**Transitioning to COVID-19 endemicity: Laboratory considerations. 21/09/21**

Report prepared by Dr Gary McAuliffe, with contributions from Dr Susan Morpeth, Dr Michael Addidle and the New Zealand Microbiology Network

**Executive summary**


- In order to control COVID-19 transmission testing strategies need to adapt to meet changing needs.
- Test performance for detection of infection becomes less critical than ability to detect infectiousness, speed and availability of tests, increasing the applicability of rapid antigen tests, self-testing methods and saliva PCR testing.
- An overarching strategy is needed which indicates why and how different tests would be used and what the actions would be for positive test results under different scenarios as we transition to endemic COVID-19; as well as the trigger points for each phase, in order to build appropriate resources across the stakeholders involved.
- NZ's current testing capacity is a third of the equivalent per-population testing being carried out in Denmark, a country with high vaccination rates and endemic COVID-19.
- Upscaling of PCR test capacity and introduction of rapid antigen testing will be needed to bridge this gap.
- This work needs to be done now with urgency to prepare for endemic COVID-19 and will require significant investment in equipment and staff, pilot studies, and operational planning.


**Background**

Several countries previously pursuing elimination approach e.g. Singapore, Australia have signalled their intentions to move to COVID endemic or resilience phases once their vaccinated population reaches a certain threshold. In Australia this signal has come prior to reaching target population vaccination due to lockdown fatigue and inability to achieve elimination. Other countries pursuing mitigation strategies e.g. the UK, Denmark have signalled a shift in public health approach with increasing levels of immunity due to vaccination and prior infection. These changes in approach have consequences for testing strategy and required laboratory capacity, in both the transition phase, and the endemic phase. However, it is clear that in order to avoid overwhelming healthcare, testing will remain a key pillar of the response. We explore this and what that would require using examples from overseas including New South Wales, Denmark, Singapore and the United Kingdom.

Table. Current COVID-19 cases, vaccination and testing situations in NZ, NSW and Denmark, current as of 21/9/21

| | NZ current | New South Wales | Denmark | Singapore |
|---|---|---|---|---|
| Population: | 5,122,600 | 8,200,000 | 5,816,000 | 5,690,000 |
| Fully vaccinated: | 1,618,673 (32% total population) | 3,482,945 (43% total population) | 4,210,892 (72% total population) | 4,455,536 (78% total population) |
| Cases: (7 day average) | 21 | 1194 | 850 | 1178 |
| Antigen tests/day (7 day average) | 0 | Not publically available | 82,212 | Not publically available |
| PCR tests/day (7 day average) | 12,971 | 143,235 | 70,723 | 67,100 |
| Total tests/day | 12,971 (0.25% popn/day) | 143,235 (1.7% popn/day) | 152935 (2.6% popn/day | 67,100 (1.2% popn/day) |
| Tests per case | 597 | 120 | 180 | 56.9 |

https://www.moh.gov.sg/news-highlights/details/update-on-local-covid-19-situation-(21-sep-2021); https://www.sst.dk/en/english/corona-eng/status-of-the-epidemic/covid-19-updates-statistics-and-charts; https://www.health.nsw.gov.au/Infectious/covid-19/Pages/default.aspx; https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/testing-covid-19

**Changes to testing strategy**

Based on overseas experience (see appendices) elements of NZ's testing strategy will change; these include a lesser focus on the sensitivity of the test to pick up all individuals with COVID-19, compared with factors such as tolerability, rapidity and accessibility e.g. rapid antigen testing, saliva PCR testing, self-testing.

The European CDC described testing strategies and objectives for COVID-19 in September 2020 which are important considerations as public health strategy changes from an elimination approach, key relevant points over and above NZ's current testing focuses are:

*All people with COVID-19 symptoms should be tested as soon as possible which requires easy access to testing for all, including non-residents. Test turnaround time should be minimised, people testing positive should isolate and timely contact tracing should be carried out, ensuring that all close contacts are tested, irrespective of symptoms.*

*Healthcare and social care settings require intensive testing when there is documented community transmission. Periodic and comprehensive testing of all staff and residents/patients is recommended to prevent nosocomial transmission. Furthermore, all patients/residents should be tested upon or immediately prior to admission.*

*Clusters or outbreaks may occur in certain settings, such as workplaces, healthcare facilities, educational facilities, prisons, and migrant detention centres. Testing policies and systems should be in place for rapid detection and control to protect the relevant populations in these settings and to protect the community from amplified transmission.*

In the face of increasing COVID-19 prevalence, addressing these elements requires increased laboratory capacity for PCR testing, particularly for testing symptomatic individuals, and routine surveillance testing of patients and hospital staff. PCR will also be required to confirm positive RAT results and for testing of contacts of cases. Further details are available in the appendix.

**Laboratory capacity requirements**

In the transition phase and early to mid-endemic phase, sustained high rates of laboratory based PCR testing will be needed in order to support mitigation of transmission.

In New South Wales currently, 143,235 tests have been performed on average each day for the last seven days. The equivalent, relative to the NZ population, would be 88,805 tests per day. When compared with the 49,736 performed on the largest day by NZ labs in the current outbreak, this indicates a significant gap in capacity. Test capacity requirements should be modelled based on this scenario as an indicator of required surge capacity, particularly during transition and early endemic phase. Additional modelling, including the impact of healthcare worker screening on laboratory capacity and ability to maintain the workforce is also necessary.

Thinking beyond a transition period, in Denmark, the equivalent number of PCR tests that would need to be performed sustainably in NZ would be 62,236 tests.

Table. NZ current and future projected testing requirements

| | NZ current | NZ testing capacity requirements equivalent to NSW | NZ testing Capacity requirements equivalent to Denmark | NZ testing capacity requirements equivalent to Singapore |
|---|---|---|---|---|
| | Baseline | 62% of NSW testing | 88% of Denmark testing | 90% of Singapore testing |
| Antigen tests/day (7 day average) | 0 | Not recorded | 72,346 | Not recorded |
| PCR tests/day (7 day average) | 12,971 | 88,805 | 62,236 | 60,390 |
| Total tests/day | 12,971 (maximum daily tests performed= 49,736) | 88,805 | 134,582 | 60,390 |

Consideration needs to be given to the capacity of the different NZ regions, as Auckland has performed 56% of the country's tests but has also relied on sending tests elsewhere. With endemic COVID-19 this may not be possible as the regions will need to support their own public health

interventions, necessitating higher capacity in the Auckland region e.g. 36-52,000 tests/day based on the case scenarios described. The regions themselves have not yet been pressure tested.

We also anticipate current laboratory capacity will need to transition to the ability to incorporate saliva-based PCR testing as a higher proportion of workload. Whilst this work is ongoing, and generally capacity is increasing, faster progress and strategic leadership is needed in this area.

**What resources will laboratories need to upscale and maintain PCR testing?**

Several laboratories are currently looking at this. In order to upscale and maintain ability to test the projected high numbers of PCR tests the key elements are:

*Staff*. A sustainable workforce, taking into account the peaks and troughs of test volumes. A mobile molecular workforce that can ebb and flow into other areas of the lab as required. Requires investment beyond the short term requirements.

*Space.* Many laboratories are unable to expand and work safely within their existing environments, and assistance to rapidly source and outfit new suitable areas.

*Equipment*. Automating as much of the process as possible. These platforms are expensive but are necessary in order to upscale and maintain capacity. Further PCR machines may be required in larger laboratory hubs and smaller laboratories in the regions e.g. Northland, Taranaki to reduce turnaround time to results. Diversity of platforms has been a strength, due to supply constraints, equipment downtime etc. and needs to be an ongoing consideration.

*Supply chain*. National oversight to help with negotiations with suppliers/mitigate stock shortages, watch global supply for key reagents

We recommend all labs work regionally and nationally to scope their requirements based on the estimates above, with clear accountability lines for resourcing and investment e.g. from the Ministry of Health or District Health Boards/Health NZ.

**Rapid antigen testing**

The elimination approach in NZ to date has necessitated the exclusive use of high sensitivity PCR laboratory-based assays in order to minimise the risk of false negative results (See NZMN position statement on RATs). A COVID-endemic setting will likely require the use of testing modalities outside of laboratories e.g. rapid antigen testing (RAT), in order to help mitigate the impact of COVID-19 on healthcare and the wider activities of the population.

There are several different potential applications of RATs (see appendices for specific examples):

- Workplace surveillance, particularly in “higher risk” workplaces, e.g. dine-in food and beverage establishments, personal care services, and gym and fitness studios, amongst others.
- Surveillance in educational settings
- Pre-event surveillance testing
- Surveillance prior to crossing state boundaries
- Testing of “low risk” COVID contacts

- Rapid diagnosis of symptomatic people. Would require to be done in parallel with PCR. Could be used in hospital admission setting or where investigating outbreaks in institutions such as remand facilities and aged residential care

When used for surveillance purposes, using RATs at higher frequency, e.g. 2-3 times per week, can counteract their reduced sensitivity compared to PCR testing.

We anticipate RATs will be needed to combat staff shortages, both in healthcare and the wider workforce by testing before coming to work to avoid stand-down amongst other workers.

It is notable that in the UK only 14% of 691 million RATs have been registered as used by 26th May 2021 and it is therefore difficult to know how they have been used and what the impact has been. It is therefore important to have a system for recording results at a national level for visibility and impact assessment. There is also a need to support access to testing in vulnerable groups. Language barriers and health literacy are significant risks with at home testing.

Another challenge is integrating RATs into policy within and outside the healthcare setting. Maintaining quality, recording results, and where funding for these tests will come from all need consideration. Whilst testing of prisoners and those in social care settings may fall under the mandate of public policy, does testing of workers outside these spheres fall on the businesses themselves under a mandate from central government?

Whilst NZ labs should initially be involved in RAT piloting and rollout, consideration needs to be given how these will be governed and monitored when widespread as this will fall outside laboratory capability and remit.

**Other laboratory considerations**

Whole genome sequencing technology should be more widely available for surveillance of variants and supporting contact tracing efforts using low complexity platforms in regional hubs in conjunction with ESR's bioinformatics pipeline.

Immunity testing may play an important part in determining risk of outbreaks in certain geographical areas and for certain individuals exposed to the virus.

With border reopening in the future, influenza and RSV testing should be available to detect and differentiate COVID-19, RSV and influenza infections.

Information technology is critical for registering, tracking and reporting results for COVID-19 and we need to build on existing capabilities to ensure a robust national system for this which includes RATs.

**Conclusions/strategic needs**

There is a need for an overarching strategy across labs, health, and government to incorporate testing through healthcare and wider society.

A mixture of PCR and RAT will be required for endemic COVID-19. Fast results (and action based on the results) and low resource impact become more important than sensitivity; self-testing and saliva

based testing should be available, though for scalability across the country nasopharyngeal swab testing remains an important modality.

Implementation planning for implementing RATs is required for intended use scenarios including frequent testing in healthcare workers, schools, work places, mass events. These require piloting now as time is not on our side.

PCR testing capacity needs further upscaling—ability to surge comfortably to 90,000 tests per day (50,000 in Auckland region) which requires investment in space, staff, robotics and local, regional and national coordination.

Whole genome sequencing capability should be increased across the laboratory network.

**Summary**

We should urgently plan for an alternative testing strategy for NZ in order to have the key elements available should widespread community transmission arise. This is one part of an overarching national plan that is needed addressing healthcare, social care, workforce, and productivity.

Investment in the elements required to increase and sustain additional laboratory capacity is needed. A mixture of PCR and RAT will be required and RAT testing should be piloted in use case scenarios now. The funding, recording, governance of any RAT based testing outside traditional healthcare settings e.g. at mass events, workplaces requires consideration.

**Appendices**

*Appendix 1.*

Principles of testing strategies (from ECDC COVID-19 testing strategies and objectives. 15 Sep 2020) **https://www.ecdc.europa.eu/en/covid-19/surveillance/testing-strategies**

- ECDC proposes five main objectives for testing:
  - in order to control transmission;
  - reliably monitor SARS-CoV-2 transmission rates and severity;
  - mitigate the impact of COVID-19 in healthcare and social care settings;
  - detect clusters or outbreaks in specific settings and
  - maintain sustained control of COVID-19 once achieved.
- Testing strategies should be flexible and rapidly adaptable to change, depending on the local epidemiology, transmission, population dynamics and resources.
- Ideally, all people with COVID-19 symptoms should be tested as soon as possible after symptom onset.
- This requires easy access to testing for all, including non-residents. Test turnaround time should be minimised, people testing positive should isolate and timely contact tracing should be carried out, ensuring that all close contacts are tested, irrespective of symptoms.
- All patients with acute respiratory symptoms in hospitals and other healthcare settings, and all specimens from sentinel primary care surveillance should be tested for both SARS-CoV-2 and influenza during the influenza season to monitor incidence and trends over time.
- Healthcare and social care settings require intensive testing when there is documented community transmission. Periodic and comprehensive testing of all staff and residents/patients is recommended to prevent nosocomial transmission. Furthermore, all patients/residents should be tested upon or immediately prior to admission.
- Clusters or outbreaks may occur in certain settings, such as workplaces, educational facilities, prisons, and migrant detention centres. Testing policies and systems should be in place for rapid detection and control to protect the relevant populations in these settings and to protect the community from amplified transmission.
- Countries experiencing high SARS-CoV-2 transmission in a local community should consider testing the whole population of the affected area. This would enable identification of infectious COVID-19 cases and allow for their prompt isolation to interrupt chains of transmission. Depending on the epidemiological situation, size and population density of the affected area, such an approach could be less disruptive for society than having to introduce and ensure compliance with more stringent public health measures.
- To prevent re-introduction, countries or sub-national areas that have achieved sustained control of SARSCoV-2 circulation should, in addition to quarantine measures, consider targeted testing and follow-up of individuals coming from other areas within the within the same country, or from other countries that have not yet achieved sustained control of the virus.

**Appendix 2.**

Case study: New South Wales

New South Wales; transitioning to endemic COVID in context of an outbreak. Currently in suppression phase. Likely represents surge capacity needed in short term for NZ transition.

High levels of PCR testing on a per population basis compared with NZ.

Additional use of RATs e.g. in unvaccinated aged care sector workers: https://www.health.gov.au/news/announcements/rapid-antigen-testing-kits-for-high-risk-nsw-local-government-areas

Table: Vaccination, cases and tests in New South Wales

| | New South Wales |
|---|---|
| Population: | 8,200,000 |
| Fully vaccinated: | 3,482,945 (42.5% total population) |
| Cases: (7 day average) | 1194 |
| Antigen tests/day (7 day average) | Not publically available |
| PCR tests/day (7 day average) | 143,235 |
| Total tests/day | 143,235 (1.7% popn/day) |
| Tests per case | 120 |

**Appendix 3.**

Case study: Denmark

Denmark has transitioned to endemic COVID

Use of RATs appears to be widespread for asymptomatic testing, particularly in those attending workplaces. PCR appears to be used for symptomatic individuals, those who are close contacts of cases, and those with a positive RAT.

From COVID-19 Surveillance, Danish Health Authority: https://www.sst.dk/en/english/corona-eng/status-of-the-epidemic/covid-19-updates-statistics-and-charts

Testing Guidance from: https://www.sst.dk/en/English/Corona-eng/Symptoms_tested-positive-or-a-close-contact/On-being-tested

Table. Vaccination, cases and tests in Denmark

| | Denmark |
|---|---|
| Population: | 5,816,000 |
| Fully vaccinated: | 4,210,892 (72 % total population) |
| Cases: (7 day average) | 850/ day |
| Antigen tests/day (7 | 82,212 |

| | |
|---|---|
| day average) | |
| PCR tests/day (7 day average) | 70,723 |
| Total tests/day | 152935= 2.6% population/day |
| Tests per case= | 180 |

**Appendix 4.**

Case study: COVID Rapid Antigen Test Rollout Singapore

Singapore, with a population of 5.7 million people, are currently in the early transition phase towards living alongside COVID. This Public Health plan seems to be labelled "**COVID Resilience**". However, the Singapore government are quite clear about the fact that they are now transitioning to endemic COVID. Vaccination rates are high within Singapore, with 78.5% of their total population having been vaccinated against COVID-19 (as of 11th Sept)

Singapore have started rolling out Rapid Antigen Tests (RATs/ARTs) to Households, Workplaces &ECEs/primary schools. They are also being used as a test option (along with PCR) for unvaccinated attendees at mass gatherings.

They have also been used in parallel with PCR testing to rapidly screen a prison population following a positive case.

Most of the Rapid Antigen Testing is performed by self-testing, with the exception being if it is prior to a formal mass gathering (see below). If the rapid antigen test is positive, the process is to take a photograph of the RAT result along with identification and call/attend a "Swab and Send Home" clinic for a confirmatory PCR test. Test data is only collected on positive RAT results, not negative.

They are recommending RATs for **asymptomatic** people in the following situations:

*Households*

Households will get 6 RAT tests issued per household, funded from the government. Any additional tests that are required are to be purchased. The indications for the use of these tests in the household setting are a little unclear. To be used if in a "high-risk situation", or if there is a possible contact with a positive COVID case. However, if symptomatic, then patient should **not** use a RAT and should attend a "Swab and Send Home" (SASH) clinic for PCR testing. Rapid antigen tests are being rolled out to all households from 28th Aug to 27th Sept 2021.

*Workplaces*

High risk workplaces are undergoing (asymptomatic) surveillance by Rostered Routine Testing (RRT), the frequency of which is dictated by the current underlying national case prevalence, either weekly or fortnightly.

"High risk" workplaces are defined as dine-in food and beverage establishments, personal care services, and gym and fitness studios.

During the recent increase in cases in Singapore (first two weeks Sept 2021), workplace surveillance has also been extended to retail mall workers, supermarket staff, delivery personnel (including parcel and food delivery personnel), and public and private transport workers (taxi drivers, private hire car drivers and all public transport frontline staff)

RATs for workplaces are administered through "Employer Supervised Self Swabbing" (ESSS). The government are funding this workplace testing until the end of 2021.

*ECEs, Primary schools*

3 ART test kits are being given to each child attending ECE/primary school on return from the September school holidays

*Large Scale Events/Mass Gatherings*

Pre- Event Testing (PET) is required, if unvaccinated, and attending a mass gathering. This can be done by either PCR or RAT at a designated provider site, a maximum of 24 hrs before the event.

PET is not necessary for children or those people who have been fully vaccinated.

See exemplar table below for event types:

For Large-Scale Events^

| Timeline | Pre-Endemic Transition Phase | |
|---|---|---|
| **Activity** | Max No. of Attendees (Fully Vaccinated)* | Max No. of Attendees (Without PET) |
| MICE including consumer tradeshows | 1000 | 50 |
| Live performance (seated audience), pilot spectator sport event | 1000 | 50 |
| Worship Services | 1000 | 50 |
| Cinemas | 1000 | 50 |
| Spectator Sports | 1000 | 50 |

For Wedding Events^

| Timeline | Pre-Endemic Transition Phase | |
|---|---|---|
| **Activity** | Max No. of Attendees (fully vaccinated)* | Max No. of Attendees (without PET) |
| Solemnisation only 500 | 1000 | 50 |
| Wedding Receptions (5 attendees per table) | 250 | NIL |

**If you are **fully vaccinated**, you do not have to undergo PET. Please refer to **Section 3: For Attendees/Patrons** for more information.*

*^ Provision for children aged 12 and below: If there is more than one child in the group, all children must be from the same household. Other vaccinated* individuals can be from different households as the child(ren). For large-scale PET events, the number of children is capped at 20% of the actual event size.*

*Hospitals*

RATs are being used to screen hospital visitors. See the Singapore General Hospital guideline as an example. The surveillance programmes may vary between hospitals.

With regards to hospital staff and patients, surveillance is mostly PCR based, but may include RATs, and may be supplemented with regular RAT tests during times of increased prevalence. (see Singapore Hospital guidelines for staff and patients in Appendix A)

*Authorised RAT kits*

A list of test kits authorised by MOH Singapore can be found here

*FAQs*

FAQs on RATs/ARTs is available on the Singapore MOH website

*Contact Tracing*

From 18th September, people who receive a health risk warning or a health risk alert via SMS will be given instructions by the Singapore MOH on a testing regime that they must follow. This varies according to the "risk" of the potential contact.

A **health risk warning** is issued to those who, based on contact tracing data, have been in close proximity with a Covid-19 case for an extended period, or are identified as a close contact of a case. These patients should attend a SASH (Swab And Send Home) clinic for **PCR** testing. PCR is done within 48 hrs of the notification and then at Day 8 from exposure.

A **health risk alert** is sent to people who, based on contact tracing data, are considered to be at a lower risk of infection compared with those issued with a health risk warning. These patients require **RAT** testing and they can collect the necessary kits (three in total) from pre-designated "vending machines" free of charge using their identification cards. The RAT tests are performed at Days 3, 5 & 7 from exposure.

People are required by law to comply with these testing and isolation requirements.

https://www.moh.gov.sg/covid-19/general/faqs---border-measures-and-changes-to-stay-home-notice-requirements/faqs---surgical-health-alerts

Table. Vaccination, cases and tests in Singapore

| | Singapore |
|---|---|
| Population: | 5,690,000 |
| Fully vaccinated: | 4,455,536<br>(78% total population) |
| Cases: (7 day average) | 1178 |
| Antigen tests/day (7 day average) | Not publically available |
| PCR tests/day (7 day average) | 67,100 |
| Total tests/day | 67,100<br>(1.2% popn/day) |
| Tests per case= | 56.9 |