Document 1

MINUTES: COVID-19 Testing Technical Advisory Group

Date:	3 May 2022
Time:	11:00 am to 12:00 pm
Location:	s 9(2)(k) [redacted]
Chair:	Kirsten Beynon
Members:	Maia Brewerton, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Brooke Hollingshead, Chris Hedlund, Christian Marchello, Ian Town, Imogen Roth, Kate Murphy, Mark Ayson
Guests:	
Apologies:	David Murdoch, Patricia Priest, Pisila Fanolua,

1.0	**Welcome and Previous Minutes** Kirsten Beynon welcomed all Members and Attendees in her capacity as Chair of the COVID-19 Testing Technical Advisory Group (CT TAG). Minutes of the last meeting (23 March 2022) were accepted.
2.0	**Update on Open Actions** *Noted in Actions tables*
3.0	**Testing Strategy Update** • It was noted this document has been discussed with the New Zealand Microbiology Network (NZMN). Members raised concern that the document may have been oversimplified. CT TAG members felt they could have given valuable input for this document but were not given the opportunity. The members of CT TAG asked for the Ministry to seek their involvement in the early stages of these documents. It was believed that the direction had not been clearly outlined and there is little reflection on future planning and potential scenarios, e.g., a new variant, and this document would not be sufficient in outlining how testing would be used. It was suggested that labs should be given clearer details to plan for PCR capacity. • A member gave feedback on the current use of Rapid Antigen Tests (RATs) and a need for discussion on their ongoing utility. It was noted that these tests are most reliable with high community prevalence, or doing a series of two RAT tests to confirm the result. • NZNM has had several labs reported influenza appearing. A member of CT TAG reminded the group of deaths related to this and the potential to broaden the scope of Testing plan. • The Ministry acknowledged the points for concern and noted their request for more descriptive documents informing this work.

	• The Chair asked for the documentation informing the Plan to be shared with the group through email to give further clarity of the test modalities and rationale behind it. • It was noted that the CT TAG members could give valuable input on the ongoing use of RATs in a New Zealand context to support decision making, recognising that tests are imperfect, and implementation will look different for different scenarios. • CT TAG members advice on the Implementation Plan would be welcomed. This will be communicated through email to the members of the Group and will focus on the more granular details needed for health care providers. • The members were encouraged to bring questions and feedback to the following CT TAG meeting. ACTION: CT TAG to support the Testing team to form an Implementation Plan.
4.0	**SARS-CoV-2 Antibody and Immunity Testing Memo** • The Chair thanked the TAG for their input into this document. • This paper has supported conversations in the space, and is now being shaped into a Health Report to be utilised more widely. The members of the group will receive a copy of this once finalised.
5.0	**Draft Memo: Proposed Direction of CT TAG** • The Ministry apologised for the memo taking longer than anticipated and highlighted the members feedback is being collated. ACTION UPDATE: The Chair and STA will work together to progress the memo to DG.
6.0	**Testing Plan** *Discussed in agenda item 3.0*
7.0	**Surveillance Plan** • It was noted there was little information surrounding the timeline for implementation. In general, the Plan was seen to have been oversimplified and overly broad. It was agreed that further clarity on implementation was needed. • Whole genome sequencing on all imported cases could be difficult to execute. A member noted the rationale for whole genome sequencing was not included in the document and there is uncertainty of how new variants would be detected. • It was suggested ESR should link into routine diagnostics. CT TAG would like to clarify with ESR what they are doing with regards to new variants and seek input into the surveillance design. ACTION: Ministry to invite ESR to a CT TAG meeting to give input into the surveillance design.
8.0	**COVID-19 Therapeutics TAG: Use of Serology** • The ability to perform serologic testing is currently under discussion for diagnosing those with persistent COVID infection, and this would aid discussions on eligibility for convalescent plasma or monoclonal antibody therapies. It was noted that it would be useful for both prevention and treatment of persistent COVID infection in the immunosuppressed. • A question was raised on how to interpret the result for those that return a low serological response. • The Ministry noted the importance of this to be included in Hospital Guidelines. • It was agreed that there is the need to consider broadening who is eligible to donate blood. This will aim to increase the supply for convalescent plasma treatments. • It was suggested that the Ministry contact the New Zealand Blood service and request broadening eligible donations to include those who lived in the United Kingdom between 1980 and 1996. It was noted they could also be contacted about conducting antibody testing for immunoglobulin therapy in IVIg products, however this can be an expensive product and hard to secure supply to a large number of patients.

	• Guidelines for the use of serology in the immunosuppressed are being progressed by CT TAG members, and must note the limitations on interpreting serology. This it to be sent to NZMN for review and for final review by the wider CT TAG members. The final version will be sent to COVID-19 Therapeutics Technical Advisory Group. ACTION: Tim Blackmore to draft the guideline document with collaboration from David Murdoch and Maia Brewton. ACTION: Ian Town to contact the New Zealand Blood service regarding expanding eligibility for blood donations
9.0	**Update on COVID Testing team Changes** *Update to follow in next CT TAG meeting*
10.0	**Next Steps/Decisions Pending** *None noted*
11.0	**Any Other Business** • A member noted the announcement of LAMP testing in NZ and asked for updates on new innovative point of care test (POCT) devices. • It was noted that this test was currently being assessed through the criteria developed by the CT TAG. The Ministry will aim to update the members of any new/innovative devices that may require input into the strategic testing plan. ACTION: The Testing Team in the Ministry aim to supply a report on nucleic acid based or other new devices (excluding standard RATs) testing with the support of STA.
12.0	**Agenda Items for Next Meeting**
Meeting closed at **12:27pm** Next meeting: **17 May 2022**	

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
10	**Testing Strategy Update**	CT TAG to support the Testing team in the Ministry to form an implementation plan.	Christian Marchello	03/05 – Action raised.
11	**Surveillance Plan**	Invite ESR to the following CT TAG meeting to give input into the surveillance design	STA	03/05 – Action raised
12	**COVID-19 Therapeutics TAG: Use of Serology**	Tim Blackmore to draft the guideline document	Tim Blackmore	03/05 – Action raised
13	**COVID-19 Therapeutics TAG: Use of Serology**	To contact the NZ Blood service and request broadening the donations	Ian Town	03/05 – Action raised
14	**Any Other Business**	The Testing Team in the Ministry aim to supply a report on nucleic	Christian Marchello	03/05 - Action raised

		acid based or other new devices (excluding standard RATs) testing with the support of STA.		
6	**Draft Memo: Proposed Direction of CT TAG**	Kirsten Beynon to provide feedback to the DG on the previous memo on next steps.	Chair	11/03 – Action raised 03/05 - The Chair and STA will work together to progress the memo

Closed Actions:

#	Agenda item	Actions	Action Owner	Updates
4		To approach the Ministry Chief Science Advisor regarding CT TAG membership when he is back from leave. To provide feedback and discuss next steps.	Chair	11/03 – Action raised 03/05 – Membership will be discussed in greater detail following the Director General's approval for the proposed direction of CT TAG. Action closed.
7	**Serology Antibody Testing**	The Chair asks for all members input into this document and welcomes any comments via email by Friday 25 March 2022.	Chair	23/03 – Action raised 03/05 – Members of CT TAG contributed to the document that is now finalised. Action closed.
8	**Serology Antibody Testing**	Document to be shared with NZNM for comment.	Susan Morpeth	23/03 – Action raised 25/03 – Action closed
9	**Testing Strategy**	Updated documents to be circulated to CT TAG for further input	Chair	23/03 – Action raised 03/05 – Action closed

Document 2

MINUTES: COVID-19 Testing Technical Advisory Group

Date:	17 May 2022
Time:	11:00 am to 12:00 pm
Location:	s 9(2)(k) [redacted]
Chair:	Kirsten Beynon
Members:	Maia Brewerton, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Brooke Hollingshead, Chris Hedlund, Christian Marchello, Ian Town, Imogen Roth, Kate Murphy, Mark Ayson, Zoe Smith
Guests:	Nick Kendall
Apologies:	David Murdoch, Patricia Priest, Pisila Fanolua

1.0	**Welcome and Previous Minutes** Kirsten Beynon welcomed all Members and Attendees in her capacity as Chair of the COVID-19 Testing Technical Advisory Group (CT TAG). Minutes of the last meeting (3 May 2022) were accepted noting the following changes: • The spelling of border to be corrected • The correction from convoluted plasma to convalescent plasma • Comment in item 8.0 regarding the exacerbation of other illnesses to be removed
2.0	**Update on Open Actions** *Noted in actions table below.*
3.0	**Airfinity update I Horizon scanning** Airfinity give biweekly updates to the Ministry. The Ministry requested that the CT TAG members raise any topics of interest or questions which can guide the Ministry and Airfinity on what to explore. This will be brought to CT TAG meetings as a standing item on the agenda. STA gave an overview of the most recent Airfinity information on the testing landscape and new technology developments. • It was noted the following novel diagnostic technologies were discussed in the European Congress of Clinical Microbiology & Infectious Diseases meeting held in April 2022: • **Digital PCR** is in routine use in research labs. It may become more important in clinical diagnostics, including for SARS-CoV-2, as it can offer absolute quantification of viral load and have a high level of precision. However, it has not replaced PCR and will not do so in the future. • **A host response molecular diagnostic** has been trialled using a 29-mRNA host response assay to identify patients with COVID-19. This is currently in a prospective multi-centre trial. • **Saliva Direct** has been granted an EUA by the FDA. This is a low-cost test solution that can be run with existing lab structure. In the US this protocol is now being widely used with a capacity of 300,000 tests per day.

	Discussion: • Digital PCR: A member noted they were not sure if there was a strong need for this in routine laboratories. It was noted it may be useful in niche circumstances for immunosuppressed patients with persistent COVID infection, or if there was a desire to precisely monitor viral load. • Host response molecular diagnostic: A member noted that these have been in development in various settings for a long time, but have never been proven to have any clinical utility as immune cell biomarkers are impossible to interpret clinically and if not used in a clinical trial setting with the key therapeutic included, they are not useful. • Saliva Direct: It noted this is currently in use in New Zealand and can be incorporated as laboratories see fit and where there is a service need. It was noted by a member that if saliva testing was felt to be important it should be decided by strategy rather than an assay. • Members requested further information when available on rapid testing, especially very rapid PCR platforms that are up to date in their design and LAMP tests, and T and B cell immunity in QuantiFERON assays for SARS-CoV-2. • The Chair raised a point following interest in urine antibody testing. ACTION: The associated paper will be shared with the group following the meeting for discussion in the next meeting under horizon scanning.
4.0	**Seroprevalence survey:** • The Ministry noted they are establishing an Infection survey. Nasopharyngeal swab testing will proceed in early July followed by a seroprevalence survey for which the timeline is to be confirmed. Design details are still to be confirmed, however at this stage the survey will be for COVID-19 only. • CT TAG will be updated by the Ministry as plans progress. Questions surrounding the survey will be brought to CT TAG in future meetings by SS&I. ACTION: The Ministry will provide an update of all surveillance work streams and ESR surveillance at the next meet including WGS surveillance. Discussion: • It was noted by the Ministry that the options for accessing passive surveillance information with change to mandates has required a reassessment of the current planning and the importance of active surveillance programmes is recognised for a range of respiratory pathogens including SARS-CoV-2.
5.0	**Serologic testing – Persistent infection** • A member updated progress on the *DRAFT Serological testing for SARS v3 document* being developed by the New Zealand Microbiology Network (NZMN) with minor amendments. • The difficulties of creating clear guidance on interpreting results were expressed, specifically for antibody levels with results that sit in the middle range. Care needs to be given to developing thresholds in this grey area when using this to decide on a patient's eligibility for convalescent plasma treatment or Evusheld. • It was noted further input from CT TAG members is needed into the document. This document will be brought back to the next CT TAG meeting. • Once the document is finalised the Ministry will link into clinical and public guidance and will link with the COVID-19 Therapeutics Technical Advisory Group (Therapeutics TAG). Discussion: • It was noted this will be a helpful document with a range of audiences. • A member commented on the limited supply of convalescent plasma and the need for it to be rationalised and targeted to those who need it. The Therapeutics TAG may be the best option for understanding the availability of this treatment. Due to the cross over with some of the work between the two groups the action was raised to connect the chairs of the two meeting to discuss further overlap. • The possibility of sharing minutes from the TAG meeting was discussed. This will need to be discussed between the chairs of the different groups to share this information.

	ACTION: The Chair of CT TAG and Therapeutics TAG to discuss serologic testing and shared topics of interest including sharing the minutes from the meetings. ACTION: Members to update the paper and bring back to the next meeting.
6.0	**Antibody Health Report on Serology and Immunity Testing** • STA is currently working on translating the antibody memo into a Health Report for Minister Verrall. • The first draft re *DRAFT Briefing Use of serology in COVID-19 CT TAG* has been shared with the agenda, this was shared as an initial draft for early comments and input from members. The following questions were raised to the members: o What are key messages that need to be brought through? o What information would you advise should be included? ACTION: Members were encouraged to send through their input to STA following the meeting. ACTION: STA will follow up in the next meeting with the final draft for review. Discussion • The members of CT TAG recommended that equity is considered consistently throughout the document/report as opposed to a separate section at the end. This would require a change in the Health Report/Memo template. STA will feed this back to the Ministry for review. • A member noted serology testing could also be used for assessment of performance of Rapid Antigen Tests (RATs) with either false positives or false negatives. • It was noted the use of serology for timing of boosters should be explored further. With additional booster vaccines on the horizon. Timing of boosters and what testing markers could support this. This could be of benefit for those who suffer negative side effects related to the vaccine. • It was noted some of the information from the COVID-19 Vaccine Technical Advisory Group (CV TAG) would be useful for CT TAG members and asked if it was possible to receive the minutes from these minutes to better inform their decisions. ACTION: STA to follow up on changing the content include equity considerations for each section. ACTION: STA include in the HR consideration of utility of serology testing to inform timing of vaccine boosters. ACTION: The Chair of CT TAG to contact the Chair of CV TAG to discuss information sharing across TAGs including minutes.
7.0	**Update on device applications and approvals (non-RAT)** • The draft memo re *Memo Seeking approval to exempt POCT molecular from the Order DRAFT* was shared with the members in the updated agenda to seek input before going to the Director-General for approval. Currently this is restricted to a few entities. This seeks to broaden the exemption to any device. • It was noted the need to open access to more sensitive and better performing tests particularly in the at-risk groups and settings. ACTION: Input from the CT TAG members by Friday, 20 May 2022 is requested.
8.0	**RAT and PCR utility - HR Health Report** • This item was noted and is still in development. Members were requested to provide recommendations to STA on key components that should be covered within the HR to support future decision making and planning.
9.0	**Next Steps/Decisions Pending** *None noted*
10.0	**Any Other Business** *None noted*
11.0	**Agenda Items for Next Meeting**

	• LAMP update (deferred from this meeting) • Members requested the need for a Testing Strategy document to underpin development of plans and advice should be discussed in the next meeting. • RAT and NAAT utility – refresh of current settings.
Meeting closed at **12:07pm** Next meeting: **31 May 2022**	

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
11	**Surveillance Plan**	Invite ESR to the following CT TAG meeting to give input into the surveillance design	STA	03/05 – Action raised 17/05 – The invite has been sent. Further coordination is needed to confirm.
12	**COVID-19 Therapeutics TAG: Use of Serology**	Tim Blackmore to draft the guideline document	Tim Blackmore	03/05 – Action raised 17/05 – Draft document shared with CT TAG for input. Members to give feedback, specifically Maia. Tim to bring the document to next meeting.
6	**Draft Memo: Proposed Direction of CT TAG**	Kirsten Beynon to provide feedback to the DG on the previous memo on next steps.	Chair	11/03 – Action raised 03/05 - The Chair and STA will work together to progress the memo. 17/05 – Update given. Memo is currently with the Science, Surveillance & Insight's Group manager before progressing to the D-G.
15	**Serologic testing – Persistent infection**	Kirsten Beynon to contact the Chair of Therapeutics TAG.	STA/Chair	17/05 – Action raised.
16	**Antibody Health Report on Serology and Immunity Testing**	STA to follow up on changing the template to include equity considerations for each section	STA	17/05 – Action raised
17	**Antibody Health Report on Serology and Immunity Testing**	Kirsten Beynon to contact the Chair of CV TAG to ask for minutes to be shared	Chair	17/05 – Action raised

Closed Actions:

#	Agenda item	Actions	Action Owner	Updates
10	**Testing Strategy Update**	CT TAG to support the Testing team in the Ministry to form an implementation plan.	Christian Marchello	03/05 – Action raised. 17/05 this will be an ongoing agenda item. Action closed.
14	**Any Other Business**	The Testing Team in the Ministry aim to supply a report on nucleic acid based or other new devices (excluding standard RATs) testing with the support of STA.	Christian Marchello	03/05 - Action raised 17/05 – This is included as a monthly standing item to the agenda. The next update is due 14/05 17/05 - Action closed
13	**COVID-19 Therapeutics TAG: Use of Serology**	To contact the NZ Blood service and request broadening the donations	Ian Town	03/05 – Action raised 18/05 – Response from NZBS shared with the group. Action closed.

Document 3

MINUTES: COVID-19 Testing Technical Advisory Group

Date:	31 May 2022
Time:	11:00 am to 12:00 pm
Location:	s 9(2)(k) [redacted]
Chair:	Ian Town
Members:	Maia Brewerton, Patricia Priest, Pisila Fanolua, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Brittany Illingworth, Brooke Hollingshead, Christian Marchello, Imogen Roth, Mark Ayson, Sammy Kelly
Guests:	Jennifer Keys, Nick Kendall
Apologies:	David Murdoch, Kirsten Beynon

1.0	**Welcome and Previous Minutes** Ian Town welcomed all Members and Attendees in his capacity as Acting Chair of the COVID-19 Testing Technical Advisory Group (CT TAG). Kirsten Beynon has sent her apologies. Minutes of the last meeting (17 May 2022) were accepted.
2.0	**Update on Open Actions** • RAT and PCR Utility Draft Paper is still in progress.

3.0	**Reinfection Update for Clinical Guidance**
	• Initial interim advice on reinfection was released in May. This was developed rapidly in a fast-changing environment and may require amendments in the future.
	• An updated Clinical Guidance document is expected to be issued in the next week or so. Amendments include changes to the COVID isolation order, including:
	  ○ a positive test will now not be counted as a new case if they are within 28 days of prior infection
	  ○ changes to advice for cases of suspected reinfection between 28 and 90 days. This will shift from 'you should not test' to 'you are not recommended to test'. The emphasis is to be placed on seeking medical advice for suspected reinfection cases in this timeframe.
	• It was noted that early reinfection may become more common with new variants.
	Discussion:
	• The context for taking a test and the risk for the individual is important to consider. In particular:

	○ members raised the increased importance of testing immunocompromised or people with regular interactions with immunocompromised people ○ the ability to detect reinfection requires accurate first detection. This depends on the type of test (whether it was PCR or RAT, a self-test, or requested by a healthcare professional) ○ the appropriate advice will be defined by the strategy and what it is trying to be achieved (ie, different advice is required if the goal is to identify all cases, instruct them to isolate, and prevent the spread of Omicron, or if the goal is to help those who need treatment) ○ it was acknowledged that the exact risk of reinfection is still unknown, and depends on vaccination status, whether the person is immunosuppressed and it is a persistent infection or reinfection, or whether it may be a false positive. • The TAG advised that the Ministry should continue to discourage people from testing too early and unnecessarily. The message should continue to be to test only when it makes a difference, and this should be consistent across other winter viruses. • CT TAG acknowledged that future variants are a concern which require flexibility and could see higher rates of reinfection. ○ Specific advice was requested on what testing regime to recommend to a GP in a situation where a patient has plausible symptoms, if their second RAT is negative, and whether it is enough to not note them as a case. It was raised that a second negative test could be enough to consider the person negative, and that this has social and economic impacts on the individual. ○ Advice for symptomatic people should be to stay home. This is a pragmatic approach and true for other viruses (Influenza, RSV). ○ There was a call for integration of advice for COVID-19 and other winter respiratory viruses to align.
4.0	**Update on Device Applications and Approvals (non-RAT)** A general update was presented on device applications and approvals. • Work is underway to determine where the regulation of COVID-19 point of care tests will go after transitioning to Health New Zealand and the Public Health Agency. An overview of RAT and NAAT applications received was given. • Feedback was requested on the update, and the TAG were asked at what stage they want to be made aware of applications for new devices. Discussion: • The pressure on evaluating, approving and increasing capacity to deliver further Rapid Antigen Tests is dropping due to the number already approved. It was noted that there is no opportunity for quality assurance once a device is in the community, and no information on historically approved devices and their detection or performance against new variants. • A member updated the group on a meeting with New Zealand Microbiology Network (NZMN). Concerns were raised on the currently approved molecular tests and what the scope is beyond COVID-19. ○ If these are removed from legislation it will be difficult to reverse, as it would be difficult to withdraw a publicly available test. ○ The potential for scope creep for the testing to move beyond COVID-19 was noted. There could also be health, safety and quality assurance issues. **ACTION**: Periodic updates to be brought to CT TAG meetings about the progress of these applications, with a particular focus on new emerging technologies and how they will be used.

5.0	**Infection and Seroprevalence Survey Overview** An update was provided on the oversight of seroprevalence and sampling. The Infection survey review is underway. It was noted that there is an opportunity to collect reinfection data from this survey. **ACTION**: Further documentation relating to this survey to be circulated to CT TAG.
6.0	**Health Report Serology Antibody Testing - Immunity** • It was noted that the Report is a high-level update for the Minister. It has been circulated to CT TAG members for feedback on key messages. Discussion: • Members noted some limitations of the document. It was noted that the Report does not allude to the limitations of the quantification of testing, which can limit use when deciding if another vaccination dose is appropriate due to having no validated cut off and no correlation between levels and protection. There is also not great reproducibility between tests. • The Report could also mention new emerging technologies. There is no comment on T cell tests and how things have changed in last month, and commercial surrogate viral assays are now available which may move into diagnostics. **ACTION**: Health Report will be updated based on CT TAG feedback.
7.0	**Airfinity update I Horizon scanning** • Information on rapid diagnostics and quantiFERON has been requested from Airfinity. This will be included in the next report. • Any further topics of interest raised will be passed on to Airfinity when raised by CT TAG members. **ACTION**: Rapid diagnostics and QuantiFERON deep dives to be reported to CT TAG when available.
8.0	**Testing Strategy** This item was not discussed.
9.0	**Next Steps/Decisions Pending** *None noted.*
10.0	**Any Other Business** *None noted.*
11.0	**Agenda Items for Next Meeting**
Meeting closed at **11:59 pm** Next meeting: **14 June 2022**	

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
11	**Surveillance Plan**	Invite ESR to the following CT TAG meeting to give input into the surveillance design	STA	03/05 – Action raised 17/05 – The invite has been sent. Further coordination is needed to confirm.
12	**COVID-19 Therapeutics TAG: Use of Serology**	Tim Blackmore to draft the guideline document	Tim Blackmore	03/05 – Action raised 17/05 – Draft document shared with CT TAG for input. Members to give feedback, specifically Maia. Tim to bring the document to next meeting.
6	**Draft Memo: Proposed Direction of CT TAG**	Kirsten Beynon to provide feedback to the DG on the previous memo on next steps.	Chair	11/03 – Action raised 03/05 - The Chair and STA will work together to progress the memo. 17/05 – Update given. Memo is currently with the Science, Surveillance & Insight's Group manager before progressing to the D-G.
15	**Serologic testing – Persistent infection**	CT TAG engagement with Therapeutics TAG. Kirsten Beynon to contact the Chair of Therapeutics TAG.	STA/Chair	17/05 – Action raised. 31/05 – Action closed.
16	**Antibody Health Report on Serology and Immunity Testing**	STA to follow up on changing the template to include equity considerations for each section	STA	17/05 – Action raised 31/05 - Action Closed
17	**Antibody Health Report on Serology and Immunity Testing**	Kirsten Beynon to contact the Chair of CV TAG to ask for minutes to be shared	Chair	17/05 – Action raised 31/05 – Action closed.
18	**Update on Device Applications and Approvals (non-RAT)**	Periodic updates to be brought to CT TAG meetings about the progress of these applications, with a particular focus on new emerging technologies and how they will be used.	Christian Marchello	31/05 – Action raised. This will be an ongoing update and has been added as a standing item to the agenda. Item closed
19	**Infection and Seroprevalence Survey Overview**	Further documentation relating to this survey to be circulated to CT TAG.	Nick Kendall	31/05 – Action raised

20	**Health Report Serology Antibody Testing - Immunity**	Feedback provided by CT TAG to be added into report	STA	31/05 Action raised
21	**Airfinity update I Horizon scanning**	Rapid diagnostics and QuantiFERON deep dives to be reported to CT TAG when available	STA	31/05 - Action raised

Closed Actions:

#	Agenda item	Actions	Action Owner	Updates
10	**Testing Strategy Update**	CT TAG to support the Testing team in the Ministry to form an implementation plan.	Christian Marchello	03/05 – Action raised. 17/05 this will be an ongoing agenda item. Action closed.
14	**Any Other Business**	The Testing Team in the Ministry aim to supply a report on nucleic acid based or other new devices (excluding standard RATs) testing with the support of STA.	Christian Marchello	03/05 - Action raised 17/05 – This is included as a monthly standing item to the agenda. The next update is due 14/05 17/05 - Action closed
13	**COVID-19 Therapeutics TAG: Use of Serology**	To contact the NZ Blood service and request broadening the donations	Ian Town	03/05 – Action raised 18/05 – Response from NZBS shared with the group. Action closed.

Document 4

MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Testing Technical Advisory Group

Date:	14 June 2022
Time:	11:00 am to 12:00 pm
Location:	s 9(2)(k) [redacted]
Chair:	Kirsten Beynon
Members:	David Murdoch, Patricia Priest, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Brittany Illingworth, Brooke Hollingshead, Imogen Roth, Mark Ayson
Guests:	Andrea McNeill
Apologies:	Christian Marchello, Ian Town, Maia Brewerton, Pisila Fanolua

1.0	**Welcome and Previous Minutes** Kirsten Beynon welcomed all Members and Attendees in her capacity as Chair of the COVID-19 Testing Technical Advisory Group (CT TAG). Minutes of the last meeting (21 May 2022) were accepted.
2.0	**Update on Open Actions** • Item #11 was closed. • Item #16 was closed, and the Request for Advice has gone to the Minister. • Item #20: a further update from the team is needed. The Chair will follow up via email to provide support.

3.0	**Respiratory Sentinel Surveillance Plan (presentation attached)**
	An update was provided from ESR on national influenza like surveillance:
	• There are three types of surveillance that ESR performs:
	  ○ SARI syndromic surveillance
	  ○ pathogen specific surveillance
	  ○ ILI syndromic surveillance
	• Many of these types of surveillance have been disrupted but also enhanced by the COVID-19 response. There is an ongoing need to integrate COVID-19 into the surveillance.
	• The core objectives for community sentinel ILI surveillance are:
	  ○ to provide information on trends, ILI incidence, disease burden in specific populations

	○ for early detection on ILI activity, seasonality, the start and end of traditional influenza season, and to provide historic rates for annual comparisons ○ to gain information on which viruses are circulating and where • This information will be used long term to inform vaccine design and policy. • It was noted that the sentinel surveillance will use the ILI definition (fever and cough), which will only capture a small subset of COVID-19 cases. • While system development is occurring throughout the season, the weekly ILI dashboard has been stood up. This includes 54 sentinel GP practices utilising the current existing systems (with an embedded HealthLink form). Discussion: • Incorporation of existing laboratory respiratory viral testing information into the ILI surveillance reporting. • It was recommended by a member CTCs may be a source to increase ILI update and do panel testing on some of these samples. • There is an aim for ESR to get data through the result depository moving forward. • A member questioned whether Shivers data would be included. Shivers practices are using an RE case definition rather than ILI definition, but noted that there is rich data available there. • A member emphasised the importance of real time information on circulating viruses at a local level to support clinicians. It was observed in the past there was a delay in updates from the ILI sentinel surveillance. Weekly information is now being uploaded. • The TAG highlighted the importance of push notifications processes to updating relevant groups. • It was also noted that it comes down to which testing panels are run (triplex or multiplex). Push notifications to convey this would be very useful. CT TAG will look at some options for a push notification system at both a national and regional level. • Another member noted that influenza and RSV activity in Australia should also be incorporated. Often a couple of weeks after Australia sees an upsurge in either influenza or RSV we also see an upsurge in case numbers in New Zealand. ESR advised this is occurring. • A member noted there is a combination of datasets being gathered and encourage ESR to lead integration of this.
4.0	**Airfinity update I Horizon scanning** • Airfinity scanning on QUANTiferon will be circulated and feedback is to be given by CT TAG at the next meeting. A member commented that the review does not use the same platform as QuantiFERON so it is a more complicated Elisa method, and the labs cannot jump in and do this easily for verification. • There is ongoing engagement with the Doherty Institute as part of horizon scanning. • It was noted that there are a few quick to market RAT saliva tests which have been released to market in some jurisdictions. • Slides and paper from Airfinity to be sent to TAG members before next meeting. Discussion: GPs for urine antibody paper

	• A member noted issues with the study design and method description being unclear and not well defined. This was deemed not relevant for a NZ context. Recommend no diagnostic utility for this method at this time. • Another member noted that a wide range of results for urine is unsurprising as urine samples can be very concentrated or diluted depending on hydration levels and timing of collection, and therefore it cannot be used quantitively.

5.0	**Persistent infection**
	• An updated version of the persistent infection and serology testing was received from NZMN.
	Discussion:
	• The document was formally endorsed by CT TAG. It was noted that as more information comes to light, the situation is likely to change.
	• A discussion occurred on distribution and whether it should be made publicly available through the NZMN or Ministry of Health websites. It was queried whether it should be formally sent to the group who worked on the persistent infection guidelines, as it could potentially be linked.
	• It was noted that this was written more for the benefit of the TAG than for the general public, and there was not considered to be a wide readership.
	  ○ It was agreed that this would be most appropriate place for clinicians looking after patients who are immunosuppressed likely to have persistent COVID-19 infection.
	  ○ The idea of using push notifications was also raised as a way of updating clinicians on new information made available as it is not currently clear where persistent infection guidance goes, as this is not a national clinical care formal document. Mostly because its all-expert opinion with some data behind it.
	ACTION: Discuss with Therapeutics TAG and STA to consider incorporation into existing Clinical Guidance from a MOH perspective.

6.0	**Update on Device Applications and Approvals (non-RAT)** • s 9(2)(f)(iv) [redacted] • CT TAG were asked for comments relating to self-use NAATs, recognising the public can choose to purchase it similar to purchasing RATs privately. Discussion: • A member asked about the funding criteria/process. • Concerns were raised regarding the lack of clarity of quality assurance processes, and the need to keep up to date with new variants. • It was noted that previous discussion has occurred with the NZMN about the point of care nucleic acid tests, with feedback given on the potential issues with health and safety, quality assurance and data governance while following privacy guidelines. ○ It was noted that RATs were made available rapidly before mechanisms to capture results were available. This was needed due to qPCR testing being overwhelmed.

	○ The context in which NAAT's are used need to be carefully considered before being made widely available. • Another member mentioned that it comes down to accessibility of tests and reporting requirements need to be addressed before release to the market. If this can be done, then some parts of the country with accessibility issues are likely to benefit from NAAT tests. ○ A member also advised if these tests were run by point of care teams with training and reporting, then these issues might be mitigated but opening sale to anyone has many potential issues with regulation. • The importance of clear with the public messaging on utility of tests and potential downsides of each. It was noted there is a general lack of public understanding regarding sensitivity for RATs and NAATs can detect genetic material after a person is no longer infectious. Businesses also need to be aware of other respiratory illnesses outside of COVID-19. The TAG supports the message of if you are unwell stay home; seek health professional support if you have underlying conditions or your symptoms worsen irrespective of COVID-19 testing results. • s 9(2)(f)(iv) [redacted]
7.0	**Proposed direction of CT TAG memo** • The Ministry leads met with the Director-General last week where the importance of the TAG was acknowledged. • An update was provided on this memo detailing the future direction of CT TAG. This is still in progress. Discussion: • A member questioned whether the purpose of this group is going to mainly be focused on the technical aspects of new technology and clinical scenarios. The member noted the lack of external advisory on how tests are used in surveillance and other public health responses and how CT TAG can assist with this. • The TAG noted a need for clearer terms of reference and role or advice on surveillance. • The Chair and STA will finalise memo the memo and bring it back to CT TAG. **ACTION**: Finalise memo and bring back to CT TAG.
8.0	**Engagement with Therapeutics TAG** • The Chair met with the Chair of the Therapeutics TAG to discuss how issues pertaining to both groups could be discussed. • Moving forward minutes from CT TAG and Therapeutics TAG will be shared after each meeting. STA team will coordinate this.
9.0	**Reinfection Update** • Interim advice will be released; this will be under regular review. • The updated guidance was overviewed by the team for the Chair. Discussion: • A member noted that the guidelines are very complicated and need to be tailored for each target audience. The key message to emphasise is that if you are unwell, stay home.

	• The importance of reiterating for high-risk individuals to seek care from health care professionals was also highlighted. The guidance for healthy young individual is likely to be very different than those with comorbidities of concern.
10.0	**Next Steps/Decisions Pending** *None noted*
11.0	**Any Other Business** *None noted*
12.0	**Agenda Items for Next Meeting** *None noted*
Meeting closed at **12:16pm** Next meeting: **28 June 2022**	

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
12	**COVID-19 Therapeutics TAG: Use of Serology**	Tim Blackmore to draft the guideline document	Tim Blackmore	03/05 – Action raised 17/05 – Draft document shared with CT TAG for input. Members to give feedback, specifically Maia. Tim to bring the document to next meeting. 14/06 Verbal update
6	**Draft Memo: Proposed Direction of CT TAG**	Kirsten Beynon to provide feedback to the DG on the previous memo on next steps.	Chair	11/03 – Action raised 03/05 - The Chair and STA will work together to progress the memo. 17/05 – Update given. Memo is currently with the Science, Surveillance & Insight's Group manager before progressing to the D-G. 14/06 Verbal update. Clarity of focus and scope, balance between strategic surveillance and planned testing of devices will be clarified in the memo and brought to CT TAG when finalised.

19	**Infection and Seroprevalence Survey Overview**	Further documentation relating to this survey to be circulated to CT TAG.	Nick Kendall	31/05 – Action raised 14/06 STA lead not available to attend. Update to be given next meeting.
21	**Airfinity update l Horizon scanning**	Rapid diagnostics and QuantiFERON deep dives to be reported to CT TAG when available	STA	31/05 - Action raised 14/06 – In progress. Slides and paper from Airfinity to be sent to TAG members before next meeting.
22	**Persistent infection**	Discuss with Therapeutics TAG and STA to consider incorporation into existing Clinical Guidance from a MOH perspective.	Chair/STA	14/06 – Action raised

Closed Actions:

#	Agenda item	Actions	Action Owner	Updates
11	**Surveillance Plan**	Invite ESR to the following CT TAG meeting to give input into the surveillance design	STA	03/05 – Action raised 17/05 – The invite has been sent. Further coordination is needed to confirm. 14/06 Closed
20	**Health Report Serology Antibody Testing - Immunity**	Feedback provided by CT TAG to be added into report	STA	31/05 - Action raised 14/06 Feedback CT TAG integrated into report. Item closed.

Document 5

MINUTES: COVID-19 Testing Technical Advisory Group

Date:	12 July 2022
Time:	11:00 am to 12:00 pm
Location:	s 9(2)(k) [redacted]
Chair:	Kirsten Beynon
Members:	David Murdoch, Maia Brewerton, Patricia Priest, Pisila Fanolua, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Brittany Illingworth, Brooke Hollingshead, Christian Marchello, Imogen Roth, Mark Ayson
Guests:	Fiona Callaghan, Nick Kendall
Apologies:	Christian Marchello, David Murdoch, Imogen Roth, Pisila Fanolua, Susan Morpeth

1.0	**Welcome and Previous Minutes** Kirsten Beynon welcomed all Members and Attendees in her capacity as Chair of the COVID-19 Testing Technical Advisory Group (CT TAG). Minutes of the last meeting (14 June 2022) were accepted.
2.0	**Update on Open Actions** N/A
3.0	**Seroprevalence Survey Update: Questions about SARS-CoV-2 antibody testing used in Sero surveillance** An update was provided on the seroprevalence survey. Key questions that are in need of advice include: - Q1. How do we take into account waning Ab levels over time especially anti-N as it seems to wane faster than anti-S?

- Q2. What is your advice regarding a single (cross-sectional) Ab level test vs. serial Ab levels?

* Note, there is potential to collect data from: multiple cross-sectional population samples (eg, weekly for 6-months); and an additional sub-group recruited for repeat testing (eg, monthly for 6-months).

- Q3. Where would you recommend, we access blood samples (eg, random pop sample, residual, or blood donors?)

Discussion:

Q1 feedback

- An epidemiological serosurvey will provide a snapshot of the past and is not suited for purpose in the current fast-paced environment of emerging SARS-CoV-2 Omicron variants. Members questioned the value of a seroprevalence survey that included anti-nucleocapsid antibody testing for the following reasons;
    - we already know that many have had COVID-19
    - it will underestimate cases
    - it will not be possible to get a full picture of everyone who's had an infection
    - it will not provide insight into immunity against future strains.
- Serosurveys need to be in context of what virus variants are currently of concern and what variants are coming (ie, how a population previously infected with Omicron are responding to latest (or future) variants).
- With COVID-19 and emerging variants the timing of a serosurvey is critical to inform immunity and decision making; the Ministry should consider waiting until the current wave has passed.
- The purpose of a seroprevalence survey is to use the most appropriate test as a surrogate for immunity and for informing vaccination decisions. Standard commercial anti-nucleocapsid antibody testing will not provide this information.
- It is recommended by TAG members that pseudo-virus neutralisation assays are considered for any seroprevalence study undertaken. They are relatively simple to perform, are updated regularly and a laboratory could implement this if needed. Also, knowing whether antibodies can neutralise (circulating or new) variants is more useful than determining if people have had an infection.

Q2 feedback

- The overall purpose of the surveillance should inform which assays are selected and the sampling design.
- The TAG asked for clarity on how this will feed into future decision making for public health.

Q3 feedback

- The Ministry needs to be clear on the purpose of the survey before determining sampling design and access to samples/participants.
- Cross sectional sampling: the timing of the serum sample being taken relative to infection and/or vaccination and within a relatively short timeframe is important. Also,

	TAG members suggested that it should be asked what would be gained from a public health perspective from the investment. • A priority objective should be to identify who are our most vulnerable populations or individuals. **Key Feedback from CT TAG Members** ○ **Pseudo-virus neutralisation assays are investigated for use in the seroprevalence survey as they are the most suitable test to give information about population immunity.** ○ **The Ministry should consider the value of undertaking a cross-sectional seroprevalence survey at a single point of time from a public health perspective.** ○ **Sampling and study design needs to be dependent on the overall purpose of the seroprevalence survey.** ○ **Identify the most vulnerable populations.** ○ **CT TAG members requested that papers submitted have a clear purpose and executive summary for ease of reading.** ACTION: Feedback to be sent to ISK surveillance team.
4.0	**Whole genome sequencing (WGS) update** Dr Fiona Callaghan presented to CT TAG an update on wastewater (WW) and WGS surveillance programs in place. **Discussion**: Members noted that there would be regional differences and inconsistencies in sampling. For example, labs in Wellington are using POCT devices as their primary testing method so numbers of samples available for WGS testing is lower. It was also noted that Auckland WGS testing is disproportionately low based on population and vulnerable population profile compared to other regions. • It was noted work with ESR and testing labs is in progress to achieve more consistent and representative sampling by region. Members observed and encouraged that longer term cost/benefit analysis should be undertaken as to the value of focussing on only COVID-19 testing. • It was noted more complete surveillance data over the next wave will be of value to inform future surveillance priorities and design. A concern was raised regarding the value of WGS for assessing reinfections: Members noted: • differentiation by WGS at an individual level to assess persistent- versus re-infection would be of benefit for a small population (the immunocompromised) • as WGS is focussed on population surveillance, the systems are not well set up for reporting individuals' information to clinicians or the patient. WGS results need to be in the patient record to be of value for clinicians managing patient's care including access to previous RAT results

	• as per current protocols, for patients who will benefit from targeted therapies, WGS can be of value irrespective of first, second or third infection. It was noted that reinfections are now being captured and rates will be monitored against WGS population surveillance from WW, border, hospital, and community.
5.0	**Airfinity update I Horizon scanning** STA presented an update, which included key updates on developing novel diagnostics using saliva with a recent study looking at a lollipop RAT. Several papers looked at gargling as a way to collect a specimen. There were also additional papers about QuantiFERON but still lacking a link to clinical response. Finally, it was shared that the Ministry are meeting with the Doherty institute regularly to share experiences and discuss testing modalities. Multiplex rapid antigen tests are not going ahead in Australia, while multiplex PCR is being used in selected settings. Of interest, they have had success in undertaking sequencing using the paper strips inside used rapid antigen test devices and are currently working to operationalise this. Deep engagement with labs is required for this to be successful.
6.0	**Ministry of Health update** - To be sent by email ACTION: STA to share an update via email outlining the new Ministry structures
7.1	**Any Other Business** The Surveillance Strategy, Testing Plan, Reinfection Guidance and Infection survey were shared with CT TAG for noting so that they are aware of the current versions and status of these. Work is being undertaken on updating the Testing A3 and Clinical Guidance. This will be shared with CT TAG for comment once the new format is agreed and content updated. ACTION: Add to agenda template 'AOB' time to discuss new issues as raised by members
7.5	**Rapid regulatory review underway for POCT devices approvals** Members were informed this review was underway. Members requested regular updates on the ongoing post market monitoring of devices that are used in the open market. Particularly performance against emerging Omicron and other variants. ACTION: Process to be established by STA for regular monitoring or recalling approved RATS and monitoring performance against new variants.
7.6	**Cross government workshop on testing innovation** Members were informed this is underway, as part of a wider review of the end-to-end process of the innovation pathway. Members noted ongoing interest in this work and implications for all medical devices.

	Agenda Items for Next Meeting Meeting schedule changing to monthly and meeting length changing to 90 minutes.
Meeting closed at **12:14 pm** Next meeting: **2.08.2022**	

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
12	**COVID-19 Therapeutics TAG: Use of Serology**	Tim Blackmore to draft the guideline document	Tim Blackmore	03/05 - Action raised 17/05 - Draft document shared with CT TAG for input. Members to give feedback, specifically Maia. Tim to bring the document to next meeting. 14/06 - Verbal update
6	**Draft Memo: Proposed Direction of CT TAG**	Kirsten Beynon to provide feedback to the DG on the previous memo on next steps.	Chair	11/03 - Action raised 03/05 - The Chair and STA will work together to progress the memo. 17/05 - Update given. Memo is currently with the Science, Surveillance & Insight's Group manager before progressing to the D-G. 14/06 - Verbal update. Clarity of focus and scope, balance between strategic surveillance and planned testing of devices will be clarified in the memo and brought to CT TAG when finalised.
19	**Infection and Seroprevalence Survey Overview**	Further documentation relating to this survey to be circulated to CT TAG.	Nick Kendall	31/05 - Action raised 14/06 STA lead not available to attend. Update to be given next meeting. 12/07 - Update given. Feedback from CT TAG to be sent to ISK surveillance team.

23	**Persistent infection**	Discuss with Therapeutics TAG and STA to consider incorporation into existing Clinical Guidance from a MOH perspective.	Chair/STA	14/06 - Action raised
24	**Rapid regulatory review underway for POCT devices approvals**	Process to be established for regular monitoring or recalling approved RATS and monitoring performance against new variants.	STA	12/07 - Action raised
25	**Any Other Business**	Add to agenda template 'AOB' time to discuss new issues as raised by members	Chair	12/07 - Action raised

Closed Actions:

#	Agenda item	Actions	Action Owner	Updates
21	**Airfinity update I Horizon scanning**	Rapid diagnostics and QuantiFERON deep dives to be reported to CT TAG when available	STA	14/06 - Action raised 12/07 - Action closed, moved to regular business
22	**MOH update**	ACTION: STA to share an update via email outlining the new Ministry structures	STA	12/07 - Action raised

Document 6

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 8 April 2022
Time:	1:30pm to 2:30pm
Location:	s 9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Saleimoa Sami, Susan Morpeth
Attendees:	Andi Shirtcliffe, Andrew Oliver, Brooke Hollingshead, Daniel Bernal, Derek Fitzgerald, James Entwisle, Justine Lancaster, Josh Wiles, Ian Town, Kate Murphy, Mark Ayson
Guests:	Robert Haua
Apologies:	Anne Buckley, Michael Maze, Tim Cutfield

1.0	**Welcome and Accept Previous Minutes** **Opening Karakia** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Minutes of the last meeting (25 March 2022) were accepted with one addition to recommended early access to a PCR test before prescribing antivirals.
2.0	**Therapeutics** **PHARMAC Update** • Paxlovid has now arrived and is available from nominated community pharmacies. Pharmac has published the access criteria for Paxlovid and molnupiravir on its website. Pharmac is working with the COVID-19 Care in the Community team at the Ministry. Note that there are likely to be small ongoing changes to improve the usability of the criteria. • Pharmac acknowledges the importance of having Paxlovid available in hospitals and is working with Ministry to achieve this. A further update for arrangements is expected next week. • Negotiations for molnupiravir are complete but Medsafe assessment is still ongoing. • Pharmac has secured a supply of Evusheld (AstraZeneca monoclonal antibody). This is likely to be available mid-2022 but is dependent on a Medsafe submission and assessment.

	• There was a spike in demand for inhaled budesonide in March. AstraZeneca and Pharmac are monitoring what this means for stock holdings. Current stock holdings are between 2-7 months. Pharmac is interested in feedback from the group on how useful this is for treating COVID-19. • Remdesivir: following a shipment last week there is an increase in stock from what was communicated previously. • For baricitinib, both 4mg and 2mg remain available. Pharmac are working with the supplier to establish longer term supply. • Tocilizumab: Pharmac are working with the supplier to establish the next delivery. • Pharmac has concluded the initial discussions with Novartis (ensovibep) and GSK (sotrovimab) about COVID-19 treatments and is currently waiting for the clinical information from the supplier before bringing to the advisory group for assessment and recommendations. **Medsafe Update** • The Medsafe assessment for molnupiravir is complete. This will be referred to the Medicine Assessment Advisory Committee (MAAC) on 12 April 2022 for advice. **STA Update** • Airfinity provided information about a decrease in neutralisation against omicron sub-variants BA.1 and BA.2. for both Evusheld and sotrovimab. Discussion: The Chair noted it would be important to consider the role of Evusheld and sotrovimab by the time they become available in New Zealand.
3.0	**Equity Considerations** • The community space has been busy with the roll-out of Paxlovid. Webinars, readings, and peer groups are being hosted to educate the community on the best way of getting Paxlovid to those who need it. The regional roll-out is being incorporated into local health pathways. • It was noted there is variation of practice in the community specifically around prescribing budesonide. There is concern about this, particularly with the roll-out of further medications especially in improving communication to and by community providers. Noting there was a need to simplify the drug guidance provided to community providers. Discussion: The advisory group acknowledged these challenges and noted that there was significant work going into producing infographics and easier-to-follow guidance.
4.0	**Paxlovid roll-out** • Paxlovid became available to prescribe on 5 April. • The access criteria for Paxlovid was published on the Pharmac website on 31 March 2022. This links back to the Ministry webpage for who is at high risk of severe outcomes with COVID-19. • Health Pathways have published a localised list of pharmacies where Paxlovid is available. • A supporting resource was produced by He Ako Hiringa that provides guidance for clinicians regarding drug interactions. • Health Navigator has worked with He Ako Hiringa to make sure there is a consumer information pamphlet handed out when dispensing. This has been translated into 6 more languages. • There is going to be a combined webinar on 13 April with the Ministry, The College of General Practitioners, and Pharmac. This will largely focus on Paxlovid prescribing and dispensing.

- A second shipment of Paxlovid has arrived meaning there are more courses available than originally anticipated. Pharmac is not expecting any future shipments of Paxlovid before July 2022.
- Since becoming available there has been slightly less courses of Paxlovid dispensed than expected.
- Of the original shipment 15 percent has been kept as an essential reserve. A further 15 percent has been reserved for the localities. This allows pharmacy portfolio managers to approve further orders from the reserve stock if needed.
- ProPharma is the community wholesaler and contracted provider to distribute stock. Every pharmacy that has been identified as a participating pharmacy is now able to order stock. ProPharma does not usually distribute to hospitals.
- Due to low stock the initial decision was made to not supply Paxlovid to hospitals. The aim of Paxlovid is to avoid the need for people to go to hospital. Those that meet the access criteria are likely to require ongoing monitoring through primary care. The limitations of ProPharma distribution and data collection in hospitals also aided this decision.
- The monitoring tool that has been developed relies on NZEPS data for what has been dispensed. This is not currently used in hospitals. Consideration needs to be given for maintaining oversight.
- Supplying to hospitals aims to make Paxlovid available to patients who are currently taking the medication and admitted. Additionally, patients may be diagnosed with COVID in hospital and Paxlovid may be the best course of treatment. There also needs to be a supply in EDs for people visiting ED that may not otherwise interact with the health sector.
- It was noted that rural hospitals have been able to access stock provided through local pharmacies.
- The Ministry's data and digital team have created a dashboard that calculates:
    - How much stock is available at the wholesale level
    - How much is distributed to pharmacies
    - How much DHBs have available

  This tool also captures the demographics of patients being prescribed Paxlovid. The aim is to ensure the prescribing of Paxlovid is equitable and to help inform possible changes needed to the access criteria if stock becomes limited.
- It was noted the access criteria now includes high-risk individuals who have symptoms of COVID-19 but aren't a household contact and don't have access to a PCR test within the therapeutic window.

Discussion:

A member noted that as NZ moves into winter, there will be a greater prevalence of other viruses with similar symptoms. As there is limited supply of Paxlovid, rapid PCR tests need to prioritised going forward. This feeds back into the testing strategy and how the vulnerable population are identified.

STA have been in discussion with the Chair of COVID-19 Testing Technical Advisory Group in regard to timely access to PCR tests. A position statement is currently in progress for this.

The group agreed some attention may be needed for publicising the availability of Paxlovid to the public, so they are aware this is a treatment option.

Proposed changes to Paxlovid access criteria:

	• Currently, being incompletely vaccinated is only a risk factor when combined with age in the 50-65 year old group. It is proposed that vaccination status should be an independent risk factor for this age strata.
	• The proposed changes are as follows:
	  ○ That age over 65 years accounts for two risk factor points
	  ○ That the age strata of 50-65 years counts as one risk factor point regardless of vaccination status
	• There is current work towards creating one set of access criteria for all antivirals currently available. The aim is to set a broader threshold for considering a patient for one or more options of early treatment. Within this access criteria, there needs to be a way to prioritise the different treatment options.
	Discussion:
	Pharmac was happy to receive and consider the proposed changes.

5.0	**Horizon scanning** **Molnupiravir** • It was noted the need to be clear about the role of this drug in the community roll-out of anti-virals. Noting it should not be prioritised over the other treatments available. The access criteria should account for this within the gradient/risk matrix for treatment proposed in the guideline update. • Medsafe noted the availability of molnupiravir depends on advice from MAAC. The time frame for this can vary.
6.0	**Guideline Updates** • Last guideline update was on 1 April with the addition of Paxlovid as an option for early treatment. With this addition, remdesivir has moved down the list in order of treatment. An infographic was included to give an overview of the early treatment of COVID. • To simplify the guidance further, it is proposed to have a single access criterion. This will include a risk matrix for guidance on how to choose between the different treatment options. The risk matrix is formatted in a similar way to the cardiovascular risk matrix. • The risk matrix creates an order of preference represented by red, orange, and green. Those in the 'red' group require the highest priority of treatment (i.e., Paxlovid). Patients who meet the access criteria but are in the lower end of the threshold could be considered for other options if Paxlovid is not available and remdesivir isn't suitable. • Anyone who is severely immunocompromised is automatically considered to be 'red'. This criterion has been removed from the graph to further simplify this. Discussion: Phamac noted the system in place still requires bullet point lists to be published, however it is possible to incorporate the graphical risk tables. It was noted by a member the difficulty in reducing complexity. Real data and evidence should be used to refine and formalise the advice for each colour group. This further brings up the need to define what is meant by 'fully vaccinated' and identify who is most at risk.
7.0	**Any Other Business**
8.0	**Agenda Items for Next Meeting**

Meeting closed at **2:44pm**

Next meeting **22 April 2022 – 1:30pm to 2:30pm**

Open Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Chis to collate input from the group via email and send to Pharmac	Chris Hopkins	08/04/22 Action raised 14/04/22 Updated guideline including groups input sent to Pharmac for consideration
26	Equity Considerations	Feedback to digital team re usability and availability of different instructions for logging RAT results specifically around having an instructional video available	Justine Lancaster	25/03/22 Action raised 08/04/22 Waiting for response for digital team
28	Nirmatrelvir/Ritonavir (Paxlovid) & Guideline Updates	Ministry to look into using external contractors that use Visio to develop infographics.	STA	25/03/22 Action raised 07/04/22 Comms are reviewing the guideline document and infographic with a view to providing advice on where/how improvements in layout could be achieved. Some feedback from the Guideline Development group on how it is thought the guideline is being used/accessed for example, in regional hospitals (eg, viewed on laptop on the ward/changes reviewed on phone etc) would be helpful in identifying best changes to format.
29	Guideline update	Bring question on risk and timing from second vaccination to COVID-19 Vaccine TAG for input.	STA	25/03/22 Action raised. STA progressing with Vaccine TAG 08/04/22 An initial draft has been written and will go to CV TAG's next meeting.

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Review update and publish revised guideline 12/11/21 Guideline update to be brought forward and prepared within 2 weeks if possible to provide guidance on baricitinib use - aligning with arrival of baricitinib supply. 26/11/21 Next guideline update planned for 3 December 2021. 10/12/21 Next planned update 21 January 2021 1& 4/2 22 Guideline updated with Ronapreve content	Tim Cutfield/STA	17/09 – Action raised Guideline update published 5/11/21 Guideline update published 22/11/21- including guidance on baricitinib Guideline update published 3/12/21 Guideline update published 21/01/22 Guideline update published 04/03/22 Guideline update published 01/04/22
27	Nirmatrelvir/Ritonavir (Paxlovid)	Send Health Navigator advice on pregnancy and contraception to members for comment.	Justine	25/03/22 Action raised 08/04/22 Action noted as completed

Document 7

MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 22 April 2022
Time:	1:30pm to 2:30pm
Location:	s 9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Colin McArthur, Eamon Duffy, Elaine Yap, Michael Maze, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Derek Fitzgerald, Josh Wiles, Ian Town, Kate Murphy, Mark Ayson
Guests:	Imogen Roth, Robyn Carey, Timothy Blackmore, David Hughes
Apologies:	Brooke Hollingshead, Dan Bernal, Chris Hopkins, Jessica Keepa, Justine Lancaster, James Entwisle

1.0	**Welcome and Accept Previous Minutes** **Opening Karakia** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Minutes of the last meeting (08 April 2022) were accepted.

2.0	**Therapeutics**
	PHARMAC Update
	• Paxlovid is now available in DHB hospitals through Onelink.
	• Following the approval by Medsafe, the arrival of molnupiravir in New Zealand is immanent.
	• Remdesivir and baricitinib remain available as needed.
	• Pharmac have reviewed the proposed changes to the access criteria with the inclusion of the risk matrix and offer the following considerations:
	  • In further consultation, Pharmac has looked at adding specific conditions that add risk for severe disease.
	  • Pharmac have included the suggestion that Paxlovid should be considered first, therefore if that is unavailable or unsuitable then molnupiravir and remdesivir can be considered.
	  • Pinnacle PHO have completed modelling looking into the eligible population and state the current access criteria for Paxlovid and molnupiravir equates for 0.5 percent of the current

population. The proposed changes to the access criteria and risk matrix increase the eligibility to approximately 1.5 percent of the population (around 75,000 people).

- Pharmac is currently considering updating the risk matrix and access criteria to extend this to 2 percent by extending the access criteria to include the following:
  - other ethnicities over the age of 65 with one co-morbidity
  - Māori and Pacific peoples over the age of 25

Pinnacle modelled an additional 0.5 percent of the population becoming eligible to bring the total eligible population to 2 percent. This would increase the amount of eligible people to approximately 100,000, in line with the amount of Paxlovid courses for treatment available.

Discussion:

- There was discussion about what the threshold risk of hospitalisation should be, with members commenting this could be in the range of 5-10%. There are limitations to the data on risk of hospitalisation, particularly for comorbidities.
- A member asked if it was possible before publishing to analyse the risk for each box represented, to confirm if the highest risk groups are being accurately identified. Pharmac noted they are using data from British Colombia (BC) to analyse this. This BC data was collected between December 2021 and January 2022. Pharmac acknowledges the data from BC does not represent the ethnicity represented in New Zealand.
- Pharmac acknowledge the data collected from the Auckland hospitals. This data shows the strong risk associated with age and the need for this to be weighted appropriately in the risk matrix. The data also shows vaccination status as the next strongest driver for risk. From this data, Māori and Pacific peoples present the highest risk for ethnicity groups.
- It was suggested by several members to include percentages in the risk matrix if there is sufficient information available surrounding co-morbidities in New Zealand.
- A member noted the low number of courses prescribed for Paxlovid and encouraged efforts to extend the access criteria.
- A member raised concern over the possibility that molnupiravir would become the preferred medication to prescribe over Paxlovid due to the ease to prescribe.
- A member noted the possibility to further stratify the age categories to provide a more nuanced approach from those aged 65.
- Pharmac welcomes feedback and acknowledges there will be further input considered going forward.

ACTION: The Ministry will look into data which could better inform the percent risk of hospitalisation.

Medsafe Update

- Molnupiravir (Lagevrio): now approved under s23 (provisional approval) on 14 April 2022.
- Evusheld: Medsafe is expecting an application from AstraZeneca middle of the week beginning 25 April.
- Actemra (tocilizumab): In relation to the Changed Medicine Notification (CMN) application to extend indications to include COVID treatment, the evaluation has been completed and a decision on approval is imminent

STA Update

- STA brought the members attention to the Airfinity report shared with the minutes, and in particular the information on antivirals being administered intranasally with studies on hydroxiclorum and remdesivir.
- STA is expecting a further update on the infographics for the following meeting

3.0	**Equity Considerations** • There is ongoing concern for the prescribing of Paxlovid mainly with patients recognising and presenting within the first five days of infection. It was suggested stronger public messaging surrounding available treatments be prioritised. • The number of patients presenting is also significantly lower than that previously. This factor adds to the lower-than-expected numbers of Paxlovid being dispensed. Discussion: • Pharmac acknowledged the efforts of Pinnacle at identifying at-risk groups and making direct contact with information surrounding treatment options. It was suggested this level of personalised care be taken into consideration in the primary care sector. • A member questioned the practicality of GPs pre-emptively reaching out to high-risk patients understanding the restrictions in resources. • A proposal for oseltamivir funding for influenza over the coming winter viral season was discussed, which Pharmac acknowledged as an important concept to consider. **ACTION:** STA to relay information to the comms team and suggest a marketing campaign for therapeutic options for high-risk individuals.
4.0	**Primary Care Update** • Currently 689 courses of Paxlovid have been prescribed. This is lower than anticipated. • Molnupiravir communications update: Health Navigator are planning to release a plain language information sheet; the New Zealand Formulary (NZF) have released a drug monograph; and He Ako Hiringa are creating a resource to be available with the roll-out of molnupiravir. • There is currently no webinar planned for this release of molnupiravir. In comparison to Paxlovid there is less complexity involved in prescribing. • The slides presented will be circulated following the meeting. Feedback from the group is welcome. Discussion: • A member raised concern regarding the risk of pregnancy, as it was noted that the baseline risk for severe outcomes of COVID-19 would not meet the threshold risk criteria. • It was noted that Paxlovid should be prioritised over molnupiravir. Pharmac is currently in discussion about including this in the guidelines.
5.0	**Immunosuppressed** Perspectives on serology use • Currently it is known that the serological tests can vary by about 30 percent between assays. Its best application is in recognising those with very high or very low immunity. In most cases it is being used to identify those who are severely immunocompromised, who have not clearly mounted an immune response to vaccination. • In some situations, serological testing is being used to assess immune responses in people for the eligibility of ongoing antiviral therapy and modulators. • Rapid Antigen Tests are known to be 30 percent less sensitive to the Omicron variant than to Delta. Serology testing can play a role in identifying what portion of the population have been exposed to COVID-19 and who is immune.

	• In some cases, it helps people assess their own risk avoidance. It can give peace of mind to patients that receive a high immune response, especially those with other medical conditions. Discussion: • A member noted that serological testing could be an important tool in identifying those who are severely immunocompromised for the purpose of prescribing Evusheld. • Specialists should be looking after patients with diagnostic tests to help guide advice. The Ministry in interested in conducting a seroprevalence survey in order to understand who in NZ has been exposed but are not currently looking to base therapeutic advice on this. **Northern region guideline on Persistent SARS-CoV-2 Infection** • Concern was raised on the efficacy of antiviral monotherapy. The member encouraged increasing communication, information, and availability of Evusheld in NZ and stressed the need for an effective antibody therapy. • Convalescent plasma treatment has been used on occasion with the support of NZ Blood Service. This has been effective anecdotally particularly for eliminating persistent infection in profoundly immunosuppressed patients. The NZ Blood service is currently reserving supply for a REMAP-CAP trial to clarify the usefulness of the treatment. • The guideline deals with the persistent infected group and caring for the severely immunocompromised. This falls outside of the scope of the Hospital Guideline. Discussion on turning this into a formal guideline is welcomed. Discussion: • A member added support noting there are currently very sick people experiencing long hospital stays and again stressed the need for an objective monoclonal antiviral as pre-exposure prophylaxis for COVID-19.
6.0	**STA Information Request** • STA wish to highlight the recent information available for risk based on time since vaccination. The latest information stems from three large studies which have been shared with the group • The primary goal of vaccination for SARS-CoV-2 remains protection against severe disease, hospitalisation, and death. Efficacy against protection against infection is known to wane after a primary vaccination course. • SARS-CoV-2 therapeutics may be used in some clinical situations where patients with COVID-19 are more at risk of hospitalisation and death • There is limited data looking at the long-term (more than six months) effectiveness of vaccination in preventing hospitalisation and death • There is no data looking at long-term vaccine effectiveness in preventing hospitalisation and death across Omicron-dominant time periods, nor data from booster doses following a primary vaccination course • There is no data looking at important intersecting factors for the New Zealand setting, in particular Māori and Pacific peoples, who are known to have poorer outcomes as a result of SARS-CoV-2 infection • Current data indicates that eight months after the first dose, two doses of the Pfizer vaccine provides ~90% protection against hospitalisation and ~90% against death • Current data indicates that protection against hospitalisation death from two doses of the AstraZeneca vaccine is not sustained to the same level, particularly in elderly and clinically vulnerable populations Discussion:

	• A member noted recent literature showing a significant drop in vaccine effectiveness over time with the Omicron variant. • A member commented on personal clinical observation of people with two doses six months prior, presenting similar to those who are unvaccinated.
7.0	**Guideline Updates** • The next guideline update is planned for 29 April 2022. • The guideline may require further updates to include molnupiravir as it is likely this will become available in hospitals. There is the possibility for a delay in supply to hospitals similar to Paxlovid however this is uncertain as Onelink has been established. • The next guideline would likely include the updated risk matrix from Pharmac. **ACTION:** Pharmac to communicate the availability of molnupiravir in hospitals before the publication of the guideline update scheduled 29 April 2022.
8.0	**Next Steps/Decisions Pending** It was noted by the Chair to further include the percentage risk into the risk matrix. This is to be led by the Ministry. There was discussion on inviting an expert in epidemiology for the meeting 6 May 2022 to gather knowledge on the work being done in this area.
7.0	**Any Other Business** *None noted*
8.0	**Agenda Items for Next Meeting** *None noted*
Meeting closed at **2:40pm** Next meeting **06 May 2022 – 1:30pm to 2:40pm**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Pharmac to communicate the availability of molnupiravir in hospitals before the publication of the guideline update scheduled 29 April 2022.	Tim Cutfield	29/04/22 Planned guideline update 28/04 Guideline update deferred to 6/05/2022 following the announced arrival of molnupiravir.
26	Equity Considerations	Feedback to digital team re usability and availability of different instructions for logging RAT results specifically around having an instructional video available	Justine Lancaster	25/03/22 Action raised 08/04/22 Waiting for response from digital team
28	Nirmatrelvir/Ritonavir (Paxlovid) & Guideline Updates	Ministry to look into using external contractors that use Visio to develop infographics.	STA	25/03/22 Action raised 07/04/22 Comms are reviewing the guideline document and infographic with a view to providing advice on where/how improvements in layout could be achieved. Some feedback from the Guideline Development group on how it is thought the guideline is being used/accessed for example, in regional hospitals (eg, viewed on laptop on the ward/changes reviewed on phone etc) would be helpful in identifying best changes to format. 22/04/22 further updates expected in following week
30	Equity Considerations	STA to relay information to the comms team and suggest a marketing campaign for therapeutic options for high-risk individuals.	Justine Lancaster	22/04/22 Action raised
31	Therapeutics • Pharmac update	The Ministry will look into data which could better inform the percent risk of hospitalisation.	Robyn Carey	22/04/22 Action raised

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Chis to collate input from the group via email and send to Pharmac	Chris Hopkins	08/04/22 Action raised 14/04/22 Updated guideline including groups input sent to Pharmac for consideration
29	Guideline update	Bring question on risk and timing from second vaccination to COVID-19 Vaccine TAG for input.	STA	25/03/22 Action raised. STA progressing with Vaccine TAG 08/04/22 An initial draft has been written and will go to CV TAG's next meeting. 22/04 STA presented current data. Action closed.

Document 8

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 20 May 2022
Time:	1:30pm to 2:30pm
Location:	s 9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Elaine Yap, Jessica Keepa
Attendees:	Andi Shirtcliffe, Andrew Oliver, Brooke Hollingshead, Dan Bernal, Derek Fitzgerald, Eloise Williams, Ian Town, Justine Lancaster, Josh Wiles, Kate Murphy, Mark Ayson, Robyn Carey
Guests:	James Entwisle
Apologies:	Colin McArthur, Chris Hopkins, Eamon Duffy, Michael Maze, Saleimoa Sami, Susan Morpeth, Tim Cutfield

1.0	**Opening Karakia**
2.0	**Welcome and Accept Previous Minutes** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Minutes of the last meeting (6 April 2022) were accepted. Membership update: • s 9(2)(a) [redacted] • The Therapeutics TAG expressed gratitude to Chris and his great work. It was noted that he was an instigator of the Middlemore guidelines, from which the first 'Clinical management of COVID-19 in hospitalised adults' guidelines were based. Additionally, he played a significant role in initiating and contributing to much of the TAGs work, such as contributing to the 'Heatmap' for determining eligibility for antivirals based on risk. • A letter of acknowledgment and appreciation will be sent to Chris on behalf of the TAG. Update on open actions: • Feedback was provided to the Data and Digital team about the difficulty in uploading of RATs results to the Ministry website. o An educational video had been suggested as a useful tool, however current Data and Digital do not have capacity to assist with this.

	○ There are no updates to the usability of systems, however there is awareness that the rate of self-reporting of RATs has gone down. ○ It was noted that there may be other factors contributing to the reduced rates of self-reporting of RATs than just the data loading and/or technical issues. This could be due to attitudinal issues within the population towards COVID-19 and COVID-19 testing more generally, and therefore requires broader communication strategies, particularly for winter planning. ○ This item is now closed. • Infographics to assist with the current Paxlovid guideline have been presented in a basic form in a Microsoft word document. Previously it was discussed that a Visio infographic was to be used, however the Ministry Comms team believed a simple table in Word may be more useful. This action is still underway with the Comms team.
3.0	**Therapeutics** **PHARMAC Update** • There are increased signs of usage of antiviral treatments: ○ Increases have been seen since treatment criteria was widened (5 May 2022). ○ Continued monitoring and data collection will be used to determine if future updates to the criteria are required. ○ A web-based tool has been created to guide interpretation of the antiviral treatments criteria. This is expected to be particularly useful in understanding how many risk factors are required for access. ○ The 'He Ako Hiringa' resource has been developed and released. This contains general guidance on how to use and prescribe Molnupiravir and Paxlovid. • Evusheld (tixagevimab/cilgavimab) has been secured with likely availability from June 2022. ○ Pharmac's Treatment Advisory Group have discussed the eligibility criteria, and advice for use is in progress. ○ 20,000 courses have been secured with the option for an extension of a further 20,000 however, evidence is still evolving on the duration of protection and timing of further doses that may be required. ○ Pharmac continues to seek advice from the COVID-19 Care in the Community team on serology to determine how this treatment will work in a primary and secondary care setting. • Remdesivir stock for approximately 1,200 people is available, with ability to access more if required. • Baricitnib remains available, with stock available for approximately 330 people. It was noted there has been very little use of this in the last few weeks. • It is expected that more stock of tocilizumab will be received. ○ Ongoing work is in place with the supplier to understand when the stock will arrive. ○ An updated approach of managing ongoing supply is in progress. ○ Assessment is required to determine how to restart treatments in patients who may have had to stop taking tocilizumab due to the supply issues. Discussion: • A member enquired whether there is any work correlating changes of prescribing and availability of the oral antiviral treatments with patient outcomes or hospitalisation data. ○ The COVID-19 Care in the Community team are working with the Data and Digital team to provide this and are aiming for something to show by end of next week.

- It was raised that data had been presented for older people being prescribed Paxlovid and it was asked whether Pharmac should consider lowering some of the thresholds for access, or if any other fine tuning is required on the criteria for prescribing Paxlovid.
    - Pharmac confirmed that they were continuing to collect data and feedback as the new criteria is rolled out. This will be used to help them identify:
        1. who it is getting treatment
        2. who is missing out
        3. a clearer picture of if any updates to the criteria are needed.
    - It was noted that any updates to criteria will be reviewed as identified.
- Discussion occurred on the use and importance of serology testing with regards to Evusheld. It was noted:
    - That advice has been given by the COVID-19 Testing TAG to formally go to the New Zealand Microbiology Network for comment.
    - Currently there is no clarity around how many people would be eligible for this medicine.
    - That clarity is needed on the interpretation, practicality and logistics of serology testing as opposed to criteria that might rely on empirical views.
        - It was discussed that the serology could be used prophylactically (e.g., transplant patients that might be at high risk of severe outcomes from COVID-19 due to not mounting an immune response to the vaccine might get Evusheld injections at the appropriately determined frequency)
        - It was discussed that this would not be used for acute treatment under the current Medsafe application.
    - Data from the Auckland Hospital Renal Transplant study showed that the renal dialysis and transplant cohort showed low serological conversion after second or third vaccines.
    - Data at a national level would be helpful when determining the volume of patients that this treatment could be appropriate for. (i.e., it could be clearly defined that transplant patients could benefit, but more information is required to determine which other specialties would benefit, with mention of immunocompromised including haematological and rhetological specialties.)
    - A memo agreeing on risk factors would be of use.
    - Providing information to doctors ahead of making Evusheld available would:
        1. Allow time for patient identification
            - Patient identification can be difficult in primary care and with large cohorts
        2. Allow serology testing to begin ahead of the approval
            - This could help reduce the burden on serology labs when it is available

ACTION:

- *None stated.*

Medsafe Update

- Actemra (tocilizumab) was approved on 12 May for use in COVID-19 hospitalised patients who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilations.
- Evusheld and Sotrovimab have both been approved in EU and Australia.
- A meeting was held with Gilead to discuss Remdesivir. They are expected to respond to a request for further information by end of June. s 9(2)(b)(ii) [redacted]

STA Update

- Highlights from the latest developments in science were presented. This included:
    - A deep dive on Paxlovid trials in vaccinated patients.
        - It was estimated that vaccination reduces risk of hospitalisation by 35%, and new numbers needed to treat (NNT) have been produced

        - Based on the adjusted risk:
            - EPIC-HR trial (Paxlovid) NNT will increase from 18 to 27
            - MOVe-OUT trial (Molnupiravir) NNT will increase from 34 to 53
    - A deep dive assessed pre-exposure prophylaxis and post-exposure prophylaxis of Paxlovid
        - The trial did not meet its primary end point (i.e., it did not significantly reduce household infections when used as a post-exposure prophylaxis)
    - There were no changes in the international approved treatments lists.
- An update on the data for risk of hospitalisation data for the heat map and access criteria was given:
    - The Ministry's Insights team have worked in this space and the final data is in progress towards sign-out. Data should be ready for the Therapeutics TAG by end of next week for crude and adjusted risk ratios for standard demographic factors and vaccination for population level risk and case level risk.

Discussion:

- It was noted that this data should connect with data from the COVID-19 Care in the Community work.

ACTION:

- STA data team and COVID-19 Care in the Community to liaise and align collected data.

Primary Care Update

- An update accompanied by slides was presented: Data showing numbers of Molnupiravir and Paxlovid prescribed to date:
    - The access criteria widened on the 5 May. Increased rates of prescribing were seen within 24 hours of the criteria widening. This has been maintained since, with dips in prescriptions over the weekends.
    - The rates of Molnupiravir and Paxlovid prescribed appear to track in parallel with each other (i.e., there has not yet been an increased proportion of Molnupiravir to Paxlovid seen).
- Prescription data was broken down according to ethnicities:
    - Work is being completed with the Data and Digital team as this could be used to see if the rates prescribed match the prevalence of COVID-19 in the community (i.e., used as a measure of equity).
    - Rate in prescribing to Māori appear to be increasing
    - No increases seen in Pacific peoples.
- Data on the dispensing rates of Paxlovid for its first month (4 April to 5 May):
    - Prescribing rates for older Māori and Pacific peoples were higher than Asian/European.
    - This was expected given the increased risks in these populations
    - A deeper dive is to be completed as more information is collected.
- Data on prescriptions was broken down by deprivation status:
    - Deprivation appears to be a strong indicator of hospitalisation risk
    - The data showed a peak in the most deprived being prescribed the most recently. It was noted this is encouraging, however not a sustained pattern yet.
    - The least deprived group were often among those most prescribed to.
    - It was noted that the deprivation data should be interpreted with caution as it can be misleading due to a lot of factors contributing differences within deprivation status. One point mentioned was that wealthier people tended to live longer and older people were identified more as requiring therapeutics. This could be a contributor to why we are see high prescribing in higher deprivation groups.

- Data of prescriptions per DHB:
  - It was noted this should be led by where the outbreak is more dominant
  - Noted that the data of DHB with highest rates of infection were not aligned with where the highest prescribing was seen.
  - It was discussed that high rates of infection are not always an indicative of hospitalisation and severe disease, therefore it was of limited data using rates of infection as a main metric for comparing rates of prescriptions too.
- Data from an RNZCGP survey on barriers to prescribing was presented:
  - This identified complicated access criteria (proactively promoting Pharmac's criteria tools to assist with prescribing)
  - Approximately 50% of eligible patients were perhaps unnecessarily excluded due to contraindication and drug interactions
  - Other identified barriers included: insufficient time/resources/lack of systemic support identifying the vulnerable/eligible.
  - Key ways to support barriers to prescribing were identified:
    - Encouraging pharmacists and specialists to work closely with GPs to support their decision making
    - Primary Health Organisations (PHOs) are helping to support
    - The National Risk Stratification tool is not yet accurate enough to support the decision making of who can be proactively identified.
- The Care in the Community team are looking at equitable outcomes using data, communication plans (through multi-pronged approach to people directly and the health sector) and raising awareness (through webinars).
  - Risk scores can be another facilitator aiding people to get access to therapeutics
  - Meetings with Global Health, Pharmac and MFAT to understand how to donate therapeutics to the Pacific are underway.
- Other:
  - The team is continuing to monitor utilisation against supply (with Pharmac support), actively encouraging review of the eligibility criteria/access barriers
  - Working with Pinnacle PHO to conduct an audit of:
    - Who met access criteria
    - Who tested positive
    - How many people received therapeutics
- He Ako Hiringa published a practice-level self-audit tool for Paxlovid prescribing.
- They are also developing a communications plan, which involves liaising with Iwi and Pacific community providers, Equity and Treaty responsiveness team, Disability support providers, Care coordination hubs and Interagency partners, to ensure the work is targeted to priority and vulnerable populations.

Discussion:

- Information on the number of prescriptions divided by DHB needs more information to get a full picture. Suggestions included:
  - Dataset to account for size of DHB
  - Dataset to account for demographics of DHB
  - Data to capture DHB end goals. (i.e., the DHBs with highest infection rates also had very low or no hospitalisation/deaths)
    - More work is being done by Data and Digital to add strength to this dataset
    - It seems likely that some DHBs are likely still under-utilising therapeutics
- STA noted that MoH have a Behaviour Science team conducting surveys within the population with similar questions as asked in the RNZCGP survey.
  - It was noted that now therapeutics are available it would be good to get questions about them addressed to the general public as well as health providers.

	• It was clarified that the Health Pathway Webinar is to talk to:
	  ○ The 50% contraindication to spread key messaging, with follow up survey to see if this has an impact on educating.
	  ○ Drug interaction and working with pharmacists, (i.e., spread the work, collaboration key)
	  ○ Treaty advisor to raise awareness of barrier to access.
	  ○ It was noted that many ED practitioners firmly believe antiviral treatments in scope of GP. This would be an area to explore to increase prescribing as:
	  ▪ Could be an issue as many people use ED in lieu of GP services
	  ▪ ED staff are able to prescribe (particularly promoted in rural areas)
	  ▪ Noted that there is a risk due additional monitoring required on antiviral treatment and good process are required and in place
	  ▪ After diagnosis in ED the case needs to be linked into the GP and ED Eclair notification can take 3 days so this may take them out of time.
	
	ACTION**:** Memo to specialist for Antiviral (Elaine to work on)
	
	• Data team with STA to link in with COVID in the Community team to have fullest utilisation as possible

4.0	**Equity Considerations**
	
	• ED Eclair notification can take three days and therefore patients presenting at later stages can miss the window of opportunity for treatment. This could include high-risk people who would benefit from treatment.
	• Good to see meaningful response from GPs on barriers to prescribing
	• Support in prescribing was discussed:
	  ○ Support differs between clinics
	  ○ Update with Health Pathways link to Pharmac has been helpful for prescribers.
	
	Discussion:
	
	None noted

5.0	**Antiviral Access Criteria Update** *None noted*
6.0	**Future of Therapeutics TAG** Scope and context of reforms • The Group were thanked for their contributions to date. With the STA's move to the Public Health Agency, there needs to be a conversation about where is the best place for the Therapeutics TAG to sit. • The original mandate of the Group was to develop and support hospital guidelines and to provide advice to ministry. • The Group's role has expanded to provide advice and support of community guidelines, whether treatments are reaching the right people and whether there are gaps Core elements to keep for success for the future: • Need to keep the Therapeutic TAG sustainable for all involved, therefore there was a suggestion to move to monthly meetings, with an ability to meet more rapidly if required for a particular reason • Suggested to discuss further at the next Therapeutic TAG meeting, as several member were apologies for the current meeting.

7.0	**Guideline Updates** *None noted*
8.0	**Next Steps/Decisions Pending** *None noted*
9.0	**Any Other Business** *None noted*
10.0	**Agenda Items for Next Meeting** *None noted*
11.0	**Closing Karakia**
Meeting closed at **2:36pm** Next meeting **3 June 2022 – 1:30pm to 2:30pm**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Pharmac to communicate the availability of Molnupiravir in hospitals before the publication of the guideline update scheduled 29 April 2022.	Tim Cutfield	29/04/22 Planned guideline update 28/04/22 Guideline update deferred to 6/05/2022 following the announced arrival of molnupiravir. 06/05/22 Guideline updated. 20/05/22 No update.
30	Equity Considerations	STA to relay information to the comms team and suggest a marketing campaign for therapeutic options for high-risk individuals.	Justine Lancaster	22/04/22 Action raised 06/05/22 In progress 20/05/22 Updates on equity considerations: -COVID-19 Care in the Community (CiC) and MoH equity advisors are meeting regularly and engaging with Māori and Pacific providers to understand any inequities in the prescribing or supply of COVID-19 therapeutics. - A pamphlet is in development to raise public awareness of COVID-19 therapeutics that can be handed out to patients who these providers engage with. CinC are considering the

				prospect of a targeted campaign however this would require approval for resource. - CinC are also in the process of getting funding approval for a SMS/email notification to go to all who have received 3rd primary dose of a COVID vaccine to inform them they are likely to be eligible for covid therapeutics should they become infected. - An 0800 number has been set up (run by Whakarongorau) to answer questions to "all things COVID".
31	Therapeutics • Pharmac update	The Ministry will look into data which could better inform the percent risk of hospitalisation.	Robyn Carey	22/04/22 Action raised 06/05/22 STA and Pharmac are aware of the issue and this item is being progressed.
32	Therapeutics • STA update	Memo outlining the information and guidance for DHB clinicians on antiviral agents for treatment of COVID-19 is to be drafted and circulated for members to comment on ahead of next meeting.	STA/ Elaine Yap	06/05/22 Action raised 20/05/22 In progress

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
26	Equity Considerations	Feedback to digital team re usability and availability of different instructions for logging RAT results specifically around having an instructional video available	Justine Lancaster	25/03/22 Action raised 08/04/22 Waiting for response from digital team 06/05/22 Waiting for response from digital team 20/05/22 digital team can not make this a priority currently. Item closed

28	Nirmatrelvir/Ritonavir (Paxlovid) & Guideline Updates	Ministry to look into using external contractors that use Visio to develop infographics.	STA	25/03/22 Action raised 07/04/22 Comms are reviewing the guideline document and infographic with a view to providing advice on where/how improvements in layout could be achieved. Some feedback from the Guideline Development group on how it is thought the guideline is being used/accessed for example, in regional hospitals (eg, viewed on laptop on the ward/changes reviewed on phone etc) would be helpful in identifying best changes to format. 22/04/22 further updates expected in following week 06/05/22 In progress 20/05/22 Infographics and current guidelines have been passed on to MoH Comms team. Item closed.
33	Therapeutics • Primary care update	Justine to follow-up on logging of RAT results	Justine Lancaster	06/05/22 Action raised 20/05/22 There is no update on the usability of their systems, however there is awareness that the rate of self-reporting of RATs has gone down. It was noted that the reduced rates of self-reporting of RATs may be issues other than just the data loading and/or technical issues. This could be due to attitudinal issues within the population towards COVID-19 and COVID-19 testing. i.e. more than just digital solution but also feeds into communication strategies, (i.e. winter planning). Item is now closed

Document 9

MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 03 June 2022
Time:	1:30pm to 2:30pm
Location:	s 9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Eamon Duffy, Jessica Keepa, Michael Maze, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Brittany Illingworth, Brooke Hollingshead, Dan Bernal, Derek Fitzgerald, Eloise Williams, Ian Town, Justine Lancaster, Josh Wiles, Robyn Carey
Guests:	Antoinette Righarts, Rachel Webb
Apologies:	Colin McArthur, Elaine Yap, Mark Ayson, Saleimoa Sami

1.0 Opening Karakia

2.0 Welcome and Accept Previous Minutes

Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group.

Minutes of the last meeting 20 May 2022 were accepted.

Update on open actions:

30	Equity Considerations	STA to relay information to the comms team and suggest a marketing campaign for therapeutic options for high-risk individuals.	Justine Lancaster	

COVID Care in the Community (CinC) are actively engaging with community and Iwi providers. Bespoke communication approaches are being implemented by each of the individual providers with the communities. This includes preparing and commissioning written pamphlets which will be available to hand out at events and 1:1 interactions, to ensure communications are not relying solely on digital means only for messaging – Item to be closed.

3.0	**Therapeutics**
	
	PHARMAC Update
	
	• Evusheld: Pharmac have secured a supply of Evusheld (AstraZeneca's monoclonal antibody). This is expected to be available later this month or early July, dependant on Medsafe approval.
	  ○ Pharmac have been seeking advice from their COVID-19 technical advisory group and external experts on the possibility of using serology within the access criteria. Based on this advice, this is not being pursued initially due to various complications associated. Alternatively, a list will be provided of the various conditions or situations that could mean someone is severely immunocompromised, as has been used by other jurisdictions overseas.
	  ○ The access criteria are still subject to a consultation, which is expected to be released next week. Feedback will be welcomed on criteria and whether the conditions and groups targeted are captured correctly.
	  ○ Pharmac are working closely with CinC to determine how the implementation of Evusheld will work across primary and secondary care settings.
	• Oral antiviral treatments (Paxlovid and Molnupiravir): Pharmac are working closely with CinC to monitor usage and to update the criteria as new data, evidence and usage trends emerge.
	• Remdesivir: There is stock for approximately 1100 people available, and more stock can be obtained from the supplier as needed. Advice has been received from the Pharmac COVID-19 advisory group that there is interest in widening the criteria. This is something that may be progressed after Evusheld is completed.
	• Baricitinib has had a low uptake in usage over the last few weeks. Currently there is stock for approximately 330 people still available.
	• Tocilizumab: stock has started to be received however the stock level requires close management as the pandemic is continuing.
	
	Discussion:
	
	Evusheld
	
	• Members noted that it would be useful to see some data about severely immunocompromised people. However, is appreciated that the people who are best placed to collate this data would find this difficult in the current clinical setting.
	• It was discussed that it would be helpful for providers to receive more information from CinC relating to the implementation, in particular the expectations about delivery and supply of Evusheld.
	  ○ Currently there is no plan signed off on the implementation process, however the proposal is for a joint effort between primary, community, and secondary care.
	  ○ This would likely have an emphasis on secondary care capturing a large number of the urban and community population to ensure that more rural or remote people who are not regularly linked into outpatient clinics also get access.
	  ○ Secondary care has the advantage of having full clinics of people that meet the eligibility criteria.
	• Pharmac are currently not drafting serology into the criteria but welcome feedback if a use is identified. It was noted that the criteria may widen to more groups as more stock becomes available.
	
	Medsafe Update
	
	• The initial evaluation for Evusheld has been completed and Medsafe are expecting the additional requested information from the company by 17 June.

- The initial evaluation for Sotrovimab has been partially completed. A request for further information has been requested on quality control.

STA Update

- Two pre-prints about the real-world evidence of effectiveness of Molnupiravir and Paxlovid have been published. These have reported that:
  - both Molnupiravir and Paxlovid reduced disease progression in moderately ill in-patients who were not on supplemental oxygen
  - Paxlovid (but not Molnupiravir) reduced the risk of hospitalisation in out-patients.
- Evusheld (AZD7442) retains neutralising ability against BA.4 and BA.5.
- Rebound infections have been associated with Paxlovid. Reports of rebound infectious are increasing, but as yet none have reported severe disease. The CDC recommends anyone experiencing a rebound in COVID-19 symptoms after the completion of a 5-day Paxlovid course should isolate for a further 5 days (but does not recommend a second course). COVID-19 monoclonal antibodies have significantly longer half-lives and bioavailability than antivirals, hence are less susceptible to rebound.
- RCT (ACTT-4) reports no significant difference in mortality, clinical progression, use of invasive (and non-invasive) ventilation between dexamethasone and baricitinib in hospitalised individuals; baricitinib had a better safety profile.

Discussion:

- It was noted that although there may be some equivalence between dexamethasone and baricitinib, there is a significant difference in their costs.
  - Some people experience significant harm from treatment with dexamethasone, particularly people with diabetes.
  - Careful considerations between risks and benefits are needed before prescribing dexamethasone.
  - It was also acknowledged that dexamethasone is significantly more affordable.

Primary Care Update

- Data was presented on prescribing of oral therapeutics, showing that rates in prescriptions are rising as prescribers become more familiar with the therapeutics. It was noted that the number of prescriptions understandably dips during the weekends.
- CinC are exploring ways to overcome prescribing barriers that represent workforce availability. Additional planning is underway for winter and bigger surges, and how the stresses from this to the healthcare system can be managed.
- Pharmacist prescribers can now prescribe oral therapeutics.
- Overall, Europeans are currently receiving the largest numbers of prescriptions. Pacific peoples have had the highest numbers of Paxlovid prescriptions per proportion of active cases, with 1.5% of Pacific peoples who become a case receiving a course of Paxlovid within 5 days. Māori have been receiving Molnupiravir at a much higher rate than other ethnicities in last few days.
- As expected, older people are receiving drugs at greater rate than younger. There has been higher prescribing for older Māori than Pacific peoples or Europeans. Asian currently have the highest rates of prescription in the 85-89 age bracket in the past week. These trends will need to be monitored to help detect divergence between groups over time.
- In terms of deprivation status, people in the least deprived quintile have been receiving a greater portion of oral therapeutics than the other deprivation groups. It is unclear at this stage if this bias is due to people being less deprived being more likely to live to an older age. All other deprivation statuses appear to be prescribed to in an equal amount.
- Data has been collected on the number of prescriptions in each DHB. Currently Canterbury is ahead which is reflective of the high rates of infection in the region. Auckland, Southern and Waikato all also had high rates of prescription.

	• CinC are conducting regular meetings with equity advisors to ensure hard to reach populations have awareness and access to these drugs. Communications are being produced in different languages and in accessible formats to ensure as many people can access them as possible. Additionally, resources and webpages are being developed specifically for the providers of disability services to help with funding applications and to improve accessibility for people in their care. Discussion: • It was noted that primary care colleagues could find it useful to see information and specific data from countries already successfully using the therapeutics. ○ CinC indicated that they are intending to do this.
4.0	**Equity Considerations** • No new information was discussed. It was noted that there had been a lot of mahi in putting equity at the core of the CinC work.

5.0	**Future of Therapeutics TAG**
	
	• There is an ongoing need to discuss how to make sure the group remains sustainable moving forwards, what purpose the group serves and for whom, the scope of requests that the TAG is used for, and how advice should be commissioned through the group.
	• Monthly meetings were discussed as an ideal option, with some flexibility to deal with bigger issues when they arise.
	• It was noted the appropriate levels of support required by the group moving forwards would need to be discussed and determined.
	
	Monkeypox
	
	• The response to Monkeypox has shown a potential strength and future utility of the group. It was possible to turn around hugely valuable advice in a quick timeframe partly because the group is already established and ready to go.
	
	Discussion:
	
	• The possibility of the Therapeutics TAG moving away from specific responses and setting up an emerging infectious diseases response was discussed.
	  ○ This included suggestion of a high consequences infectious disease system where all emerging diseases have same people set up and ready to respond.
	  ○ An example of this has been seen in the UK.
	  ○ It was noted that some flexibility to the scope/agenda would allow the TAG to deal with bigger topics when they arose would be helpful.
	  ○ These will be part of ongoing discussions as the new entities come into place, with feedback sought on the advice needed from within the Ministry.

6.0	**Hospitalisation risk data** Preliminary data from the Ministry's Science, Surveillance and Insights team was presented that looks at an epidemiological analysis of the risk of a COVID-19 cases becoming hospitalised and the associated mortality risk estimates. It was noted that there is now a new larger hospitalisation dataset (the National Minimum) which was used. • The data includes hospitalisations from a list of causes that might be related to COVID-19. • It then excludes anyone who was known to be not a COVID-19 case.

	• The definitions are very wide, so it is expected that approximately 75% of the dataset are possibly COVID-19 related.
	• Further updates to the dataset are expected.
	
	The presentation showed:
	
	• The cumulative incidences for hospitalisation amongst cases.
	• The incidence ratios between groups including adjusted risk.
	• Data broken down by basic demographics, including gender, ethnicity, deprivation status and vaccination status. It was noted that:
	  ○ at this stage the vaccination status had not been adjusted to account for the timing of the vaccination, although this is something that will be completed
	  ○ Pacific peoples appear to have higher risk than other ethnicities even when deprivation status is considered
	• The next steps are to include some stratification to see what is happening within the adjusted risk models. This will be completed by adding morbidity measures, such as M3 and P3 scores while considering timing since vaccination.
	
	Discussion:
	
	• The dataset was considered very valuable for discussions of who is at risk, which has been an ongoing concern of the Therapeutics TAG.
	• It was noted that the total numbers of COVID-19 deaths reported do not appear to match the numbers of COVID-19 deaths at hospital. It was speculated this is likely due to elderly dying at home or in rest homes.
	  ○ Although the dataset captures mortality rates and hospitalisation dates, it does not record where a case has died.
	• There is potential to import a model of therapeutics use into the dataset.
	  ▪ It may be possible to run a model comparing people who did get therapeutics with people who did not to see if this changed the risk of hospitalisation. It was noted that it could be challenging to get perfectly matched groups of people who did and did not get therapeutics due to the complex eligibility criteria.
	  ○ Additionally, hospitalisation and any subsequent length of hospitalisation as well as mortality can be investigated between these two groups.
	  ○ Therapeutics models would likely rely on data relating to dispensed therapeutics versus an outcome.
	  ▪ It was cautioned that non-adherence would not be considered in these models and would be a limitation.
	  ▪ This is a common limitation to epidemiology studies, however, this data would provide an indication when used together with other evidence.
	  ○ It was noted that it would be of interest to check what therapeutic data-points can be accessed.
	
	The data will be brought back to the Therapeutics TAG once this further information has been collated and analysed.

7.0	**Guideline Updates** • No updates for this meeting, however, it was noted that the next planned update to the Guideline was scheduled for the end of this month. Evusheld is the next item which will require updates to allow it to be included in the in-hospital guidance, and the group are not expecting any other major changes. **Memo on antivirals**

	• The antivirals memo is formatted and ready to go except for one last comment. This was to confirm with Medsafe if there is going to be a change to Remdesivir and its availability as an unapproved drug under section 29. o Medsafe confirmed that an application is under review, however there is no timeframe on when this will be resolved.
8.0	**Next Steps/Decisions Pending** Any Other Business: None raised. **Paediatric infectious disease update:** Discussions are in progress relating to the access criteria for antivirals and how they might apply to children and teenagers who do not meet the stipulated number of criteria but may have one or two significant clinical illnesses. It was noted that there is a particular interest in Evusheld and that considerations are needed in particular for its use in the 12-17 age group.
9.0	**Closing Karakia**
Meeting closed at **2:29 pm** Next meeting **8 July 2022**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Pharmac to communicate the availability of Molnupiravir in hospitals before the publication of the guideline update scheduled 29 April 2022.	Tim Cutfield	29/04/22 Planned guideline update 28/04/22 Guideline update deferred to 6/05/2022 following the announced arrival of molnupiravir. 06/05/22 Guideline updated. 20/05/22 No update. 03/06/22 No updates for this meeting, Evusheld due for updates soon.
31	Therapeutics • Pharmac update	The Ministry will look into data which could better inform the percent risk of hospitalisation.	Robyn Carey	22/04/22 Action raised 06/05/22 STA and Pharmac are aware of the issue and this item is being progressed. 03/06/22 Presentation from MoH SS&I team. Further data to be presented when available.

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
30	Equity Considerations	STA to relay information to the comms team and suggest a marketing campaign for therapeutic options for high-risk individuals.	Justine Lancaster	22/04/22 Action raised 06/05/22 In progress 20/05/22 Updates on equity considerations: 03/06/22 Item to be closed.
32	Therapeutics STA update	Memo outlining the information and guidance for DHB clinicians on antiviral agents for treatment of COVID-19 is to be drafted and circulated for members to comment on ahead of next meeting.	STA/ Elaine Yap	06/05/22 Action raised 20/05/22 In progress 03/06/22 Memo circulated. Item closed

Document 10

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 08 July 2022
Time:	1:30 pm to 2:30 pm
Location:	s 9(2)(a) [redacted]
Chair:	Nigel Raymond
Members:	Elaine Yap, Jessica Keepa, Michael Maze, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Brittany Illingworth, Brooke Hollingshead, Dan Bernal, Derek Fitzgerald, Eloise Williams, Josh Wiles, Mark Ayson
Guests:	Antoinette Righarts, Jennifer Keys, Robyn Carey
Apologies:	Eamon Duffy, Colin McArthur

1.0	**Opening Karakia**
2.0	**Welcome and Accept Previous Minutes** Dr Nigel Raymond welcomed all members and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Minutes of the last meeting 03 June 2022 were accepted.

3.0	**Therapeutics**
	PHARMAC Update
	• Both Evusheld and Sotrovimab have been listed on the pharmaceutical schedule (01 July 2022). A focus has been on finalising their access criteria's. Pharmac has incorporated feedback from this TAG, its own advisory groups, and a public consultation.
	• The public consultation closed last week. Information is still being incorporated, however overall:
	  ○ feedback included a suggestion for increasing the time frame for the access criteria for Evusheld. This would increase access to people who are on inhibitor or immunosuppression drugs (i.e., solid organs transplant recipients).
	  ○ limited feedback relating to Sotrovimab. It was noted that there is a relatively restricted criteria proposed. Additionally, it has limited efficacy against current variants.
	  ○ feedback was supportive of the proposed persistent infection guidelines.
	• It was noted that Medsafe approval is still ongoing, therefore it is uncertain when these will be available for approved use in New Zealand.

	• 216 vials of Evusheld are available for use now and can be ordered from Healthcare Logistics (HCL). These have no current access criteria, however Pharmac have made suggested criteria available. • There is ongoing review of antiviral access criteria being completed in collaboration with COVID care in the community (CinC) team. • Remdesivir has been added to the Pharmac schedule under section H (hospital use). • Tocilizumab stock levels and management is returning to normal and the patients who were taken off this treatment due to supply issues may be changed back to it if required. • Baricitinib still has enough stock for approximately 330 patients. A member queried how the remdesivir stock supply is going and whether there was enough stock for new surges. Pharmac noted that there is currently about 800 patient's worth of stock available. Pharmac can access more stock if required and are likely to look into doing this. **Medsafe Update** Medsafe evaluations are nearing completion for both Evusheld and sotrovimab. It is expected that decisions on whether consent can be given for both drugs and if either will need to be referred to Medicines Assessment Advisory Committee are likely to be made within the next week. If these do go to the committee, this will be meeting later this month. **STA Update** • An update was given by the STA representative. This matched the information circulated with the agenda. **Primary Care Update** • It was noted that pharmacists will soon be able to prescribe Paxlovid and molnupiravir. • Due to changes in staff, specific questions relating to primary care will be required ahead of meetings to help staff prepare.
4.0	**Equity Considerations** An update was requested in relation to the improvements of access of oral antiviral in the community, specifically relating pharmacists being able to prescribe oral vials and improve weekend access. • It was reported that work is in progress, with advice being sought from the successful implementation of prescriptions through community pharmacies in Quebec. • A mechanism is being put in place to reclassify medicines temporarily and rapidly to pharmacist use.
5.0	**Update on Hospitalisation and Mortality Data** Data on the risks of hospitalisation and mortality associated with COVID was presented the TAG by a guest from the Intelligence, Surveillance and Knowledge team. This built on the presentation shown at the previous TAG. • Data relating to hospitalisation was restricted to cases in which COVID-19 could not be ruled out as a cause/contributor. • Data relating to mortality included cases which can be attributed to COVID-19 as an underlying or contributing factor to death. • Mortality report uses different age split to usual COVID-19 data sets due to the increased association between age and mortality. Overall, in terms of mortality: • There had been relatively low rates in people over 60 prior to March 2022

	• Generally decreasing rates for most age groups since the first wave. However, this is not true for the older age groups:
	  ○ For 80-89 and 90+ year olds mortality has continued to rise
	• In the latest data, significant increases in 65+ age group
	  ○ Approximately 50% increase in Maori
	
	There is the potential to investigate the link between hospitalisation and the potential for therapeutic intervention.
	
	A preliminary look at data has investigated the window of time from onset of symptoms or COVID-19 report date to hospitalisation
	
	• Minimal numbers of people reported symptoms prior to hospitalisation with most people self-reporting symptom onset as the day of hospitalisation.
	• Data surrounding the onset of symptoms was only recorded for 50% of hospitalisation cases. From this:
	  ○ Approximately 25% had symptoms start on the day of hospitalisation (Day 0)
	  ○ Approximately 50% reported symptoms within days 1-5
	  ○ Approximately 20% reported symptoms after more than 5 days.
	• Risk factors for hospitalisation showed vaccination was the strongest modifiable risk factor for people going to hospital. Increased age and co-morbidities were also strong indicators of hospital risk.
	
	Action: To share slides with the Therapeutics TAG.

6.0	**Query about change in access criteria to primary care** Criteria for Paxlovid use based on Canadian experience have been included in the hospital guideline to allow consideration of an option for its use in people with severe renal impairment (eGFR<30 or on dialysis) in a hospital setting. This has led to a discussion on if this widening is also appropriate to extend to a primary care setting and if so, what are the appropriate safeguards required. Rational for the extension to a hospital setting was: • The initial exclusion of people with advanced kidney disease from treatment with Paxlovid was that there was no evidence relating to this group from initial Paxlovid validation trails. ○ This is likely due to this group presenting as high risk during the initial phase of clinical trial where safety and efficacy are still being proved. • Chronic kidney disease is frequently a marker of multi-morbidity and high risk from COVID-19 • Other countries have working groups that have put together a proposal for dosing based on small numbers of a pharmacokinetics study that suggest dosing is appropriate for people with advanced renal dysfunction, including dialysis. • This is a ‘consider use’ as there is not yet data from a large-scale study supporting the safely, however there is a compelling argument that the from early phase 1 trials that this is safe and tolerable. • Currently the only other COVID-19 antiviral treatments available to these patients in NZ are remdesivir and molnupiravir. However, with remdesivir the excipient betadex sulfobutyl ether sodium is renally cleared and accumulates in patients with decreased renal function; requiring caution if eGFR is less than 30 mL/min/1.73m2 (limited information available). Molnupiravir can be used, but from published studies is expected to be considerably less effective. Therefore, the NZ guideline group felt that it was reasonable to follow other countries and recommend “consider use” of Paxlovid for patients in these groups that are in hospital. • Use in the hospital may be the appropriate place to build experience with this treatment initially. • This could be a way to treat people who may otherwise be excluded from efficacious early treatment options, however some safety concerns are appropriate.

	• Noted the dispensing issues (day night, half doses) The regulator point of view is that as this is prescribed under Section 29, the medical practitioner would have to make a professional judgement that its use is appropriate. The TAG noted the following in relation to providing advice for use of Paxlovid in primary care: • It may be reasonable and beneficial for people with eGRF<30 to be considered for treatment with Paxlovid. • Providing clear guidance would be more useful than a generic 'discuss with GP/nephrologist/infectious disease physician'. This is particularly relevant in smaller centres where no/less specialists are on hand. • The logistics of dispensing the drug at an appropriate and easy to use way for the patient needs to be considered. • Support required to pharmacist on the challenges of the treatment and adjustments to dose. ○ May result in some parts of packs being disposed of due to adjusted dose • In summary, it seems reasonable to provide in a primary care setting and may prove to be less of a safety issue and more of a dispensing problem. **Action:** To draft guidelines for GPs and seek Medsafe advice.
7.0	**Fully vaccinated definition and access criteria** It has been noticed that some hyperlinks in guidelines currently lead to pages that no longer exist. In particular, the page that defined 'fully vaccinated' has been removed. The concept of 'fully vaccinated' is changing as new evidence emerges throughout the pandemic. The discussion relates to what is the threshold with regards to vaccination where risk shifts from a lower risk to higher and where the threshold lies in access to therapeutics. It was noted that the COVID-19 Vaccine TAG (CV TAG) is working on a definition of fully vaccinated **Action:** To check in with CV TAG for their definition and ensure this is relevant in therapeutics.

8.0	**Guideline Updates**
	
	• The updates to hospital guideline include:
	  ○ The use of Paxlovid in hospital setting (discussed in item 6.0).
	  ○ A definition of 'fully vaccinated' (discussed in item 7.0).
	  ○ Support for using remdesivir for people with moderate COVID-19 who are early in illness (based on the Solidarity trail results)
	  ○ Evusheld referenced in guideline.
	  ○ A recommendation not to use baricitnib instead of steroids (based on current limited supply, cost, availability). This could be reassessed if changes to stock are implemented by Pharmac.
	
	Action: To draft a memo with support from the Therapeutics TAG.

9.0	**New structure of MOH/PHA** A presentation was given to explain the new structure of the Health Teams: • Health NZ: providing the operational and delivery roles. (This includes the National Public Health Service Organisation) • Ministry of Health: providing the chief stewardship role (i.e., performance, regulation, advice to the minister etc.) In total there will be nine directorates that make up the Ministry of Health (These are: Public Health Agency (PHA), Evidence Research and Innovation (ERI), Strategy and Policy, Maori Health and Maori

	Crown relations, Regulations, System Performance and Monitoring, Government and Executive Services, Corporate Services and Clinical leadership) Key take home: • Science Technical and Advisory (STA) team will stay at the MoH within PHA directory • PHA includes: the Intelligence, Surveillance and Knowledge team (this is made up of STA, Intelligence and analytics and some broader communicable disease teams). • The ERI may also be of interest to TAG members. This is a completely new directorate which will working with STA on many pieces of advice.
10.0	**Next Steps/Decisions Pending** **Monkeypox update:** • There has of yet been no probable or confirmed case of Monkeypox in New Zealand, as of the current date (8th July). • A test definition has been agreed on and monkeypox has been made a notifiable disease. • The advice provided by this TAG was to use vaccination as a strategic approach, targeting close contacts post-exposure rather than a broader public health vaccination. • New Zealand government is looking at options to secure the third-generation vaccine. Of note the current stock is second-generation and expired • There is a small pool of stock of cidofovir. Trying to get access to tecovirimat, however this is limited internationally. • Work is underway to get access to vaccinia immune globulin and antivirals from Australia if required. New Zealand is in the queue for next year, although exact quantities has been requested. • A request for advice has been received around pre-exposure prophylaxis for specific groups (i.e., MSM) and if this is relevant in a New Zealand context. Discussion with CV TAG members suggested use post exposure for close contacts may be more appropriate (pending international experience).
11.0	**Closing Karakia**
Meeting closed at **2:53 pm** Next meeting **05 August 2022**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
33	**Paxlovid use in primary care**	To draft guidelines for GPs and seek Medsafe advice.	Jennifer Keys/STA	8/7/22 Item opened
34	**Fully vaccinated definition and access criteria**	To check in with CV TAG for their definition and ensure this is relevant in Therapeutics.	STA	8/7/22 Item opened
35	**Evusheld advice**	To draft a memo with support from the Therapeutics TAG.	STA/Tim Cutfield	8/7/22 Item opened

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
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31	Therapeutics Pharmac update	The Ministry will look into data which could better inform the percent risk of hospitalisation.	Robyn Carey	22/04/22 Action raised 06/05/22 STA and Pharmac are aware of the issue and this item is being progressed. 03/06/22 Presentation from MoH SS&I team. Further data to be presented when available. 08/07/2022 Updated presentation on hospitalisation and mortality data was given. To share slides with Therapeutics TAG. Item closed.

Document 11

MINUTES: COVID-19 Therapeutics Technical Advisory Group
Te Rōpū Haumanu Kowheori-19

Date:	Friday 08 July 2022
Time:	1:30 pm to 2:30 pm
Location:	s 9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Elaine Yap, Jessica Keepa, Michael Maze, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Brittany Illingworth, Brooke Hollingshead, Dan Bernal, Derek Fitzgerald, Eloise Williams, Josh Wiles, Mark Ayson
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	• The public consultation closed last week. Information is still being incorporated, however overall:
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	  ○ limited feedback relating to Sotrovimab. It was noted that there is a relatively restricted criteria proposed. Additionally, it has limited efficacy against current variants.
	  ○ feedback was supportive of the proposed persistent infection guidelines.
	• It was noted that Medsafe approval is still ongoing, therefore it is uncertain when these will be available for approved use in New Zealand.

	• 216 vials of Evusheld are available for use now and can be ordered from Healthcare Logistics (HCL). These have no current access criteria, however Pharmac have made suggested criteria available. • There is ongoing review of antiviral access criteria being completed in collaboration with COVID care in the community (CinC) team. • Remdesivir has been added to the Pharmac schedule under section H (hospital use). • Tocilizumab stock levels and management is returning to normal and the patients who were taken off this treatment due to supply issues may be changed back to it if required. • Baricitinib still has enough stock for approximately 330 patients. A member queried how the remdesivir stock supply is going and whether there was enough stock for new surges. Pharmac noted that there is currently about 800 patient's worth of stock available. Pharmac can access more stock if required and are likely to look into doing this. **Medsafe Update** Medsafe evaluations are nearing completion for both Evusheld and sotrovimab. It is expected that decisions on whether consent can be given for both drugs and if either will need to be referred to Medicines Assessment Advisory Committee are likely to be made within the next week. If these do go to the committee, this will be meeting later this month. **STA Update** • An update was given by the STA representative. This matched the information circulated with the agenda. **Primary Care Update** • It was noted that pharmacists will soon be able to prescribe Paxlovid and molnupiravir. • Due to changes in staff, specific questions relating to primary care will be required ahead of meetings to help staff prepare.
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	• Generally decreasing rates for most age groups since the first wave. However, this is not true for the older age groups:
	  ○ For 80-89 and 90+ year olds mortality has continued to rise
	• In the latest data, significant increases in 65+ age group
	  ○ Approximately 50% increase in Maori
	
	There is the potential to investigate the link between hospitalisation and the potential for therapeutic intervention.
	
	A preliminary look at data has investigated the window of time from onset of symptoms or COVID-19 report date to hospitalisation
	
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	• Data surrounding the onset of symptoms was only recorded for 50% of hospitalisation cases. From this:
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	• Risk factors for hospitalisation showed vaccination was the strongest modifiable risk factor for people going to hospital. Increased age and co-morbidities were also strong indicators of hospital risk.
	
	Action: To share slides with the Therapeutics TAG.

6.0	**Query about change in access criteria to primary care** Criteria for Paxlovid use based on Canadian experience have been included in the hospital guideline to allow consideration of an option for its use in people with severe renal impairment (eGFR<30 or on dialysis) in a hospital setting. This has led to a discussion on if this widening is also appropriate to extend to a primary care setting and if so, what are the appropriate safeguards required. Rational for the extension to a hospital setting was: • The initial exclusion of people with advanced kidney disease from treatment with Paxlovid was that there was no evidence relating to this group from initial Paxlovid validation trails. ○ This is likely due to this group presenting as high risk during the initial phase of clinical trial where safety and efficacy are still being proved. • Chronic kidney disease is frequently a marker of multi-morbidity and high risk from COVID-19 • Other countries have working groups that have put together a proposal for dosing based on small numbers of a pharmacokinetics study that suggest dosing is appropriate for people with advanced renal dysfunction, including dialysis. • This is a ‘consider use’ as there is not yet data from a large-scale study supporting the safely, however there is a compelling argument that the from early phase 1 trials that this is safe and tolerable. • Currently the only other COVID-19 antiviral treatments available to these patients in NZ are remdesivir and molnupiravir. However, with remdesivir the excipient betadex sulfobutyl ether sodium is renally cleared and accumulates in patients with decreased renal function; requiring caution if eGFR is less than 30 mL/min/1.73m2 (limited information available). Molnupiravir can be used, but from published studies is expected to be considerably less effective. Therefore, the NZ guideline group felt that it was reasonable to follow other countries and recommend “consider use” of Paxlovid for patients in these groups that are in hospital. • Use in the hospital may be the appropriate place to build experience with this treatment initially. • This could be a way to treat people who may otherwise be excluded from efficacious early treatment options, however some safety concerns are appropriate.

	• Noted the dispensing issues (day night, half doses) The regulator point of view is that as this is prescribed under Section 29, the medical practitioner would have to make a professional judgement that its use is appropriate. The TAG noted the following in relation to providing advice for use of Paxlovid in primary care: • It may be reasonable and beneficial for people with eGRF<30 to be considered for treatment with Paxlovid. • Providing clear guidance would be more useful than a generic 'discuss with GP/nephrologist/infectious disease physician'. This is particularly relevant in smaller centres where no/less specialists are on hand. • The logistics of dispensing the drug at an appropriate and easy to use way for the patient needs to be considered. • Support required to pharmacist on the challenges of the treatment and adjustments to dose. ○ May result in some parts of packs being disposed of due to adjusted dose • In summary, it seems reasonable to provide in a primary care setting and may prove to be less of a safety issue and more of a dispensing problem. **Action:** To draft guidelines for GPs and seek Medsafe advice.
7.0	**Fully vaccinated definition and access criteria** It has been noticed that some hyperlinks in guidelines currently lead to pages that no longer exist. In particular, the page that defined 'fully vaccinated' has been removed. The concept of 'fully vaccinated' is changing as new evidence emerges throughout the pandemic. The discussion relates to what is the threshold with regards to vaccination where risk shifts from a lower risk to higher and where the threshold lies in access to therapeutics. It was noted that the COVID-19 Vaccine TAG (CV TAG) is working on a definition of fully vaccinated **Action:** To check in with CV TAG for their definition and ensure this is relevant in therapeutics.

8.0	**Guideline Updates**
	
	• The updates to hospital guideline include:
	  ○ The use of Paxlovid in hospital setting (discussed in item 6.0).
	  ○ A definition of 'fully vaccinated' (discussed in item 7.0).
	  ○ Support for using remdesivir for people with moderate COVID-19 who are early in illness (based on the Solidarity trail results)
	  ○ Evusheld referenced in guideline.
	  ○ A recommendation not to use baricitnib instead of steroids (based on current limited supply, cost, availability). This could be reassessed if changes to stock are implemented by Pharmac.
	
	Action: To draft a memo with support from the Therapeutics TAG.

9.0	**New structure of MOH/PHA** A presentation was given to explain the new structure of the Health Teams: • Health NZ: providing the operational and delivery roles. (This includes the National Public Health Service Organisation) • Ministry of Health: providing the chief stewardship role (i.e., performance, regulation, advice to the minister etc.) In total there will be nine directorates that make up the Ministry of Health (These are: Public Health Agency (PHA), Evidence Research and Innovation (ERI), Strategy and Policy, Maori Health and Maori

	Crown relations, Regulations, System Performance and Monitoring, Government and Executive Services, Corporate Services and Clinical leadership) Key take home: • Science Technical and Advisory (STA) team will stay at the MoH within PHA directory • PHA includes: the Intelligence, Surveillance and Knowledge team (this is made up of STA, Intelligence and analytics and some broader communicable disease teams). • The ERI may also be of interest to TAG members. This is a completely new directorate which will working with STA on many pieces of advice.
10.0	**Next Steps/Decisions Pending** **Monkeypox update:** • There has of yet been no probable or confirmed case of Monkeypox in New Zealand, as of the current date (8th July). • A test definition has been agreed on and monkeypox has been made a notifiable disease. • The advice provided by this TAG was to use vaccination as a strategic approach, targeting close contacts post-exposure rather than a broader public health vaccination. • New Zealand government is looking at options to secure the third-generation vaccine. Of note the current stock is second-generation and expired • There is a small pool of stock of cidofovir. Trying to get access to tecovirimat, however this is limited internationally. • Work is underway to get access to vaccinia immune globulin and antivirals from Australia if required. New Zealand is in the queue for next year, although exact quantities has been requested. • A request for advice has been received around pre-exposure prophylaxis for specific groups (i.e., MSM) and if this is relevant in a New Zealand context. Discussion with CV TAG members suggested use post exposure for close contacts may be more appropriate (pending international experience).
11.0	**Closing Karakia**
Meeting closed at **2:53 pm** Next meeting **05 August 2022**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
33	**Paxlovid use in primary care**	To draft guidelines for GPs and seek Medsafe advice.	Jennifer Keys/STA	8/7/22 Item opened
34	**Fully vaccinated definition and access criteria**	To check in with CV TAG for their definition and ensure this is relevant in Therapeutics.	STA	8/7/22 Item opened
35	**Evusheld advice**	To draft a memo with support from the Therapeutics TAG.	STA/Tim Cutfield	8/7/22 Item opened

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
5	Guideline update	Pharmac to communicate the availability of Molnupiravir in hospitals before the publication of the guideline update scheduled 29 April 2022.	Tim Cutfield	29/04/22 Planned guideline update 28/04/22 Guideline update deferred to 6/05/2022 following the announced arrival of molnupiravir. 06/05/22 Guideline updated. 20/05/22 No update. 03/06/22 No updates for this meeting, Evusheld due for updates soon. 08/07/2022 Update to guidelines was given. Action closed as now standing item.
31	Therapeutics Pharmac update	The Ministry will look into data which could better inform the percent risk of hospitalisation.	Robyn Carey	22/04/22 Action raised 06/05/22 STA and Pharmac are aware of the issue and this item is being progressed. 03/06/22 Presentation from MoH SS&I team. Further data to be presented when available. 08/07/2022 Updated presentation on hospitalisation and mortality data was given. To share slides with Therapeutics TAG. Item closed.

Document 12

Memo

Internal Review of COVID-19 Testing Technical Advisory Group (CT TAG) for Purpose and Function

Date:	14 February 2022
To:	Dr Ashley Bloomfield, Director General of Health
Copy to:	Dr Ian Town, Chief Science Advisor Bridget White, Deputy Chief Executive, COVID-19 Health System Response Gill Hall, Group Manager, Science and Insights Darryl Carpenter, Group Manager COVID-19 Testing and Supply Dr Dan Bernal, Manager, Scientific and Technical Advisory
From:	Kirsten Beynon, Chief Testing Advisor
For your:	Decision

Purpose of report

1. The purpose of this memo is to outline the initial findings of the internal review of the COVID-19 Testing Technical Advisory Group (CT TAG). In particular, this review has focused on the purpose and function of the Group, and how this expertise can be best used in the future.

Background

2. In June 2021, Sir David Skegg as Chair of the Strategic Public Health Advisory Group, recommended to Hon Dr Ayesha Verrall, Associate Minister of Health, that the government establish an expert committee to advice on laboratory testing issues and ongoing strategy that should arise over the following eighteen months.

3. The CT TAG was established in October 2021 to provide rapid, independent, and practical advice to the Director General of Health on testing technologies, to inform New Zealand's COVID-19 response and the work to reconnect Aotearoa New Zealand to the world *[refer to HR 20211861]*.

4. It was envisaged that the function of the CT TAG was to advise and give expert oversight on:

    a. assessment of the benefits and limitations of new testing technologies and paradigms for New Zealand, including the suitability of new technologies in different settings and scenarios,

    b. comparison of new technologies to those currently in use,

    c. technical guidance on the expected timeframe for adopting a new technology,

    d. horizon-scanning to identify technologies being developed locally and overseas, and

e. the application of new technologies to assist in reconnecting New Zealand, including their use in border management, and managed isolation and quarantine settings.

5. Members were appointed, with Professor David Murdoch as the Chair. The group initially comprised of a Chair and members with expertise in relevant areas such as microbiology, epidemiology, immunology, clinical diagnostic testing review and development, operational implementation and management and primary care. In addition, the Ministry's Chief Science Advisor was also a member.

Internal Review

Review Process

CT TAG work to date

6. In October 2021, a sub-group of the CT TAG led by Professor Murdoch, undertook *A Rapid Review of COVID-19 Testing in Aotearoa New Zealand,* often referred to as the 'Murdoch Review.' The group was also engaged in the development of some rapid pieces of work including the endorsement of the minimum criterial for selection and approval of Point of Care (POC) technologies and input into the *COVID-19 Testing Strategy for Aotearoa New Zealand*.

7. The Murdoch review made a range of recommendations including to "strengthen the leadership capacity and capability for testing within the Ministry of Health…. a new appointment with a strong leadership background in laboratory operations, diagnostic testing and testing strategy."[1]

8. To meet this requirement within the Ministry of Health (the Ministry) I, Kirsten Beynon, was appointed Chief Advisor Testing. In addition, the Murdoch review articulated a further 12 recommendations for the Ministry of Health (the Ministry), including developing strategies, a focus on innovation, modelling, workforce, horizon scanning, regular assessment and review. The Ministry responded to these recommendations in a report to Minister Verrall, *Response to the Rapid Review of COVID-19 Testing in Aotearoa New Zealand* [HR20212072 refers].

9. CT TAG members were notified by you, the Director General of Health, in an email dated 24 December 2021 that my appointment had brought us to a 'natural point of review' as to the purpose of the group. It was indicated that there would be steps taken in the New Year and that as Chief Advisor Testing, I would lead engagement with the group on this matter.

10. To date, I have engaged with both the CT TAG and members of the group, on a range of urgent and emerging issues, including the rapid revision of the minimum criteria for selection and approval of POC technology and on a population based targeted testing approach for PCR to optimise laboratory capacity. I have also engaged the New Zealand Microbiology Network (NZMN) on a range of topics when wider Clinical Microbiologist expertise and opinion has been required. These engagements have highlighted the challenges of and need to, pivot the purpose, function and focus of the CT TAG to ensure we use their advice and expertise in a way that is most beneficial to New Zealanders.

[1] COVID-19 Testing Technical Advisory Group – Sir David Murdoch, *A Rapid Review of COVID-19 Testing in Aotearoa New Zealand,* 4 October 2021, page 4.

Initial Findings

11. Since my appointment, the CT TAG has been convened on a 'as required' basis to support decision making. This was managed predominantly through email engagement to support rapid input into reports.

12. It is clear that within the context of both the Delta and Omicron outbreaks, and subsequently the requirement to rapidly reassess the national testing response, the CT TAG have been essential. They have provided independent expert opinion and advice, in particular on POC testing, Rapid Antigen Tests (RATs), and the international supply chain challenges.

13. Informed by discussions, the CT TAG members must be in an environment where they can speak freely to provide advice for consideration, rather than comment on completed papers and decisions.

Proposed changes to CT TAG

Purpose and function

14. COVID-19 Testing is, will remain, a core pillar of any pandemic response strategy. The need for expert advice on the use and type of testing as we move forward, will become even more important as begin move through the phases of the Omicron Strategy and look to reconnect New Zealanders with the world.

15. Horizon scanning, equitable testing approaches, advising on laboratory capacity, role of surveillance testing and seroprevalence, managing the ongoing challenge of RATs and potential for the introduction of new pathogens with relaxed border controls, are areas that we are aware will require the expertise of this group. By pivoting the purpose and focus of the CT TAG, we aim to respond to some of these challenges.

16. From discussions and observations, it is my view that the use of the CT TAG scientific expertise and industry knowledge is better achieved through a proactive planning and engagement approach, compared to the rapid reactive advice seeking methods.

17. I recommend that the CT TAG is repurposed as a testing advisory group with a focus on industry intelligence providing advice on all facets of the COVID-19 testing system. I also recommend that the membership and terms of reference are reviewed.

18. The group should shift to a fortnightly meeting schedule, to be fully engaged in the provision of advice, is forward-thinking. It is envisaged these meetings are less formal than they have been, unless a specific decision is required from the group.

19. Three areas which we are aware will require specific consideration and input are a formal review of testing operations, re-evaluation of POC RAT tests, and advance planning for testing plan in phase 3 and beyond of the Omicron Strategy.

20. As Ministry representative on the group, I propose to provide regular updates to you and the Chief Science Advisor following each meeting.

Membership

21. I recommend that:

    a. to best align membership moving forward with a new purpose and function, we consider including additional expertise and perspectives to the group,

b. we fill the role of scientific expertise on the group (currently vacant), ideally an individual with a doctorate in laboratory science,

c. we seek additional members who will bring a strong equity and community perspective, and

d. we consolidate attendees from the Ministry of Health.

22. If the purpose and function is agreed in principle, we will provide further advice on membership, reflective of the expertise required; noting that may not include some current members.

Next Steps

23. Following your 'in-principle' agreement to the changes outlined above, these will be discussed with the current members of the Group to ensure clarity of purpose and function moving forward and seek their feedback.

24. A final paper seeking your agreement to update the CT TAG membership and terms of reference, will be provided to you in early March 2022.

Recommendations

It is recommended that you:

1.	Agree	The purpose of the CT TAG is shifted to a focus on considering industry intelligence and providing advice on all facets of the COVID-19 testing system.	Yes/No
2.	Agree	The function of the CT TAG shifting to a fortnightly meeting with a forward thinking, proactive approach to advice.	Yes/No
3.	Note	If agreed, in principle, we will consult current members on the proposed changes.	Noted
4.	Note	We will update you on proposed membership and revised terms of reference and revised terms of reference in early March 2022.	Noted

Electronic

Signature _____ Date:

Kirsten Beynon

Chief Testing Advisor

COVID-19 Health System Response

Signature _____ Date:

Dr Ashley Bloomfield

Director General of Health