MINISTRY OF HEALTH
MANATŪ HAUORA

Terms of Reference – COVID-19 Testing Technical Advisory Group

25 August 2021

Contents

Introduction

The Ministry of Health (the Ministry) is the kaitiaki of the health and disability system in Aotearoa New Zealand and the principal health advisor to Government. We do this by providing a fair, effective, and sustainable system and advice that people can trust. The Ministry is responsible for providing active stewardship and leadership across the health and disability system to ensure it provides people with the highest level of care, regardless of who they are or where they live.

The COVID-19 pandemic has rapidly evolved internationally and in Aotearoa New Zealand. Responding to COVID 19 in a very rapidly changing environment is a significant ongoing challenge.

The Government's overall public health strategy in respect of the COVID-19 pandemic affecting New Zealand is elimination. That is, to apply a range of control measures to stop the transmission of COVID-19 in Aotearoa New Zealand.

There are four pillars to our elimination strategy, these are:

- Keep it out (pre- and border settings, managed isolation and quarantine)
- Prepare for it (robust case detection and surveillance, and public health measures)
- Stamp it out (effective contact tracing and case management, and stronger public health measures)
- Manage the impact (health system readiness and resilience)

The Ministry has established the COVID-19 Health System Response Directorate (the Directorate) to give effect to the elimination strategy. The Ministry is working to ensure the response to COVID-19:

- is evidence-based
- is consumer-centred
- is equity-focussed and guided by the Treaty of Waitangi
- effectively manages clinical and public health issues and risks
- supports an open and transparent culture
- has a continuous quality improvement and safety focus
- monitors and reviews clinical processes and outcomes
- guides the development of the Ministry and All of Government strategies to address COVID-19.

Context

On 24 June 2021, Sir David Skegg, Chair of the Strategic Public Health Advisory Group recommended that the government establish an expert committee to advise on the suitability of the current approach to COVID-19 testing within New Zealand and how this approach should evolve in response to new testing technologies, where appropriate. In particular, the approach to reconnecting Aotearoa New Zealand, will pose new paradigms, which will require the broad range of expertise obtained through engagement with the COVID-19 Testing Technical Advisory Group.

Purpose and Function

The COVID-19 Testing Technical Advisory Group (CT TAG) will provide rapid, independent, and practical advice to the Director-General of Health on testing technologies and paradigms, to inform New Zealand's COVID-19 response and the work to reconnect Aotearoa New Zealand to the world. CT TAG members will be asked 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

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

The group's advice will assist the Ministry and Government to:

a) Ensure that the COVID-19 surveillance strategy and testing guidance is fit-for-purpose for the goals of the elimination strategy or any future pandemic response strategy as it may be adopted.

b) Ensure that the COVID-19 surveillance strategy and testing guidance be appropriately reviewed in light of the Reconnecting New Zealanders work programme.

c) ensure that a decision to use any COVID-19 testing strategy is honouring the Crown's obligation under Te Tiriti o Waitangi

d) position equity at the centre of choices about which testing technologies and strategies should be used

e) consider implementation including validation and scale-up of new technologies

f) consider the suitability of new testing strategies or technologies for whānau, hapū, iwi, Māori communities

CT TAG may convene appropriate subgroups to meet and provide specialist advice when requested by the Ministry. A Chair will be nominated for each of these subgroups.

CT TAG does not hold decision-making authority or responsibility for the acceptance or application of advice provided. The scientific and technical advice and recommendations from CT TAG are provided to the Director-General and the Ministry to inform and contribute to advice to Ministers, decisions, operations, guidelines, and policy required in the management of COVID-19 and reconnecting Aotearoa New Zealand to the world.

The Ministry may receive advice on testing and other COVID-19 matters from a variety of sources other than CT TAG. CT TAG should maintain awareness of how it's advice compliments advice to the Ministry from other Ministry technical advisory groups.

CT TAG is guided by Te Tiriti o Waitangi principles as they apply to the health and disability sector; tino rangatiratanga, equity, active protection, options, and partnership. This involves ensuring advice is evidence-based and aimed at achieving equity of outcomes, and contributing to wellbeing for all, including Māori and Pacific peoples.

Membership

In order to contribute to the delivery of the Group's functions, members are selected to bring multi-disciplinary expertise on the latest scientific, clinical, technical and equity evidence relating to COVID-19 testing technologies and paradigms.

Membership are expected to understand the systems, structures, stakeholders, and to hold in-depth specialist knowledge in their respective disciplines.

Members will focus on the core scientific, technical, and/or clinical basis for advice, referenc ng the evidence base alongside the rationale for advice in the context of operational limitations and/or precedent.

CT TAG will have a standing membership comprised of technical experts from disciplines relevant to the matters the Group is asked to advise on.

The Chair and members of CT TAG will be appointed by the Director-General of Health in consultation with the Associate Minister of Health, Hon Dr Ayesha Verrall.

Co-opted Advisors

With the agreement of the DCE COVID-19 Directorate, the Chairperson may invite Ministry Technical experts to be advisors to the Group.

Members of CT TAG agree:

- **to keep all information provided to them strictly confidential** and, except as expressly permitted, not share, publish, copy in whole or in part or modify or adapt any confidential information in any way without the Ministry's prior written consent which may be given or withheld in its absolute discretion.
- **not to use any confidential information** for any purpose other than participating in CT TAG activities without the Ministry's prior written consent which may be given or withheld in its absolute discretion.
- that whe e the CT TAG Member wishes to use the information provided for research purposes, a detailed letter seeking permission to use the data, and describing how the data will be used including the ethical safeguards that will be used to protect the integrity of the data, must be submitted to the Chief Science Advisor for approval, prior to any research occurring. The Ministry may put conditions on the use of data, including acknowledgements as appropriate.
- that pre-existing intellectual property rights relating to the provision of advice remain the property of their current owner. New intellectual property rights in work created for the Ministry as part of CT TAG become the property of the Ministry when they are created unless otherwise agreed in writing.
- **to declare any real or perceived Conflicts of Interest** - CT TAG Members should perform their functions in good faith, honestly, fairly, impartially, responsibly and avoid situations that might compromise their integrity

or otherwise lead to conflicts of interest. The Conflict of Interest form provided by the Ministry must be completed, returned to S9(2)(a)

- inform the Ministry upon becoming aware of the existence of the possibility of a conflict arising after completing the form. A register of Conflict of Interest will be recorded and addressed through the processes outlined above.

- that they are **not authorised to make statements on behalf of the COVID-19 Testing Technical Advisory Group or the Ministry**. The Ministry has strict protocols for managing media enquiries and all such requests should be directed to S9(2)(a) and copied to the STA email S9(2)(a) .govt.nz.

- they have the right to comment to the media on any matter in their professional capacity, as long as they do not attribute the comment to CT TAG or imply that they are speaking on behalf of CT TAG or wider Ministry. If a Member is forewarned of being asked to comment to the media, they should advise the STA accordingly. If a Member is not forewarned, they should advise the STA immediately after making comment to the media.

- they are not authorised to commit COVID-19 Testing Technical Advisory Group, any Members of it, or the Ministry to any financial or legal commitments or to otherwise purport to act as agents for the Ministry.

Membership of CT TAG will be for a period of 12 months with the option for a further extension as agreed by the Director-General.

A register of membership of CT TAG is maintained and kept within the STA filing system within the Ministry and accessible to Ministry staff. Names of CT TAG Members and any other information provided by Members are subject to the Official Information Act 1982 and the Ministry will be required to release such information on request under that Act unless there are valid reasons for withholding the information under the Act.

Duties and Responsibilities

Duties and responsibilities of the Chairperson of COVID-19 Testing Technical Advisory Group

The Chairperson agrees to:

- provide leadership and ensure the group retains a focus on its scope as defined in this Terms of Reference and priorities as determined by the Ministry
- determine suitability of CT TAG as the recipient of requests for advice, work to be commissioned, tasks, and facilitators of consultation
- ensure meetings are duly convened and that a quorum of Members is present each meeting
- ensure meetings are conducted in an efficient, effective, and focused manner
- ensure the group has the required information to permit provision of advice and to make recommendations
- consider the principles of Te Tiriti o Waitangi in every action, through ensuring CT TAG is supported to interact and act with equity as a key consideration, and provides advice that is congruent with these obligations
- appoint Members to CT TAG based on scientific and technical expertise and the need for effective representation and tino-rangatiratanga (self-determination and autonomy) of Māori and Pacific peoples
- facilitate communications internally and externally, including; with other key stakeholders as appropriate; presenting advice and recommendations to decision makers after each meeting; and summarising any aspects of discussion or advice that should or should not be communicated by Members

- ensure minutes are taken during meetings and approval given for the minutes as an accurate record of the summary of the meeting.
- ensure actions and recommendations are noted and actioned within agreed timeframes
- act as a key contact point for agenda items, responses, absences, and delegations to the meeting, and will be informed of all activities requested of and undertaken by CT TAG.

Duties and responsibilities of a Member of COVID-19 Testing Technical Advisory Group

CT TAG Members are not employees of the Ministry. They agree to:

- familiarise themselves with background material (if any) sent prior to and after meetings
- actively participate in meetings or provide feedback and/or comments as required
- undertake additional activities agreed by the group (such as commenting on advice or guidance, providing research material, or contacts), and to alert the Chairperson to limitations on availability and interim delegation arrangements
- share expert knowledge and engage constructively in discussions, acting only in the role they are representing and within their scope of expertise
- individually ensure familiarity with, and provide advice that is congruent with the principles and obligations of Te Tiriti o Waitangi in ensuring the active protection of Māori health, achieving equity across access, quality of care and outcomes
- ensure that all activity and advice is undertaken with consideration of and respect for equity of outcomes across all peoples of Aotearoa New Zealand, including but not limited to; ethnicity, dis/ability, geographic location, age, health, gender and socioeconomic position, living and working conditions
- lead/facilitate the completion of respectively owned action items within the agreed timeframes
- assume collective responsibility for advice through; working together in a collegial manner; seeking consensus on provision of advice wherever possible; and noting any unresolved differences of opinion, limitations of evidence or opportunity for consultation, or concessions made due to time or logistical constraints
- exercise all due professional care and diligence in the performance of their obligations under these Terms of Reference in accordance with the standards of skill, care, and diligence normally practised by suitably qualified and experienced persons in performing services of a similar nature.
- to make themselves available for meetings convened for the purpose of providing advice to the Ministry as described above.

Duties and responsibilities of Co-opted Advisors to the COVID-19 Testing Technical Advisory Group

Co-opted Advisors are employees of the Ministry. They agree to:

- represent the Ministry by presenting requests for advice or commissioned pieces of work and providing relevant background information, context, and communications to support the Members in providing advice which is shaped for the question or issue at hand
- familiarise themselves with background material (if any) sent prior to meetings
- share expert knowledge and engage constructively in discussions, acting only in the role they are representing and within their scope of expertise
- communicate relevant information, activities, decisions, and issues of interest from the Ministry to CT TAG, and vice versa, through endorsed communication channels and methods
- individually ensure familiarity with and provide advice congruent with the principles and obligations of Te Tiriti o Waitangi in ensuring the active protection of Māori health and achieve equity across access, quality of care and outcomes

- ensure that all activity and advice is undertaken with consideration of and respect for equity of outcomes across all peoples of Aotearoa New Zealand, including but not limited to; ethnicity, dis/ability, geographic location, age, gender, health, and socioeconomic position, living and working conditions.

Secretariat of COVID-19 Testing Technical Advisory Group

The Secretariat is not a Member of CT TAG. The Secretariat supports the group and the Chairperson with:

- disseminating information required for each meeting
- writing-up the agenda as directed by the Chairperson
- writing the minutes and disseminating these within the group
- update any new Members or additional Members with the Terms of Reference
- receive and store the Conflict of Interest declarations
- receive fee claims and organise fees payments
- assist the Chairperson with the onboarding arrangements with Members.

Meeting protocols

Secretariat

The Ministry will ensure adequate secretariat support and other support as may be required from time to time, for CT TAG to carry out their mandate efficiently and effectively.

Meeting coordination

Coordination of the meetings will be managed by the Secretariat under direction of the Chairperson. This will include all the logistics, documentation, and administration. Members will receive relevant documentation through email or other digital tools used within the Ministry.

Members must have regular access to electronic and digital tools in which CT TAG meetings are conducted. Meetings conducted in workplaces must remain confidential and not visual or audible to workplace colleagues.

Delegates

Members will attend all meetings whenever reasonably possible and delegates are not permitted. Apologies must be in writing (email) to the Chairperson and Secretariat prior to the meeting.

Other attendees

Guests with relevant expertise may be invited to discuss specific issues and when attending the whole meeting will abide by the same Terms of Reference.

Non Members may only attend by invitation of the Chairperson.

Quorum

A meeting quorum for CT TAG requires 50% of standing external Members, including the Chairperson.

The quorum for a meeting is the minimum number of Members required to make the meeting valid. If a meeting is inquorate, it cannot make recommendations on behalf of the group. It can hold discussions and make recommendations for later confirmation or rejection by the group.

Official Information Act requests

All agendas, emails and other communication and information relating to the Network are subject to the Official Information Act 1982, and the Ministry may be required to release such information on request unless there are valid reasons for withholding the information under the Act.

Fees framework

The daily rate has been set in accordance with the Ministry's Fees Framework and has been approved by the Director-General of Health and may be paid to Members who are self-employed or privately employed.

Members who are paid for their time/employed through the wider state sector (eg they work for Universities, District Health Boards, Government departments and State agencies) are not personally eligible for a fee, although on the production of an invoice, the Ministry can reimburse a government funded agency employing organisation for the Member's time.

The membership register will indicate those Members that are eligible to claim a fee under the Fees Framework and the level of the fee, based on the above declaration.

A working day of eight hours is the basis of the daily fee is calculation, with hourly pro-rata rates calculated accordingly. A working day of longer than eight hours does not attract extra payment beyond the daily fee. The daily fee applies to all work, including the work performed outside of meetings that is required for the group to carry out its role (e.g. preparation, representing the group at other forums or administrative work).

All fees and expenses (where agreed) are to be submi ted either on a Ministry claim form or as an invoice. Reasonable expenses are to be agreed in writing in advance and should be supported by tax invoices and/or receipts.

Payments will be made in accordance with the Ministry's accounts payable guidelines.

Work outside of meetings that has been formally commissioned by the Ministry will be formally described in a written request with anticipated days or hours of work required and the fee rate, which the individual or group may accept or decline. Additional days or hours of work required must be agreed in writing with the Manager of STA prior to commencement of the hours worked.

Guidance on organisations that form part of the wider state sector can be found on the SSC website.

For more information, please refer to the Cabinet Fees Framework.

Review of Membership

The Deputy Chief Executive, COVID-19 Directorate will advise the Director-General on a review of membership of the COVID-19 Testing Technical Advisory Group by the end of December 2021.

MINISTRY OF HEALTH
MANATŪ HAUORA

Briefing

COVID-19 Testing Technical Advisory Group Membership and Terms of Reference

Date due to MO:	25 August 2021	**Action required by:**	25 August 2021
Security level:	IN CONFIDENCE	**Health Report number:**	20211861
To:	Hon Dr Ayesha Verrall, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Director-General of Health	S9(2)(a)

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

COVID-19 Testing Technical Advisory Group Membership and Terms of Reference

Security level:	IN CONFIDENCE	**Date:**	25 August 2021
To:	Hon Dr Ayesha Verrall, Associate Minister of Health		

Purpose of report

1. This report provides the proposed membership and Terms of Reference for the COVID-19 Testing Technical Advisory Group (CT TAG) for your consideration and approval.

Recommendations

We recommend you:

a) **note** our intention to establish the COVID-19 Testing Technical Advisory Group.

b) **approve** the draft Terms of Reference in Appendix A. **Yes/No**

c) **approve** the proposed members listed in Appendix B for the COVID-19 Testing Technical Advisory Group **Yes/No**

Dr Ashley Bloomfield
Director-General of Health
Date:

Hon Dr Ayesha Verrall
Associate Minister of Health
Date:

COVID-19 Testing Technical Advisory Group Membership and Terms of Reference

Background and context

2. On 24 June 2021, Sir David Skegg, 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 advise on laboratory testing issues that should arise over the next eighteen months.

3. As the Ministry's response to COVID-19 has continued to mature and evolve, a commitment to continuous learning and improvement has been fundamental to delivering a quality response to COVID-19 and keeping New Zealand safe. In particular, significant effort has been placed into strengthening the scientific and technical advisory capabilities within the Ministry of Health.

4. The Ministry's current advisory groups have continued to provide sufficient robust scientific and technical advice to support the Ministry's COVID-19 Response. However, the rise of problematic variants such as the Delta variant, which has increased transmission and the potential to cause more severe disease, and the focus on strategies to safely reconnect New Zealanders to the world, has raised the need to further elevate our technical advisory capability with regards to testing technology. It is anticipated that an additional expert advisory group with a focus on testing technologies will strengthen our response to COVID-19.

Purpose and function of the Group

5. The COVID-19 Testing Technical Advisory Group (CT TAG) will provide expert, multi-disciplinary advice on testing, based on the latest scientific, clinical and technical evidence.

6. The scientific and technical advice and recommendations from CT TAG will be provided to the Director-General and the Ministry to inform and contribute advice to Ministers, decisions, operations, guidelines, and policy required in the management of COVID-19 and reconnecting Aotearoa New Zealand to the world.

7. The Terms of Reference for CT TAG are attached as Appendix 1 and the proposed membership list is attached as Appendix 2.

Expertise

8. The group will comprise of a Chair and members with expertise in relevant areas, including:

   a) Microbiology

   b) Epidemiology

   c) Immunology

   d) Clinical diagnostic testing review and development

   e) Operational implementation and management

f) Primary care

Function

9. CT TAG members will be asked 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

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

10. The group's advice will assist the Ministry and Government to:

   a) Ensure that the COVID-19 surveillance strategy and testing guidance is fit-for-purpose for the goals of the elimination strategy or any future pandemic response strategy as it may be adopted.

   b) Ensure that the COVID-19 surveillance strategy and testing guidance be appropriately reviewed in light of the Reconnecting New Zealanders work programme.

   c) ensure that a decision to use any COVID-19 testing strategy is honouring the Crown's obligation under Te Tiriti o Waitangi

   d) position equity at the centre of choice about which testing technologies and strategies should be used

   e) consider implementation including validation and scale-up of new technologies

   f) consider the suitability of new testing strategies or technologies for whānau, hapū, iwi, Māori communities

Next steps

11. The Ministry of Health will complete the process to appoint external members to the Group and schedule the first meeting at the earliest opportunity. We will keep you informed of progress.

ENDS.

Appendix A - Proposed Terms of Reference

Terms of Reference – COVID-19 Testing Technical Advisory Group

10 August 2021

Contents

Introduction

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i) ensure that a decision to use any COVID-19 testing strategy is honouring the Crown's obligation under Te Tiriti o Waitangi

j) position equity at the centre of choices about which testing technologies and strategies should be used

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- **not to use any confidential information** for any purpose other than participating in CT TAG activities without the Ministry's prior written consent which may be given or withheld in its absolute discretion.
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Duties and Responsibilities

Duties and responsibili ies of the Chairperson of COVID-19 Testing Technical Advisory Group

The Chairperson agrees to:

- provide leadership and ensure the group retains a focus on its scope as defined in this Terms of Reference and priorities as determined by the Ministry
- determine suitability of CT TAG as the recipient of requests for advice, work to be commissioned, tasks, and facilitators of consultation
- ensure meetings are duly convened and that a quorum of Members is present each meeting
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- lead/facilitate the completion of respectively owned action items within the agreed timeframes
- assume collective responsibility for advice through; working together in a collegial manner; seeking consensus on provision of advice wherever possible; and noting any unresolved differences of opinion, limitations of evidence or opportunity for consultation, or concessions made due to time or logistical constraints
- exercise all due professional care and diligence in the performance of their obligations under these Terms of Reference in accordance with the standards of skill, care, and diligence normally practised by suitably qualified and experienced persons in performing services of a similar nature.
- to make themselves available for meetings convened for the purpose of providing advice to the Ministry as described above.

Duties and responsibilities of Co-opted Advisors to the COVID-19 Testing Technical Advisory Group

Co-opted Advisors are employees of the Ministry. They agree to:

- represent the Ministry by presenting requests for advice or commissioned pieces of work and providing relevant background information, context, and communications to support the Members in providing advice which is shaped for the question or issue at hand
- familiarise themselves with background material (if any) sent prior to meetings
- share expert knowledge and engage constructively in discussions, acting only in the role they are representing and within their scope of expertise

- communicate relevant information, activities, decisions, and issues of interest from the Ministry to CT TAG, and vice versa, through endorsed communication channels and methods
- individually ensure familiarity with and provide advice congruent with the principles and obligations of Te Tiriti o Waitangi in ensuring the active protection of Māori health and achieve equity across access, quality of care and outcomes
- ensure that all activity and advice is undertaken with consideration of and respect for equity of outcomes across all peoples of Aotearoa New Zealand, including but not limited to; ethnicity, dis/ability, geographic location, age, gender, health, and socioeconomic position, living and working conditions.

Secretariat of COVID-19 Testing Technical Advisory Group

The Secretariat is not a Member of CT TAG. The Secretariat supports the group and the Chairperson with:

- disseminating information required for each meeting
- writing-up the agenda as directed by the Chairperson
- writing the minutes and disseminating these within the group
- update any new Members or additional Members with the Terms of Reference
- receive and store the Conflict of Interest declarations
- receive fee claims and organise fees payments
- assist the Chairperson with the onboarding arrangements with Members.

Meeting protocols

Secretariat

The Ministry will ensure adequate secretariat support and other support as may be required from time to time, for CT TAG to carry out their mandate efficiently and effectively.

Meetings coordination

Coordination of the meetings will be managed by the Secretariat under direction of the Chairperson. This will include all the logistics, documentation, and administration. Members will receive relevant documentation through email or other digital tools used within the Ministry.

Members must have regular access to electronic and digital tools in which CT TAG meetings are conducted. Meetings conducted in workplaces must remain confidential and not visual or audible to workplace colleagues.

Delegates

Members will attend all meetings whenever reasonably possible and delegates are not permitted. Apologies must be in writing (email) to the Chairperson and Secretariat prior to the meeting.

Other attendees

Guests with relevant expertise may be invited to discuss specific issues and when attending the whole meeting will abide by the same Terms of Reference.

Non-Members may only attend by invitation of the Chairperson.

Quorum

A meeting quorum for CT TAG requires 50% of standing external Members, including the Chairperson.

The quorum for a meeting is the minimum number of Members required to make the meeting valid. If a meeting is inquorate, it cannot make recommendations on behalf of the group. It can hold discussions and make recommendations for later confirmation or rejection by the group.

Official Information Act requests

All agendas, emails and other communication and information relating to the Network are subject to the Official Information Act 1982, and the Ministry may be required to release such information on request unless there are valid reasons for withholding the information under the Act.

Fees framework

The daily rate has been set in accordance with the Ministry's Fees Framework and has been approved by the Director-General of Health and may be paid to Members who are self-employed or privately employed.

Members who are paid for their time/employed through the wider state sector (eg they work for Universities, District Health Boards, Government departments and State agencies) are not personally eligible for a fee, although on the production of an invoice, the Ministry can reimburse a government funded agency employing organisation for the Member's time.

The membership register will indicate those Members that are eligible to claim a fee under the Fees Framework and the level of the fee, based on the above declaration.

A working day of eight hours is the basis of the daily fee is calculation, with hourly pro-rata rates calculated accordingly. A working day of longer than eight hours does not attract extra payment beyond the daily fee. The daily fee applies to all work, including the work performed outside of meetings that is required for the group to carry out its role (e.g. preparation, representing the group at other forums, or administrative work).

All fees and expenses (where agreed) are to be submitted either on a Ministry claim form or as an invoice. Reasonable expenses are to be agreed in writing in advance and should be supported by tax invoices and/or receipts.

Payments will be made in accordance with the Ministry's accounts payable guidelines.

Work outside of meetings that has been formally commissioned by the Ministry will be formally described in a written request with anticipated days or hours of work required and the fee rate, which the individual or group may accept or decline. Additional days or hours of work required must be agreed in writing with the Manager of STA prior to commencement of the hours worked.

Guidance on organisations that form part of the wider state sector can be found on the SSC website.

For more information, please refer to the Cabinet Fees Framework.

Review of Membership

The Deputy Chief Executive, COVID-19 Directorate will advise the Director-General on a review of membership of the COVID-19 Testing Technical Advisory Group by the end of December 2021.

Appendix B - Proposed Membership List

Role	Incumbent
Chair (and Microbiology expertise)	Professor David Murdoch, Dean and Head of Campus, University of Otago, Christchurch; and Vice Chancellor Designate, University of Otago
Clinical Immunology and diagnostic expertise	Dr Maia Brewerton, Lead Clinician, Immunology, WDHB
Microbiology and Infectious Diseases expertise and leadership	Dr Susan Morpeth, Chair of the Microbiology Network Aotearoa New Zealand; and Clinical Microbiologist, Counties Manukau Health Laboratory Services
Microbiology and Infectious Diseases expertise	Dr Tim Blackmore, CCDHB, Wellington
Infectious Diseases Epidemiology, Public Health	Professor Patricia Priest, University of Otago
Medical Laboratory Science expertise and Laboratory Leadership	Kirsten Beynon, General Manager, Canterbury Health Laboratories and West Coast DHB Laboratory
Pacific representative and behavioural insights	Pisi'a Fanolua, Clinical Nurse Manager, Sebel and Waipuna MIFs

Co-opted Ministry employees likely to be regular attendees

Chief Science Officer (Ministry of Health)	Dr Ian Town or delegate
GM Data and Digital	Jon Herries
GM Logistics and Inventory, COVID-19 Vaccine and Immunisation Programme	Ian Costello
GM COVID-19 Testing and Supply	Darryl Carpenter or delegate

Memo

Surveillance of Healthcare workers during an outbreak of COVID-19 in Aotearoa New Zealand – COVID-19 Testing Technical Advisory Group recommendations

Date:	27 August 2021
To:	Ashely Bloomfield, Director-General, Ministry of Health
From:	David Murdoch, Chair of COVID-19 Testing Technical Advisory Group (CT TAG)
Cc:	Ian Town, Chief Science Advisor Darryl Carpenter, Group Manager, COVID-19 Testing and Supply
For your:	Consideration

Purpose of report

1. To summarise the COVID-19 Testing Technical Advisory Group's recommendations on the Surveillance of Healthcare workers during an outbreak of COVID-19 in Aotearoa New Zealand.

Context

2. Currently, those caring for patients with COVID-19 within a healthcare setting are offered participation in voluntary surveillance testing. As this is a voluntary programme, the uptake is not currently recorded by the Ministry of Health but has been reported anecdotally as low.
3. As part of the public health response within the elimination strategy against COVID-19 the identification of contacts of cases and strict adherence to isolation and testing is essential.
4. In the setting of a community outbreak of COVID-19, as we are currently experiencing in August 2021, a single case of COVID-19 presenting in a healthcare setting who has a number of contacts and the outcome being that entire units and departments may need to be isolated and tested under the legal direction of Section 70 notification, significantly impacting on the delivery of healthcare to New Zealanders.
5. While this has been particularly evident in Auckland-based hospitals, this dilemma is recognised as a potential risk to any healthcare setting in areas where there is uncontrolled community transmission.
6. An intensified surveillance strategy has been suggested for healthcare workers, similar to that required of border workers, whereby surveillance testing is both routine and potentially mandatory.
7. Such an increase in testing could out-strip current capacity. Options other than nasopharyngeal swab PCR testing need to be considered. Two options were proposed for CT TAG to consider:

a. Expansion of saliva-based PCR testing to include healthcare workers, noting the ability for self-sampling, self-delivery to the lab, and increased tolerability of regular testing as advantages over nasopharyngeal or oropharyngeal based RT-PCR.

b. Adoption of rapid antigen tests for healthcare workers, although potentially can return a result on the spot, are only currently approved in New Zealand detection of symptomatic cases.

Recommendations

8. CT TAG noted that within the current outbreak there may not be a current need to intensify surveillance testing as the impacts on health care workers appear to be manageable.

9. However the opportunity should be taken to act and prepare for situations where there would be a need to intensify the surveillance strategy in response to a new outbreak of COVID-19.

10. With regards to testing modalities to deliver this strategy, CT TAG proposed:

    a. That when a more intense surveillance strategy for healthcare workers is required, consideration should be given to making the testing mandatory.

    b. Healthcare workers should be given the opportunity to choose their preferred sample type for RT-PCR testing; either nasopharyngeal swab, anterior nasal / oropharyngeal swab or saliva, with the intent that such choice should improve adherence to the testing schedule.

    c. Noting the current operational constraints (volume, supply chain and turnaround time) affecting the current provider of saliva-based PCR testing, consideration should be given to alternative solutions to deliver this strategy as saliva-based PCR is likely to be a popular option.

    d. Rapid antigen tests may have a role in this situation in future, however they require further assessment and field trials prior to their implementation within Aotearoa New Zealand.

Professor David Murdoch

Chair, CT TAG

Document Four

AGENDA: COVID-19 Testing Technical Advisory Group

Date:	14 October 2021
Time:	1:30pm to 2:30pm
Location:	Out of Scope [redacted]
Chair:	David Murdoch
Members:	Kirsten Beynon, Maia Brewerton, Patricia Priest, Pisila Fanolua, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Christian Marchello, Christina Bir, Darryl Carpenter, Ian Costello, Ian Town, Jon Herries, Kelsey Bilek, Mark Ayson
Guests:	Steve Wakeling, Gill Hall, Kirsten Stephenson
Apologies:	Daniel Bernal

** Supporting papers are provided in-confidence and are not for further distribution **

#	Agenda Item	Duration	Purpose	Owner	Paper
1.0	Welcome and Accept Previous Minutes	5 min	Governance	Chair	COVID-19 Testing TAG Minutes 23 Septe
2.0	Work in progress in response to rapid review • HR response to rapid review • Draft actions to each recommendation • Testing strategy draft	15 min	Discussion	Ian Town/Kirsten Stephenson Gill Hall	HR20212072 Response to A Rapi COVID-19 Testing TAG Review Report R DRAFT Aotearoa New Zealand COVID-19 Te

3.0	Pilot projects for RAT • 2x workshops with business leads exploring RAT pilots • Middlemore/ADHD/Waitemata pilots • DG authorisation of RAT	15 min	Discussion	Darryl Carpenter Christina Bir	Signed memo authorisation for or Signed memo authorisation for 3 I
4.0	New tests evaluation and approval framework	10 min	Sign-off	Darryl Carpenter Christina Bir	DRAFT_Evaluation and authorisation fi
5.0	Next Steps/Decisions Pending			All	Verbal
6.0	Agenda Items for Next Meeting			Chair	Verbal

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
2	Testing TAG Work Programme	To develop reconnecting/community outbreak scenarios for CT TAG to consider and then discuss which tests might be most helpful.	Policy	09/09 – Action raised
4	Testing TAG Work Programme	Engage with Members to develop CT TAG work programme	Chair	09/09 – Action raised 14/10 - Ongoing

Closed Actions:

#	Agenda item	Actions	Action Owner	Updates
1	Where Ministry Testing and Supply gets advice from and how decisions are made	To share flow chart/tracing of advice and decisions on saliva testing	Testing and Supply	09/09 – Action raised 23/09 – Item shared. Action closed. Tracing of advice for saliva testing.pd
3	Testing TAG Work Programme	Secure NZMN draft statement on saliva testing to share with the group	Susan Morpeth	09/09 – Action raised 23/09 – Item shared. Action closed.

Document Four

				NZMN-position-statement-saliva-testing

Document Five

AGENDA: COVID-19 Testing Technical Advisory Group

Date:	23 September 2021
Time:	2:30pm to 3:30pm
Location:	Out of Scope [redacted]
Chair:	David Murdoch
Members:	Kirsten Beynon, Maia Brewerton, Patricia Priest, Pisila Fanolua, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Christian Marchello, Christina Bir, Daniel Bernal, Darryl Carpenter, Ian Costello, Ian Town, Jon Herries, Kelsey Bilek, Mark Ayson
Guests:	James Harris, Antoinette Righarts
Apologies:	

** Supporting papers are provided in confidence and are not for further distribution **

#	Agenda Item	Duration	Purpose	Owner	Paper
1.0	Welcome and Accept Previous Minutes	5 min	Governance	Chair	COVID-19 Testing TAG Minutes 09 Septe
2.0	Update on Open Actions	5 min	Governance	Chair	Verbal
3.0	Testing TAG Work Programme Reconnecting scenarios	10 min	Discussion	Chair	Verbal
4.0	Rapid review of COVID-19 laboratory diagnostic activities and systems	15 min	Discussion	Chair	Verbal
5.0	Surveillance and Testing Plan 2021	5 min	Information	James Harris	Surveillance and Testing Plan 2021 -

6.0	Testing fact sheets approved by DG	5 min	Information	Dan Bernal	Saliva testing for COVID-19 - factshee Antigen testing for COVID-19 - factshee Testing for SARS-CoV-2 summa
7.0	Next Steps/Decisions Pending			All	Verbal
8.0	Agenda Items for Next Meeting			Chair	Verbal

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
1	Where Ministry Testing and Supply gets advice from and how decisions are made	To share flow chart/tracing of advice and decisions on saliva testing	Testing and Supply	09/09 – Action raised 23/09 – Item shared: Tracing of advice for saliva testing.pd
2	Testing TAG Work Programme	To develop reconnecting/community outbreak scenarios for CT TAG to consider and then discuss which tests might be most helpful	Testing and Supply	09/09 – Action raised
3	Testing TAG Work Programme	Secure NZMN draft statement on saliva testing to share with the group	Susan Morpeth	09/09 – Action raised 23/09 – Item shared: NZMN-position-statement-saliva-testing
4	Testing TAG Work Programme	Engage with Members to develop CT TAG work programme	Chair	09/09 – Action raised

Document Six

MINISTRY OF HEALTH
MANATŪ HAUORA

AGENDA: COVID-19 Testing Technical Advisory Group

Date:	09 September 2021
Time:	2:30pm to 3:30pm
Location:	[redacted] S6(a) [redacted]
Chair:	David Murdoch
Members:	Kirsten Beynon, Maia Brewerton, Patricia Priest, Pisila Fanolua, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Christian Marchello, Christina Bir, Daniel Bernal, Darryl Carpenter, Ian Costello, Ian Town, Jon Herries, Kelsey Bilek, Mark Ayson
Guests:	
Apologies:	

** Supporting papers are provided in-confidence and are not for further distribution **

#	Agenda Item	Duration	Purpose	Owner	Paper
1.0	Welcome and Accept Previous Minutes		Governance	Chair	COVID-19 Testing TAG Minutes 26 Augu
2.0	Where Ministry Testing and Supply gets advice from and how decisions are made		Discussion	Darryl Carpenter/ Christina Bir	MoH Testing and Supply work stream a
3.0	Surveillance Testing for the Auckland Healthcare Workforce - Update		Discussion	Darryl Carpenter/ Christina Bir	Verbal
4.0	Testing TAG Work Programme		Discussion	Chair	COVID-19 Testing TAG Work Programr Briefing 2021-4449 Status of COVID-19 JetPark saliva method comparison

6.0	Next Steps/Decisions Pending			All	Verbal
7.0	Agenda Items for Next Meeting			Chair	Verbal

Document Seven

AGENDA: COVID-19 Testing Technical Advisory Group

Date:	26 August 2021
Time:	2:30pm to 3:30pm
Location:	[redacted] S6(a) [redacted]
Chair:	David Murdoch
Members:	Kirsten Beynon, Maia Brewerton, Patricia Priest, Pisila Fanolua, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Christina Bir, Daniel Bernal, Darryl Carpenter, Helena Woods, Ian Costello, Ian Town, Jon Herries, Christian Marchello, Kelsey Bilek, Mark Ayson
Guests:	
Apologies:	

** Supporting papers are provided in-confidence and are not for further distribution **

#	Agenda Item	Duration	Purpose	Owner	Paper
1.0	Welcome and Introductions		Governance	Chair	
2.0	Group membership, Terms of Reference, Meeting Frequency		Discussion	Chair	COVID-19 Testing Technical Advisory
3.0	Surveillance Testing for the Auckland Healthcare Workforce		Discussion	Chair	294 Surveillance testing for the Auck
4.0	Testing Update as Background Please note the STA Summary of ERS Rapid Antigen Report has been done at pace		Discussion	Chair	188 SARS-CoV-2 TestingStrategies 1 STA Summary of ES Rapid Antigen Repo
5.0	Next Steps/Decisions Pending			All	Verbal
5.0	Agenda Items for Next Meeting			Chair	Verbal

Document Eight

MINUTES: COVID-19 Testing Technical Advisory Group

Date:	23 September 2021
Time:	2:30pm to 3:30pm
Location:	Out of Scope [redacted]
Chair:	David Murdoch
Members:	Kirsten Beynon, Maia Brewerton, Patricia Priest, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Christian Marchello, Daniel Bernal, Darryl Carpenter, Jon Herries, Kelsey Bilek, Mark Ayson
Guests:	James Harris, Antoinette Righarts
Apologies:	Pisila Fanolua, Christina Bir, Ian Town, Ian Costello

1.0	**Welcome and Previous Minutes** Professor David Murdoch welcomed all members and attendees in his capacity as Chair of the COVID-19 Testing Technical Advisory Group. Minutes of the last meeting (09 September 2021) were accepted. Chair noted ESR document on last agenda has not been discussed and has been tabled this meeting.
2.0	**Update on Open Actions** Where Ministry Testing and Supply gets advice from and how decisions are made: • Timeline and tracing of advice for saliva testing shared with the group. Action item has been closed Testing TAG Work Programme / Reconnecting scenarios: • Tabled until next meeting. Will not have time at today's meeting to properly discuss due to focusing on the rapid review NZMN statement on saliva testing was shared with the group. Action item has been closed. Chair continues to engage with members offline for the work programme and coordinating the rapid review. • Today's priority is developing and organising the rapid review of COVID-19 laboratory diagnostic activities and systems.
3.0	**Testing TAG Work Programme / Reconnecting scenarios** • Tabled until next meeting

4.0	**Rapid review of COVID-19 laboratory diagnostic activities and systems**
	
	The purpose of the rapid review is to ensure the ongoing and efficient delivery of high-quality, equitable, scalable and adaptable COVID-19 diagnostic testing to support the objectives of New Zealand's pandemic response and reconnection plan. This will be done by:
	
	1. Reviewing, evaluating and making recommendations on the coordination of COVID-19 laboratory activities/workstreams and requirements.
	2. Identifying potential challenges, constraints, gaps and unrecognised opportunities to ensure ongoing sustainable and fit for purpose COVID-19 testing within New Zealand
	
	• Government requests the report to be delivered by Friday 1 October 2021.
	• Tentative schedule is to have interviews Friday afternoon, all day Monday, and Tuesday morning. Monday meetings will be face-to-face and Chair will be travelling to Wellington. A debrief and writing of the report will occur Tuesday and Wednesday with a plan to deliver a draft to the DG by Thursday.
	• Chair will attend all meetings. It was requested Testing TAG members also join each interview but schedules may be difficult to align.
	• It was noted several representative groups would like to be scheduled for Monday afternoon. STA is working on the logistics and will do its best to accommodate the various groups.
	• There is a desire to have the perspective of laboratory IT and data management. There is little regulation on what data is provided and what level of detail for data is required. It was recognised this is an important consideration and a group will be organised for an interview for their input into the review.
	• There are 15 interview times set aside at the moment. It was requested that because there are so many groups and limited time, that bullet points or key points are shared with each group when sending invites.
	• Due to the time constraints, it was suggested that contributors write to the Chair if they are unable to attend an interview.
	• A member asked about confidentiality and what will be discoverable. It was noted individuals will not be identified but the report can be OIA if requested. Since the report is systems focused, there should be no concerns. If minutes are OIA, members will be notified.
	• A concern was raised that during interviews there may be some people who feel they cannot speak freely because of others in attendance. The Chair will be sure to express anyone can contact him directly if they want to be confidential.
	• A member asked if the representatives from POC should be interviewed. It was agreed this is an important perspective. The member will send a list of individuals from POC to STA to contact.
	• A question was raised whether commercial companies should be interviewed and if there was value there because at the moment none were on the list to be interviewed.
	  ○ It was suggested to get written feedback from them instead of setting aside interview time.
	  ○ It was suggested the Chair contact them separate from the rapid review and not engage in a formal context.
	  ○ A member noted the Terms of Reference (TOR) need to be clear so that they are fulfilled and a boundary put in place on the scope. Commercial entities may not have much to add to the TOR.

	○ A member noted that Rako and Hill have both contributed significantly the COVID-19 response since the beginning of the pandemic and it would be valuable to get their perspective since this rapid review is focusing on systems and workstreams. ○ A concern was raised commercial laboratories would see this as a way to pitch technologies. It was proposed that when inviting them that the purpose is clear and to pose specific questions. ○ The end consensus was to invite representatives from both Rako and Hill since these have been active partners for COVID-19 testing. A member requested that information be shared about how many other companies have approach the Ministry and turned down.
5.0	**Surveillance and Testing Plan 2021** • Shared with the TAG as an FYI. • Surveillance plan will be updated weekly as needed. • Chair requested any comments or feedback to be delivered directly to Ministry of Health Intel and Surveillance
6.0	**Any Other Business** None noted
7.0	**Agenda Items for Next Meeting** • Testing TAG Work Programme/Reconnecting scenarios
8.0	**New Action Items Raised During Meeting** None raised during this meeting
Meeting closed at **3:42pm** Next meeting **TBD**	

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
2	Testing TAG Work Programme	To develop reconnecting/community outbreak scenarios for CT TAG to consider and then discuss which tests might be most helpful.	Policy	09/09 – Action raised
4	Testing TAG Work Programme	Engage with Members to develop CT TAG work programme	Chair	09/09 – Action raised 14/10 - Ongoing

Closed Actions:

#	Agenda item	Actions	Action Owner	Updates

1	Where Ministry Testing and Supply gets advice from and how decisions are made	To share flow chart/tracing of advice and decisions on saliva testing	Testing and Supply	09/09 – Action raised 23/09 – Item shared. Action closed. Tracing of advice for saliva testing.pd
3	Testing TAG Work Programme	Secure NZMN draft statement on saliva testing to share with the group	Susan Morpeth	09/09 – Action raised 23/09 – Item shared. Action closed. NZMN-position stat ement-saliva-testing

Document Nine

MINUTES: COVID-19 Testing Technical Advisory Group

Date:	09 September 2021
Time:	2:30pm to 3:30pm
Location:	[redacted] Out of Scope [redacted]
Chair:	David Murdoch
Members:	Kirsten Beynon, Maia Brewerton, Patricia Priest, Pisila Fanolua, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Christian Marchello, Christina Bir, Daniel Bernal, Ian Town, Jon Herries, Kelsey Bilek, Mark Ayson
Guests:	
Apologies:	Darryl Carpenter, Ian Costello

1.0	**Welcome and Previous Minutes** Professor David Murdoch welcomed all members and attendees in his capacity as Chair of the COVID-19 Testing Technical Advisory Group. Minutes of the last meeting (26 August 2021) were accepted, subject to the following changes (marked in in red) on item **3.0 Surveillance Testing for the Auckland Healthcare Workforce** • Turnaround time (TAT) would ~~decrease~~ increase substantially if all healthcare workers were tested. The system is already at capacity testing in the community, especially with the growing number of LOI.
2.0	**Where Ministry Testing and Supply gets advice from and how decisions are made** • Chair expressed the desire to understand where the Ministry's COVID-19 Testing and Supply has gotten advice from previously and how decisions are made based on that advice in order to set a work programme for Testing TAG. • Testing and Supply seeks advice from a number of sources, examples include, but not limited to: Ministry Science and Insights, New Zealand Microbiology Network, ESR, NZ POC TAG, Saliva Testing Clinical Governance Group, and individuals within and outside the Ministry. • A member expressed a visualisation document would be helpful to view the advice network. • A document that charted the timing of advice and decisions made about saliva testing was requested and was agreed to be shared with the TAG by Testing and Supply. • Several members commented and agreed that there needs to be a clearer sense about what happens to TAG advice and clarity on the decision-making process. There needs to be an understanding of the trajectory for where the advice goes, who listens to the advice, and what results come from the advice.

	• It was outlined that TAG advice will be especially useful in understanding testing technology and how it can support Aotearoa New Zealand with reconnecting. Advice may be provide support for ministries, or provide detail if ministers require knowledge and insights on certain tests. It was noted the minutes of Testing TAG are subject to OIA. • A concern was raised that messaging and communications have centred on a single sample type (saliva), which is often discussed out of context. • It was noted some laboratory workers needed a test but were unable to self-administer and did not have any information on performing collection of the samples. It would helpful if Ministry put out a video or animation similar to the vaccine programme to explain how COVID-19 samples are collected.
3.0	**Surveillance Testing for the Auckland Healthcare Workforce - Update** <u>Update</u> • Advice was provided to the 3 DHBs in Auckland and all 3 have onsite surveillance testing available for healthcare workers. They can also visit a CTC if needed. Approximately 3,000 staff have had a surveillance test in addition to staff testing already in place. There was not a breakdown of who was getting a test for surveillance, for being a contact, or for being symptomatic. DHBs were instructed healthcare workers should be tested weekly. <u>TAG feedback</u> • It was not clear from those familiar with the DHBs and hospitals that this process had been put in place. It was also unclear whether this surveillance testing was strongly recommended/encouraged or mandatory. It was noted the testing was voluntary, but options were being considered for making it a requirement. • Knowing the number of tests is not helpful without knowing which were part of regular surveillance or were people getting tested for other reasons. • A member commented there has not been any communications or promotion of the surveillance testing. • Legal aspects are also important to consider, especially with regards to health and safety assessments of the workplace. • The feedback was welcomed, and Testing and Supply will take the comments back to the appropriate people.

4.0	**Testing TAG Work Programme**
	<u>Background</u>
	• The Work Programme provided was a rough draft from various discussions among members.
	• The proposed Work Programme had 5 key points:
	  ○ Saliva testing
	  ○ Reconnecting New Zealand
	  ○ Community testing
	  ○ New Zealand initiatives
	  ○ Standard operating procedures for obtaining operational advice

- A member noted there is pressure to get ahead of the curve and the benefits of the Testing Tag would be getting proper advice on these key points and how technology and commercial developments can be used.
- Chair opened the floor for discussion.

TAG Feedback on Work Programme

- A concern was raised about lab capacity and resources. Advanced notice is needed to scale up.
- An authoritative statement on the role of saliva from this group would be helpful in easing concerns about the sample type.
- A member said laboratories need leadership for what is needed from them now and in the future. How many tests will be run, how sensitive those tests need to be, will testing be done on anyone with common colds, what is the scale of testing, will laboratories be expected to pay or will there be public funding. Individual laboratories will not want to invest in high throughput equipment if it is not clear that it is needed. Planning is needed for how testing will work under the elimination strategy and moving forward through the reconnecting NZ phases.
- It was requested that a paper by an outside member on laboratory investments could be made in the short to medium term to highlight issues for the agenda.
- It was noted that Testing TAG should prioritise advice on lower sensitive POC tests so that advice can be given quickly when it is requested. An interest in testing later in disease, such as inflammatory T-cell tests, was noted so TAG was more forward looking.
- A member raised concern about relying on one type of laboratory test will increase the likelihood of failure and diversity of testing is preferred.
- There are now borders in place within the country for Auckland Level 4 and the rest of the country at Level 2. A question was raised about testing being different in Auckland versus for someone outside the border as well as those crossing the border.
- Member noted that operational guidance should be irrespective of test type and more on delivery, scaling, and capacity during each reconnecting NZ phases. That is, categorising different phases and responding with the right test scenarios is needed.
- It was suggested that the maximum testing capacity that is achievable be considered first and work back from there so that it is understood what can and cannot be done.
- The topic of having a statement from Testing TAG on saliva was raised again:
    - Useful to develop and keep for when needed. Can write up and deliver so that the decision to be used would be on Ministers.
    - NZMN will have a statement and is in advanced draft. Member will try to secure the statement and share with the group.
- No action is needed for MBIE document. MBIE plans to do continue work on briefing paper to fill in further information on testing technologies. When questions arise, they will be brought back to the group.
- The different phases and scenarios for reconnecting NZ and the tests being considered will be brought to the group for feedback and input by Testing and Supply.
- It was noted that pilot studies and informed consent for new tests limits the ability to consider new specimens and assays. A process such as a verbal informed consent and collecting 2 samples at the same time could speed up the process.
- Wastewater testing was also addressed as a surveillance tool that is within the scope of the Testing TAG and valuable to have on board.

	• Chair noted the discussion for developing the Work Programme would be taken offline. A standard operating procedure with a scenario-based approach will clarify how Testing TAG can be most helpful. • Chair will engage with members and work up a plan for next meeting.
5.0	**Any Other Business** None noted
6.0	**Agenda Items for Next Meeting** None raised during this meeting
7.0	**New Action Items Raised During Meeting**

#	Agenda item	Actions	Action Owner
1	Where Ministry Testing and Supply gets advice from and how decisions are made	To share flow chart/tracing of advice and decisions on saliva testing	Testing and Supply
2	Testing TAG Work Programme	To develop reconnecting/community outbreak scenarios for CT TAG to consider and then discuss which tests might be most helpful.	Testing and Supply
3	Testing TAG Work Programme	Secure NZMN draft statement on saliva testing to share with the group	Susan Morpeth
4	Testing TAG Work Programme	Engage with Members to develop CT TAG work programme	Chair

Meeting closed at **3:34pm**

Next meeting **23 September 2021 – 2:30pm to 3:30pm**

Open Actions:

#	Agenda item	Actions	Action Owner	Updates
1	Where Ministry Testing and Supply gets advice from and how decisions are made	To share flow chart/tracing of advice and decisions on saliva testing	Testing and Supply	09/09 – Action raised
2	Testing TAG Work Programme	To develop reconnecting/community outbreak scenarios for CT TAG to consider and then discuss	Testing and Supply	09/09 – Action raised

		which tests might be most helpful.		
3	Testing TAG Work Programme	Secure NZMN draft statement on saliva testing to share with the group	Susan Morpeth	09/09 – Action raised
4	Testing TAG Work Programme	Engage with Members to develop CT TAG work programme	Chair	09/09 – Action raised

Document Ten

MINUTES: COVID-19 Testing Technical Advisory Group

Date:	26 August 2021
Time:	2:30pm to 3:30pm
Location:	[redacted] Out of Scope
Chair:	David Murdoch
Members:	Kirsten Beynon, Maia Brewerton, Patricia Priest, Pisila Fanolua, Susan Morpeth, Tim Blackmore
Ministry of Health Attendees:	Dan Bernal, Darryl Carpenter, Helena Woods, Ian Town, Jon Herries, Christian Marchello, Kelsey Bilek, Mark Ayson, Chris Hedlund
Guests:	
Apologies:	Christina Bir, Ian Costello

1.0	**Welcome and Previous Minutes** Professor David Murdoch welcomed all members and attendees in his capacity as Chair of the COVID-19 Testing Technical Advisory Group. The Chair thanked the group for coming together with urgency as we manage the current the outbreak.
2.0	**Group membership, Terms of Reference and Meeting Frequency** The Chair welcomed feedback for the Terms of Reference • The purpose of the group is to provide oversight to some of the testing issues for COVID-19. • A member inquired about the expectation and need to utilise personal networks and contacts to inform advice that is brought to the TAG. All members agree this is essential for providing best advice but as long as it is done with consideration for confidentiality and abides by the Terms of Reference. • Regularly scheduled CT TAG meetings will be fortnightly. Agenda items will be circulated prior to meetings with the aim to have specific questions for the group to answer.
3.0	**Surveillance Testing for the Auckland Healthcare Workforce** Background and context • Currently healthcare workers are asked to present for testing in the same way as other members of the public through the CTCs, CBACs, and GPs network if they are symptomatic or close contacts of cases. • If anyone in the healthcare workforce is a close contact or the hospital where they work is a location of interest (LOI) then the potential loss of capability and capacity in the hospital setting is significant. • Questions posed to TAG group:

	○ Is surveillance testing of healthcare workforce and workers across greater DHBs justified and appropriate? ○ If testing surveillance is appropriate, should nasopharyngeal (NP) swabs, saliva, or rapid antigen tests (RAT) be used? • CT TAG is not to consider operationalising the proposed surveillance methods, only if it is appropriate and what testing method to use if so. • It was noted there is currently an Expression of Interest (EOI) received to perform saliva testing. <u>Feedback from CT TAG</u> • A question was posed asking what is currently happening for testing border workers ○ Border workers can choose saliva to replace NP as of 12/08/2021. If they choose to do so, the workers need to provide a series of 2 saliva tests at least 2 days apart over a 7-day period as part of the mandatory testing requirement • Member noted that the question brought to CT TAG on the appropriateness of surveillance should be considered by a broader group, including Ministry's Science and Insights, and ODPH. Once advice is provided by those groups, CT TAG can advise on testing methods. • A concern was raised that doing surveillance testing on healthcare workers not directly caring for COVID-19 patients would undermine standard IPC. • A question was asked about how many border workers have selected taking a saliva test over NP. Based on the Border Operations survey, it is believed approximately 25% of the border workforce will opt-in to saliva. • It was noted that this requested advice from CT TAG is specific to the current outbreak. The EOI for saliva testing is for the duration of the outbreak for Auckland healthcare workers. • A member expressed that the situation is very dynamic. Today, next week, and 3 months from now could be different. Member does not believe surveillance is needed today but may be needed next week or down the road. Preparations should begin now to be able implement immediately when needed. • Turnaround time (TAT) would decrease substantially if all healthcare workers were tested. The system is already at capacity testing in the community, especially with the growing number of LOI. • Member noted that if surveillance testing is already occurring among border workers, we should be testing other critical services as well. • It was noted that the document proposing the 3 testing options (NP, saliva, and RAT) did not consider point of care (POC) NAAT such as RT-LAMP. These more sensitive methods could be produced rapidly and test a large number of people if enough machines were put in place. • Most data on POC RAT are pre-Delta. The Ct values with Delta might change RAT assumptions. RAT was discounted initially and might be more sensitive now. ○ Limitations of RAT were noted, sensitivity in asymptomatic is unknown and using RAT would be off label for asymptomatic screening by Medsafe. ○ Limitations less of an issue if you can increase frequency of doing a RAT. ○ RAT likely will not work because a swab is still needed. • Three hospitals in Auckland have set up testing collection sites for workers so they do not have to travel to a CTC/CBAC. It was noted that some healthcare workers may be lost if testing was made mandatory. • A member noted that not all LOI are the same, referring to exposure risk. Without additional information, it was driving a surge in testing in the community. • Member agreed with the limitations of RAT and suggested saliva as the appropriate testing method. Saliva could be done at home by the worker and dropped off.

	• Member noted that we need to be flexible and that giving people a choice may help. We should be prepared to consider all options. A combination of tests (e.g., offering the worker either NP or saliva) is the best approach. • From the clinical side, it was addressed that many healthcare workers are used to having NP swabs and continuing this approach would also not be a bad idea. • It was expressed that saliva has an 'image problem', that even though it is not inferior to NP, many still believe it is. • We need to be able to stand up healthcare testing surveillance quickly and not just in Auckland. A plan is needed to be able to do this anywhere in Aotearoa New Zealand. • It was noted 'healthcare' needs to mean every worker at the facility (e.g., not just doctors and nurses, but all staff). This meeting is discussing implications for hospitals at the moment, but advice can be adapted to GPs and other DHB staff. • Member expressed concern about EOI on saliva to not be over-reliant on one supplier. There are global shortages and could pose a significant problem later. <u>Main takeaways</u> • Within the current outbreak there may not be a current need to intensify surveillance testing as the impacts on health care workers appear to be manageable. • The opportunity should be taken to act and prepare for situations where there would be a need to intensify the surveillance strategy in response to a new outbreak of COVID-19. • Healthcare workers should be given the opportunity to choose their preferred sample type for RT-PCR testing; either nasopharyngeal swab, anterior nasal / oropharyngeal swab or saliva, with the intent that such choice should improve adherence to the testing schedule. • Noting the current operational constraints (volume, supply chain and turnaround time) affecting the current provider of saliva-based PCR testing, consideration should be given to alternative solutions to deliver this strategy as saliva-based PCR is likely to be a popular option. • Rapid antigen tests may have a role in this situation in future, however they require further assessment and field trials prior to their implementation within Aotearoa New Zealand
4.0	**Testing Update as Background** • Members to review on own time and provide feedback directly to the Chair or Science & Technical Advisory after the meeting.
5.0	**Any Other Business** None noted
6.0	**Agenda Items for Next Meeting** None noted
7.0	**New Action Items Raised During Meeting** None noted
Meeting closed at **3:41pm** Next meeting **09 September 2021**	

Document Eleven

Terms of Reference – COVID-19 Therapeutics Technical Advisory Group

27 August 2021

Contents

Introduction

The Ministry of Health (the Ministry) is the kaitiaki of the health and disability system in Aotearoa New Zealand. We do this by providing a fair, effective and sustainable system that people trust. The Ministry is responsible for providing active stewardship and leadership across the health and disability system to ensure it provides people with the highest level of care, regardless of who they are or where they live.

The COVID-19 pandemic has rapidly evolved internationally and in Aotearoa New Zealand. Responding to COVID-19 in a very rapidly changing environment is a significant ongoing challenge.

The Government's overall public health strategy in respect of the COVID-19 pandemic affecting New Zealand is elimination. That is, to apply a range of control measures in order to stop the transmission of COVID-19 in Aotearoa New Zealand.

There are four pillars to our elimination strategy, these are:

- border controls
- robust case detection and surveillance
- effective contact tracing and quarantine
- strong community support of control measures

The Ministry has established the COVID-19 Health System Response Directorate (the Directorate) to give effect to the elimination strategy. The Ministry is working to ensure the response to COVID-19:

- is evidence-based
- is consumer-centred
- is equity-focused and guided by the Treaty of Waitangi
- effectively manages clinical and public health issues and risks
- supports an open and transparent culture
- has a continuous quality improvement and safety focus
- monitors and reviews clinical processes and outcomes
- guides the development of the Ministry and All of Government strategies to address COVID-19.

Purpose and Function

The COVID-19 Therapeutics Technical Advisory Group (Therapeutics TAG) comprises a standing membership of external expert advisors who will provide expert technical advice on therapeutics for use for patients with COVID-19 including but not limited to:

- Identifying therapeutics which may be beneficial in the management of COVID-19
- Enabling the acquisition of these agents for clinical use in New Zealand

- Developing appropriate guidelines for clinical use.

Therapeutics TAG has been established as part of the Ministry's response to COVID-19 and will provide expert technical advice to the Ministry during the response to COVID-19 pandemic.

Therapeutics TAG does not hold decision-making authority or responsibility for the acceptance or application of advice provided. The scientific and technical advice and recommendations from Therapeutics TAG are provided to the Ministry to inform and contribute to decisions, operations, guidelines and policy required in the management of COVID-19. The Ministry receives advice from a variety of sources including but not limited to Therapeutics TAG.

Therapeutics TAG is guided by Te Tiriti o Waitangi principles as they apply to the health and disability sector; tino rangatiratanga, equity, active protection, options, and partnership. This involves the managing of the response to COVID-19 pandemic through evidence-based approaches with the aim of achieving equity of outcomes, and contributing to wellbeing for all, including Māori and Pacific peoples.

These Therapeutics TAG Terms of Reference replace any previous terms of reference agreed by Members for Therapeutics TAG.

Membership

The Therapeutics Technical Advisory Group is to p ovide expert, multi-disciplinary expertise on the latest scientific, clinical and technical evidence-based, expert advice on COVID-19.

Members of the Therapeutics TAG will be asked to:

- provide the Ministry with rapid advice based on the most up to date clinical, scientific and technical evidence on therapeutics for the treatment of COVID-19
- identify emerging scientific, clinical or technical issues and inform the Ministry on ways this advice could be used to design the response to COVID-19 pandemic within Aotearoa New Zealand
- suggest approaches and actions to enact the principles of Te Tiriti o Waitangi and achieve equity for Māori
- advise on ways to reduce inequalities for groups in society negatively impacted by COVID-19, including but not limited to; ethnicity, dis/ability, geographic location, age, gender, health status, socioeconomic position, living and working conditions
- identify areas requiring further research, and/or reviews to inform ongoing response.

The appointment of Members of Therapeutics TAG is based on their personal, technical and specialist expertise. This includes acknowledgement of Member's understanding of the systems, structures, stakeholders, and in-depth specialist knowledge in their respective disciplines, with a view to supporting the effective development and application of technical advice.

Members will focus on the core scientific, technical, and/or clinical basis for advice, referencing the evidence base alongside the rationale for advice in the context of operational limitations and/or precedent. Therapeutics TAG will comprise equitable Māori representation, alongside representation from Pacific and the disability sector.

Membership of Therapeutics TAG will be confirmed through an appointment letter from the Chairperson and a confirmation response from the Member.

Chairperson

Therapeutics TAG will be led by the Chairperson who can be a Ministry employee.

Members

Therapeutics TAG has a standing membership comprised of external (main job is not Ministry employee) technical experts from disciplines relevant to the response required in the phases and alert levels of the COVID-19 pandemic. The membership also comprises of equitable Māori representation, alongside representation from Pacific and the disability sector.

Ex Officio Advisors

Technical experts within the Ministry can also have membership within the group in the capacity of Ex Officio Advisors as invited by the Chairperson.

Members of Therapeutics TAG must agree:

- **to keep all information provided to them strictly confidential** and, except as expressly permitted, not share, publish, copy in whole or in part or modify or adapt any confidential information in any way without the Ministry's prior written consent which may be given or withheld in its absolute discretion.

- **not to use any confidential information** for any purpose other than participating in Therapeutics TAG activities without the Ministry's prior written consent which may be given or withheld in its absolute discretion.

  Where the Therapeutics TAG Member wishes to use the information provided for research purposes, a detailed letter seeking permission to use the data, and describing how the data will be used including the ethical safeguards that will be used to protect the integrity of the data, must be submitted to the Chief Science Advisor for approval, prior to any research occurring. The Ministry may put conditions on the use of data, including acknowledgements as appropriate.

  Pre-existing intellectual property rights relating to the provision of advice remain the property of their current owner. New intellectual property rights in work created for the Ministry as part of Therapeutics TAG become the property of the Ministry when they are created unless otherwise agreed in writing.

- **to declare any real or perceived Conflicts of Interest** - Therapeutics TAG Members should perform their functions in good faith, honestly, fairly, impartially, responsibly and avoid situations that might compromise

their integrity or otherwise lead to conflicts of interest. The Conflict of Interest form provided by the Ministry must be completed, returned to S9(2)(a)

The Member must inform the Ministry upon becoming aware of the existence of the possibility of a conflict arising after completing the form. A register of Conflict of Interest will be recorded and addressed through the processes outlined above.

- Members of Therapeutics TAG are **not authorised to make statements on behalf of Therapeutics TAG or the Ministry**. The Ministry has strict protocols for managing media enquiries and all such requests should be directed to S9(2)(a) and copied to the Science & Technical Advisory (STA) email S9(2)

  Members have the right to comment to the media on any matter in their professional capacity, as long as they do not attribute the comment to Therapeutics TAG or imply that they are speaking on behalf of Therapeutics TAG or wider Ministry. If a Member is forewarned of being asked to comment to the media, they should advise the STA accordingly. If a Member is not forewarned, they should advise the STA immediately after making comment to the media.

- Members are not authorised to commit Therapeutics TAG, any Members of it, or the Ministry to any financial or legal commitments or to otherwise purport to act as agents for the Ministry.

  Membership of Therapeutics TAG will be for a period of 12 months with the option for a further extension as offered by the Ministry.

  A register of membership of Therapeutics TAG is maintained and kept within the STA filing system within the Ministry and accessible to Ministry staff. Names of Therapeutics TAG Members and any other information provided by Members are subject to the Official Information Act 1982 and the Ministry will be required to release such information on request under that Act unless there are valid reasons for withholding the information under the Act.

Duties and Responsibilities

The duties and responsibilities for the Chairperson, Members and Ex Officio advisors are outlined below.

Duties and responsibilities of the Chairperson of Therapeutics TAG

The Chairperson agrees to:

- provide leadership and ensure the group retains a focus on its scope as defined in this Terms of Reference and priorities as determined by the Ministry
- determine suitability of Therapeutics TAG as the recipient of requests for advice, work to be commissioned, tasks, and facilitators of consultation
- ensure meetings are duly convened and that a quorum of Members is present each meeting
- ensure meetings are conducted in an efficient, effective and focused manner

- ensure the group has the required information to permit provision of advice and to make recommendations
- consider the principles of Te Tiriti o Waitangi in every action, through ensuring Therapeutics TAG is supported to interact and act with equity as a key consideration, and provides advice that is congruent with these obligations
- appoint Members to Therapeutics TAG based on scientific and technical expertise and the need for effective representation and tino-rangatiratanga (self-determination and autonomy) of Māori and Pacific peoples
- facilitate communications internally and externally, including: with other key stakeholders as appropriate; presenting advice and recommendations to decision makers after each meeting; and summarising any aspects of discussion or advice that should or should not be communicated by Members
- ensure minutes are taken during meetings and approval given for the minutes as an accurate record of the summary of the meeting.
- ensure actions and recommendations are noted and actioned within agreed timeframes
- act as a key contact point for agenda items, responses, absences, and delegations to the meeting, and will be informed of all activities requested of and undertaken by Therapeutics TAG.

Duties and responsibilities of a Member of Therapeutics TAG

Therapeutics TAG Members are not employees of the Ministry. They agree to:

- familiarise themselves with background material (if any) sent prior to and after meetings
- actively participate in meetings or provide feedback and/or comments as required
- undertake additional activities agreed by the group (such as commenting on advice or guidance, providing research material, or contacts), and to alert the Chairperson to limitations on availability and interim delegation arrangements
- share expert knowledge and engage constructively in discussions, acting only in the role they are representing and within their scope of expertise
- individually ensure familiarity with, and provide advice that is congruent with the principles and obligations of Te Tiriti o Waitangi in ensuring the active protection of Māori health, achieving equity across access, quality of care and outcomes
- ensure that all activity and advice is undertaken with consideration of and respect for equity of outcomes across all peoples of Aotearoa New Zealand, including but not limited to; ethnicity, dis/ability, geographic location, age, health, gender and socioeconomic position, living and working conditions
- lead/facilitate the completion of respectively owned action items within the agreed timeframes
- assume collective responsibility for advice through; working together in a collegial manner; seeking consensus on provision of advice wherever possible; and noting any unresolved differences of opinion,

limitations of evidence or opportunity for consultation, or concessions made due to time or logistical constraints

- exercise all due professional care and diligence in the performance of their obligations under these Terms of Reference in accordance with the standards of skill, care, and diligence normally practised by suitably qualified and experienced persons in performing services of a similar nature.
- to make themselves available for meetings convened for the purpose of providing advice to the Ministry as described above.

Duties and responsibilities of an Ex Officio Advisors of Therapeutics TAG

Therapeutics TAG Ex Officio Advisors are employees of the Ministry who hold specialist technical positions in a relevant field. The Ex Officio Advisors are appointed by the Chairperson.

The Ex Officio Advisors agree to:

- represent the Ministry by presenting requests for advice or commissioned pieces of work and providing relevant background information, context, and communications to support the Members in providing advice which is shaped for the question or issue at hand
- familiarise themselves with background material (if any) sent prior to meetings
- share expert knowledge and engage constructively in discussions, acting only in the role they are representing and within their scope of expertise
- communicate relevant information, activities, decisions, and issues of interest from the Ministry to Therapeutics TAG, and vice versa, through endorsed communication channels and methods
- individually ensure familiarity with and provide advice congruent with the principles and obligations of Te Tiriti o Waitangi in ensuring the active protection of Māori health and achieve equity across access, quality of care and outcomes
- ensure that all activity and advice is undertaken with consideration of and respect for equity of outcomes across all peoples of Aotearoa New Zealand, including but not limited to; ethnicity, dis/ability, geographic location, age, gender, health, and socioeconomic position, living and working conditions.

Secretariat of Therapeutics TAG

The Secretariat is not a Member of Therapeutics TAG but supports the group and the Chairperson with secretariat duties including

- disseminating information required for each meeting
- writing-up the agenda as directed by the Chairperson
- writing the minutes and disseminating these within the group
- updating any new Members or additional Members with the Terms of Reference
- receiving and storing the Conflict of Interest declarations

- receiving fee claims and organising fees payments
- assisting the Chairperson with the onboarding arrangements with Members.

Advice and Other Requests

On occasion, Therapeutics TAG Members may be asked to complete a distinct piece of strategic or proactive work in an area of expertise.

Any work requested from the Therapeutics TAG Members will be formally commissioned by the COVID-19 Health System Response Directorate of the Ministry.

Requests for Advice can come from sources across the Ministry and from external agencies, and these will be:

- triaged by STA for suitability of input from the Therapeutics TAG
- formatted in a standardised manner, detailing the topic, any backg ound information or context, and specific questions for the advice being sought.

In order to develop robust advice that is fit for purpose, the Ministry may seek wider consultation or peer review of technical, clinical, scientific advice provided by Members of the Therapeutics TAG.

Therapeutics TAG Members may be asked to recommend experts with appropriate specialist health or technical expertise who could be invited to comment or review Therapeutics TAG advice. Additional targeted consultation with Māori will be resourced and utilised in conjunction with Māori advisors and the Manager of STA.

All other targeted consultation will be facilitated by the Ministry. A register of Therapeutics TAG meeting reports, requests for advice, commissioned work, activity progress, and advice will be maintained by STA staff.

Meeting Protocols

Secretariat

The Ministry will ensure adequate secretariat support and other support as may be required from time to time, for Therapeutics TAG to carry out their mandate efficiently and effectively.

Meetings logistics

Coordination of the meetings will be managed by the Secretariat through direction of the Chairperson. This will include all the logistics, documentation, and administration. Members will receive relevant documentation through email or other digital tools used within the Ministry.

Members must have regular access to electronic and digital tools in which Therapeutics TAG meetings are conducted. Meetings conducted in workplaces must remain confidential and not visual or audible to workplace colleagues.

Delegates

Members will attend all meetings whenever reasonably possible and delegates are not permitted. Apologies must be in writing (email) to the Chairperson and Secretariat prior to the meeting.

Other attendees

Guests with relevant expertise may be invited to discuss specific issues and when attending the whole meeting will abide by the same Terms of Reference.

Non-Members may only attend by invitation of the Chairperson.

Quorum

A meeting quorum for Therapeutics TAG requires 50% of standing external Members, including the Chairperson.

The quorum for a meeting is the minimum number of Members required to make the meeting valid. If a meeting is inquorate, it cannot make recommendations on behalf of the group. It can hold discussions and make recommendations for later confirmation or rejection by the group.

Official Information Act requests

All agendas, emails and other communication and information relating to the Network are subject to the Official Information Act 1982, and the Ministry may be required to release such information on request unless there are valid reasons for withholding the information under the Act.

Fees Framework

The daily rate has been set in accordance with the Ministry's Fees Framework and has been approved by the Director-General of Health and may be paid to Members who are self-employed or privately employed.

Members who are paid for their time/employed through the wider state sector (eg they work for Universities, District Health Boards, Government departments and State agencies) are not personally eligible for a fee, although on the production of an invoice, the Ministry can reimburse a government-funded agency employing organisation for the Member's time.

The membership register will indicate those Members that are eligible to claim a fee under the Fees Framework and the level of the fee, based on the above declaration.

A working day of eight hours is the basis of the daily fee calculation, with hourly pro-rata rates calculated accordingly. A working day of longer than eight hours does not attract extra payment beyond the daily fee. The daily fee applies to all work, including the work performed outside of meetings that is required for the group to carry out its role (e.g. preparation, representing the group at other forums, or administrative work).

All fees and expenses (where agreed) are to be submitted either on a Ministry claim form or as an invoice. Reasonable expenses are to be agreed in writing in advance and should be supported by tax invoices and/or receipts.

Payments will be made in accordance with the Ministry's accounts payable guidelines.

Work outside of meetings that has been formally commissioned by the Ministry will be formally described in a written request with anticipated days or hours of work required and the fee rate, which the individual or group may accept or decline. Additional days or hours of work required must be agreed in writing with the Manager of STA prior to commencement of the hours worked.

Guidance on organisations that form part of the wider state sector can be found on the SSC website.

For more information, please refer to the Cabinet Fees Framework.

Review of Membership

Membership of s TAG will be reviewed by the Deputy Chief Executive TAG Health System Response Directorate, on or before September 2022.

MINISTRY OF HEALTH
MANATŪ HAUORA

Memo

COVID-19 Therapeutic TAG recommendations: Priority therapeutics for continuous supply

Date:	7 September 2021
To:	Ashley Bloomfield, Director General of Health
Copy to:	Dan Bernal, Manager, Science and Technical Advisory Andi Shirtcliffe, Clinical Chief Advisor, Pharmacy Therese Egan, Policy
From:	Ian Town, Chief Science Advisor
For your:	Action

Purpose of report

1. To request urgent action to ensure continued access to immunomodulating drugs used in the treatment of severe-critical COVID-19 in hospitalised patients and to address supply of other priority therapeutic agents for the treatment of COVID-19.

   Supporting information on the drugs and NZ supply is included in the Appendix.

Background and context

2. On 3 September the Therapeutics TAG identified priority therapeutics for the treatment of patients in the current Auckland outbreak and for the immediate future. The TAG confirmed that a continuous supply of one or more of the COVID-19 immune modulation drugs was essential.

3. **Tocilizumab** is being used for the treatment of hospitalised patients with moderate COVID-19 (meeting specific criteria) and for patients hospitalised with severe-critical COVID-19 (meeting specific criteria) in New Zealand currently. Evidence supports the benefit of tocilizumab in reducing mortality and time on mechanical ventilation.

   a. It has been recognised that supplies of tocilizumab were in short supply globally and that the NZ supply of tocilizumab might be under threat. Since the meeting on 3 September, PHARMAC have advised that tocilizumab will be out of stock in October 2021 with re-supply not expected until January 2022. Efforts to re-distribute existing NZ supply from rheumatology (where appropriate for patient care) to COVID-19 treatment have already been initiated.

   b. A rapid review of the evidence on the treatment alternatives to tocilizumab prepared for the Therapeutics TAG had confirmed that alternatives to tocilizumab were being used in many jurisdictions when tocilizumab was unavailable.

4. **Baricitinib** is currently being used in Australia as an alternative to tocilizumab in the context of a critical supply shortage of tocilizumab. Evidence indicates that baricitinib reduces mortality and the need for invasive mechanical ventilation in hospitalised adults who require supplemental oxygen and that baricitinib has an acceptable safety profile. Baricitinib is not currently approved for use in New Zealand for any indication and is not currently available in New Zealand. Baricitinib is required in New Zealand in the context of an impending tocilizumab supply shortage.

5. **Sarilumab** is recommended in many jurisdictions for use as an alternative to tocilizumab. Evidence from the REMAP-CAP trial showed tocilizumab and sarilumab had similar efficacy in reducing mortality and the need for mechanical ventilation. Sarilumab is not currently approved for use in New Zealand for any indication and is not currently available in New Zealand. PHARMAC have advised that preliminary efforts to obtain supply of sarilumab had not been successful. Sarilumab is a suitable therapeutic alternative to tocilizumab but baricitinib is recommended as a higher priority due to supply considerations.

6. **Remdesivir** is an anti-viral agent being used for the treatment of hospitalised patients with moderate COVID-19 (meeting specific criteria). Evidence indicates remdesivir may provide a small benefit in terms of 28-day mortality for patients who are hospitalised with COVID-19, but who do not require mechanical ventilation. Remdesivir is not currently approved for use in New Zealand for any indication. A small supply held in Auckland which was procured for use is now nearly depleted.

Recommendations

7. It is recommended that you formally request that PHARMAC:

   a. Endeavour to maintain tocilizumab supply.

   b. Seek to obtain access to baricitinib and sarilumab as a matter of urgency (as alternatives to tocilizumab).

   c. Seek to obtain a continuous supply of remdesivir.

Signature

Date: 7 September 2021

Ian Town

Chief Science Advisor, Ministry of Health

Noted 7/9/21

Dr Ashley Bloomfield
Director-General of Health

Appendix

COVID-19 Therapeutics
Hospital Care – in priority order

(informed by clinical feedback and Pharmac update on discussions with manufacturers).

Therapeutic	Mortality	Need for mechanical ventilation	Stock holding	Approved anywhere in the world for:	Level of evidence and other
Tocilizumab (Priority due to inclusion in clinical guideline for national use) For patients with moderate COVID-19 meeting criteria For patients with severe-critical COVID-19 meeting criteria	Reduces mortality at day 28 in patients with severe COVID-19. Reduces duration of hospitalisation.	May reduce need in patients requiring supplemental oxygen with widespread inflammation	Across New Zealand's hospital pharmacy department approximately sufficient (at any one time) to treat 44 COVID-19 patients at maximum dose of 1600mg per course = stockholding on hand (current stockholding to support existing rheumatology patients). Stockholding in wholesale network and at drug company data held by Pharmac.	Approved internationally for COVID-19 for treatment of severe COVID-19. Approved in New Zealand for Rheumatoid Arthritis and other inflammatory conditions. Can currently be used in NZ off label by authorised prescribers. No further approval processes required to enable access. ID team needs to apply to Pharmac for a 'rapid NPPA' but the dose can be given prior to this.	High evidence for reducing mortality and need for ventilation. Low for duration of hospitalisation. Should only be given in combination with dexamethasone or another corticosteroid.
Baricitinib (Priority as alternative for tocilizumab)	Reduces mortality in hospitalised adults who require supplemental oxygen.	Reduces in hospitalised adults who require supplemental oxygen.	None at time of writing.	Approved internationally for COVID-19 for treatment of severe COVID-19. Not approved in New Zealand. If sourced could be prescribed s29 as interim measure (potentially set up 'depot' supplies, accessed as required with administrative documentation met retrospectively) until manufacturer supplies sufficient documentation to	Moderate evidence Alternative to tocilizumab in patients receiving supplemental oxygen but are not mechanically ventilated, unless contraindicated. Baricitinib with remdesivir rather than remdesivir alone in patients who cannot have standard care of a corticosteroid due to a contraindication (low evidence)

				support Medsafe approval process.	
Sarilumab (Alternative for tocilizumab)	Reduces mortality in severe or critical COVID-19. Reduces duration of hospitalisation in severe or critical COVID-19.	Reduce need for and duration in severe or critical COVID-19	None at time of writing.	Approved internationally for COVID-19 for treatment of severe COVID-19. Not approved in New Zealand. If sourced could be prescribed s29 as interim measure (potentially set up 'depot' supplies, accessed as required with administrative documentation met retrospectively) until manufacturer supplies sufficient documentation to support Medsafe approval process.	Moderate to high. Consider only using if tocilizumab is unavailable or cannot be used.
Remdesivir (Priority due to inclusion in clinical guideline for national use) For patients with moderate COVID-19 meeting criteria	Reduce mortality at day 28 for hospitalised COVID-19 patients who do not require mechanical ventilation		Stock holding in Auckland – query raised to get indication of number of patients who could be treated with stock on hand.	Approved internationally for COVID-19 for treatment of severe COVID-19. Not approved in New Zealand. New Zealand's current supply all sits in Auckland and is being prescribed s29 as interim measure. When manufacturer supplies sufficient documentation to support Medsafe approval process, approval could be considered.	

COVID-19 Therapeutics Community Care – in priority order

(informed by clinical feedback and Pharmac update on discussions with manufacturers).

Therapeutic	Mortality	Need for mechanical ventilation	Stock holding	Approved anywhere in the world for:	Level of evidence and other
Casirivimab + imdevimab (REGEN-COV or Ronapreve) Higher priority due to likelihood of potential procurement.	Reduces all-cause mortality in mild-moderate COVID-19 who are not hospitalised but at high risk of progressing to severe disease 20% reduction in hospitalised in COVID-19 patients that fail to mount an immune response.	Not identified at time of writing.	None at time of writing.	Approved internationally for prevention and treatment of mild to moderate COVID-19 disease. Not approved in New Zealand. If sourced could be prescribed s29 as interim measure (potentially set up 'depot' supplies, accessed as required with administrative documentation met retrospectively) until manufacturer supplies sufficient documentation to support Medsafe approval process.	
Sotrovimab (not used outside clinical trials)	Reduce mortality in mild to moderate COVID-19. Reduces risk of progressing to severe COVID-19 disease. Reduces risk of hospitalisation in mild to moderate COVID-19 disease in outpatient setting.	Reduce.	None at time of writing.	Approved internationally for treatment of mild to moderate COVID-19 disease. Not approved in New Zealand. If sourced could be prescribed s29 as interim measure (potentially set up 'depot' supplies, accessed as required with administrative documentation met retrospectively) until manufacturer supplies sufficient documentation to support Medsafe approval process.	Australian Living Guideline does not recommend using for treatment of COVID-19 outside of randomised clinical trials.

Document Thirteen

MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 01 October 2021
Time:	1:30pm to 2:30pm
Location:	Out of Scope [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Christian Mallo, Daniel Bernal, Derek Fitzgerald, Josh Wiles, Mark Ayson, Phoebe Currie
Guests:	Craig Butler
Apologies:	Anne Buckley, Jessica Keepa, Ian Town, Michael Maze, Justine Lancaster

1.0	**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 (17 September 2021) were accepted. **Matters arising:** • Patient information update • Interim Guidance - Clinical Management of COVID-19 in Adults was updated on 24 September 2021.
2.0	**Therapeutics: Update on COVID-19 Therapeutics Supply** • Tocilizumab –Pharmac continuing to work with Roche. Current stock is reasonable and should last through to the end of the year, dependent on the size of the outbreak. However, due to the nature of the supply and the current use to treat rheumatoid arthritis, it is hard to predict how many patients could potentially be treated by the end of the year. The outlook of supply should become clearer in the coming weeks as patients are moved to alternatives and alternative suppliers are investigated. • DHBs are progressing a stocktake and most have reported enough stock for the coming weeks. • Given the potential for 'very constrained' supplies in the future, it may be useful begin thinking about a guideline for use of baricitinib.

	• Pharmac are in active discussions for five or six other medicines, including antivirals, monoclonal antibodies, and baricitinib. Discussions are reaching the stage of confidentiality agreements which will limit how much information can be shared with the wider group. Information can still be shared with STA to assist with monitoring. • Pharmac noted a member's comments about a small minority of patients for whom baricitinib is not a suitable treatment option due to certain comorbidities. It was suggested that it would be helpful to get an indication of the potential size of this cohort. Developing guidance for baricitinib was suggested. ACTION: Group to consider the development of guidance for the use of baricitinib. • A member raised the issue of use of baricitinib, proportions of hospitalisation and numbers of people who are mechanically ventilated due to advanced renal failure. It was noted that pregnant people are excluded from those studies. The future use will be dependent on the next outbreak and the populations affected. Given the vulnerable populat on that COVID-19 is affecting in the current outbreak, pregnancy, late presentation, and advanced kidney disease should be anticipated. • The Chair noted feedback received; a reminder to consider paediatric formulations and what would be used in such situations. Noting that this is infrequent, but helpful to be aware of.
3.0	**Therapeutics: Prioritization Criteria** STA raised the discussion points that were signalled in the 'Therapeutics Prioritisation Criteria' document circulated with the agenda. • STA suggested a staged approach for the criteria using three criteria: *1. Evidence of effectiveness*, *5. Magnitude of benefit*, and *6. Magnitude of ADRs relative to context.* Looking at evidence for efficacy and safety first and once they meet the required threshold, continuing to analyse the other domains. ○ The group generally agreed with this, with a member noting that magnitude of benefit is the key aspect of how to prioritise an agent when several have evidence of efficacy and safety. The group noted that the feedback around how to apply them in practice would be helpful to receive. • In monitoring evidence of efficacy (and safety) does the TAG anticipate appraising/reviewing trial findings? How would this process be managed/resourced? Or is the view that it is appropriate to wait/use other panels for this e.g., living guidelines groups internationally? ○ The guideline group is monitoring literature and international evidence, but it is helpful to have support around accessing trials and international guidelines. It was suggested systematic support would be helpful going forward. ○ A member noted that if more than one living guideline has recommended a treatment based on their meta-analysis, that should escalate it for priority analysis, so that the approach remains current. However, this approach shouldn't automatically exclude evidence from single studies if they are powerful and deemed appropriate for consideration. ○ The group raised the need to prioritise Māori and Pacific input in this space, especially regarding research about adverse reactions, to ensure these are communicated appropriately to different communities. • Does 'Addressing a key purpose for NZ' in criterion *8 Favourable features for pipeline agents* belong here or is does it more relate to horizon scanning of therapeutics in early phase trials? ○ The group advised that this relates to horizon scanning, but also thinking about priorities, being able to alert to agents that might be important. Consider the best approach for obtaining treatments quickly if needed.

	The group had general discussion about the prioritisation of therapeutics. • STA noted that there is communication with the UK regarding therapeutics. • It was noted effectiveness and magnitude of benefit are separate and should be evaluated separately with consideration to number needed to treat and cost benefit analysis. • A member suggested that as the COVID-19 landscape in Aotearoa New Zealand changes, it will be increasingly important to think about where therapeutics can and will be used (e.g., outside of hospitals), as well as addressing the needs of different communities. It was also noted that there are equity issues involved, such as access to care and late presentation to hospital. • A member suggested that when reviewing therapeutics, it would be useful to have scoring table at the top, with areas of interest so it is clear what they are. • Members suggested that reviewing a range of therapeutics for each severity was important to 'diversify the portfolio' of therapeutics, in case the evidence changes or supply issues arise and a modification in approach is required. • Members highlighted the importance of focusing on treatments in the community that prevent hospitalisation and treatments in hospital that prevent mortality. ACTION: STA review feedback of prioritization criteria, consider further draft.
4.0	**Guideline Update/Patient information update** • The Interim Guidance - Clinical Management of COVID-19 in Adults was updated on 24 September 2021. • The group intends to update the guideline fortnightly initially, then progress to a monthly update or reactively as required. • For the next update the group will focus on any potential changes in recommendation for the use of budesonide. Pharmac has indicated there is capacity to supply a sustained increase. • It was suggested that it would be useful to have some signalling around the use and availability of baricitinib, in preparation for any potential changes. • As noted in previous minutes, there has been suggestions to incorporate pregnancy into the guideline. A member suggested that there are several options in how this could work which would be circulated to the group. ACTION: Chris Hopkins to circulate options for incorporating pregnancy into the Interim Guidance - Clinical Management of COVID-19 in Adults. • There are several obstetric physician colleagues who may be interested and available to contribute to the guidelines working subgroup. STA noted that bringing members on as part of the working group (but outside the Therapeutic TAG membership) could be facilitated. ACTION: Chair to contact obstetric physician colleagues regarding contribution to the guidelines working group. • The group discussed membership generally and noted that there may be a requirement for other involvement as the COVID-19 situation changes. • The Chair noted that there had been some discussion of documenting the decision making involved in developing the guidelines.

	ACTION: Anne Buckley to talk to Tim Cutfield regarding documenting guideline group decision making. **Patient information update** • There is a scoping discussion on 08 October 2021 to form a subgroup with the Health Navigator team and those who have been working on resources that are being used in hospitals. • The aim is to put forward a proposal to set aside budget for this patient information update work so it can progress. The team have recently done similar work for a new therapy, so they have already thought through some of the likely challenges. • The group noted that this would be a very useful and widely used document once complete.
5.0	**Equity Considerations** **Pasifika representative-led discussion** • A member raised an issue for consideration when exploring the use of budesonide. It was suggested that the age cut-offs in the Australian Living Guideline may not be appropriate for the Aotearoa New Zealand context. Using these age cut-offs could create an equity barrier for Māori and Pacific peoples, who may develop disease earlier. • There was discussion about the use of 'over 50 with comorbidities' criteria and if that would help in this situation, However the group agreed that it would be beneficial to recognise earlier onset of comorbid disease by adjusting both of the age criteria from PRINCIPLE to be reduced by 10 years for Māori and Pacific patients. (40 vs 50 years with comorbidities and 55 vs 65yrs without) • The group acknowledged that this adjustment would be stepping outside of the trial evidence but noted that the risk of introducing hazard was low, and the change seemed beneficial based on clinical experience. If a change was operationalised, ongoing surveillance of outcomes would be helpful. A member noted that this would align with what Auckland MIQ group decided to do, with similar reasoning as above. ACTION: Guideline working group to consider these suggestions of more equitable age criteria when exploring the use of budesonide. • The Chair suggested the group should write to Māori and Pacific health care providers to give more information about what the TAG is doing. Members agreed this would facilitate further feedback and important aspects to consider. It was suggested to also include Māori and Pacific Pharmacy Associations, and Te Rōpū Whakakaupapa Urutā. ACTION: Saleimoa Sami and Jessica Keepa to draft a letter to be distributed to Māori and Pacific health care providers from the group.
6.0	**Therapeutics: Clinical Trials Including in Primary Care/Community** • No update given. • The group had general discussion about reducing stigma of receiving a positive COVID-19 test and the important role that Primary Care will continue to have in the future.
7.0	**Next Steps/Other Matters** • A member noted that they will report back to the group regarding the Australasian COVID-19 Trial (ASCOT).

	• The Chair raised the issue of further developing connections with Primary Care to ensure alignment for the guidelines work. This is being followed up within the Therapeutic TAG by Ministry attendees.
8.0	**Agenda Items for Next Meeting**
9.0	**New Action Items Raised During Meeting**

#	Agenda item	Action	Action Owner
7	Therapeutics: Update on COVID-19 Therapeutics Supply	Group to consider the development of guidance for the use of baricitinib.	All
8	Guideline Update/Patient information update	Chris Hopkins to circulate options for incorporating pregnancy into the Interim Guidance - Clinical Management of COVID-19 in Adults.	Chris Hopkins
9	Guideline Update/Patient information update	Chair to contact obstetric physician colleagues regarding contribution to the guidelines working group.	Chair
10	Guideline Update/Patient information update	Anne Buckley to talk to Tim Cutfield regarding documenting guideline group decision making.	Anne Buckley
11	Equity Considerations	Guideline working group to consider these suggestions of more equitable age criteria when exploring the use of budesonide.	Guideline working group
12	Equity Considerations	Saleimoa Sami and Jessica Keepa to draft a letter to be distributed to Māori and Pacific health care providers from the group.	Saleimoa Sami and Jessica Keepa

Meeting closed at **2:35pm**

Next meeting **Friday 15 October 2021 – 1:30pm – 2:30pm**

Open Actions:

#	Agenda item	Action	Action Owner	Updates
4	**Matters arising:** Patient Information material – Health Navigator role	Discussion between Ministry contract holders & Health Navigator about production of patient information aligned with guideline content	Andi Shirtcliffe	17/09 – Action raised 01/10 - Discussions ongoing. Scoping discussion on 08 October to form sub group.

5	Guideline update	Review update and publish revised guideline	Tim Cutfield/STA	17/09 – Action raised 01/10 - Next update 8/10/21
6	Therapeutics: prioritisation criteria	Preliminary testing of prioritisation criteria	STA	17/09 – Action raised 01/10 – STA review feedback, consider further draft.
7	Therapeutics: Update on COVID-19 Therapeutics Supply	Group to consider the development of guidance for the use of baricitinib.	All	01/10 – Action raised
8	Guideline Update/Patient information update	Chris Hopkins to circulate options for incorporating pregnancy into the Interim Guidance - Clinical Management of COVID-19 in Adults.	Chris Hopkins	01/10 – Action raised
9	Guideline Update/Patient information update	Chair to contact obstetric physician colleagues regarding contribution to the guidelines working group.	Chair	01/10 – Action raised
10	Guideline Update/Patient information update	Anne Buckley to talk to Tim Cutfield regarding documenting guideline group decision making.	Anne Buckley	01/10 – Action raised
11	Equity Considerations	Guideline working group to consider these suggestions of more equitable age criteria when exploring the use of budesonide	Guideline working group	01/10 – Action raised
12	Equity Considerations	Saleimoa Sami and Jessica Keepa to draft a letter to be distributed to Māori and Pacific health care providers from the group.	Saleimoa Sami and Jessica Keepa	01/10 – Action raised

Document Fourteen

MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 17 September 2021
Time:	1:30pm to 2:30pm
Location:	Out of Scope [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Michael Maze, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Anne Buckley, Christian Marchello, Daniel Bernal, Derek Fitzgerald, Ian Town, Josh Wiles, Mark Ayson
Guests:	Craig Butler
Apologies:	Justine Lancaster

1.0	**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 (10 September 2021) were accepted. **Matters arising:** 1) The Chair thanked the group for their work on the Therapeutics Criteria for Prioritization which will be discussed later in the meeting. 2) Patient Information - Discussion of follow up to date and next actions planned: • Ministry holds contract with Health Navigator. Health Navigator have experience in producing content for health consumers and in different languages. A 'no prejudice' discussion between relevant Ministry and Health Navigator people is planned for early next week. • Query about whether content to cover 'patient journey'- within/outside scope. Need for some pictorial information and to be brief to avoid overwhelming patient/whānau with information; information on oxygen therapies needed. Content to link with guideline. • Some immediate work underway at Middlemore to draft patient information to support patient journey and to address questions about process, MDT, etc. • Patient journey information tends to be localised to the service – but if produced at Middlemore could be adapted locally for other services. • Generic information also needed e.g., on therapeutics.

	• Was advised to use existing information where available. • STA have staff involved with a 'Lived Experience' group which may be able to provide input/review.
2.0	**Therapeutics: Update on COVID-19 therapeutics supply** • Tocilizumab – Pharmac continuing to work with Roche and wholesalers on supply. Stock in hand likely to be adequate for residual RA users and current outbreak on current estimates. Query about access to tocilizumab approved for manufacture in India. This reflects Roche waiving rights to allow manufacture of tocilizumab for low-income and middle-income countries. Will therefore not factor into NZ supply issues. One member raised the issue of more definitive communication to the sector given clinicians concerns about supply. Further communications expected from Pharmac – initially via hospital pharmacists who may also be monitoring that the use of tocilizumab conforms to the priority use for COVID-19 and the selected subgroup of patients with RA. • Baricitinib – discussion progressing with Eli Lily. Supply likely to be achieved 'in weeks'. Company needing support around S29 requirements. Pharmac working towards having baricitinib available as a 'back-up' option, with a reserve in place to counter any increased tocilizumab demand (e.g., if further/extended outbreak) or increased difficulties with supply. • Ronapreve & sotrovimab – progressing discussions with suppliers. Timeframe for supply of Ronapreve likely to be some months away • Pfizer & GSK – Pharmac are in discussion about some other agents but not able to provide further information at this time due to confidentiality requirements. • Remdesivir – looking to have good supply. One member commented that one trial now showing no benefit. Recognised that the time required to put supply in place for a drug means that new evidence may emerge to support or counter its use over that time period. • Acknowledged that Pharmac are working hard to access all potentially useful medicines and that prioritisa ion for use can come from the Therapeutics TAG. The work being done in the criteria for prioritisation and by the Therapeutics TAG in general serves to keep Pharmac informed on potential supply/distribution needs.
3.0	**Therapeutics specific agents** 1. Inhaled budesonide • Noted that the Australian Living Guideline has a new Conditional Recommendation on use of inhaled budesonide. • Some discussion of the certainty of the evidence showing budesonide reduces the need for supplemental oxygen. One member stated that there is evidence for symptom reduction but the evidence is less clear for use preventing hospitalisations. • The guideline subgroup previously considered whether or not to include budesonide in the guideline and it was omitted. Decision to include will be reviewed again ahead of the next guideline update/review for those with mild COVID-19 symptoms. Guideline update/review expected date 24 September. • Pharmac note that there is a potential to disadvantage other users. If inhaled budesonide is to be included in guideline, Pharmac would like to be advised and would consider a restriction to the Pharmaceutical Schedule.

	• One member commented that the dosing should be 800 mcg b.d. (with the 400 mcg inhalers prescribed). The Symbicort inhaler (budesonide/formoterol) should not be prescribed for the COVID-19 indication. ACTION: Inclusion of inhaled budesonide to be considered for the guideline update of 24 Sept. If included, Pharmac to be advised by Therapeutics TAG. 2. remdesivir (access criteria) • Identified that the access criteria specified in the guideline differs from that specified by Pharmac. Member suggested that Pharmac change criteria to align. Pharmac have reviewed and decided their criteria needs to remain as is – based on Australian criteria Use of remdesivir a clinical decision and therefore no conflict in having more 'restrictive' use specified in the guideline. • No change to either guideline content on remdesivir or Pharmac access criteria to be made following this discussion. 3. Ronapreve, sotrovimab No further comments/discussion. **Therapeutics: Criteria for prioritisation** STA thanked members for their work on the criteria for prioritization of therapeutics which was collated during the week and circulated with the agenda. The intention was to use the criteria table to create a checklist and STA reported they would test the criteria against some of the specific agents identified in the prioritisation document as of interest to members to monitor (nafamostat, inhaled budesonide/ciclesonide (ou patient use), fluvoxamine, colchicine (outpatient use), bamlamivimab plus etesevimab monoclonal antibody combination). ACTION: STA will provide further feedback on application of prioritisation criteria at next meeting.
4.0	**Guideline Update: Feedback/pathways** Guideline update planned by 24 September. Guideline subgroup will review whether to include budesonide in th s update. A member reported that a colleague at Middlemore has experience of 'obstetric COVID' through managing cases in the current Auckland outbreak. Colleague has put together some guidance on management for this patient group. Suggested this person could be invited to participate in a guideline subgroup meeting to look at whether any information should be integrated within existing guideline or kept as a separate piece of guidance.
5.0	**Next Steps/Other matters** clinical trials in primary care/community Discussion of to be included in agenda for next meeting. Agreed that meeting schedule would now be fortnightly – next meeting Friday October 1. 1.30-2.30pm. No other business.
6.0	**Agenda Items for Next Meeting** Therapeutics: Prioritization criteria – feedback/further discussion.

	Guideline update from subgroup. Therapeutics: clinical trials in primary care/community
7.0	**New Action Items Raised During Meeting** Patient Information material – Health Navigator role Guideline update – September 24 Therapeutics: prioritisation criteria
Meeting closed at **2:38pm** Next meeting **Friday 01 October 2021 – 1:30pm – 2:30pm**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
4	**Matters arising:** Patient Information material – Health Navigator role	Discussion between Ministry contract holders & Health Navigator about production of patient information aligned with guideline content	Andi Shirtcliffe	17/09 – Action raised
5	Guideline update – for Sept 24	Review update and publish revised guideline	Tim Cutfield/STA	17/09 – Action raised
6	Therapeutics: prioritisation criteria	Preliminary testing of prioritisation criteria	STA	17/09 – Action raised

Document Fifteen

MINUTES: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 10 September 2021
Time:	1:30pm to 2:30pm
Location:	Out of Scope [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Michael Maze, Nigel Raymond, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Anne Buckley, Christian Marchello, Connie Gilfillan, Daniel Bernal, Derek Fitzgerald, Ian Town, Justine Lancaster
Guests:	Bryan Betty, Rachel Webb, Craig Butler, Sally Thomas
Apologies:	Mark Ayson

1.0	**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 September 2021) were accepted.
2.0	**Guideline Update** The work of the subgroup was acknowledged in preparing the guideline for use. The guideline was uploaded on the Ministry website on Wednesday 15 September. COVID-19: Advice for all health professionals | Ministry of Health NZ There was initial feedback on the Clearance from Isolation section. Discussion about consultation to date with MIQ and recognition of the need to harmonise guidance with other guidance currently in development for MIQ. In the immediate/short term useful to have the guideline closely aligned with planned content for MIQ guidance. In response to a query about the definition of 'moderate' used in the guideline it was clarified that the definition was as per severity definitions in the Australian Living Guideline. Suggested that the guideline make explicit that its guidance pertains to hospital care (rather than community care). Guideline subgroup and others interested to meet immediately after meeting to finalise necessary changes. Amended guideline to be uploaded before COB if possible.
3.0	**Equity Perspective** • Patient information based on guideline

	Discussion • Could be similar to NZF 1 pg format – medications for use in COVID-19. Name of drug, why given, how given etc. • Specific therapeutics used in COVID-19 rather than agents used for other aspects of general patient care. • A UK patient information example is broader than specific therapeutics only. • Need for any information prepared to be in different languages. Of note, there are a large number of Samoan patients in the current outbreak. • Pictorial information recognised as helpful. The Chair asked STA what options for the development of patient information exist/are typical. These include: – Canterbury Medicines Information Group – tend to be as described in bullet point one. However, only produced for approved medicines. – Some DHBs produce patient information about medicines. – Health Navigator – this approach may have potential. In addition to patient information material, need to also consider wider cultural services available/being used. RNZCGP has offered MIQ the support of a roster of Pacific GPs to assist.
4.0	**Therapeutics: Update on Supply of Immunomodulators** Update on supply of immunomodulators – Pharmac Tocilizumab - Pharmac liaising closely with manufacturer and distributing what is available. NZ Rheumatology Association (NZRA) have a statement in place to guide practice – reducing use for rheumatological indications. Baricitinib – promising discussions with manufacturer and looking to obtain supply. Still some work to address s29 requirements. Remdesivir – additional supply obtained. Powder that needs reconstitution. More information will be available on the Pharmac website. Sarilumab – still following up with manufacturer acknowledging Therapeutics TAG preference for sarilumab as alternative to tocilizumab. Supply this year looks unlikely. Overall, adequate supply of tocilizumab or an alternative looks achievable – especially if COVID-19 case numbers in hospital shrink rather than grow.
5.0	**Therapeutics: Pre-hospital e.g. Casirivimab & imdevimab (REGEN-COV, Ronapreve), sotrovimab – logistical issues** Pre-hospital e.g. Casirivimab & imdevimab (REGEN-COV, Ronapreve), sotrovimab – logistical issues See 2 slides attached prepared to inform the meeting discussion.  Pre-Hospital treatment considerati • Pre-hospital mainly applies to MIQ at present but over time may involve the community more widely • Primary care access and equity – need to avoid postcode inequities.

	• International experience suggests greater compliance when treatment offered closer to people's homes. • Primary care sector has capability to deliver infusion services. May be more relevant if a larger number of cases in the community. • Both REGEN-COV & sotrovimab have an alternative administration option to IV: subcutaneous injection for REGEN-COV and intra-muscular injection for sotrovimab. • Patients are aggregated into a small number of MIQ facilities currently and for the foreseeable remainder of this year. The Chair commented that while general strategy for use of therapeutics is valuable to discuss, more detailed operational issues are mostly beyond the scope of the Therapeutics TAG to address. Focus should be on the therapeutics that should be available – criteria for determining these, taking in to account the spectrum from mild disease to hospital care. Immediate comments on areas to consider: • Remdesivir in early COVID-19 in high-risk patients. Member offered to share UK experience of remdesivir use for this patient group. • Post-exposure prophylaxis could also be considered. A member commented that REGEN-COV may have some efficacy in this context.
6.0	**Next Steps/Other matters** Members agreed to meet next Friday (September 17) and to consider whether a weekly or fortnightly meeting schedule at next meeting. If a weekly schedule continues, Middlemore Hospital members could consider nominating 1 or 2 members to attend given current clinical pressures. Regular updates from Pharmac on supply of key therapeutics to continue. Could be provided as a written statement to circulate to members or a verbal update.
7.0	**Agenda Items for Next Meeting** • Update on therapeutics supply – Pharmac • Criteria for prioritization of therapeutics
8.0	**New Action Items Raised During Meeting** None noted
Meeting closed at **2:33pm** Next meeting **Friday 17 September 2021 – 1:30pm – 2:30pm**	

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
1	Organisation of group	Members to advise of interest in working subgroups	STA	27/08 – Action raised 03/09 - Action closed
2	Procurement – Preliminary list	Tocilizumab - limited supply in hospitals currently treating patients with COVID-19 raised as an issue. Andrew	Andrew Oliver (Pharmac)	27/08 – Action raised

		Oliver (Pharmac) – will follow up supply issue with wholesaler		03/09 – Initial action closed. Note that discussions with wholesaler are ongoing.
3	Guideline – Feedback from Working Group	STA to finalise the feedback pathway to be noted on Ministry website. Further communication with Professional Societies etc may be needed.	STA	03/09 – Action raised 10/09 - Amended guideline published. Action closed.

Document Sixteen

MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 03 September 2021
Time:	1:30pm to 2:30pm
Location:	Out of Scope [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Jessica Keepa, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Anne Buckley, Christian Marchello, Connie Gilfillan, Daniel Bernal, Derek Fitzgerald, Ian Town, Justine Lancaster
Guests:	Bryan Betty, Therese Egan, Craig Butler
Apologies:	Elaine Yap, Mike Maze, Mark Ayson

1.0	**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. The Chair welcomed Dr Saleimoa Sami who has joined the group. Saleimoa was recommended to provide a Pasifika perspective to the Therapeutics TAG by To'a Fereti, Chief Clinical Advisor Pacific in the Ministry's Pacific Health team. Saleimoa is currently working in ICU for Counties Manukau as an advanced trainee in Anaesthesia and is of Samoan heritage. Dr Jessica Keepa joined the Therapeutics TAG as of last meeting to provide a Māori perspective to the group. She is a GP in Hawkes Bay and a member of the DHB Council. Minutes of the last meeting (27 August 2021) were accepted, subject to the following changes (marked in in red) on item 2.0 Group membership, Terms of Reference and Meeting Frequency Meeting frequency – weekly initially. Terms of reference – Accepted but a clarification that under purpose of the group (as stated in bullet point 2) 'enabling' acquisition of agents refers to providing advice. 'Obtaining' is Pharmac's role and not the purpose of this TAG. Attendees from Pharmac may not sit as members as they would be seeking advice from Therapeutics TAG rather than contributing to it to avoid conflicts of interest. An additional member providing a Pasifika perspective is still to join the group. Paediatric Infectious Disease input was suggested. It was noted that there is the option of including guest attendees or co-opting specific additional expertise if needed

	Medsafe is an ex officio advisor to the Committee and has a role in advising on regulatory matters.
2.0	**Therapeutics: Briefing for government** Therese Egan Principal Policy Analyst, System Enablers, Public Health System Policy at the Ministry attended as a guest. Therese has shared her presentation with the Therapeutics TAG (attached) – note it is confidential to the Therapeutics TAG. In her role, Therese prepared a briefing paper for the ministers on the current therapeutics situation for COVID-19. She acknowledged the very active work being undertaken by Pharmac in this space and the work of the Therapeutic TAG in providing expert advice. Therapeutic supply: The need for active supply management was acknowledged given supply pressures on therapeutics globally. In looking at what further NZ could do, a number of additional measures were noted including actively facilitating entry of products evidenced and approved internationally, and the potential for pooled advance purchase agreements (akin to the COVAX approach). Collaboration with groups internationally: This was raised for discussion. It was noted that members all have international connections & collaborate through professional contacts and organisations. Clinical research: Members were asked whether there was further potential for engagement with clinical research. There is current involvement of members in trials, including ASCOT and REMAP-CAP. One member noted that many of the therapeutics being used overseas are not currently available in NZ and this is a potential limitation. One potential research gap suggested was in the pre-hospital setting e.g. budesonide is being used but not in the context of a clinical trial. A member commented that there is a lot involved in the setting up of a clinical trial, including engagement with DHBs. This is particularly difficult given competing priorities in the pandemic situation. Therese Egan mentioned that Pfizer are currently looking at Phase 2 & 3 clinical trials of an oral antiviral and suggested this one may be of interest to NZ clinicians to engage with. Therese welcomed any further feedback from the Therapeutics TAG on the topics of her presentation.
3.0	**Therapeutics: Update on Regulatory Issues, Update on supply issues, and Stock Holding/Projections** • **Update on regulatory issues:** Medsafe representative provided an update of regulatory issues of relevance and advised that if the Pharmac or the Therapeutics TAG made a recommendation about a specific drug/s, then Medsafe would give priority to addressing any regulatory issues pertaining to it. The details of the content presented are included in the Appendix. • **Update on supply issues:** Pharmac representative advised on current supply/supply issues:

	Dexamethasone – widely used internationally and for many indications. No problem with global supply or NZ supply currently or expected. Tocilizumab – supply shortages expected later in year. Pharmac have been in discussion with Roche but high demand worldwide. Noted by the group that Australia have already declared a critical shortage. Pharmac have also been in discussion with rheumatologists to free up existing supply for COVID-19 treatment. Sarilumab – Pharmac have been in contact with manufacturer Sanofi. Will continue to explore but not looking likely in terms of achieving ready and prompt supply. Baricitinib – Pharmac following up supply with some urgency. Sotrovimab – Pharmac are in discussion with GSK about potential supply. REGEN-COV Casirivimab + imdevimab – Pharmac expect supply more readily available. Remdesivir – need for supply acknowledged. No specific supply status minuted. • **Stock holding/Projections** Questions were raised about the quantity of tocilizumab supply – definitely have some weeks of supply. Rheumatologists supportive of re-distribution – approximately 10-15% will have to be retained for use in rheumatology patients. • **Alternatives to tocilizumab** Information on baricitinib and sarilumab was circulated to the membership in the STA-produced paper included under agenda item 4.0 **Discussion** Agreement of Members that need to have at least one of the 3 immunomodulators (tocilizumab, sarilumab, baricitinib) available for treatment of patients with COVID-19 in the hospital setting. These were identified as the top 3 therapeutic priorities (in the order listed) although Pharmac's update on supply issues with sarilumab was acknowledged. One member suggested that may be helpful to have Ministry issue advice to the sector that priority use for tocilizumab be for COVID-19 treatment.
4.0	**Therapeutics: Further prioritisation of Key Therapeutics** Further prioritisation of key therapeutics See STA paper circulated. Discussion REGEN-COV: It was noted that the administration route of IV infusion could create some challenges in the pre-hospital setting and if recommended by the membership would require planning to put in place clear clinical pathways. Remdesivir: Discussed that for mild to moderate severity only; not of benefit for those with severe COVID-19. Issue raised is how to get it to those who need it earlier ie. in the community. Noted that if looking at IV infusion delivery for REGEN-COV that may allow consideration of IV remdesivir in the pre-hospital setting also.

	Sotrovimab – likely to be included in priority list. Not discussed further.
5.0	**Equity considerations** Māori & Pasifika representative-led discussion Dr Jessica Keepa identified 3 actions for the group to consider: 1. DHBs having a statement on institutional racism 2. Collection of ethnicity data on all patients with COVID-19 3. Information available for families on therapeutics, reflecting the guideline. The Chair noted that DHB initiatives would be outside the scope of this group's ToR. The COHESION cohort study has collected previous inpatient case information, thought likely including ethnicity. In discussion, the information for families was supported as an extra piece of work that could be undertaken by a small group. Having it available in multiple languages was noted as desirable especially given difficulty in accessing interpreters. Further consideration/action on information for families/whānau once the guideline is finalised. Dr Saleimoa Sami raised issues in relation to the treatment of Pasifika patients: • Protocols and equity – protocols tend to be a 'one size fits all' approach. Using the example of remdesivir for mild to moderate COVID-19, could the protocol create a barrier to access for Pasifika? Some discussion about the relative benefits of remdesivir followed. Outcomes in Pasifika with COVID-19 – Dr Sami stated that there have been high mortality rates documented in Pasifika people e.g in the US compared with the general population. Need to ensure the needs of Pasifika patients in NZ with COVID-19 are met, with 'protocol' modifications if needed.
6.0	**Guideline – Feedback from Working Group** Guideline – feedback from working group A draft of the revised guideline was circulated ahead of the meeting. The Guideline subgroup were thanked for their work and achieving rapid progress on it. The Guideline subgroup have had two meetings. Tim Cutfield has facilitated those meetings at the Chair's request and has collated all the feedback received. The draft document is close to final but the following input is needed: 1. Equity perspective – our equity representatives in particular were asked to review the guideline with an equity lens 2. Pharmac – need to ensure aligns as necessary with Pharmac documents (Schedule) 3. Public Health input 4. Post hospital care – adding information on this is in hand. Any further feedback on the guideline draft circulated to Tim asap. The query was raised as to who would host the guideline and how would this be communicated to colleagues. The CSA advised that once the guideline was finalised the Ministry would be able to host the guideline (as an html document) and to disseminate news of the guideline via CMOs, CNOs, pharmacy managers and others to whom the guideline is relevant. The Chair proposed that the guideline be uploaded ('published') without wider consultation given urgency. However, a plan to take in any feedback provided could be formulated. The benefit of any feedback being collated by professional organisations/associations (rather than coming from

	individuals) was acknowledged. The document should be accompanied by information on a pathway for providing feedback, to inform future guideline updating ACTION: STA to finalise the feedback pathway to be noted on Ministry website. Further communication with Professional Societies etc may be needed.
7.0	**Communication/Messaging to Wider Networks About Workplan** This was not discussed – other than as related to the Guideline (see 6.0) due to time constraints.
8.0	**Next Steps/Other matters** Agreed to meet next Friday 10 September & to continue with weekly meetings for the time being. **Ivermectin** Bryan Betty advised that RNZCGP were preparing a statement to counter inappropriate use of ivermectin and asked for input from the Therapeutics TAG membership. The final RNZCGP statement is included as an Appendix to these Minutes. Medsafe advised there will be a 'warning' prepared and Pharmac advised will link to the Medsafe 'warning'. A link to the warning is included in the Appendix. A member commented that ivermectin is appropriate for a small subgroup of patients (e.g. Pasifika not born in NZ) to treat co-existing infection e.g. strongyloidiasis.
9.0	**Agenda Items for Next Meeting** • Discussion of patient information to accompany Interim Clinical Guideline • Discussion of further communication needed re pathway for feedback on Interim Clinical Guideline.
10.0	**New Action Items Raised During Meeting**

#	Agenda item	Action	Action Owner
3	Guideline – Feedback f om Working Group	STA to finalise the feedback pathway to be noted on Ministry website. Further communication with Professional Societies etc may be needed.	STA

11.0	**Appendix 1: Therapeutics: Briefing for government presentation (relates to item 2.0)** Please note this has been shared IN CONFIDENCE and are not for further distribution. Therapeutics TAG presentation 3Sep.ppt

12.0	**Appendix 2: Summary information provided by Medsafe for Therapeutics TAG Minutes 3 September 2021 (relates to item 3.0.)** A verbal update of this information was provided to Therapeutics TAG meeting 3 September 2021 **<u>Medicines Approval</u>** • The Medicines Act 1981 generally requires medicines to go through an approval process (operated by Medsafe) before they can be supplied. Approval is the best option for the supply of medicines as this gives confidence that the NZ regulator has assessed the particular product to ensure it meets internationally agreed standards of quality, safety and efficacy. There are exemptions to the requirement for approval. • There are two approval processes – section 20 (s20) is the standard approval process and almost all medicines follow this route. Section 23 (s23) is a provisional approval route which requires a smaller data set for approval (commonly but not exclusively, abbreviated clinical trial data) and is used where the benefits of having a medicine outweigh the risks presented by the lower assurance of limited data. This form of approval is time limited with a maximum period of 2 years, after which it can be renewed. Provisional approval is often issued with conditions. An example is the approval for the COVID-19 vaccines. • Section 20 approval requires a substantial data set and usually takes some time with Medsafe often asking the company for additional information. Applications are usually queued, however the priority can be changed based on urgent clinical need. It is also possible to speed the approval process if the medicine has already been approved by an overseas regulator Medsafe recognises (though this may depend on the type of approval given – emergency use authorisation overseas is not acceptable). Medsafe may also accept a 'rolling submission' process where a company will supply data as it becomes available. Medsafe and PHARMAC discuss approval timelines on a regular basis under an existing MoU. • For both types of approval Medsafe must receive an application from the company wishing to import and sell the medicine. This company (the Sponsor) must be based or have a registered office in New Zealand. • Worth noting that it is a product ('medicine') that is approved, not the use of the active ingredient. This means that a second product with the same active ingredient will also need to be specifically approved. • Timelines are dependent on the above factors and are often driven by the company's response to requests for information. Medsafe policy is to ensure COVID-19 matters are prioritised. **<u>Use of unapproved medicines (or use of approved medicines for unapproved indications)</u>** • Note that approved products can be used by clinicians for unapproved indications. While the company supplying the product cannot advertise the unapproved indication, a clinician with prescribing rights can use professional judgement to prescribe / use the product in particular patients. No prior approval is required by Medsafe and no post-use reporting is required. • A description of how unapproved products and how approved products can be used for unapproved indications is available at: http://www.medsafe.govt.nz/profs/RIss/unapp.asp. • There are two principal routes by which an unapproved product can be obtained and used. Supply via section 29 is the most commonly used. This requires a supplier (often the NZ office of the company that manufactures the product overseas, a wholesaler, a

	specialist wholesaler or sometimes a pharmacy (Licence may be required)) to import the product. It can then be supplied on demand into the supply chain. Limitations are that supply can only be made on the request of a medical practitioner (this does not extend to other prescribers or prescribing via standing orders) and only for a particular patient. The details of the patient, prescriber and location must be supplied to the product supplier and these must be kept. The supplier must provide a declaration to Medsafe each month about supply activities. The supplier cannot advertise the availability of the product. No pre-approval from Medsafe is required. While information about the prescribing is generally required before supply is made, stock can be made available in the supply chain or lodged with users before these details are known provided there is agreement that the required details will be notified back to the supplier when the product is used. • The less-used route permits a wider range of prescribers to obtain a product directly from overseas for a particular patient that is known at the time of importation. This requires no pre-approval, and has no post-event reporting requirement. • Note that informed consent is a professional practice requirement when using a medicine not approved for the purpose it is being used. • It is possible to use a product via the unapproved route whilst an approval process is taking place. • An option remains for an unapproved product to be used in a clinical trial – this requires pre-approval As the legal aspects of supply are quite complicated (some details have been simplified for clarity) and depend on circumstances, we are happy to advise on particular situations.
13.0	**Appendix 3: Ivermectin – Medsafe Warning (relates to item 8.0)** Link here: http://medsafe.govt.nz/safety/Alerts/ivermectin-covid19.htm
14.0	**Appendix 4: RNZCGP statement on Ivermectin (relates to item 8.0)** **SUBJECT: Ivermectin and COVID-19** Ivermectin has become the subject of much debate and conjecture in both the popular press and social media for the treatment of COVID-19. While there is low-quality data that supports further evaluation of Ivermectin in well-conducted clinical trials, there is as yet no evidence that supports the use of Ivermectin for treatment of COVID-19 outside the setting of one of these trials. Additionally, there is reason to doubt these trials will demonstrate benefit, as the level of Ivermectin required to inhibit SARS-CoV-2 in-vitro greatly exceeds the highest safe dose in humans. Off-label use of Ivermectin for treatment of COVID-19 is strongly not recommended. Ivermectin is a critical medicine for treating some parasitic infections, including *Strongyloides stercoralis*, which can rarely cause life threatening 'hyper infection syndrome' in people who receive immunosuppressive medications. As a result, Ivermectin is regularly used to treat proven or suspected *Strongyloidiasis* in patients who are treated with immunosuppressive medications, which include many of the proven treatments for COVID-19 (e.g., dexamethasone and tocilizumab). Some people with COVID-19, who have lived in areas endemic for *Strongyloides,* receive treatment for this condition in addition to other COVID-19 specific therapies. Ivermectin can, and does, cause harm when misused. Prescribing it could well mean that even if the patient had given consent, the doctor could still be held liable for making an ill-informed decision on a medication that at this point has not been shown to provide benefit and could cause harm. It

	would be difficult to justify this position with either the Medical Council or the Health and Disability Commissioner. For further information: 1. Frequently Asked Questions Ivermectin at Australian Living Guidelines: https://covid19evidence.net.au/ 2. WHO Guidelines - page 18 3. Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19 - page 11
Meeting closed at **2:49pm** Next meeting **Friday 10 September 2021 – 1:30pm – 2:30pm**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
3	Guideline – Feedback from Working Group	STA to finalise the feedback pathway to be noted on Ministry website. Further communication with Professional Societies etc may be needed.	STA	03/09 – Action raised

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
1	Organisation of group	Members to advise of interest in working subgroups	STA	27/08 – Action raised 03/09 - Action closed
2	Procurement – Preliminary list	Tocilizumab - limited supply in hospitals currently treating patients with COVID-19 raised as an issue. Andrew Oliver (Pharmac) – will follow up supply issue with wholesaler	Andrew Oliver (Pharmac)	27/08 – Action raised 03/09 – Initial action closed. Note that discussions with wholesaler are ongoing.

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MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 27 August 2021
Time:	1:00pm to 2:00pm
Location:	Out of Scope [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Mike Maze, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Anne Buckley, Christian Marchello, Connie Gilfillan, Dan Bernal, Derek Fitzgerald, Justine Lancaster, Ian Town, Mark Ayson
Guests:	Bryan Betty
Apologies:	

1.0	**Welcome and Introductions** Dr Nigel Raymond welcomed all membe s and attendees in his capacity as Chair of the COVID-19 Therapeutics Technical Advisory Group. Members and attendees introduced themselves. Chief Science Advisor provided an overview of the intended focus of the group to assist in identifying therapeutics which are/may be available and could be of benefit in COVID-19 treatment.
2.0	**Group membership, Terms of Reference and Meeting Frequency** Meeting frequency – weekly initially. Terms of reference – Accepted but a clarification that under purpose of the group (as stated in bullet point 2) 'enabling' acquisition of agents refers to providing advice. 'Obtaining' is Pharmac's role and not the purpose of this TAG. Attendees from Pharmac may not sit as members as they would be seeking advice from Therapeutics TAG rather than contributing to it to avoid conflicts of interest. An additional member providing a Pasifika perspective is still to join the group. Paediatrics input was suggested. It was noted that there is the option of including guest attendees or co-opting specific additional expertise if needed
3.0	**'Middlemore Guidelines' CMDHB: Management of COVID-19 in Adults - suitability as interim National guidelines** Review invited by members of group to identify key changes needed for an interim guideline for use nationally. Discussion around scope of guideline:

	• Noted that guidelines for primary care and also for paediatrics (Starship) in development. These areas not for inclusion but 'line of sight' of other guideline work needed to align if/as necessary. • Focus of this group is therapeutics but recognised that in clinical guidelines, of value to clinicians to have information on clinical management/severity & other treatments (eg. oxygen therapy) within same document – as in 'Middlemore guidelines'. • 'Middlemore guidelines' draw heavily on Australian Living Guidelines and other international guidelines. Relied on Australia review of the evidence and have not reviewed the individually studies. Detailed evidence review not within the scope of TOR for Therapeutics TAG. • Useful aspect is that give 'heads up' on 'escalation' and therapies needed – without providing detail, which can be found elsewhere. • Possibly require more detail on respiratory therapies, including oxygen – to be considered. • Detailed information available through other sources eg. Health pathways. Could include key sources/links rather than duplicate information.
4.0	**Procurement – Preliminary list** STA provided some explanatory detail about the draft Background paper (based on STA document CSU 42) and Airfinity slides (not for wider sharing due to licensing). Discussion about the areas where this group can assist and support the wider work of the Ministry/COVID-19 response: • Clinical perspective & from clinical trial involvement on potentially useful agents. • Horizon scanning – initial focus on agents for moderate-severe COVID-19 • Pharmac – well-placed to look at detail of evidence on agents identified as potentially of benefit. • Issues of supply (Pharmac) – timeliness of procurement process relevant – and of regulatory process (Medsafe) - Medicines for approval (Medicines Act) vs unapproved medicines access. • May be useful to do a stocktake of what therapeutics are currently being used in NZ for COVID-19 treatment. Discussion about specific agents: • tocilizumab in use in hospitals treating COVID-19 patients. Increased supply of tocilizumab required and/or increased access to sarilumab (as an alternative). • Baricitinib – as a second-line agent? Query safety – monitoring required. • Sotrovimab – noted that this is going through the approval process in Australia. General discussion points: • Concerns raised about therapeutics running low on supply now and need to advise on a plan for that. • Of value to see what Australians are doing/using, such as monoclonals approved in Australia. • Early priorities suggested by a member was first accessing additional tocilizumab, and/or sarilumab as an alternative, and then if insufficient supply of those two agents, baricitinib.
5.0	**GP Guidelines – Line of sight Update** Recognition of need for guidance for GPs on management of patients with mild-moderate COVID-19 in the community – what agents, when secondary care required, etc. Work has begun on this in Health Pathways drawing on guidelines in use in Ontario.

	Interface between primary and secondary care important. Note that Australian Living Guideline has a flow chart which covers home care, monitoring for deterioration, therapeutics, etc.
6.0	**Organisation of the group going forward** Chair suggested 2 working groups – one for the guideline work, one for the procurement list. One person to each – using email or small group meetings between main meeting to progress. Members were asked to their interest in either or both subgroups to STA.
7.0	**Communication/messaging to wider networks about work plan** This will be put on next meeting's agenda for discussion. Recognised that members have connections with clinical networks and related work eg. Paediatric/primary care guidelines. In general, useful to keep colleagues abreast of work being planned by the Therapeutics TAG. Member requested clarification on discussion with other colleagues in order to seek further advice to bring back to the group. Response was that this is encouraged, but to adhere to the confidentiality agreement in the TOR.
8.0	**Agenda Items for Next Meeting** • Working group formation/feedback: Guidelines; Procurement List • Communication/messaging to wider networks about work plan
9.0	**New Action Items Raised During Meeting**

#	Agenda item	Action	Action Owner
1	Organisation of group	Members to advise of interest in working subg oups	STA
2	Procurement – Preliminary list	Tocilizumab - limited supply in hospitals currently treating patients with COVID-19 raised as an issue. Andrew Oliver (Pharmac) – will follow up supply issue with wholesaler	Andrew Oliver (Pharmac)

Meeting closed at **2:12pm**

Next meeting **Friday 03 September 2021 – 1:00pm – 2:00pm**

Open Actions:

#	Agenda item	Action	Action Owner	Updates
1	Organisation of group	Members to advise of interest in working subgroups	STA	27/08 – Action raised
2	Procurement – Preliminary list	Tocilizumab - limited supply in hospitals currently treating patients with COVID-19 raised as an issue. Andrew Oliver (Pharmac) – will follow	Andrew Oliver (Pharmac)	27/08 – Action raised

		up supply issue with wholesaler		

MINISTRY OF HEALTH
MANATŪ HAUORA

AGENDA: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 15 October 2021
Time:	1:30pm to 2:30pm
Location:	Out of Scope [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Michael Maze, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Anne Buckley, Christian Marchello, Derek Fitzgerald, Ian Town, Justine Lancaster , Josh Wiles Mark Ayson
Guests:	Therese Egan, Rachel Webb
Apologies:	Saleimoa Sami, Daniel Berna , Phoebe Currie

** Supporting papers are provided in-confidence and are not for further distribution **

#	Agenda Item	Duration	Purpose	Owner	Paper
1.0	Welcome and Accept Previous Minutes Matters Arising		Governance	Chair	COVID-19 Therapeutics TAG M
2.0	Update on Open Actions	10 mins	Update	All	Verbal
3.0	COVID-19 Therapeutics Strategy	5 mins	Update	STA/Chair/Therese Egan	Verbal
4.0	Pharmac & Medsafe Updates	10 mins	Update	Pharmac/Medsafe	Verbal
5.0	Structure for Interface with Primary Care	5 mins	Update	Chair	Verbal
6.0	Community therapeutics - Oral agents Horizon scanning	10	Discussion	All	COVID-19 Therapeutics Summ

					Airfinity Intel Alert Molnupiravir - For r
7.0	Paediatric therapeutics	10 mins	Discussion	Rachel Webb	
8.0	Guideline update/patient information update	10 mins	Discussion	Tim Cutliffe Andi Shirtcliffe	Verbal
9.0	Next Steps/Decisions Pending			All	Verba
10.0	Any Other Business			All	Verbal
11.0	Agenda Items for Next Meeting			Chair	Verbal

Open Actions:

#	Agenda item	Action	Action Owner	Updates
4	**Matters arising:** Patient Information material – Health Navigator role	Discussion between Ministry contract holders & Health Navigator about production of patient information aligned with guideline content	Andi Shirtcliffe	17/09 – Action raised 01/10 - Discussions ongoing. Scoping discussion on 08 October to form sub group.
5	Guideline update	Review update and publish revised guideline Guideline update published 8/10/21	Tim Cutfield/STA	17/09 – Action raised Next update 5/11/21
6	Therapeutics: prioritisation criteria	Preliminary testing of prioritisation criteria	STA	17/09 – Action raised 01/10 – STA review feedback, consider further draft.
9	Guideline Update/Patient information update	Chair to contact obstetric physician colleagues regarding contribution to the guidelines working group.	Chair	01/10 – Action raised
10	Guideline Update/Patient information update	Anne Buckley to talk to Tim Cutfield regarding documenting guideline group decision making.	Anne Buckley	01/10 – Action raised
11	Equity Considerations	Guideline working group to consider these suggestions of more equitable age criteria when exploring the use of budesonide.	Guideline working group	01/10 – Action raised

12	Equity Considerations	Saleimoa Sami and Jessica Keepa to draft a letter to be distributed to Māori and Pacific health care providers from the group.	Saleimoa Sami and Jessica Keepa	01/10 – Action raised

Closed Actions:

#	Agenda item	Action	Action Owner	Updates
7	Therapeutics: Update on COVID-19 Therapeutics Supply	Group to consider the development of guidance for the use of baricitinib.	All	01/10 – Action raised For discussion in 13/10/2021 Guideline subgroup meeting. Closed.
8	Guideline Update/Patient information update	Chris Hopkins to circulate options for incorporating pregnancy into the Interim Guidance - Clinical Management of COVID-19 in Adults.	Chris Hopkins	01/10 – Action raised Completed. Options circulated 1.10.21. Closed.

MINISTRY OF HEALTH
MANATŪ HAUORA

AGENDA: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 01 October 2021
Time:	1:30pm to 2:30pm
Location:	Out of Scope [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Michael Maze, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Christian Marchello, Daniel Bernal, Derek Fitzgerald, Josh Wiles, Justine Lancaster, Mark Ayson, Phoebe Currie
Guests:	
Apologies:	Anne Buckley, Jessica Keepa, Ian Town

** Supporting papers are provided in-confidence and are not for further distribution **

#	Agenda Item	Duration	Purpose	Owner	Paper
1.0	Welcome and Accept Previous Minutes Matters arising	5	Governance	Chair	COVID-19 Therapeutics TAG
2.0	Therapeutics: Update on COVID-19 therapeutics supply	5	Update	Pharmac	Verbal
3.0	Therapeutics: Prioritization criteria – feedback/further discussion.	20	Discussion	STA All	Test of Therapeutics Prior
4.0	Guideline update Patient information update	10	Update	Tim Cutfield Andi Shirtcliffe/All	Verbal
5.0	Equity considerations - Pasifika representative-led discussion	10	Discussion	Saleimoa Sami	Verbal

6.0	Therapeutics: clinical trials including in primary care/community	10	Discussion	All	Verbal
7.0	Next Steps/Decisions Pending			All	Verbal
8.0	Any Other Business			All	Verbal
9.0	Agenda Items for Next Meeting			Chair	Verbal

Open Actions:

#	Agenda item	Action	Action Owner	Updates
4	**Matters arising:** Patient Information material – Health Navigator role	Discussion between Ministry contract holders & Health Navigator about production of patient information aligned with guideline content	Andi Shirtcliffe	17/09 – Action raised
5	Guideline update – for Sept 24	Review update and publish revised guideline	Tim Cutfield/STA	17/09 – Action raised
6	Therapeutics: prioritisation criteria	Preliminary testing of prioritisation criteria	STA	17/09 – Action raised

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MINISTRY OF HEALTH
MANATŪ HAUORA

AGENDA: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 17 September 2021
Time:	1:30pm to 2:30pm
Location:	Out of Scope [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Michael Maze, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Anne Buckley, Christian Marchello, Daniel Bernal, Derek Fitzgerald, Josh Wiles, Justine Lancaster, Mark Ayson
Guests:	Craig Butler
Apologies:	Ian Town

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#	Agenda Item	Duration	Purpose	Owner	Paper
1.0	Welcome and Accept Previous Minutes Matters arising	10 mins	Governance	Chair	COVID-19 Therapeutics TAG M
2.0	Therapeutics: Update on COVID-19 therapeutics supply	10 mins	Update	Pharmac	Verbal
3.0	Therapeutics: • Therapeutics: specific agents (i) inhaled budesonide, (ii) remdesivir (per Eamon's comments), (iii) Ronapreve, sotrovimab (any further comments) • Therapeutics: Criteria for prioritisation	20 mins	Discussion	All	Prioritization of Therapeutics_v14 S Prioritization of Therapeutics Table
4.0	Guideline Update: Feedback/pathways	10 mins	Discussion	All	Verbal
5.0	Next Steps/Decisions Pending	5 mins		All	Verbal

6.0	Any Other Business	5 mins		All	Verbal
7.0	Agenda Items for Next Meeting			Chair	Verbal

AGENDA: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 10 September 2021
Time:	1:30pm to 2:30pm
Location:	Out of Scope [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Mike Maze, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Anne Buckley, Christian Marchello, Connie Gilfillan, Daniel Bernal, Derek Fitzgerald, Ian Town, Justine Lancaster, Mark Ayson
Guests:	Bryan Betty, Rachel Webb
Apologies:	

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#	Agenda Item	Duration	Purpose	Owner	Paper
1.0	Welcome and Accept Previous Minutes	5 minutes	Governance	Chair	COVID-19 Therapeutics TAG M
2.0	Guideline update • Pathways for feedback • Subgroup activity and planned timeline for review	15 minutes	Discussion	Chair	COVID-19: Advice for all health professionals | Ministry of Health NZ
3.0	Equity perspective • Patient information based on guideline • Other follow up actions suggested	10 minutes	Discussion	Māori & Pasifika representatives	Verbal
4.0	Therapeutics	5 minutes	Update	Pharmac	Verbal

	• Update on supply of immunomodulators – Pharmac				
5.0	Therapeutics • Pre-hospital e.g. Casirivimab & imdevimab (REGEN-CoV, Ronapreve), sotrovimab – logistical issues	15 minutes	Discussion	Justine Lancaster	Verbal
6.0	Next Steps/Decisions Pending			All	Verba
7.0	Any Other Business			All	Verbal
8.0	Agenda Items for Next Meeting			Chair	Verbal

Open Actions:

#	Agenda item	Action	Action Owner	Updates
3	Guideline – Feedback from Working Group	STA to finalise the feedback pathway to be noted on Ministry website. Further communication with Professional Societies etc may be needed.	STA	03/09 – Action raised

MINISTRY OF HEALTH
MANATŪ HAUORA

AGENDA: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 03 September 2021
Time:	1:30pm to 2:30pm
Location:	Out of Scope [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Jessica Keepa, Mike Maze, Saleimoa Sami, Susan Morpeth, Tim Cutfield
Attendees:	Andi Shirtcliffe, Andrew Oliver, Anne Buckley, Christian Marchello, Connie Gilfillan, Daniel Bernal, Derek Fitzgerald, Ian Town, Justine Lancaster, Mark Ayson, Craig Butler
Guests:	Bryan Betty, Therese Egan
Apologies:	Elaine Yap

** Supporting papers are provided in-confidence and are not for further distribution **

#	Agenda Item	Duration	Purpose	Owner	Paper
1.0	Welcome and Accept Previous Minutes		Governance	Chair	COVID-19 Therapeutics TAG M
2.0	Therapeutics • Briefing for government		Update	Therese Egan	Verbal
3.0	Therapeutics • Update on regulatory issues • Update on supply issues • Stock holding/Projections Alternatives to tocilizumab (see paper under 4.0)		Discussion	Medsafe Pharmac Andi Shirtcliffe STA	Verbal
4.0	Therapeutics • Further prioritisation of key therapeutics		Discussion	Chair	293 COVID-19 therapeutics summ

5.0	Equity considerations • Māori & Pasifika representative-led discussion		Discussion	Jessica Keepa Saleimoa Sami	Verbal
6.0	Guideline – feedback from working group		Update	Tim Cutfield	DRAFT Clinical management of C
7.0	Communication/messaging to wider networks about workplan		Discussion	Chair	Verbal
8.0	Next Steps/Decisions Pending		Discussion	Chair	Verbal
9.0	Agenda Items for Next Meeting		Discussion	Chair	Verbal

Open Actions:

#	Agenda item	Action	Action Owner	Updates
1	Organisation of group	Members to advise of interest in working subgroups	STA	27/08 – Action raised
2	Procurement – Preliminary list	Tocilizumab - limited supply in hospitals currently treating patients with COVID-19 raised as an issue. Andrew Oliver (Pharmac) – will follow up supply issue with wholesaler	Andrew Oliver (Pharmac)	27/08 – Action raised