MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Testing Technical Advisory Group

Date:	14 October 2021
Time:	1:30pm to 2:30pm
Location:	S9(2)(k) [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 Town, Kelsey Bilek, Mark Ayson
Guests:	Steve Wakeling, Gill Hall, Kirsten Stephenson
Apologies:	Daniel Bernal, Ian Costello, Jon Herries

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 (23 September 2021) were accepted. Chair requested the second action item to be closed. It was noted that the TAG requested that the agenda and accompanying documents should be sent to members in a timely fashion before the meeting so that there is time to read them. Members had insufficient time to read the documents before this meeting.
2.0	**Work in progress in response to rapid review** • Member acknowledges and thanks the Testing TAG group for their rapid review. The final health report in response to the rapid review was shared with the TAG, no further information or input needed for this document. • The Appendix 1 to the health report was shared as a Word Document, with actions listed for each recommendation. This is a draft and being continuously updated. • Surveillance strategy is a living document, with the testing strategy under it and key component. • Ministry is pursuing a leadership role and TAG is welcome to provide suggestions confidentially. • This morning a pilot was announced in partnership with businesses and MBIE for using RATs. • Extra capacity, resources, and funding are needed to support Science and Technical for actioning recommendation #4. • Saliva as a sample type is good for the user and person taking the test but increases laboratory capacity because of inability to pool samples.

- A comment was raised that a pathway is needed for positive RAT results, which could potentially overload a laboratory if an overwhelming number of tests come back positive. That is, moving towards a PCR test to verify if a RAT has yielded a true or false positive is important and also adds additional strain
- Remaining actions for recommendations were described.

Chair opened the floor for discussion

- Some elements of the report have already been overtaken by events that have occurred since its release. Laboratories are at capacity currently and slightly over capacity in Auckland. Testing will only continue to increase and likely in the upcoming days rather than weeks to months.
- Member would like clarity on the communication and when that process will begin. Requesting timelines for specific elements of the testing strategy. Another member responded there is a health navigator to communicate with the public sector currently. Fact sheets will be available soon.
- Some iwi have been asking who to speak to for the testing plans and are seeking information on testing. Ministry to action this item and provided point of contact.
- Comment was raised that laboratories are under extreme stress and pressure everywhere in the country and that was without cases outside Auckland. Wellington has been asked to pick up some testing to support Auckland. Laboratory staff everywhere are struggling to cope. Testing needs to shift its balance from surveillance that is overburdening the system to diagnostic/clinical testing.
- Member noted that that MIQ day 12 testing is suffering delays, often receiving results several days later due to longer TAT from all of the community testing.
- Member noted there are active discussions about Auckland's outbreak management strategy.
- A member asked if the report 'Transitioning to COVID-19 endemicity: Laboratory considerations' was shared. The Chair confirmed it had been circulated previously but can be provided again to the TAG.

Testing strategy draft

- This is a very preliminary draft and will form the basis of engagement and discussion in the coming weeks.
- There are three principles underpinning the strategy: reaching high vaccination, case and contact management, and testing.
- Feedback requested from the TAG on slides 3, 5, and 6 and can be sent directly to the Science and Technical Advisory team. Another iteration will be provided at the next TAG meeting.
    - Slide 3: Does the breakdown of the four testing categories make sense?
    - Slide 5: Are the proposed testing modalities and surveillance plan appropriate?
    - Slide 6: Do the different testing modalities for different settings and communities make sense? Are the titles on sections 3 and 4 appropriate?
- Comments from the TAG on the specific slides were:
    - It is unclear what bullet point C on slide 3 means. Is this category HCW surveillance? It was noted that in low prevalence, NP by PCR is not well tolerated and as a result HCW surveillance is only once a week or fortnight when in reality should be every couple of days. NP by PCR is not a practical strategy for surveillance. Understand NP by PCR is the reference standard, especially for finding cases in low prevalence but it creates issues with laboratory capacity and TAT. Should take advantage of the NPV of RAT. Study on testing frequencies for different modalities. Science and Technical will share this study with the TAG.
    - It was noted that slides should use NAAT instead of PCR. There were too many categories that do not help choosing the right test. Should be a risk-based approach. Too much on technology and not what is trying to be achieved by the strategy.

	○ It was noted that the final statement on slide 3 that the future state will be low symptomatic rates, low symptomatic testing. This is incorrect – in a future state, everyone with any cold and flu-like symptoms are considered symptomatic testing. ○ It was noted that receiving the documents sooner would be helpful to allow for sufficient review of documents like these in the future. ○ Additional feedback to be provided in writing to Science and Technical Advisory to share with owners of the document. <u>Actions:</u> • Ministry to provide clarity on the proper communication channels for Iwi and other stakeholders to inquire about testing. • Science and Technical Advisory to share report 'Transitioning to COVID-19 endemicity: Laboratory considerations' and publication on longitudinal testing study (Smith 2021)
3.0	**Pilot projects for RAT** • Businesses requested to start using RAT. There are 29 businesses on board and are part of the consortium being run by MBIE. The Ministry of Health is providing advice and input into a charter that businesses will agree to. This charter will ensure public health is managed appropriately such as use of the tests, resulting, what to do with a positive, etc. • A member asked where the supply will come from for businesses. Testing and Supply noted 600k RAT kits have been ordered and are available for supply, but these are for the public health response and healthcare. Businesses will be responsible for their own supply. Business and health are separate pools. • A draft of the charter to be used by MBIE will be provided to Testing TAG at a later date for their input. • A member noted saliva has not been approved for RAT. This was recognised as correct but that businesses are using saliva in Australia and it was an example of protocols from Australian operations.
4.0	**New tests evaluation and approval framework** • Framework described by Testing and Supply • A member asked how the current 3 RAT kits were evaluated and approved for import and if that same criteria will be used in this framework. ○ It was noted the ESR criteria will likely be modified to be fit for purpose. Likely part of the evaluation process will incorporate TGA approval along with a review of literature and international evidence • A member questioned who will be funding the evaluation. ○ ESR received funding to source and assess kit performance. This could change in the future and include LabPLUS. • A member questioned if the role described for the Testing TAG was suitable and aligned with the TAG's Terms of Reference. This process appears more operational and not part of TAG's responsibilities. • It was noted ESR or the SME group from NZMN would complete due diligence to confirm manufacturer claims. • Testing TAG should not be endorsing every test for import and it was noted not every new test would need field evaluation. • A member noted that ESR may not be the best organisation to be completing the evaluation process. This concern was agreed by multiple members. It was initially suggested that Medsafe be in charge of this but another member noted Medsafe would not be involved with this work. • A request was made that the documents be distributed before the next meeting.

5.0	**Any Other Business** None noted
6.0	**Agenda Items for Next Meeting** None raised during meeting
7.0	**New Action Items Raised During Meeting** • Ministry to provide clarity on the proper communication channels for iwi and other stakeholders to inquire about testing. • Science and Technical Advisory to share report 'Transitioning to COVID-19 endemicity: Laboratory considerations' and publication on longitudinal testing study (Smith 2021)
Meeting closed at **2:33pm** Next meeting **28 October 2021 – 1:30pm to 2:30pm**	

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
5	Work in progress in response to rapid review	Provide clarity on the proper communication channels for Iwi and other stakeholders to inquire about testing.	Darryl Carpenter	14/10 – Action raised
6	Work in progress in response to rapid review	Share report 'Transitioning to COVID-19 endemicity: Laboratory considerations' and publication on longitudinal testing study (Smith 2021)	Science and Technical Advisory	14/10 – Action raised

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. Out of Scope [redacted]

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. Out of Scope
4	Testing TAG Work Programme	Engage with Members to develop CT TAG work programme	Chair	09/09 – Action raised 14/10 – Closed by Chair

MINISTRY OF HEALTH
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MINUTES: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 15 October 2021
Time:	1:30pm to 2:30pm
Location:	S9(2)(k) [redacted]
Chair:	Nigel Raymond
Members:	Chris Hopkins, Colin McArthur, Eamon Duffy, Elaine Yap, Jessica Keepa, Michael Maze, 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 Bernal, Phoebe Currie

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 (01 October 2021) were accepted. **Matters arising:** • There were no matters arising.
2.0	**Update on Open Actions** 4. Draft Patient Information prepared by Health Navigator was forwarded as Additional Materials to the agenda. Positive feedback at the meeting. ACTION: Members invited to send specific feedback to Andi Shirtcliffe. 9. Re. contacting obstetric physician colleagues regarding contribution to the guidelines working group. The Chair advised Drs May Soh and Ian Kando had agreed to join the Guideline subgroup as co-opted members of the subgroup. Action closed. 10. Re documenting guideline decision-making. Preliminary discussions have been had via email. A meeting between Tim Cutfield and Anne Buckley is scheduled for next week. 12. Equity: Letter has been drafted by Jessica Keepa and Saleimoa Sami and supported by Chair. It is with the Ministry for review and wider consultation prior to distribution.
3.0	**COVID-19 Therapeutics Strategy**

	Therese Egan (Principal Policy Analyst, System Enablers, Public Health System Policy at the Ministry) joined the meeting to provide a brief preliminary update on the strategy. The COVID-19 Therapeutics Strategy is a briefing document for Ministers to support an overall strategic approach to therapeutics and communication with the sector. The roles of agencies, including Pharmac are specified within the Strategy, with the Ministry leading the work overall and coordinating efforts on deployment. Therese also advised that the Ministry of Foreign Affairs & Trade (MFAT) has a number of posts in various countries reporting on latest COVID-19 developments & there is potential to look at joint purchasing approaches and to convene meetings with relevant personnel on issues of interest such as models of care/research. Members were invited to provide any feedback through the Chair or secretariat.
4.0	**Pharmac & Medsafe Updates** **Pharmac Update** An ad hoc committee has been formed by Pharmac to support the work of purchasing & supply of COVID-19 therapeutics. This group was formed from two previous Pharmac groups - one focused on tocilizumab and the other remdesivir. In addition to combining these groups, Pharmac has co-opted 4 members of the Therapeutic TAG as members of this advisory group. The work of the Pharmac Advisory Group and the Therapeutics TAG are complementary. Specific agents: • Tocilizumab - Current supply was discussed. Pharmac are continuing to work to access extra supply. - The group discussed international experience (notably Canada) of a 400mg dose (most patients in NZ receiving 800mg) which could potentially reduce the dose needed per patient and extend supply. The group agreed that of interest but further review of the evidence is needed before a recommendation on the 400mg dose could be made. S9(2)(b)(ii) [redacted] • Baricitinib - Pharmac are working on accessing an initial supply for treatment of approximately 200 patients. Re-supply is not seen as posing a difficulty once initial supply is achieved. • Remdesivir Current supply is seen as adequate (treatment for approximately 400 patients). • Other drugs – S9(2)(b)(ii) [redacted] • Molnupiravir - Pharmac have signed an advance purchase agreement for this community oral antiviral treatment. - The agreement is subject to Medsafe approval.

	- Roche have provided results of Phase 3 trials to Pharmac. These results documents are supplied under a confidentiality agreement and therefore cannot be shared with the Therapeutics TAG at this time. They will be reviewed by the Pharmac advisory group and general comments may be shared across the two groups. • Further discussion points: - A member commented that will be important to align the testing and therapeutics implementation approaches, especially if/as community-delivered therapeutics become available. - A member asked if projections of case numbers from modelling (per admission rather than bed days) could be made available to assist management of current supply. This modelling data was circulated electronically from the CSA via the Secretariat during the meeting. **Medsafe Update** Medsafe provided an update on the status of COVID-19 treatment applications and approvals. This included a Medsafe update in relation to the following therapeutics: • Dexamethasone • Tocilizumab (Actemra) • Casirivimab + Imdevimab (Ronapreve) • Regdanvimab • PF-07321332 +ritonavir • Remdesivir • Molnupiravir The update is included in full as an appendix to the Minutes. The main points in relation to each therapeutic in the update were presented verbally in the meeting.
5.0	**Structure for Interface with Primary Care** Justine Lancaster provided an update of work being completed in the Ministry to develop models of care and also by Health Pathways with the aim of both to provide guidance for primary care. ACTION: CSA requested a brief summary be circulated to the therapeutics TAG of the work being undertaken in developing models of care for Primary Care. ACTION: Chair of Therapeutics TAG to meet with lead/s for the Primary Care work to identify next steps in aligning work. Justine Lancaster to convene meeting.
6.0	**Community Therapeutics** The focus of discussion was oral antivirals and the recognition of their potential in ease of community delivery – compared with the complexity of delivering parenteral treatments in the community. The Chair acknowledged the wide networking and research interests of group members and asked members to bring the group's attention to any emerging treatments as they come to their attention. Additional points in discussion: • Horizon scanning: Pfizer oral antiviral (PF-07321332); favipiravir. Favipiravir – some trials, with reporting expected in next few weeks. Preliminary reports suggest not as promising as molnupiravir.

	• Remdesivir supply in hospitals that is not needed could potentially be available for community use. Remdesivir is administered by IV infusion (over 3 days In Auckland hospitals). Any use outside hospital setting would require discussion with DHBs re operational matters etc. • Importance of socialising information about new treatments before they are 'rolled out', especially from an equity perspective to ensure that the value of the treatments are understood within the community and thus facilitate good uptake. • Alignment of testing and treatment seen as important in community setting. MIQ facilities may not be well-placed to administer IV treatment given pressure of numbers. One member suggested there would be value in a 'testing plus infusion centre'. Operational issues are important considerations.
7.0	**Paediatric Therapeutics** The meeting was attended by a guest infectious diseases paediatrician who led discussion on this topic. • To date there have been few paediatric cases hospitalised but this appears likely to increase in the future. Treatments include tocilizumab, steroids, remdesivir. • Paediatric dosing: - noted that older children and teenagers often weigh same as adults - FDA 'pushing' for information on paediatric dosing to be provided by drug companies for COVID-19 treatments • Molnupiravir: Queried whether potential for molnupiravir use in children given the trials included people 18 years plus. NZ paediatricians in contact with Australian & UK colleagues on matters of COVID-19 clinical practice. Royal Children's Hospital (Australia) currently preparing guidelines and NZ likely to follow this lead.
8.0	**Guideline Update/Patient Information Update** • The latest update of the Guideline was published on the Ministry site for health professionals on 8 October 2021. Next update planned for 5 November 2021. • Update frequency has moved to a monthly schedule though a more frequent update may occur if there is a significant recommendation/content change to make. • Guideline subgroup last met Wednesday 13 October. • The Chair advised 2 Obstetrics & Gynaecology specialists have been co-opted on to the Guideline Working Group and will lead drafting of additional content for guideline on management of COVID-19 in pregnant women. • A recommendation regarding the use of baricitinib will be prepared for a coming update, anticipating availability of this therapeutic in the near future as an alternative to tocilizumab (if there are tocilizumab supply shortages). Patient population will be specified. • Budesonide - It is not currently included in the Guideline but this is under review. Of note, it is now included as a 'consider' in the Australian Guideline and Ontario Guideline. Also noted that the age cut-off of 50 years used in other guidelines may not be appropriate in the NZ Context. From an equity perspective may be appropriate to include adults of any age with one or more c-morbidities. There is currently a

	document guiding when to consider using in MIQ and this potentially serves as a model. - Evidence to date would support a 'conditional' rather than 'strong' recommendation; associated with a reduction in duration of symptoms. Noted that the good safety record of budesonide supports its use in the community. - Suggestion proffered of a community trial to gather more evidence – lengthy set-up time precludes this & already in use in MIQ. - A member advised that a trial of ciclesonide in the community is currently underway in NSW. - Raised that if making a recommendation for use in the guideline, there will be supply issues to consider. - A member of the group reported they have been approached about the Therapeutics TAG view on the use of budesonide. The group supported possible development of a Position Statement on community use of budesonide. ACTION: Guideline working group to prepare a draft position statement for discussion at the next meeting.
9.0	**Next Steps/Other Matters**
10.0	**Agenda Items for Next Meeting** • Position Statement on Budesonide use in the community
11.0	**New Action Items Raised During Meeting**
Meeting closed at **2:53pm** Next meeting **Friday 29 October 2021 – 1:30pm – 2:30pm**	

Open Actions:

#	Agenda item	Action	Action Owner	Updates
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.
10	Guideline Update/Patient information update	Anne Buckley to talk to Tim Cutfield regarding	Anne Buckley	01/10 – Action raised

		documenting guideline group decision making.		15/10 – Action updated on item 2.0
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 15/10 – Action updated on item 2.0
13	Structure for Interface with Primary Care	CSA requested a brief summary be circulated to the therapeutics TAG of the work being undertaken in developing models of care for Primary Care.	Justine Lancaster	15/10 – Action raised
14	Structure for Interface with Primary Care	Chair of Therapeutics TAG to meet with lead/s for the Primary Care work to identify next steps in aligning work. Justine Lancaster to convene meeting.	Chair	15/10 – Action raised
15	Guideline Update/Patient Information Update	Guideline working group to prepare a draft position statement for discussion at the next meeting.	Tim Cutfield	15/10 – Action raised

Closed 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. 15/10 - Draft patient information forwarded to members for feedback. Action closed.
9	Guideline Update/Patient information update	Chair to contact obstetric physician colleagues regarding contribution to the guidelines working group.	Chair	01/10 – Action raised 15/10 – Closed.
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 15/10 – Closed.

Appendix: Medsafe Update to the Therapeutics TAG

Status of COVID-19 treatment applications and approvals

This information relates to products where the product sponsor (manufacturer / supplier) has had contact with Medsafe about approval / application processes.
Note that some of this information would likely be regarded as commercial in confidence so should not be shared beyond the group without first checking with Medsafe.

Dexamethasone:

- Only medicine currently approved for treatment of COVID-19 in NZ
- Dexamethasone tablets approved in November 2020 for treatment of COVID-19 in patients aged 12 years and older who require supplemental oxygen therapy

Tocilizumab (Actemra):

- Actemra is currently approved for use in rheumatoid arthritis
- S9(2)(b)(ii) [redacted]

Casirivimab + Imdevimab (Ronapreve):

- Medsafe has received an application for approval of this new medicine and is being assessed under priority
- The proposed indications include:
  - treatment of COVID-19 in patents over 12 years old that do not require supplemental oxygen and who are at high risk of progressing to severe COVID-19.
  - prevention of COVID-19 in individuals aged 12 years and older who have been exposed or at high risk of exposure to SARS-CoV-2, or have a medical condition making them unlikely to be protected by vaccination. Ronapreve is not intended to be used as a substitute for vaccination.
- This is the first application for a new medicine to treat COVID-19 that Medsafe has received.
- S9(2)(b)(ii) [redacted]

Regdanvimab:

- S9(2)(b)(ii) [redacted]
- It is indicated for the treatment of COVID-19 in adult patients who do not require supplemental oxygen and who are at high risk of progressing to severe COVID-19
- S9(2)(b)(ii) [redacted]

PF-07321332 + ritonavir:

- A novel antiviral medicine in an oral tablet formulation with existing antiviral ritonavir currently under clinical development by Pfizer
- Proposed indications are:
  - the treatment of adult patients with symptomatic confirmed SARS-CoV-2 infection
    the post-exposure prophylaxis of potential SARS-CoV-2 infection (e.g. close contacts)
- S9(2)(b)(ii) [redacted]

Remdesivir:

- S9(2)(b)(ii) [redacted]

Molnupiravir:

- A novel antiviral medicine in an oral formulation currently under clinical development by MSD
- Proposed indications are:
  - the treatment of adult patients with symptomatic confirmed SARS-CoV-2 infection
  - the post-exposure prophylaxis of potential SARS-CoV-2 infection (e.g. close contacts)
- S9(2)(b)(ii) [redacted]

Document Three

MINISTRY OF HEALTH
MANATŪ HAUORA

MINUTES: COVID-19 Therapeutics Technical Advisory Group

Date:	Friday 01 October 2021
Time:	1:30pm to 2:30pm
Location:	S9(2)(k) [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 Marchello, 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 population 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