 2021

Hon Andrew Little
Minister of Health
Date: 15/4/21

COVID-19 vaccines

Restricting importation and use outside the COVID-19 Immunisation Programme

Background / context

7. The Government is offering COVID-19 vaccination free of charge for all people who can safely receive it. A COVID-19 Immunisation Programme (the Programme) is underway to deliver vaccine sequentially in order to support the elimination strategy, lower the impacts of outbreaks and protect those most at risk.

8. Progress towards recovery from the impacts of COVID-19 requires that health system resources are directed to the most effective, equitable and safe delivery of vaccine while maintaining the pillars of the elimination strategy. The Programme is designed to achieve this for the New Zealand population, and to support the countries of Polynesia in their rollouts within the same time period.

9. Over 2021, the Programme will offer vaccine free of charge to all people in New Zealand (or Polynesia, via Polynesian governments) who can safely receive it. The Government has secured a portfolio of four COVID-19 vaccine candidates, each in quantities sufficient to vaccinate the people of New Zealand and Polynesia, subject to approval by Medsafe.

10. Rolling out the Programme will be the biggest ever immunisation effort in New Zealand. It will take highly coordinated and directed health system efforts to ensure safe delivery. In the midst of the pandemic, development of these vaccines has been driven by speed and effectiveness rather than ease of deployment. Strict transport, storage and vaccination conditions and active safety monitoring are requirements of their use.

11. Now, in the early stages of the Programme, most people will have to wait for vaccination. Medsafe has granted provisional consent for one vaccine (the Pfizer/BioNTech Comirnaty vaccine) to be used for people 16 years of age and over, and has received applications for three other vaccines. Limited quantities of vaccine are being delivered now for those at highest risk and the vaccinator workforce and Programme delivery capacity are building up.

12. From mid-year, the Programme will be rolled out to all people in New Zealand who are 16 years and over. Planning is underway for full population coverage by the end of 2021 (subject to logistical challenges and on-going risks). While this is a very fast rollout for such a large programme, inevitably there will be people who are waiting some months to be offered vaccination.

13. It is possible that some people in New Zealand will wish to "jump the queue" and receive vaccine before those deemed to be at higher risk, or to use an alternative vaccine product that they prefer for various reasons based on a range of information sources. This paper examines the risks associated with importing or using vaccines outside the Programme and without Medsafe approval. It presents the Ministry's assessment that additional regulatory controls are required.

Risks with vaccine use outside Medsafe approval and the Programme

Likelihood of importation and use of vaccines not approved by Medsafe

14. Vaccines are medicines under the Medicines Act 1981 (the Act). They are required to be approved by Medsafe in order to be imported, supplied, prescribed or administered. However, there are exception provisions in the Act that allow importation and use of an unapproved medicine by, or for, a medical practitioner for a particular (named) patient under that practitioner's care.

15. In general circumstances, these provisions (in sections 25 and 29 of the Act) allow for uncommon clinical needs to be met when there is not a suitable approved product available. This is not the case with COVID-19 vaccines. The Ministry has acquired a portfolio of vaccines and there is sufficient vaccine for all people in New Zealand.

16. However, unless further regulatory controls are implemented, these provisions are almost certain to be used to import and supply unapproved COVID-19 vaccines. There have already been several enquiries from s 6(a) and migrant communities about importing unapproved vaccines developed or used elsewhere in the world.

Human health and safety

17. Use of vaccines outside Medsafe approval raises safety risks. Vaccines that do not have regulatory approval for New Zealand's situation may expose people to harm through poor quality, ineffective, unsafe and counterfeit products, and increase their risks should they contract COVID-19. The components of an unapproved vaccine could be falsified and contain no active ingredient or be adulterated or of poor quality and contain a potentially harmful or counterfeit ingredient.

18. In the absence of Medsafe approval, even vaccines approved by other prominent international regulators may not meet the safety assurance required for a New Zealand context. Emergency use authorisations, given by many countries, are based on a higher risk tolerance than is applicable in New Zealand. Medsafe approval is based on its usual criteria and is specific to the manufacturing sites assessed. (Vaccines with the same branding but manufactured in different sites are not approved.)

19. Unapproved vaccines also lack New Zealand regulatory oversight and controls during their use. COVID-19 vaccines are for the most part novel vaccines to a novel virus, and the ability to take regulatory action based on post-market monitoring is very important. Regulatory action could include, for example, extending or tightening the population groups for whom use is approved, or cancelling approval and instituting recalls if a serious concern was to arise, whether in New Zealand or globally.

20. Similar concerns exist with using outside clinical restrictions (so-called "off-label prescribing") for population groups for whom there is no supporting safety evidence (such as children) or where there are increased safety risks. There may be instances where individuals at heightened risk of COVID-19 impacts should not be denied access to vaccine because of clinical restrictions and the Programme is designed to allow for such instances.

Diversion of health system resources

21. As the largest ever immunisation effort, the Programme will require a concentration of health system effort to ensure quality and a timely rollout.

22. Effective rollout of the Programme includes intensive monitoring of and adherence to vaccine conditions of use. These conditions rely on the data and digital infrastructure, workforce, facilities and service design approach set up around the vaccines being delivered. This includes monitoring of vaccine uptake, supporting optimal timing for follow-up to receive a second dose, and track and trace information. Such monitoring and responsiveness cannot easily or efficiently accommodate other vaccines from outside the Programme.

23. Advice for health practitioners and individuals about vaccination, including how it interfaces with many pre-existing clinical conditions, cannot easily be provided for vaccines not being used in the Programme. Fewer vaccines being used makes it easier for practitioners to develop expertise, including rapid responses to any health concerns that might arise. More vaccines being considered would add pressure and potential for confusion for busy health practitioners involved in a large and complex vaccine rollout.

24. Active monitoring for adverse events with causality assessment, investigation and response is a particularly important requirement for these relatively new vaccines and the added complexity of additional vaccines could be difficult, time-consuming and ineffective.

25. The use of unapproved products creates additional professional and ethical obligations for medical practitioners under the Code of Health and Disability Services Consumers' Rights. These include enhanced requirements for patients' informed consent and to undertake proportionate research into the unapproved product and alternatives. Because responsibility and liability for adverse effects lies with the prescriber, enhanced documentation of decisions and consultation is recommended.

Undermining public confidence in Programme equity and effectiveness

26. With short supply of vaccine and delivery capacity in the starting stages, public confidence in the Programme requires continued confidence in the overall elimination strategy (that New Zealand continues to be safe from COVID-19) and acceptance that sequencing is fair and offers the best overall protection for the community (that the people who most need protection will be protected).

27. Instances of "queue jumping" are likely to undermine overall public confidence in the Programme and the Government's ability to lead our pandemic response effectively and fairly.

Undermining New Zealand's global leadership for equitable vaccine access

28. Any private importation of vaccines to New Zealand would risk undermining confidence in our promotion of equitable global access to safe and effective vaccines. New Zealand has been a strong advocate of vaccine distribution throughout the world including in developing nations, and for governments to donate or share vaccine doses to achieve

maximal protection against COVID-19. Private markets are likely to increase competition for doses, rather than promote their effective deployment.

29. The presence in New Zealand of non-approved vaccines could also, by association with New Zealand's overall reputation, increase the risk of unsafe and ineffective vaccine use elsewhere and delay global pandemic recovery. Regional pandemic recovery may be at particular risk as Pacific countries may be a geostrategic destination for donated vaccines.

Environmental risks

30. Certain COVID-19 vaccines in development around the world may be based on new biological organisms or material. Environmental Protection Authority review may be required prior to importation of vaccines that may contain hazardous substances and new organisms. This review may be missed without Medsafe's scrutiny.

31. Safe waste management and disposal of vaccines is required for safety of human health and the environment, whether or not hazardous substances or new organisms are involved. Good practice in waste management is built into the Ministry's purchase and management plans but may be lacking unregulated imports.

Liability for any injury or damages

32. COVID-19 vaccine suppliers in general are requiring those using their vaccines to indemnify them, in view of their rapid development of products during the pandemic. The New Zealand Government has provided this indemnity for suppliers of vaccines purchased by the Ministry of Health and approved by Medsafe. People in New Zealand have access to compensation and health care for any injury that might potentially occur.

33. Liability for any injury or damages to persons or the environment from unapproved vaccines is unclear.

Risk mitigation

34. Strong communication is key to reducing risks, focused on free vaccine for all, the benefits of vaccine being given first to those at high risk, and the ongoing importance of our elimination strategy.

35. Free access to vaccine for everyone in New Zealand will reduce, but not eliminate, demand for private importation. Cabinet has agreed to expand eligibility for publicly funded COVID-19 immunisation to everyone in New Zealand, regardless of immigration status. Some 270,000 people not generally eligible for publicly funded health services will be offered free COVID-19 vaccination. This includes temporary visitors, workers under the Recognised Seasonal Employers (RSE) scheme, s 6(a) [redacted] and people in New Zealand unlawfully.

36. Strong communication for all communities, stressing the importance of pulling together to support the team of 5 million, will reduce anxiety and promote confidence in the Programme and in New Zealand's overall response to COVID-19. Communication supports widespread understanding of the benefits of the Programme with its sequencing approach and the continued importance of public health measures and the elimination strategy.

37. In particular, information and support for health practitioners will increase the trusted information and support available to the public.

Requirement for additional regulatory controls

Current regulatory controls

38. Medsafe, as the New Zealand medicines and medical devices regulator, assesses the safety, efficacy and quality of medicines (including vaccines) before approving them, if appropriate, for use in New Zealand under the Medicines Act 1981. This Act provides for the regulation, classification and permissions for distribution and use of medicines, including vaccines, in New Zealand. The Medicines Act allows for the importation and use of unapproved medicines in New Zealand; importation by or for prescribers for administration to particular patients is permitted, and in general circumstances allows for uncommon clinical needs to be met when there is not a suitable approved product available.

39. The current regulatory controls are not sufficient to ensure the safety or efficacy of vaccines sourced outside of Medsafe approval. This is particularly true given the current unprecedented demand for vaccines globally, including in New Zealand.

Additional regulatory control options

40. Two options exist for additional regulatory controls – a Medicines Act notice (time limited) or a COVID Act order (less easily enforced).

41. Section 37 of the Medicines Act allows the Minister of Health to issue a notice prohibiting the import, manufacture, packing, sale, possession, supply, administration, or other use of medicines or medical devices of any specified description. The Minister of Health has delegated this responsibility to the Group Manager, Medsafe. The issuance of section 37 notices is rare, and the practice has been to proceed after there is policy agreement that the additional regulatory control is required.

42. A section 37 notice could be drafted to prohibit the importation manufacture, possession, advertising, packing, sale, supply or use of COVID-19 vaccines unless they are approved by Medsafe and imported by the Ministry of Health. This would would contribute to increasing uptake and efficient delivery of vaccines offered through the Programme and to lowering the risks that could lower compliance with public health measures to prevent spread of COVID-19.

43. The section 37 provision was exercised successfully in April 2020 to prevent the importation, manufacture, packing, sale, supply or use of any kits and/or other test materials intended for use as point-of-care testing for COVID-19 infection, or for post-infection confirmation, using an antigen or antibody detection system. The powers in the Medicines Act are substantial to deter, detect, enforce and prosecute offences. Communication routes for prescribers, suppliers and other key parties are well established.

44. However, the section 37 provision can only be utilised once, for a specified time period not exceeding one year. A section 11 order under the COVID-19 Public Health Response Act 2020 (COVID Act order) was required for test kits when the 12-month period expired and continued prohibitions were needed.

45. A COVID Act order contributes to preventing the risk of outbreak or spread of COVID-19 by requiring people to take, comply with or refrain from actions, activities or measures. A COVID Act order could be used to effect the same prohibitions and exceptions available through a Medicines Act notice. While a Medicines Act notice is preferred at this time because of its specificity and wellestablished powers, processes and communication systems, a section 11 order could be used in future should a longer timeframe be required.

Specific exceptions to the recommended prohibition

46. Specific exceptions to prohibition will be few and, we anticipate, able to be tightly managed through existing processes (eg, for research) or through Programme design and management (eg, for unusual clinical indications).

47. Clinical trials of vaccines would remain permitted and subject to Medsafe approval, on the recommendation of the Health Research Council of New Zealand, under section 30 of the Medicines Act.

48. There may be rare clinical situations where a certain vaccine delivered through the Programme cannot be used. The recommended approach will be for another vaccine that is available to the Programme to be considered, where applicable. (It is likely that, in the coming months, other vaccines the Government has purchased in advance may be approved by Medsafe and available to the Programme.)

s 6(a)

[redacted]

s 6(a) [redacted]

Equity

53. The Ministry's risk assessment has considered equity of outcomes in New Zealand, as promoted through the Immunisation Programme and sequencing framework. Deviation from the Immunisation Programme may have a negative effect on equity of protection from the impacts of COVID-19 afforded by vaccination by diverting health system resource and attention. In the same way, it may impact equity of recovery from COVID-19 across communities in New Zealand and in our neighbouring Pacific countries.

54. The risk assessment has also considered global equity through access to vaccination and recovery from the pandemic. New Zealand has played an influential role in supporting the World Health Organization and Gavi, the vaccines alliance, in promoting equitable access to vaccines. This work continues, such as in working towards a mechanism whereby countries can share vaccine doses through the COVAX Facility.

Next steps

55. Medsafe is drafting a section 37 Gazette Notice that would prohibit importation, manufacture, possession, advertising, packing, sale, supply or use of COVID-19 vaccines under sections 25 and 29 of the Act, for one year. In line with any feedback you provide on this report, such a notice would be issued together with associated communications for suppliers, prescribers and practitioners.

56. The Ministry will continue to update communications for the public, health practitioners and particular communities that emphasise the benefits for the whole community of the Government's COVID-19 Immunisation Programme and continued adherence to public health advice.

s 6(a) [redacted]

ENDS.

Briefing

Strategic planning for potential new variants of concern: Scenarios, planned responses and next steps

Date due to MO:	28 April 2022	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	20220674
To:	Hon Dr Ayesha Verrall, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, System Strategy and Policy	s 9(2)(a)
Dr Ian Town	Chief Science Advisor	

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Strategic planning for potential new variants of concern: Scenarios, planned responses and next steps

Security level:	IN CONFIDENCE	**Date:**	28 April 2022
To:	Hon Dr Ayesha Verrall, Associate Minister of Health		

Purpose of report

1. This report provides initial advice on strategic planning for new COVID-19 variants of concern that may emerge, including detailed scenarios and proposed responses that have been reviewed by the Strategic Public Health Advisory Group (SPHAG) and COVID-19 Technical Advisory Group (TAG). The report also covers how this work relates to other relevant strategic work underway and provides information on next steps. The content in this Health Report will inform the development of the COVID-19 variants of concern plan.

Summary

2. We are currently working to develop a COVID-19 variants of concern plan, responding to the likelihood that New Zealand will be faced with a new variant of SARS-CoV-2, potentially within the next few months.

3. Given the inherent uncertainty in planning for new COVID-19 variants of concern (we cannot predict the likely severity or transmissibility) we have based planning around five proposed scenarios. These scenarios are based on evidence and informed by global approaches to scenario planning. These scenarios range from:

    a. Scenario 1: High clinical severity and high immune evasion (worst case scenario)

    b. Scenario 2: High clinical severity and low immune evasion

    c. Scenario 3: Low clinical severity and high immune evasion

    d. Scenario 4: Low clinical severity and low immune evasion

    e. Scenario 5: Multiple co-circulating variants.

4. These scenarios are intended to be representative, and any planning will need to consider key contextual factors and the specific genetic characteristics of any further variants to inform the response.

5. Based on these scenarios, we have proposed high-level health system responses for your consideration based on a first principles approach. The proposed responses include consideration of vaccination and therapeutics, surveillance and testing, border measures, contact-tracing and infection prevention and control (IPC) measures as well as other measures including capacity limits. Appropriate alignment of these measures to each

scenario requires more detailed planning and will be expanded on in the variant plan to inform operational planning, as well as include further detail around global responses and the legal framework.

6. Given timeframes, we are concurrently developing the initial variant of concern plan for delivery on 6 May 2022, before completing targeted engagement in the following fortnight with Iwi leaders, regional leaders and public health experts from the COVID-19 Technical Advisory Group and the Strategic Public Health Advisory Group. The intention is to have a finalised variant plan in for Cabinet consideration by June 2022.

Recommendations

We recommend you:

a) **Note** that we are preparing responses based on 5 potential scenarios: **Noted**
   - High clinical severity and high immune evasion
   - High clinical severity and low immune evasion
   - Low clinical severity and high immune evasion
   - Low clinical severity and low immune evasion
   - Multiple co-circulating variants of concern.

b) **Note** that responses will need to be considered against variant characteristics, including incubation period, infectious period, generation interval, propensity for chronic infection, and efficacy of vaccines, therapeutics and testing. **Noted**

c) **Note** that responses will need to respond to contextual factors too, including prevalence of the variant is in the community, the potential effect on vulnerable communities and the extent to which people are likely to comply with public health measures. **Noted**

d) **Note** that the Ministry of Health has undertaken initial policy research on global variant planning and are working with the Ministry of Foreign Affairs and Trade to learn from comparative jurisdictions. **Noted**

e) **Note** that the Ministry of Health will deliver an initial version of the variant of concern plan by 6 May. **Noted**

f) **Note** as part of developing a variant plan, the Ministry of Health will work with other relevant agencies to identify and plan for public health measures that may need to be deployed in each of the scenarios. **Noted**

h) **Note** that the Ministry of Health will be conducting targeted engagement based on the initial draft of the variant plan, including with Iwi leaders, regional leaders and public health experts. **Noted**

i) **Note** that we will develop a Cabinet paper for consideration at the Social Wellbeing Committee on 8 June, followed by Cabinet Committee on June 13 2022. **Noted**

Dr Ashley Bloomfield
Director-General of Health
Te Tumu Whakarae mō te Hauora
Date:

Hon Dr Ayesha Verrall
Associate Minister of Health
Date:

Strategic planning for potential new variants of concern: Scenarios, planned responses and next steps

Background / context

New variants of concern need to be considered due to the high mutagenicity of SARS-CoV-2

7. The emergence of new SARS-CoV-2 variants of concern is a threat globally due to the high mutagenicity, high levels of infection globally (particularly in populations with a large number of immunocompromised people), waning natural and vaccine induced immunity, and the possibility of animal reservoirs. Accordingly, new SARS-CoV-2 variants of concern are expected to emerge globally over the next 12 months and beyond.

8. A detailed review of the evidence around the potential mutation of the virus is included in Appendix 1. To date, SARS-CoV-2 and COVID-19 have been characterised by the rapid development of new variants, with "successful" new variants rapidly becoming dominant strains worldwide (Alpha, Delta, Omicron). All of those variants have had a transmission advantage over previous variants. The rapidity of the emergence and dominance of new variants is demonstrated by the replacement of Delta by Omicron BA.1 within about one month in New Zealand, and the subsequent replacement of BA.1 by BA.2 (different sub-variants of Omicron) within a similar period.

9. Because increased transmissibility presents a substantial evolutionary advantage to the virus, the pattern of increasing transmission advantage with each new variant is likely to continue. This transmission advantage would be enhanced further in the possible event that a new variant evades immunity to vaccination or previous infection. However, there is currently no evidence on the likelihood of particular scenarios emerging over other scenarios.

10. These new mutations or variants of concern need 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 look to shift to an environment where COVID-19 is likely to be endemic in Aotearoa New Zealand and globally. We know that it is unlikely that there will be a smooth transition, with it being possible that new variants of concern will emerge and that we will need to manage surges in case numbers, potentially alongside other infectious disease outbreaks.

11. In preparation for further new variants, we are developing a strategic health response, to ensure that preparedness actions have been considered and planned. The intent is also to support consistency in planning for the future, drawing on an evidence-based set of scenarios and responses that have been carefully reviewed and tested that can inform health responses and planning in other areas of government.

This work is informed by and relevant to a range of strategy and planning activities.

s 9(2)(g)(i)

13. We will work with Department of Prime Minister and Cabinet (DPMC), Ministry of Business Innovation and Employment (MBIE), and border agencies to ensure the plan to respond to variants of concern reflects the need for an all of government health 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.

Global responses

International scenario planning

14. We have considered global approaches in the development of our scenarios and proposed responses. For example, our scenarios broadly align to the Scientific Advisory Group for Emergencies (SAGE) from the UK scenarios for the emergence of new variants, and the World Health Organization's (WHO) *Strategic Preparedness, Readiness and Response Plan to End the COVID-19 Emergency in 2022*. There is consensus in these plans that milder variants are going to have lower severity and vaccines will remain effective while a worst-case scenario would have significant immune escape and high severity of disease. For comparison, the worst-case scenarios proposed by SAGE and the WHO are as follows:

SAGE:

a. Reasonable worst-case: 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:

b. Worst-case: Future variants are highly transmissible and able to evade vaccines and immunity requiring vaccine alteration and broader boosting.

15. 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.

International approaches to strategic planning

16. We have also considered global approaches to variant planning, and advice from WHO. The *Strategic Preparedness, Readiness and Response Plan to End the COVID-19 Emergency in 2022*. This report outlines a global strategic response to COVID-19 based around scenarios that include new variants of concern, and a proposed roadmap to inform national and local planning. The plan will consider these proposals as part of detailed planning. We will also continue to consider Temporary Recommendations issued / updated by the Director-General of WHO under the International Health Regulations 2005.

s 6(b)(i)

Global surveillance efforts

18. In planning for new variants of concern, global surveillance efforts will also be vital to the early identification and response to new variants. We have processes in place to send and receive early notification from / to the WHO under the International Health Regulations (IHR) that requires the notification of new variants of interest and variants of concern. Our response will also be informed by other global surveillance efforts including:

    a. 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.

    b. 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.

19. These global efforts are a key part of the response, and under the IHR all member countries have committed to strengthening global surveillance efforts and increase the sharing of information.

20. Recent discussions with the WHO have 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 have used scenarios to manage the inherent uncertainty in planning for new variants of concern

The process to develop scenarios

21. Scenarios have been developed to inform the potential range of responses that may emerge. We know in reality there may be particular characteristics that may change plans, and any decisions are likely to be made before a detailed evidence base is formed. However, they can inform a framework of likely responses.

22. The scenarios are based on research around the likely characteristics of new variant scenarios and their genetic characteristics, including research into similar scenarios that other countries have used.

23. They have then been externally reviewed by COVID-19 Technical Advisory Group and the Strategic Public Health Advisory Group. However, due to the more substantive nature of the Strategic Public Health Advisory Group's comments and timeframes, some of these are still being considered. Their comments will be reflected where appropriate for the variant plan.

The scenarios are based on assumptions including transmission advantage, and some prior immunity.

24. It is assumed that in all scenarios there is a transmission advantage (increased R_{eff}) for the new variant, due to changes in features of the infection (e.g., increasing rate of viral shedding, increasing duration of infectiousness, increasing asymptomatic period or asymptomatic proportion of people) and/or immune escape. For each new variant it will take a period of time to establish the scenario into which it falls.

25. We have assumed that in the scenarios there is also degree of prior immunity. 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 exhibits mild disease in individuals with vaccination or prior infection, but can be severe in unvaccinated individuals.

Five scenarios are being used, ranging from high clinical severity and high immune escape to low clinical severity and low immune escape, and one that includes co-circulating diseases

26. We have considered five scenarios, all of which assume a highly transmissible variant, and one scenario is included with co-circulating variants of concern similar to the situation with influenza currently.

27. The scenarios are:

    a. Scenario 1: High clinical severity, high immune evasion: similar to Omicron but with greater severity. Therapeutics, vaccines and/or prior infection may not work well.

    b. Scenario 2: Low clinical severity, high immune evasion: similar to Omicron. Therapeutics and vaccine may not be effective at controlling spread or symptoms, but hospitalisation rates remain manageable.

c. Scenario 3: High clinical severity, low immune evasion: the virus is highly transmissible with high case numbers, but current effective immunity and vaccination is protective for most.

d. Scenario 4: Low clinical severity, low immune evasion: the virus has enough transmissibility to create a high case load, but current effective immunity is protective and what disease there is, is milder than experienced in previous waves. Effective treatments are available for vulnerable populations.

e. Multiple co-circulating variants of concern with different levels of severity and different levels of cross-protection, as we see with influenza. This scenario potentially draws features from the other scenarios. Please note, the response to co-circulating variants is still being developed due to the complexity of this planning, and the need to consult on the response.

Any response would need to be informed by different genetic factors and contextual factors

28. There are a range of issues that will need to be accounted for that could apply to all scenarios and these may impact on the response. For example, evidence of chronic infections or a longer infectious period may lead to a more severe response. These are outlined in the below:

Table 1: Issues that could be present in all scenarios

Changes to viral dynamics	**Testing**	**Efficacy of therapeutics**
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 **Longer infectious period:** Particularly if this is asymptomatic, could lead to more transmission **Shorter/longer generation interval:** This may 'condense' or 'lengthen' an outbreak and have implications for the health system (by raising or lowering peak) and the amount of time it takes patient to recover. **Chronic infections**. If a variant is able to set up chronic infections in patients there is the potential for it to further adapt to evade the immune system and/or antivirals. **New variants of concern** may be able to infect other animals and set up new reservoirs.	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. Some testing procedures may be affected (e.g., S-gene dropout) 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 Wastewater testing may detect variants prior to detecting it in the community. Improved genome-based global surveillance systems may enable a effective early warning system for new variants.	Although selection pressure for treatment resistance is not yet high, variants of concern that evade immunity, may also evade antibody-based therapeutics Escape from other 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

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

a. Is or may the variant already be in the country? And if so, what is the known prevalence?

b. Is the disease appearing severe enough to warrant consideration of implementing quarantine requirements – either through self-quarantine or a Managed Isolation and Quarantine facility?

c. How would the new variant affect vulnerable communities or those that experience inequitable health outcomes?

d. How willing are citizens to comply with significant restrictions on public health grounds?

e. Is the rate of transmissibility likely to be contained with measures that are acceptable to the public?

Planning will need to factor in the absence of detailed information

30. The variant plan will include a process for information gathering and management in the period before the scenario becomes clear. For each new variant, it will take a period of time for researchers to determine the features and epidemiological characteristics of the virus, and therefore the threat that the new variant poses.

31. As an indication of timeframes, in the 2-4 weeks following initial detection of the Omicron variant, anecdotal findings and early data gave indications on the transmissibility, immune evasion and severity characteristics of Omicron. However, strong epidemiological and clinical data to support these findings only emerged in the 1-2 months following detection.

32. In the past, decision making has been supported by the use of MIQ and depending on initial indications may highlight the need to re-establish MIQ facilities at scale or consider border measures. However, with more open borders it will be more challenging to employ the same 'wait and see' approach. It is likely that a highly transmissible novel variant would rapidly enter and potentially become established. In the variant plan we will explore the thresholds for the potential use of MIQ facilities or other border measures.

Plans to respond to new variants of concern

33. Based on the scenarios, we have taken a first principles approach to potential public health responses for each of the scenarios, however the proposed response to scenario 5 (multiple co-circulating variants of concern) is still being developed and tested.

34. This planning is intended to assist preparedness and planning. However, given the unpredictability of the virus, it will only be a basis for advice on responses to new variants.

35. The initial proposed responses to each of the four scenarios is outlined in Appendix 2, and we have summarised the high-level responses in the table below.

Table 2: Summary of proposed responses to scenarios 1-4

	Scenario 1: High clinical severity, high transmissibility	Scenario 2: Low clinical severity, high transmissibility	Scenario 3: High clinical severity, low transmissibility	Scenario 4: Low clinical severity, low transmissibility
Vaccination and therapeutics	If an additional dose of the existing vaccine is effective against a new variant then will need to consider if it is worth buying time to increase coverage. In this situation there would be a focus on maximising coverage in existing eligible groups. If a new vaccine is required, and there would be unacceptable levels of mortality, then border closures and lockdowns may be required while new vaccines are developed. Many therapeutics are variant dependent, with Paxlovid being the notable exception. This is unlikely to affect decision making.	If an Omicron-like variant occurs but there are no effective vaccines or therapies available in the short-term, and current levels of immunity are less effective, then protecting vulnerable populations with non-pharmaceutical interventions becomes the focus. If an Omicron-like variant occurs again and an effective vaccine is available, then the goal will be to vaccinate priority populations, protect vulnerable groups, and reduce community transmission through other measures until that is achieved and protect vulnerable communities. Respond to changes in the virus and emerging evidence on boosters or new vaccines	If an additional vaccination is determined to be beneficial for priority groups, then some non-pharmaceutical measures would be introduced to protect the vulnerable and some lighter-touch community measures may be used (e.g., masking in indoor public venues). If the current definition of 'up to date' provides sufficient protection against severe disease, then as with scenario 2, some additional layers of protection, Public Health and Social Measures (PHSMs) should be considered for vulnerable groups, e.g., masking, testing to enter ARCs etc.	The new variant would be monitored, and no significant response would be required. Vulnerable groups may continue to require additional layers of protection, where appropriate e.g., indoor masking at aged care facilities, and continued focus on vaccine coverage. One feature of this scenario that should be evaluated, however, is the degree to which infection with this variant provides an additional layer of protection from reinfection. This may be important if we move to an 'influenza' scenario of co-circulating variants of concern (Scenario 5).
Testing and surveillance	In general, surveillance would have a greater emphasis on sensitivity including the use of PCR tests and waste-water surveillance Border surveillance of arrivals may aim to identify all cases for a period of time. Community surveillance would focus on protecting the vulnerable, and detecting the emergence of the variant in the community- particularly through targeted whole-genome sequencing e.g for ICU cases, and healthcare and aged care workers. WGS would be a vital part of surveillance, particularly at the border and identifying cases in the community e.g through hospital admission. Would need to assess the effectiveness of RATs and LAMP tests against a new variant.	If vaccines are not effective, PCR testing at aged care facilities, PCR testing and whole-genome sequencing in hospitals potentially for vulnerable patients and their visitors and caregivers. Surveillance would continue at the border. If vaccines are effective, it is likely that there would be heightened surveillance at aged care facilities and hospitals.	For a period of time, there may be heightened surveillance (PCR and WGS) at the border and in hospitals and ICUs to monitor the spread of the new variant. Wastewater testing for the new variant would be adapted. As with scenario 1, the new variant would be assessed for testing types.	
Border measures	Border measures may need to be considered if there is significant value in preventing or slowing the entry of a new variant. Depending on the situation, we could consider a combination of the following measures: • Closing the border • Re-instating managed isolation • Self-isolation • Pre-departure testing • Testing at the border These measures could also be targeted to specific countries if they were seen to be of greater risk.	Ongoing border surveillance, particularly in the event of no effective vaccines.	No border measures in place, although if the potential for harm is considered high enough border measures may be used.	
Contact tracing	With initial cases of the variant identified via WGS, intensive contact tracing of cases could be used to identify source and limit transmission, in conjunction with capacity and gathering limits. Case numbers expected to increase quickly, rapidly reducing the effectiveness of contact tracing due to the high level of transmissibility. With large case numbers, focus amalgamate with existing approach to Omicron response to identification of priority settings and support priority populations to access health services.	Maintain existing Omicron response, including contact tracing arrangements, which focuses on identification of priority settings and support priority populations to access health services.	Low transmissibility would support intensive contact tracing of cases identified through WGS to identify source and limit or eliminate transmission.	
Infection Prevention and Control measures	PPE will be widely utilised across health and disability settings Widespread used of 3 ply medical masks or face masks may become a priority with coverage and mandates changing Capacity limits may also need to be considered.	PPE will continue to be utilised across health and disability settings. Masks in public spaces in both scenarios- until levels of effective vaccine coverage increases Potentially consider some capacity limits depending on the time to the vaccine or the severity in some populations.	Masking would be considered for indoor venues if the vaccine wasn't effective, while mask use may be limited to aged care facilities and similar settings if it was.	
Other	Review CPF in light of variant characteristics to ensure it is still fit for purpose, and if in place, consider shifting back to red. It is likely that more intensive case management for severe cases would be required. We would also need to review isolation requirements for cases, as they may need to isolate for longer.			

Operational planning will form an important part of our response

36. We have commenced detailed operational planning to inform the development of the variant plan. The intention is to provide a detailed breakdown of the responses in each scenario at different stages and key decisions to be made. For example when a new variant is identified overseas, decisions around preventing entry to New Zealand may need to be considered, through to potential responses in the post-peak period. At this time, it may be appropriate to consider relaxing any public health measures in place.

37. As part of this detailed planning, we will also be considering:

    a. how each of these responses will impact on Māori and support equity of outcomes, and where specific responses may be required.

    b. the impact on hospitals, the health system more broadly and initiatives like Care in the Community and what we may need to do to manage demand.

    c. any actions that need to be undertaken to ensure that we are prepared, including consideration of the legislative framework.

    d. cost implications relating to the responses.

38. We will also be working with other government agencies who are likely to have a role in the broader health response to inform planning.

Equity

39. Te Tiriti o Waitangi and equity considerations will be vital to the development of the variant plan. Engaging with Māori and other communities, particularly given they are at greater risk, has been shown to be very important to a successful health response to pandemics. New variants of concern are likely to impact vulnerable communities, particularly where there is lower vaccine coverage and higher co-morbidities, and detailed planning will need to reflect this.

40. Consistent with the principles underpinning long-term COVID-19 Strategy, this plan will need to:

    a. Meet obligations to Te Tiriti o Waitangi

    b. Support equity of outcomes via different approaches and resources.

41. In the development of the variant plan, we will clearly outline the impact of each scenario on Māori, and how Te Tiriti o Waitangi and equity will be central in our advice for responding and managing risks under scenario will be woven through the proposed responses. We will also provide more detail in the scenarios on how they will impact on potential communities, including where there is lower level of vaccination. This will include consideration of how national and regional responses will be impact communities differently.

42. As part of the development of the plan, we are engaging with the Iwi leaders Pandemic Response Group, and the Regional Leadership Group to test and develop the plan to ensure it is more responsive to Māori, and other communities who may be subject to inequitable outcomes.

Next steps

43. The scenarios and responses in this advice will inform the development of an initial version of the variant of concern plan that we will provide to you by 6 May, before being finalised by 25 May 2022.

44. As part of finalising the plan, we will seek to engage further with COVID-19 Technical Advisory Group, the Strategic Public Health Advisory Group, and work with DPMC to engage with the COVID-19 Pandemic Response Group and the Regional Leadership Groups.

45. We will also work closely with other agencies to test the proposed plan and ensure that ongoing strategic planning reflects this detailed consideration of variants of concern. The scenarios are also likely to inform key pieces of work, including DPMC led work on the post winter strategy, and MBIE's consideration of the ongoing National Quarantine Capability.

46. Alongside finalising the plan, we will develop a Cabinet paper on the proposed plan, including consideration of the financial implications. We are currently working to the following key dates:

    a. Ministerial consultation from 25 May to 1 June

    b. Lodging the Cabinet paper on 2 June

    c. Social Wellbeing Committee on 8 June

    d. Cabinet Committee on 13 June.

ENDS.

Appendix one: Evidence on the likely emergence of new variants of concern

47. SARS-CoV-2 and COVID-19 have 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]

48. 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. Although none of these have yet been identified in New Zealand, introductions of new BA.1 and BA.2 lineages from overseas continues and the inevitable introduction of new mutations.

49. 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.

50. SARS-CoV-2, as with many viruses, has an intrinsic ability to mutate frequently. This, coupled with extensive global transmission, means the 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.

51. 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 it's intrinsic transmissibility, ability to evade immunity or disease characteristics such as severity. Concerning SARS-CoV-2 variants can be classified in several ways:

52. 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]

53. 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, t treatments.

54. 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.

55. 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.

56. Many Omicron mutations associated with the spike protein were unexpected and had not previously been seen in any previously circulating variants. Concerningly, 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.

57. 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.

58. 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.

59. 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.

60. 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:

61. 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.

62. 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 have to have access to a large pool of susceptible individuals from those with some, or no, prior immunity.[8]

63. 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:

64. 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

65. 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

66. A variant associated with a higher likelihood of chronic infections (especially in immunocompromised patients) may generate further subvariants with unknown characteristics.

67. 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.

68. 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.

69. 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 the most vulnerable; 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.

70. 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 plan for less optimistic scenarios, as they still remain a possibility.[1]

71. 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]

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Appendix 2: Detailed information on the proposed responses to each scenario

Scenario 1: High clinical severity, high immune escape:

Overview

72. The scenario with high clinical severity and high immune escape is the worst-case scenario. Essentially, this situation is similar to the challenge New Zealand faced in March 2020 against 'wild type': a highly contagious respiratory pathogen with concerning severity and no effective vaccines or treatments are currently available. In that situation, the first challenge is to gather enough data, to determine if, indeed, the current vaccines and current levels of population immunity are insufficient, and the potential level of severity. If it is determined that there is sufficient risk that the health care systems and other functions of society may be overwhelmed, then the goal in that situation is to reduce transmission using public health and social measures (PHSMs). This would lessen the impact of the novel variant, until more data is gathered. Potentially, we may then have new vaccines available, or a be able to roll out a 'booster' program of current vaccines, depending on what the data indicates.

73. New vaccines were not implemented for either Omicron (increased immune escape) or Delta (increased severity) as the current vaccines remained effective against severe disease and the Omicron-specific vaccine showed little improvement over the original formulation in animal testing. However, time was required to roll out the immunisation program.

74. Severity of disease can be characterised in several different ways, but the primary metrics are mortality and hospitalisation. Use of ventilation, oxygen and ICU admissions can also be important measures of severity that may tend to be more robust than hospital admission. It is important to remember that mortality rates for COVID-19 tend to improve over time as clinicians and researchers learn how to prevent and treat infections. Severity may also vary from country to country based on several factors, including differences in demographics, health care systems, prior immunity, and prevalence of comorbidities.

75. The case fatality rate for COVID-19 (ratio between confirmed deaths and confirmed cases) has varied with time over the pandemic. It has been estimated at between 0.2% and 0.5% worldwide throughout the Omicron wave,[19] but is highly dependent on age and vaccination status. However, it is important to be prepared for the possibility of a more severe form of COVID-19. Increased severity has been observed in other coronaviruses in recent times. For example, the severity of the two emergent coronaviruses, SARS-CoV-1 (emerged 2003) and MERS (emerged 2012), are higher than SARS-CoV-2: approximately 10-20% of cases of SARS-CoV-1 required intubation and mechanical ventilation, and around 3% died. Like COVID-19, the risk of severe outcomes and death for SARS-CoV-1 was higher in the elderly and those with pre-existing conditions. The revised WHO estimates, based on data from four countries, came on the heels of a Lancet article in which researchers studied case records from Hong Kong and calculated a case-fatality ratio as high as 55% for patients aged 60 and older.[20] The case fatality rate for MERS is about 34%.[21] It is possible that there is some inverse relationship between severity and transmissibility as outlined above; but because SARS-CoV-2 has a relatively long period of infectiousness without symptoms necessarily

developing and because mortality occurs some weeks after infection, severity is not necessarily related to transmissibility for SARS-CoV-2.[22]

76. Modelling for a new variant associated with high severity and high levels of immune escape is being developed by COVID-19 Modelling Aotearoa (preliminary work, to appear). This will aid planning and preparation.

However, the situation now has several advantages compared to March 2020:

77. Some level of protection will already exist: The immunity that New Zealand has built over the last two years likely will provide some level of protection against severe disease, as the mRNA vaccines did for Omicron. Our effective immunity will not be starting from a naïve place. However, waning immunity, unvaccinated groups, and immunocompromised individuals should be considered; there will be a significant proportion of the population who remain highly vulnerable to severe disease. However, this scenario is assuming that a variant evolves that has enough immune escape that it challenges current vaccines and/or prior infection, and therefore requires new vaccines or a 'booster' rollout of the currently available vaccines. Even if we have access to effective vaccines, we may not have time to implement an immunisation program; we were fortunate with Omicron that three doses of the existing vaccine was protective, and that the booster program was already underway. Modelling may be helpful to understand the impact of any potential vaccination program, and was helpful in the case of Omicron.[23]

78. Nationally and internationally, there is better surveillance than in 2020, although some jurisdictions are beginning to significantly scale down surveillance testing and genomics, including the United Kingdom. Nonetheless, this will mean that we will likely have some advanced warning of a new threat. The genetic profile of a new variant with many concerning mutations will be uploaded to international databases sometimes days after the sample is taken and analysed. Nonetheless, it is quite possible that, without border restrictions, a new variant will already be circulating within the community by the time we are alerted to a new variant of concern internationally. Therefore, planning should account for the possibility that community transmission is already occurring; speedy identification and management of the cases may still be effective (as those tactics were in March 2020), particularly if the new variant has a modest transmission advantage over the prevalent variant. Furthermore, we have more knowledge of which mutations are associated with immune escape, and therefore we may have early warning of a potential immune escape variant. Therefore, within weeks we may have early evidence of immune escape and transmissibility. This is less true of severity; it is difficult to tell the severity of a new variant from the genetic profile and it takes 1-2 months for the data to accumulate.

79. However, early detection of variants causing severe disease can be obtained by sequencing severe cases, in particular all of those individuals who are hospitalised or admitted to ICU. The association of even a small number of severely ill individuals with a new mutation, may provide sufficient evidence to enact regulatory measures. These measures are discussed below.

80. Vaccines can likely be developed at event greater speed than the original vaccines against SARS-CoV-2. The first vaccines were developed in about 11 months. Now with RNA technology, vaccines can be developed for deployment in, potentially a few months, but with global demand it may be several months before they are available.

However, the FDA and others are planning for updating the vaccines for SARS-CoV-2 periodically, in a similar manner to the current process for the influenza vaccine.[24] Therefore, once that process is operationalised, there will likely be a vaccine for the current SARS-CoV-2 'season' in development. However, as with the current situation with the influenza vaccine, some prediction is involved and there is no guarantee of a good 'match' between the vaccine in development and the actual virus that occurs during the season. It is unknown at this point, whether that process will be an annual update, similar to influenza, or less frequent. 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.

81. New Zealand is more prepared for a pandemic: There are several pandemic measures in place, or that could be 'stood up' relatively quickly in order to respond to a new variant threat, such as contact tracing, MIQ and healthcare system preparedness measures.

There are several disadvantages compared to March 2020:

82. Speed of transmission: 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. Any new successful variant would have to be more transmissible than the existing predominant variants. As we have seen with Omicron, the speed with which a new variant can replace the old variants can be very swift; Omicron is estimated to have infected about 50% of the US population in about 10 weeks.[6] On the other hand, a new variant may also spread relatively slowly, on its way to becoming the dominant variant. For example, the new recombinant of Omicron sublineages BA.1 and BA.2 ("XE"), appears to have a relatively small transmissibility advantage of about 10-20% over BA.2, which means that it is destined to become the dominant variant (all else being equal) but it may be a relatively 'slow burn', over a period of some months.[25] Therefore, it is not the case that all new variants that are destined to become predominant will travel with the speed of the original Omicron. Therefore, we may have time to plan with a new variant, depending on the degree of transmissibility.

83. Degree of transmissibility may mean fewer public health measures are effective: A related issue to the speed of transmission, is that the degree of infectiousness of a new variant may be so great that some PHSMs may not be effective, including MIQ. With respect to Delta, PHSMs including MIQ were used in order to buy time to reach high levels of population immunity (above 90%). Notably, MIQ was effective in stopping the introduction of Delta into the community for an extended period of time, from May to August 2021. With respect to Omicron, effective vaccines were available, but substantial protection was only provided by 3 doses and therefore, again, it was important to buy time until sufficient numbers of the population (particularly the elderly) could receive 3 doses. Fortunately, the MIQ and other border restrictions were still in place at that time, which slowed, but did not prevent, the introduction of Omicron into the community within weeks. However, even though MIQ was far less effective, and there was a relatively short 'Omicron-free' period from December 2021 to January/February 2022, it was still enough time to ramp up the delivery of the third dose, particularly to the elderly and vulnerable, and this very likely had a substantial impact on the subsequent transmission and burden on the healthcare system.[23] It is important to note, that the most effective way of protecting the vulnerable is to reduce the overall risk, i.e., reduce the levels of community transmission if possible.

84. Loss of social licence: Understandably, as the pandemic has extended for over two years, communities may become less willing to cooperate with some public health measures, and as such there may be fewer public health 'levers' available, and/or the interventions that are still available may be less effective. Strong messaging would be required to attempt to gain general support of the population for further widespread restrictive public health measures. There will also be an ongoing need for research assessing population attitudes.

Responses:

85. In general, the response to a highly severe and immune evasive variant will be broadly similar to New Zealand's successful response to COVID-19 in March 2020 – with the addition of some existing effective immunity and pandemic preparedness already in place – when we also faced a novel infectious disease with a substantial case fatality rate and no vaccines were available. However, some PHSMs will likely not be available or as effective, e.g., MIQ, lockdowns.

Surveillance and Testing:

86. In general, surveillance would have a greater emphasis on high sensitivity (the ability of a test to correctly identify those with the disease i.e. low rates of false negatives) than during the Omicron outbreak, because of the increased importance of detecting any variant associated with high severity; when there is high risk to many individuals a sensitive test such as qPCR that identifies most cases would be preferred, e.g., ARC, hospitals, border. Depending on the severity, qPCR may be used in schools or certain workplaces.

87. Wastewater, in general a potentially sensitive indicator for determining presence and absence of SARS-CoV-2, would continue, and testing for the new variant would begin.

88. In general, the purpose of the test determines the level of specificity and sensitivity required. In general, both high sensitivity and specificity are important, but sensitivity becomes a primary focus the more severe the disease. Clinical diagnostics require high sensitivity to identify patients, as well as access to tests and results early in infection. Whereas surveillance and screening require high specificity (the ability of the test to correctly identify those without the disease i.e. low rates of false positives), particularly at low prevalence. Testing for entry into high-risk populations, e.g., ARC, hospitals, may require high sensitivity to detect a virulent variant.

Border surveillance:

89. *Objective*: It may be necessary to aim to identify all cases, for a period of time, similar to the situation in March 2020. The overall plan will be to keep out the new variant if possible, at least for a period of time, until more data is collected, e.g., on the magnitude of the threat, the severity, and/or until a vaccine is developed or rolled-out, depending on the situation. In essence, the plan may be similar to a 'keep it out' plan for the new variant, at least for some weeks while we assess the magnitude of the threat, and would need to be accompanied by the use of quarantine. As in March 2020, the focus for surveillance would be on arrivals, before sustained community transmission of the

variant has occurred. In order to achieve this, the focus of testing would be on highly sensitive tests, i.e., there would be increased use of PCR and WGS of border cases.

90. WGS should be carried out on all border cases for the same purpose as previously, during 2020: in order to track the spread, until it is no longer feasible and there is widespread transmission. However, given potential numbers of people crossing the border we may need to focus on targeted responses.

91. Wastewater variant surveillance, particularly in Auckland, Wellington, Christchurch and Queenstown would be a focus for the border. Wastewater testing is also important for variant surveillance of the community and regionally, for example in vulnerable and Māori and Pacific communities.

Community surveillance:

92. *Objectives*: 1) Identify the emergence of variants in high-risk populations e.g., elderly, hospital patients, healthcare workers. 2) Detect the emergence of the variant in the community. Hospital and ICU admissions should be a focus of community surveillance with a more severe variant, as cases in the community of the new variant will likely be detected here first. All cases hospitalised for COVID-19 and all ICU cases should have WGS performed. Routine surveillance PCR testing should be considered for healthcare workers, ARC workers and visitors.

93. A proportion of cases in the wider community should be sent for WGS, from the prevalence survey (if available) and/or the sentinel ILI surveillance locations.

94. In general, if severity is affected by the type of prior immunity (e.g., the disease is more severe for those who have not had prior infection), then data on seroprevalence or types of prior immunity in the population will be important in order to plan the immunisation programme that may be needed. The data available at that time on previous cases, serology information (seroprevalence study results if available), and vaccination status of the population will be reviewed to help characterise who is at the most risk from the new variant, including an estimate of the proportion of the population that may require (further) vaccination.

95. Some tests may be more or less effective depending on the variant. With regard to testing, generally, within 1-2 weeks of the notification of a new variant of concern, data will emerge internationally on the sensitivity and specificity of some tests and whether the new variant is able to be detected by the current testing procedures. WGS will generally be unaffected by the changes to the variant, but other testing such as RAT, LAMP, or testing that relies on a characteristic 'signature' in the genome may be less effective at identifying the new variant. For example, some considerations may be:

96. Testing modalities may be affected by the features of different variants. For example, strains with higher viral load tend to be easier to detect for RATs; or infections of variants that tend to proliferate in the nasal passage, throat or lungs, may lead to different test sensitivities depending on the sample type

97. Wastewater tests may take a few weeks to purchase new assays or otherwise adapt to detect new variants; globally there is demand for the same assay at the same time. This underlines the need for rapid decision making, particularly with respect to testing, soon after the notification of a new variant of concern.

Border measures

98. Closing the border was very effective in controlling the spread of SARS-CoV-2 within New Zealand. However, the ability to re-impose such sanctions may be extremely limited, unless there is clear evidence of a very substantial threat. However, Scenario 1 describes a variant with high severity and transmissibility, and, as such, this option could be given consideration in the most serious cases.

99. Border measures may need to be considered if there is significant value in preventing or slowing the entry of a new variant. Depending on the situation, we could consider a combination of the following measures:

    a. Closing the border
    b. Re-instating managed isolation
    c. Self-isolation
    d. Pre-departure testing
    e. Testing at the border

100. These measures could also be targeted to specific countries if they were seen to be of greater risk.

101. The information from previous waves will provide evidence of the impact, both economically, socially of closing the border and may be sufficient to make a rough estimate of the conditions that would be required to close the border. It would be useful to undertake further scenario modelling to identify the conditions in which closing the border may be required. Such modelling would consider the likely speed of the rollout. Socialising the concept of closing the border in the face of a significant threat may be useful.

Pre-departure testing

102. Pre-departure testing has almost certainly decreased the number of arrivals of individuals with infectious COVID-19 into New Zealand. Pre-departure testing is not without difficulties. In particular, there are substantial verification issues, practical difficulties for travellers from many countries, and test results are not reported to New Zealand. The science and technology for testing arrivals into New Zealand for SARS-CoV-2 has progressed substantially. However, to be effective, it is likely that PDT will also need to be associated with a form of isolation after arrival, as pre-departure testing alone will not stop cases arriving in New Zealand, it will just decrease pressure on the system.

103. Monitoring cases arriving into New Zealand for new variants is now in place. 80% of arrivals are giving valid New Zealand Traveller Declarations that enable monitoring of self-testing rates. Positive RAT results are referred to confirmatory PCR, and those

samples are shared with ESR for whole genomic sequencing. While adherence is less than 100%, this is building up to be a substantial sampling rate on arrivals, and work is continuing to improve adherence and reduce barriers to the flow of data and samples. Current WGS capacity is roughly enough to sequence most or all recent arrivals who report a positive RAT. Should case numbers surge, ESR will freeze samples and process relevant ones over the following two or three weeks would be possible. This would enable retrospective analysis of the risk of individuals arriving into the country with highly infectious and severe variants, targeted to arrivals from high-risk flights or country of origin.

Immigration Controls

104. Immigration controls decrease the number of people arriving into New Zealand and prioritises the arrival of Citizens and Residents, who have a right of re-entry. The implications of restriction in multiple sectors should be available from previous restrictions.

Managed Isolation and Quarantine

105. Managed quarantine or self-quarantine is likely to be a requirement for completion of border controls which aim to prevent the arrival of any infectious individuals into the country. It is highly unlikely that any system that does not include managed isolation will effectively prevent all cases of SARS-CoV-2 arriving through the border. It can be argued that managed isolation was highly efficient in preventing onward spread into the community, notwithstanding the burden on individuals and its many unpopular elements.

Vaccination

106. If the current level of vaccination is determined to be likely ineffective (for example, based on lab neutralisation data that is available within 1-2 weeks of a new variant being identified, as was the case with Omicron) then the following questions need to be addressed with the available data:

a. Will an additional dose of an existing vaccine be effective, particularly against severe disease?

b. Will a new vaccine be required and when will it be available?

107. It should be noted that there are important limitations to the neutralisation data that is available early on after a new variant is identified. Firstly, there is no 'correlate of protection' available, meaning that the level of antibody neutralisation estimated in those studies is interpreted relative to other variants, but there is no known level of antibody neutralisation that correlates to a particular vaccine effectiveness or level of protection for an individual. Secondly, the neutralisation studies tend to focus on humoral immunity, and not take into account cell-mediated immunity that may play more of a role in protecting against severe disease. Nonetheless, decisions early on in the identification of a more severe variant may be based on imperfect information.

108. If the existing vaccines are protective after an additional dose, then the decision will be made whether to 'buy time' with other measures in order to rollout the additional doses, prioritised to the most vulnerable, Māori and Pacific Peoples, and /or the wider community. The time it may take to implement an immunisation program relative to the speed of transmission, may impact its effectiveness. It is important to note that, in the case of Omicron, time for an additional fourth dose was required in order to protect the most vulnerable, including the elderly and immunocompromised.

109. If a new vaccine is required to protect against severe disease and reduce otherwise high mortality rates, then NPIs including potentially lockdowns and border closures maybe required until the new vaccine is available: this scenario is very unlikely, but it is a possible worst-case scenario. There would likely be a significant period of time before a new vaccine was developed and global supplies were sufficient.

Treatments

110. Generally speaking, three broad groups of therapies for COVID-19: (i) antivirals (e.g., Paxlovid, molnupiravir, remdesivir); (ii) virus-targeting monoclonal antibodies (e.g., Ronapreve, Evusheld); and (iii) anti-inflammatory agents (e.g., dexamethasone, tocilizumab, baricitinib). The first two groups have been found to most effective during the first 5-7 days of symptoms, although there are multiple practical issues to targeting and providing this treatment. The anti-inflammatory agents have an established role in hospital in those more severely unwell to reduce mortality or the need for ICU.

111. However, to date, there are only a few treatments that have been developed specifically to address SARS-CoV-2 infection that are currently effective. Omicron and BA.2, particularly, have shown that variants can blunt the effectiveness of therapeutics, especially monoclonal therapies. Paxlovid is a notable exception; this oral treatment that can be used in outpatient settings, is used extensively in the US and the UK. Lack of effectiveness against Omicron has been a problem for the virus-targeting monoclonal antibody treatments such as Ronapreve and Sotrovimab; however, so far, the immune evasion of Omicron has been less of an issue for the antivirals. Other aspects are currently a greater challenge for wider use of antivirals, e.g., limited supply, reaching people at most risk (e.g. unvaccinated), and early diagnosis.

112. However, in New Zealand and Australia, the treatments for COVID-19 have not relied on COVID-specific treatments for the bulk of the treatment, and to date this has not had a big impact on the decision to relax restrictions. Therefore, the impact of the immune evasiveness on treatments may not affect our decision-making process if a more severe and immune evasive variant occurs, unless new approaches emerge such as effective cocktails of anti-virals.

PPE

113. PPE has proved an effective barrier to infection, particularly in hospital or other clinical settings. PPE can be more or less effective depending on how and where it is used, but in general it is unlikely that the virus would evolve in such a way as to make PPE ineffective. With respect to masks, widespread use of more effective masks may become

a priority with a variant associated with more severe disease. Masks should be used in schools, and other indoor public spaces.

Contact Tracing

114. Similar to the Delta and Omicron waves, at least initially, contact tracing may be needed to identify source and limit onward transmission. During 'Delta', a more intensive contact tracing approach was taken with comprehensive management of all cases and contacts. It may be appropriate to consider this with initial cases of a new variant. At the point that the greater transmissibility results in a large volume of cases, contact tracing will be less effective at preventing onward transmission, and the system then shifts to a lighter touch 'Omicron' level of contact tracing, with greater self-management by both cases and contacts and resources redirected to support priority populations.

115. Changes in features of the virus associated with viral dynamics will impact the effectiveness of contact tracing, i.e., the incubation period (time from infection to symptoms), latency period (time from infection to infectiousness), generation interval (time between the infection in the first person to the onwards transmission to the second infected person), serial interval (time between the onset of symptoms in the infected person and the person they infect) and the duration of the infectious period.

116. A primary metric of the effectiveness of contact tracing is the proportion of contacts that are identified before they themselves become infectious. It takes time to identify contacts, however electronic tools supporting case investigation and contact tracing have decreased this timeframe. If a variant is highly transmissible and transmits *quickly*, then the contact tracing system can become less effective at limiting onward transmission, as we saw with the Omicron pandemic wave. The value in contact tracing then shifts to identification of priority populations to ensure that they engage and access the care they need from the health system and identification of priority exposure events.

117. As noted above, a new variant may not spread quickly; for example, the 'XE' recombinant is estimated to have a transmission advantage of ~10-20% but is spreading relatively slowly against the prevalent BA.2 variant. A more severe variant with this transmissibility advantage would allow more time for contact tracing to be effective, i.e., for contact tracers to identify the source of infection and identify contacts before they are infected.

Other

118. Capacity limits and other measures may be considered again temporarily until more information is available.

Scenario 2: "Omicron model" (low clinical severity, high immune escape)

119. This scenario is similar to the situation New Zealand faced with Omicron, although noting that in the case of Omicron an effective immunisation strategy was available (3 doses of mRNA vaccine) that substantially reduced the impact on the healthcare system. We need to consider the possibility that available vaccines would not be effective at reducing hospitalisation. However, if the severity is low given the current effective immunity in the population (prior infection and vaccination), the cost-benefit of any

potential new vaccines or other interventions is less clear-cut, and would need to be considered in this scenario. In the case of Omicron, it was clear that using NPIs to buy some time to roll out booster doses, particularly to the elderly, was likely to reduce burden on the healthcare system and reduce mortality from COVID-19. The main difference if another 'Omicron-like' variant were to occur again, relative to the current background of effective immunity, is the degree of prior infection in the community, which was not present in New Zealand in January 2022. This may mean that vaccinations may have less benefit compared to a comparator cohort that is vaccinated with prior infection. Vaccination may not be required or, alternatively, may be targeted at those vulnerable to the new variant (e.g., elderly, immunocompromised, and, potentially, those without prior infection).

120. If an Omicron-like variant occurs again and an effective vaccine becomes available, then the goal will be to vaccinate priority populations, protect vulnerable groups, and reduce community transmission until that is achieved. Therefore, the goal will be to slow or stop the spread temporarily until sufficient vaccination is possible. In general, as we have seen with Omicron, a variant that is 'mild' for the general population may still have severe consequences for the elderly, immunocompromised, Māori and Pacific Peoples, or other subgroups. Some NPI and public health measures may be used help control spread, reduce community transmission in order to protect the vulnerable. For example, until sufficient vaccination rates are achieved, there may be masking in public places some capacity limits should be considered, heightened surveillance at aged care facilities and hospitals.

121. If an Omicron-like variant occurs but there are no effective vaccines or treatments available in the short-term, then protecting vulnerable populations with PHSMs (Public Health and Social Measures) becomes the focus. For example, PCR testing at ARCs, PCR testing and WGS in hospitals potentially for vulnerable patients and their visitors and caregivers, PPE, masks in public spaces, potentially consider some capacity limits depending on the time to the vaccine or the severity in some populations. Surveillance would continue at the border.

Scenario 3: "Delta model" (high clinical severity, low immune escape)

122. In this scenario, a new variant appears to be associated with high rates of death and hospitalisations in unvaccinated people or those without prior infection; however, the current immunisation schedule is protective for most groups. In June-July 2021 when Delta was a threat, effective vaccinations were available but New Zealand needed more time to rollout the vaccinations to an immunologically naïve population. In general, this is not the case at present. However, as with scenario 2, we would need some period of time to determine if there was a positive cost-benefit for a roll-out an additional dose of a currently available vaccine.

123. If an additional vaccination is determined to be beneficial for priority groups, then some PHSMs would be introduced to protect the vulnerable (e.g., ARCs, hospitals) and some lighter-touch measures in the community to reduce transmission may be prudent (e.g., masking in indoor public venues).

124. If the current definition of 'up to date' provides sufficient protection against severe disease, then as with scenario 2, some additional layers of protection (PHSMs) should be considered for vulnerable groups, given the heightened risk for those not sufficiently protected by vaccination, e.g., masking, testing to enter ARCs etc.

125. Otherwise, in general, surveillance and other response areas would continue BAU. There may be some exceptions. For a period of time, there may be heightened surveillance (PCR and WGS) at the border and in hospitals and ICUs to monitor the spread of the new variant should be considered. Wastewater testing for the new variant would be adapted. As with scenario 1, the new variant would be assessed for testing types and modalities to ensure that it can be reliably identified with current testing.

Scenario 4: "'Omicron light' or RSV model" (Low clinical severity, low immune escape)

126. This scenario is included mainly for completeness. Essentially, BAU surveillance and other measures would continue, the new variant would be monitored, and no significant response would be required. Vulnerable groups may continue to require additional layers of protection, where appropriate e.g., indoor masking at ARCs.

127. One feature of this scenario that should be evaluated, however, is the degree to which infection with this variant provides an additional layer of protection from reinfection. This may be important if we move to an 'influenza' scenario of co-circulating variants.

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Document 5

MINISTRY OF HEALTH
MANATŪ HAUORA

Memo

Health National Adaptation Plan

Date due to MO:	N/A	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	20220015
To:	Hon Dr Ayesha Verrall, Associate Minister of Health		
Copy to:	Hon Andrew Little, Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Deborah Woodley	Deputy Director-General, Population Health and Prevention	s 9(2)(a) [redacted]
Sally Gilbert	Manager, Environmental and Border Health	

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Document 5

Health National Adaptation Plan

Security level:	IN CONFIDENCE	**Date:**	28 April 2022
To:	Hon Dr Ayesha Verrall, Associate Minister of Health		

Purpose of report

1. This report provides you with an update on the development of the Health National Adaptation Plan (HNAP) under the broader National Adaptation Plan.

2. This report discloses all relevant information.

Background

3. The Ministry for the Environment is required to publish a National Adaptation Plan by August 2022 and is seeking approval to consult on a draft National Adaptation Plan in April or May 2022.

4. The National Adaptation Plan sets out the Government's objectives, strategies, policies and proposals to adapt to the effects of climate change. The National Adaptation Plan includes actions for the health sector, one of which is the development of a Health National Adaptation Plan (HNAP).

Health Impacts of Climate Change in New Zealand

5. The health impacts of climate change are evident across the globe. In October 2017, the Royal Society of New Zealand Te Aparangi released a report on *Human Health Impacts of Climate Change for New Zealand*[1]. This report summarised how climate change will affect the health of New Zealanders. The impacts identified are:

   a. direct health impacts of climate change (increased flooding, fires and infrastructure damage, displacement and extreme temperatures)

   b. indirect health impacts of climate change (harmful algal blooms, microbial contamination, food security, mental health and wellbeing, outdoor air quality, carriers of new diseases, migration of tropical species into New Zealand)

   c. potential health benefits (reduced cold mortality, health co-benefits from mitigating climate change effects).

Development of the Health National Adaptation Plan (HNAP)

6. It is important that the health sector is prepared to adapt to the effects of climate change. The HNAP is intended to provide high-level strategic direction for climate change adaptation in the health sector, as well as set out adaptation actions to be taken at a national level within the health sector. The HNAP will:

[1] https://www.royalsociety.org.nz/what-we-do/our-expert-advice/all-expert-advice-papers/climate-change-and-health

a. enable an evidence-based response to the effects of climate change

b. support equitable health and wellbeing outcomes

c. set out roles and responsibilities for adaptation planning in the health sector

d. identify actions that can be taken at a national level to support adaptation planning

e. support co-ordinated health adaptation planning at a regional and local health level.

7. A draft strategy for the HNAP has been developed and is currently being reviewed by a Ministry of Health steering group. The steering group has been asked to particularly consider how the HNAP can demonstrate a commitment to Te Tiriti o Waitangi.

8. Once the HNAP strategy has been finalised, we will identify the actions to be taken at a national level to support adaptation planning. We are aiming to complete this work during 2022, in parallel with the National Adaptation Plan.

Regional Health Adaptation Planning

9. The HNAP strategy also provides a framework for health adaptation planning to be carried out at a regional and local level. Regional health adaptation plans will include regional climate risk and vulnerability assessments.

10. Some district health boards have started preparing their own adaptation plans. We are working through how health adaptation planning will be carried out following the Health and Disability Sector reforms. Health NZ and the Māori Health Authority may both have important roles to play.

Other Actions for Health in the National Adaptation Plan

11. In addition to the development of a HNAP, the National Adaptation Plan includes two other actions for the Ministry of Health. Both actions are already underway.

a. **Assess healthcare service resilience**
Work is underway on a national sector level climate risk assessment of 34 main hospital campuses. This information will feed into the HNAP and the regional climate risk assessments and adaptation plans. In addition, as noted above, assessing the resilience of health sector infrastructure will be part of future regional health adaptation plans.

b. **Continue with the reform of the health and disability system**
This action was added to the National Adaptation Plan after our weekly report update of 25 March 2022. Since this is aligned with the aims of the Health and Disability Sector Reforms, it has been included as an action in the National Adaptation Plan. There are other sector reforms included in the National Adaptation Plan, including the resource management system reforms, emergency management reforms, and welfare system reforms.

Equity

12. Climate change has the potential to exacerbate existing inequities in the health system. This can be minimised by planning to adapt to the effects of climate change. Improving equity is a key principle in the HNAP and, as well as trying to address the inequitable effects of climate change, the HNAP will seek to address some causes of systemic inequities to reduce the burden on the health sector and thereby make it more resilient.

Next steps

13. Ministry of Health officials will continue to:

    a. develop the HNAP and progress the work on the infrastructure climate risk assessment

    b. work with the Ministry for the Environment on the development of the National Adaptation Plan.

14. We will provide further updates in the weekly report, as appropriate, and we will forward a copy of the HNAP to you when the first draft is completed, anticipated to be by the end of September 2022.

Deborah Woodley
Deputy Director-General
Population Health and Prevention
Date:

Document 6

Memorandum

Aotearoa New Zealand's COVID-19 Variants of Concern plan: Initial version

Date due to MO:	6 May 2022	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	20220824
To:	Hon Dr Verrall, Associate Minister for COVID-19 Response		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Director-General of Health	s 9(2)(a)
Dr Ian Town	Chief Science Advisor	

Action for Private Secretaries

N/A

Date dispatched to MO:

Document 6

Aotearoa New Zealand's COVID-19 Variants of Concern plan: Initial version

Purpose

1. This covering memo accompanies the initial version of Aotearoa New Zealand's COVID-19 Variants of Concern plan (the plan). Please refer to Document 9 attached

Aotearoa New Zealand's COVID-19 Variants of Concern plan: Initial version

2. Planning for novel SARS-CoV-2 variants is underway with the completed plan due to be considered by Cabinet on June 13 2022.

3. As requested, you will find the draft initial plan for your consideration. This plan will be used to support engagement with stakeholders and will continue to be developed and refined up until 25 May.

Purpose of the plan

4. The purpose of the plan is to:

   a. support preparedness for the potential emergence of new variants

   b. enable rapid and considered decision making in a range of potential scenarios

   c. support response planning for new variants, initially for the health response, and the plan will inform broader planning by other agencies.

Contents of the plan

5. Attached is the initial draft version of the plan, which includes:

   a. global responses to new variants of concern

   b. strategic approach to new variants of concern

   c. how we are embedding Te Tiriti o Waitangi and equity principles

   d. scenarios to inform planning for new variants of concern

   e. responses to each of the scenarios

   f. enabling factors to be considered in the development of the plan.

Consultation

6. We will distribute key components of the plan for consideration to stakeholders identified for engagement, including the strategic framework, scenarios, response plan, Te Tiriti and equity sections and next steps.

7. We are in the process of planning targeted consultation. It is likely to include engagement with the following groups:

   a. The Māori Pandemic Response Group including Iwi leaders

   b. Strategic Public Health Advisory Group

c. COVID-19 Technical Advisory Group

d. Regional Leadership Group(s)?

e. Ministry of Health advisory groups, including

   i. Equity Oversight Group

   ii. Māori Monitoring Group

   iii. Disability Leadership Forum

   iv. Pacific Technical Advisory Group.

8. We will also work closely with other agencies to test the proposed plan and ensure that ongoing strategic planning reflects this detailed consideration of variants of concern.

9. The scenarios are also likely to inform key pieces of work, including the Department of Prime Minister and Cabinet's led work on the post winter strategy, and the Ministry of Business, Innovation and Employment's consideration of the ongoing National Quarantine Capability.

Next steps

10. The scenarios and responses in this advice will be finalised by 25 May 2022.

11. Alongside finalising the plan, we will develop a Cabinet paper on the proposed plan, including consideration of the financial implications.

12. We are currently working to the following key dates:

    a. Ministerial consultation from 25 May to 1 June

    b. Lodging the Cabinet paper on 2 June

    c. Social Wellbeing Committee on 8 June

    d. Cabinet Committee on 13 June.

13. We will provide you with a finalised plan on May 25, following targeted engagement and more detailed planning taking place over the next fortnight.

Dr Ashley Bloomfield
Director-General of Health
Te Tumu Whakarae mō te Hauora
Date: 5/5/22

Document 7

Memorandum

Variants of Concern planning and preparedness rationale

Date due to MO:	20 May 2022	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	20220921
To:	Hon Ayesha Verrall, Associate Minister for COVID-19 Response		

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Action for Private Secretaries

N/A

Date dispatched to MO:

Variants of Concern planning and preparedness rationale

Purpose

1. This memo provides further advice on the rationale for the Variants of Concern planning and preparedness work that is underway. DPMC have reviewed this memo.

What is preparedness - the WHO framework

2. On 30 March 2022, the Word Health Organization (WHO) published its Strategic Preparedness, Readiness and Response Plan for 2022. In the 30 March 2022 release, WHO sets out key strategic adjustments that, if implemented rapidly and consistently at national, regional, and global levels, will enable the world to end the acute phase of the pandemic. The capacity and adjustments necessary to end the acute phase of the COVID-19 pandemic can and should lay the foundations for a future in which the world is prepared to prevent, detect, and respond to pandemic threats.
3. The WHO information and strategic narrative has influenced New Zealand's suite of tools, data advice, guidance and public messaging that has held New Zealand in good stead over the last two years. In September 2021, WHO outlined the risk factors that could prolong the COVID-19 pandemic, including the "possibility that new variants will emerge with greater transmissibility and lower susceptibility to current vaccines; the inconsistent application of public health and social measures; the continued politicization and mixed messaging around proven and effective public health interventions; the global prevalence of misinformation about COVID-19 and COVID-19 tools such as vaccines; and crucially, inequitable access to and capacity to utilise COVID-19 tools such as vaccines".

Our ongoing response

4. The COVID-19 pandemic is far from over. The surge of new cases across the world caused by the spread of the Omicron variant has combined with gaps in immunity and the lifting of public health and social measures to put health systems and societies under renewed stress and strain.
5. As a country we must be vigilant for the evolution and spread of new COVID-19 variants and redouble our efforts to protect our health systems and health workers. We need our health systems and services to remain supported to recover quickly, and to build in resilience to future shocks.
6. We want to ensure that the lessons from the past two years drives improved pandemic preparedness, readiness and response, as both the context and the COVID-19 virus continue to change.
7. We have learned a lot about what does and doesn't work as we have tried to eliminate and then manage COVID-19. We also have the advantage of having a level of immunity from vaccination and people who have had Omicron, particularly against severe disease. We also

have public health measures in place, or that can be quickly activated, including detailed surveillance at the border and in communities.

8. We have modified and adapted our response through Alert Level settings in 2020 and 2021 through to our community response and COVID-19 Protection Framework in 2021 and 2022.

Preparedness

9. We are now planning for variants of concern based on science and insights and the frameworks established by the World Health Organization in their 30 March publication MoH has developed 5 plausible scenarios to assist and inform all of government planning, and high level health and disability system responses to these scenarios. DPMC is working on an all of government COVID-19 toolbox review and how these tools could be used for all of government planning
10. Preparedness planning is intended to support preparation for and provide quick responses to future variants and does not commit the Government to any measures at this stage.
11. Should a new variant of concern emerge, a Public Health Risk Assessments will remain the integral process by which we assess the situation globally and nationally and provide considered public health advice.
12. Alongside variants of concern we are planning for Winter preparedness. This year is the first winter in which New Zealanders will face with COVID-19 circulating widely in the community. This will have a significant impact on how winter pressures will be managed across the health and disability system.

Maintaining preparedness whilst adjusting our current response

13. When variants of concern reach New Zealand, we need timely and proportionate responses. As we step the COVID-19 response measures down, we need to plan to resume some measures in the future recognising and reducing any social or economic impact.
14. We are also able to make trade-offs through stepping down certain measures while maintaining or increasing baseline capacity in others.
15. For example, while we are removing border measures, including managed isolation and quarantine, visitors to New Zealand are required to test post-arrival and self-isolate if positive; and through increased whole genome sequencing of positive results our monitoring prepares us for any imported variant of concern.

Providing assurance that we can respond in future

16. Across government we need to provide assurance that we can respond to future variants of concern. To do this we are asking across government agencies to consider and operationalise the following questions for their preparedness planning, including:
    a) What would agencies be required to do/operationalise under these scenarios; and
    b) What capacity do they have/ require to be able to stand up within one week and maintain a response in accordance with the various scenarios; and
    c) What preparedness work needs to be done now to ensure each agency can respond to the five variant of concern scenarios?

17. This work will be led by DPMC who will put together an all of government operational preparedness plan.

Next steps

18. Work continues across the Ministry of Health on the preparedness planning for a variant of concern, based on the five scenarios.
19. DPMC are leading all of government work to determine the efficacy of wider tools/levers used in the COVID-19 response to date. This process will ensure that agencies can retain foundation implementation tools such as legislative frameworks, public facing information, and business constructs alongside social support mechanisms to activate if and when required against a future variant of concern.
20. All this work will be brought together for a Cabinet paper led by DPMC. There is a question about whether this will be a separate Cabinet paper tracking to the original timeframe of 13 June or included with the long-term strategy paper at the end of June. Regardless, the paper will build on the scenario work from the variants of concern planning with a whole-of-government view on operational preparedness.

Maree Roberts
Deputy Director-General
System Strategy and Policy
Date:

New Zealand Government

MINISTRY OF HEALTH
MANATŪ HAUORA

COVID-19

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

Effective June 8 2022

Previous versions	
Initial draft version	6 May 2022
Initial draft updated for engagement	11 May 2022

Engagement on the plan	
Strategic COVID-19 Public Health Advisory Group	18 May 2022
COVID-19 Technical Advisory Group	20 May 2022
COVID-19 Independent Continuous Review, Improvement and Advice Group	24 May 20222

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I. Glossary

Term	Definition
Clinical severity	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. 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.
Frame-shift	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. 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.
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.
R_0, Reproductive number	The reproductive number R0 (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	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):
	• Features of the infection such that each infected individual is likely to infect. For example, by:
	  o the rate of virus shedding
	  o the number of days where virus is shed (increasing duration of infectiousness), or
	  o 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:
	  o 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.
	  o a previously seen variant "re-emerges" due to waning of protection from vaccination or infection.

Variant	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.
Variant of Concern (VoC)	**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: • 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)	**WHO definition:** A SARS-CoV-2 variant: • 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)	**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.

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.

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	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). 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. 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.

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

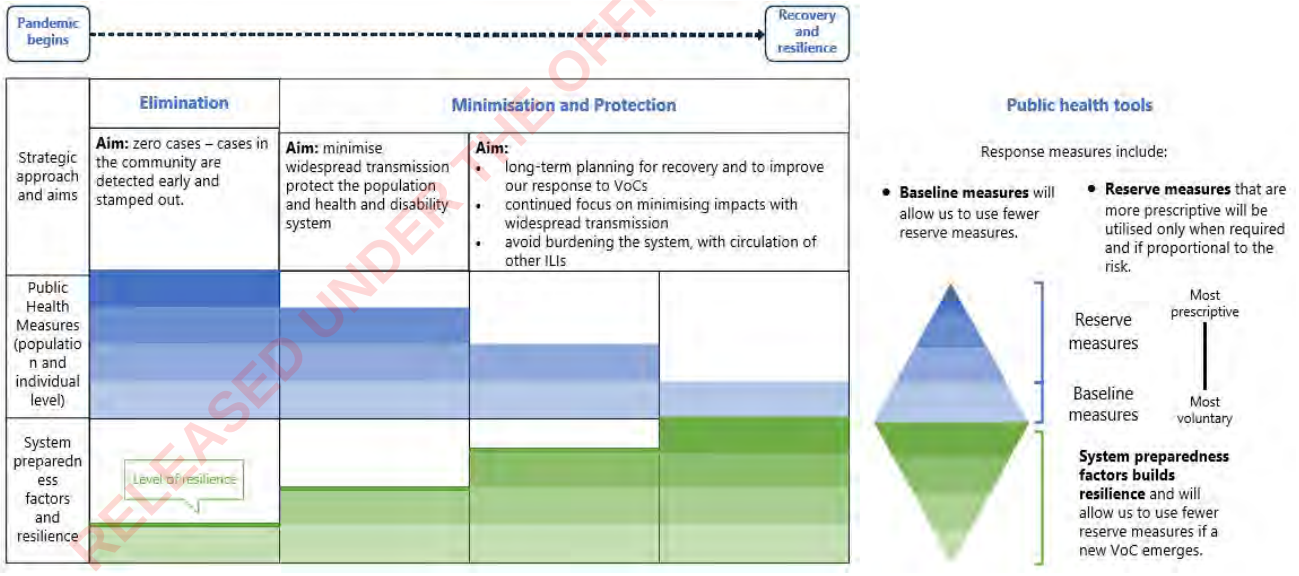
As the COVID-19 pandemic moves into its third year, Aotearoa New Zealand's health response has continually evolved as both the virus and our ability to manage it has changed. From our initial elimination strategy we have shifted to one of minimisation and protection. We have continued to refine our response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

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 $R_{o)}$) 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 which 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
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. **Longer infectious period:** Particularly if this is asymptomatic, could lead to more transmission. **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. **New Variants of Concern:** May be able to infect other animals and set up new reservoirs.	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. Some testing procedures may be affected (e.g., S-gene dropout)[1]. 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. Wastewater testing may detect variants prior to detecting it in the community. Improved genome-based global surveillance systems may enable an effective early warning system for new variants.	Although selection pressure for treatment resistance is not yet high, Variants of Concern that evade immunity, may also evade antibody-based therapeutics. 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.

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 would 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 variant[2]. Appendix 1 contains further detail on this.

[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 Team[3] 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 preferrable 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 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
- Isolation and appropriate use of sick leave
- Social distancing

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	• 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	• 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	• 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 groups s 9(2)(g)(i) [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	• 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.

Prepare communication plans, including targeted communication for communities	• 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.
Improve data collection, reporting and analysis	• 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.
Leverage contact tracing	• 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.
Surge Response Plan	• S9(2)(g)(i) [redacted]
Maintain surveillance capacity	• 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.
Laboratory device review and Innovation framework	• 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.

Contact tracing	• 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.
Leveraging our COVID-19 Variant responses and play book	• 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.
Leverage a proven COVID-19 surge Response Plan	• S9(2)(g)(i) [redacted]
Regulatory review of variant-specific versions of vaccines and treatments	• S9(2)(g)(i) [redacted]
Critical medical items supply	• 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)

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 Whakamaua: 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 hapori 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	Reasonable worst-case: 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	Worst-case: 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.

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.

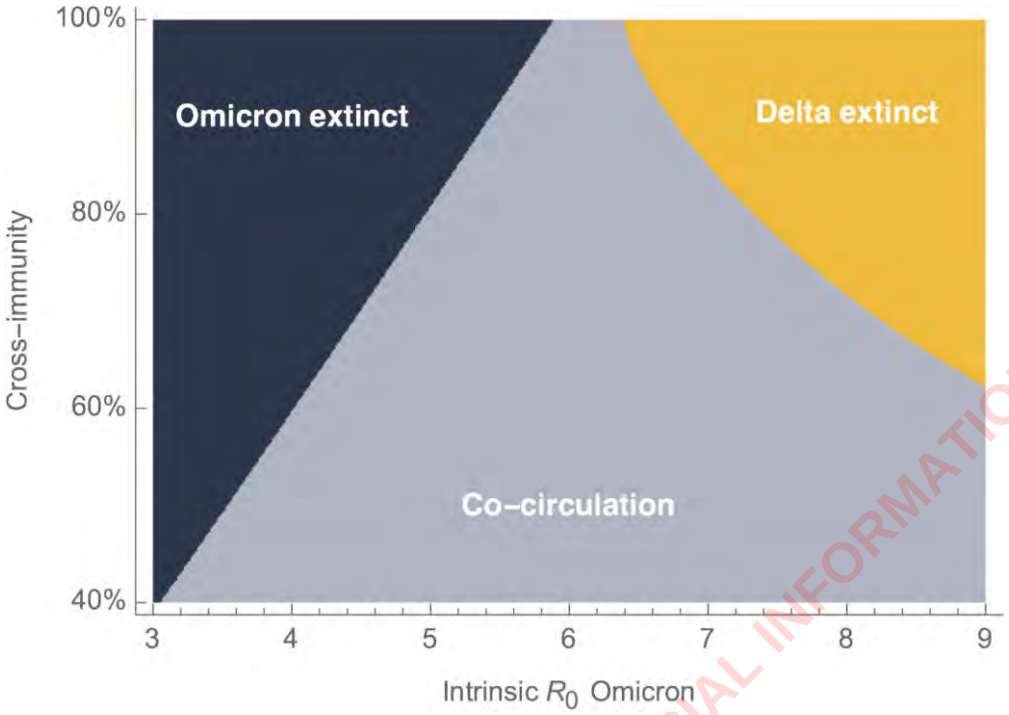
[5] This situation was common at the beginning of the pandemic with gradual replacement of the original SARS-CoV-2 variant with Beta in Africa, Gamma in South America, Alpha in Europe and Delta in India. The emergence of Omicron and other highly transmissible sub-variants has largely replaced previous 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 variant[4].

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 (R0) 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 BA4, BA5, and BA2.12.1. BA.4 and BA5 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 BA4 and BA5 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).

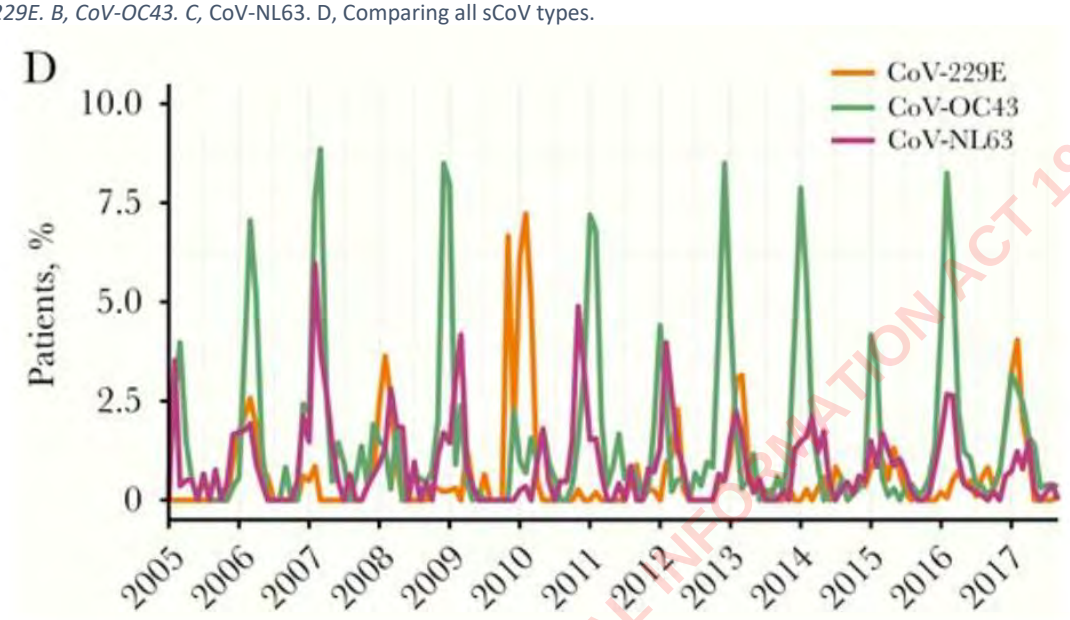
It is not yet known how SARS-CoV-2 will behave seasonally, and the extent of any cross-protection from future circulating coronaviruses.

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 R0 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 region20) if the cross-immunity was low or if Omicron's R0 was similar to Delta's (R0=6). If cross-immunity from Delta was high and Omicron's R0 was relatively low compared to Delta's, then Omicron would become extinct (dark blue); conversely, if cross-immunity was high and Omicron's R0 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.



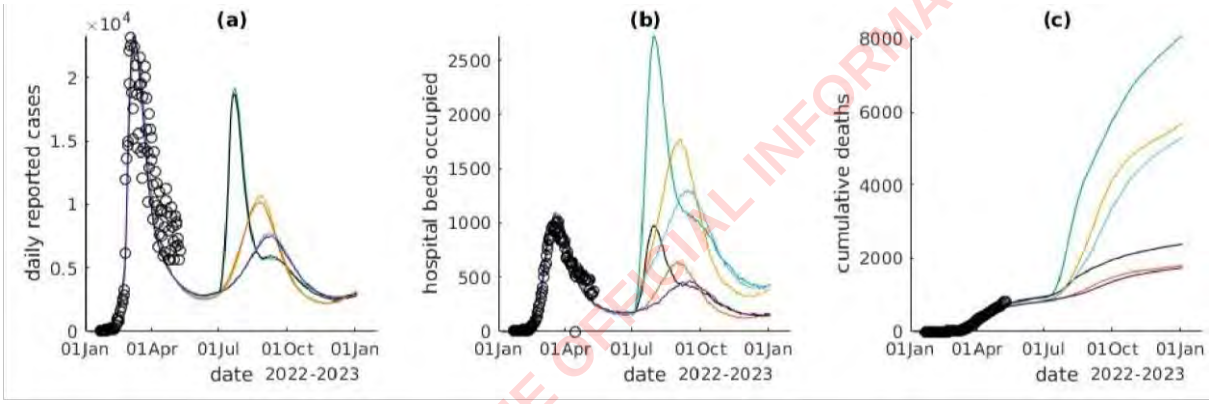
Appendix 2: Modelling on Variants of Concern

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



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 with 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

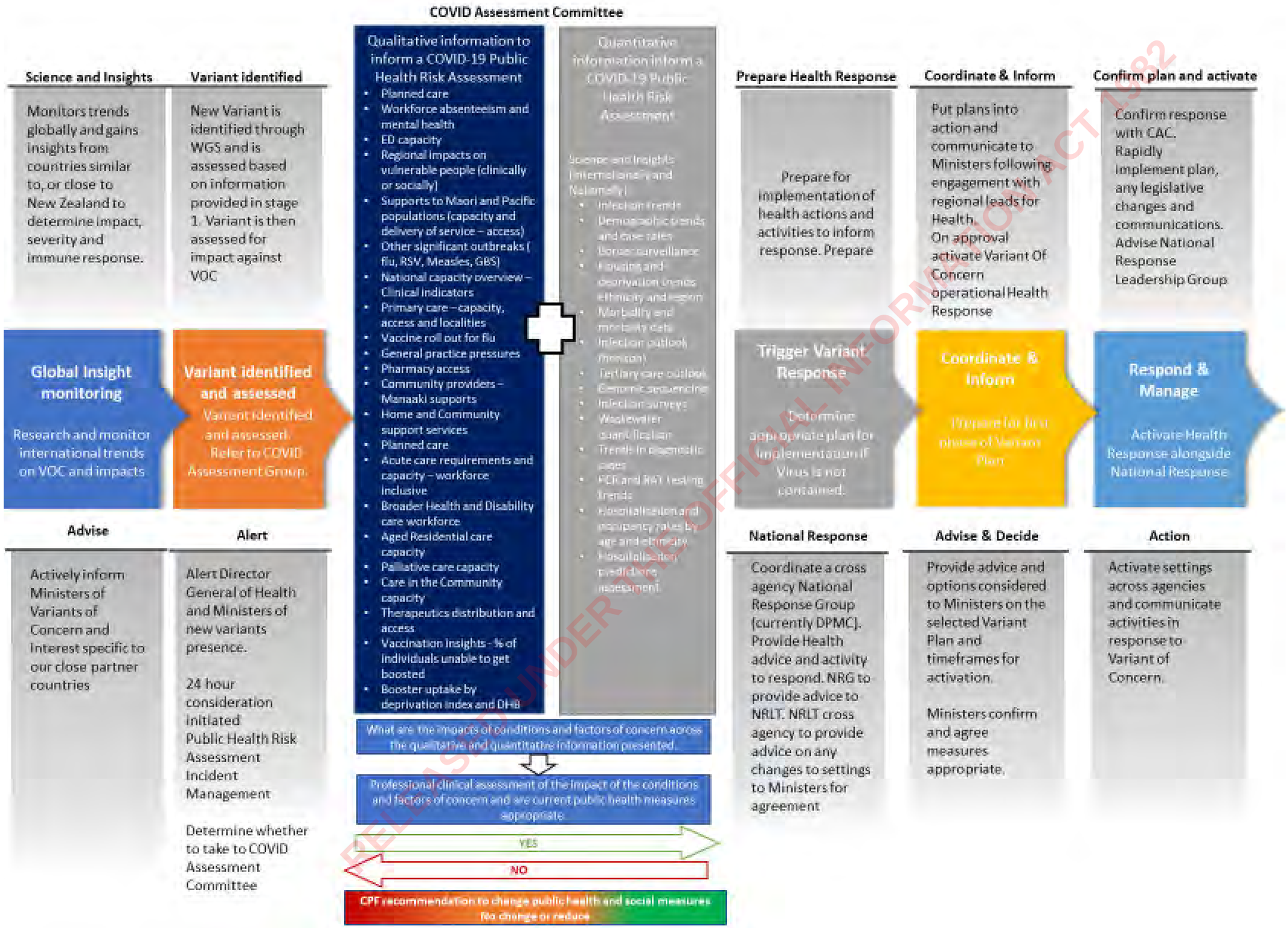
Parameter	**Variant 1**	**Variant 2**	**Variant 3**	**Variant 4**	**Variant 5**
Intrinsic transmissibility (R_0)	Omicron	Omicron	Omicron	Omicron	Omicron
Severity of new variant					
Probability of hospitalisation	Delta	Omicron	Delta	Omicron	Delta
Probability of death	Delta	Omicron	Delta	Omicron	Delta

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

Appendix 3: Process for Identifying New Variants of Concern



Appendix 4: Proposed response to scenarios

Note: This appendix did not eventuate so there is no further information for inclusion

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Document 10

Memorandum

Updated version of Aotearoa New Zealand's Variants of Concern Strategic Framework

Date due to MO:	N/A	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	20221005
To:	Hon Dr Ayesha Verrall, Associate Minister for COVID-19 Response		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Te Tumu Whakarae mō te Hauora Director-General of Health	s 9(2)(a)
Maree Roberts	Deputy Director-General, System Strategy & Policy	s 9(2)(a)

Action for Private Secretaries

N/A

Date dispatched to MO:

Document 10

MINISTRY OF HEALTH
MANATŪ HAUORA

Updated version of Aotearoa New Zealand's Variants of Concern Strategic Framework

Purpose

1. This cover memo accompanies the updated version of the Variants of Concern Strategic Framework and provides information on how we have responded to feedback from relevant advisory groups.

Context

2. You will find attached the updated Variants of Concern Strategic Framework. Since we provided a draft version of the Strategic Framework on 6 May, this has been updated following feedback from you and your office, as well as the Minister for COVID-19 Response's office. Please refer to Document 9 attached

3. As planned, we have also undertaken engagement with expert advisory groups and have updated the plan based on their feedback. We have also progressed the document further. This Memo provides further information on the changes that have been made.

Updates to the Strategic Framework document

Feedback based on engagement

4. As part of the process for finalising the Variants of Concern Strategic Framework we engaged with the following advisory groups:

   a. The COVID-19 Technical Advisory Group chaired by Dr Ian Town

   b. The Strategic COVID-19 Public Health Advisory Group chaired by Sir David Skegg

   c. COVID-19 Independent Continuous Review, Improvement and Advice Group chaired by Sir Brian Roche.

5. Overall, each of these groups were supportive of the approach and the use of scenario based-planning to inform future responses to Variants of Concern. These groups provided a range of feedback and expressed an interest in seeing the document as it develops.

6. Key pieces of feedback were:

   a. *that the document could be considerably shorter*- in response we have developed a summary version of the plan for Cabinet, however have kept a longer document that includes the more granular level of detail for internal audiences.

   b. *that the work should focus on fewer scenarios*- in response we have emphasised the scenarios that are more likely, however we have kept the broader range of scenarios as they are still possible and are required to inform detailed planning.

c. *We could provide further information on the surveillance methods used and data collection, and the extent to which they will help us understand immunity levels in the population*- in response we have added more information on the range of surveillance approaches, and noted work underway to consider seroprevalence studies.

d. *That we need to include more on how we are optimising measures for a more effective response*- As part of information on baseline resilience measures, we have highlighted work underway to improve the responses.

e. *That the equity section could be strengthened, to further emphasise the need for tailored responses to different communities and noting the impacts that are felt in South Auckland due to proximity to the border and socio-economic factors.* We have updated the document to reflect these points.

7. Each group provided further scientific and technical feedback that has been carefully considered against evidence and incorporated where appropriate.

Additional changes

8. We have made considerable additions, amendments and changes based on feedback and review, as well as planned further work and editing. We note that the overall approach remains the same, we have just sought to strengthen the document further by:

a. adding further information on the decision-making process and the relevant metrics to inform decision making.

b. adding modelling to get a potential sense of the impact of new variants.

c. adding more information on trade-offs, and further work underway to get a broader sense of the impacts of proposed measures.

d. seeking to add clarity about the objectives of the response, and the role of elimination approach style measures. Consistent with broader strategy, in certain instances we would be seeking to use measures that are less likely to infringe on people's rights or have wider socio-economic impacts.

Next steps

9. This document is intended to be a living document, that will continue to evolve based on regular scanning of emerging research and evidence, and experience in other jurisdictions. There may be further updates made in the short term based on input from the DPMC-led engagement process.

10. This 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.

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

12. When we have incorporated any further feedback that you may have, we will seek to publish a finalised version of this plan and/or the summary provided to Cabinet to support wider planning in the state and possibly private sector.

Dr Ashley Bloomfield
Director-General of Health
Te Tumu Whakarae mō te Hauora
Date: 8/6/22