"Living with COVID-19" requires governments to resource Rapid Antigen Tests

OzSAGE Working Group for Rapid Antigen Test Concerns

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COVID-19 infections – and the diagnosis and recording of infections as 'case numbers' – will always matter. To gain control of a disease you need to know the magnitude of the problem and where disease outbreaks are located. That is, count the cases. There is heated debate about whether the peak has occurred in NSW, but with the collapse in testing, test positivity rates soaring, PCR restricted to a small fraction of people and rapid antigen tests (RATs) largely unavailable, case numbers are no longer informative. Trends can only be reliably monitored by tracking hospitalisations, which lag case numbers. Testing and tracing are pillars of epidemic control, and the WHO has called on countries to strengthen both to deal with Omicron. Australia has done the opposite.

Without adequate case finding (which relies on testing at scale) and contact tracing, the Omicron epidemic will grow and both health and the economy will suffer. Testing allows us to find infected people and isolate them so they do not infect others. Now, during the Omicron wave, both the federal and New South Wales governments made a conscious decision to allow spread, but failed to plan for adequate Test, Trace, Isolate, Quarantine (TTIQ) capacity. Contact tracing is conducted because close contacts are at highest risk of becoming infected next, and if they are not identified, tested and quarantined they will go on to infect others and cause exponential epidemic growth. Contacts need to be traced and tested within 24 -48 hours to stop them infecting others. RATs become even more important as an adjunct to digital tracing with QR codes when governments cannot keep up with the scale of cases. Yet we have seen abandonment of tracing efforts.

The ongoing spread of COVID-19 continues to cause death and illness, including "long COVID", as well as disruptions such as staffing shortages across all industries and supply chains. Governments, as the central public health decision makers and system funders, have an obligation to protect citizens from premature death, widespread disease and disability.

OzSAGE believes public healthcare must be publicly funded to ensure that vulnerable communities are not left behind. Universal healthcare, including pharmaceutical and non-pharmaceutical measures such as Rapid Antigen Tests (RATs), should be based on clinical and population need, and not the capacity of an individual to pay. This is particularly the case where the benefits to society outweigh the costs of provision. Modelling suggests that the use of rapid testing is cost-effective and has economic benefit.

It is essential for RATs to be provided for free to the public and for adequate supply to be made available. The current limitation on RAT availability creates market conditions that are

conducive to price gouging and contributes to increasing infections as unconfirmed cases may continue to socialise and transmit the virus.

In a setting where Polymerase Chain Reaction (PCR) testing and contact tracing are overwhelmed, RATs provide a practical control to limit the spread of disease and decrease the load on ambulance services and Emergency Departments. For those who do not require a PCR result for return-to-work decision making or return to other environments, access to RATs reduces the burden on the national PCR testing capacity. For those essential services experiencing staffing pressures due to uncertainty about COVID-19 status, RATs provide a crucial second tier pathway to less critical isolation decisions, that frees up PCR capacity and responsiveness. Hospitals, General Practices, Residential Aged Care Facilities and Disability Services are examples that can be kept safer with a RAT program.

The fact some RATs may have approval from appropriate regulators by itself does not mean that they are appropriate or practical for certain situations. There have been concerns that these complexities, as well as the need for a link with pathology services have not been well communicated.

OzSAGE recommends:

- **RATs should be made free and readily available by government to all Australians including in regional, rural and remote areas and those in disadvantaged populations. Free RAT provision should include the close contacts including the asymptomatic and not just those who are unwell. Expanding to all beyond concession card holders, the symptomatic and some workplaces** is the most cost-beneficial way to restore Australia's testing systems, and deliver timely information to support pandemic management. Ready access and choice of saliva RAT is important as it is easier to use for some individuals, including those with disability.
- **Information regarding which RATs are approved and their appropriateness in different circumstances** (based on false positive and negative rates) **must be shared publicly, in easy-to-understand community languages**.

- **Enhanced educational material about how to properly undertake a RAT, with verbal, written and pictograph forms of information must be provided.** For example, there is concern that self-administered nasal swabbing is failing to detect some cases. Improving nasal swabbing technique to more horizontal action and swabbing the throat and then the nose may increase the chance of detecting the virus. Clear diagrams and explanation for people with limited scientific understanding is helpful. Some individuals with disability find saliva tests easier, and clear educational material for that test is important. Some guidance on the confidence of RAT results should be provided, i.e., why false positive or negatives may occur.
- **QR code or equivalent system should be set up with RATs that link into digital result tracking to assist with case identification, case surveillance and contact tracing.** Platforms for uploading positive, negative and void results need

to be easy to read and it is critical that people of differing first language groups and with disabilities can also easily navigate them.

- **Website/hotline be established of where RATs are available, in real time.**

We note that rapid tests are simply one of the Vaccines Plus tools. All other controls, including child vaccination, third dose vaccination, safe indoor air ventilation and N95-level respirators are also vital to cut the spread of disease.

Appendix 1. Therapeutic Goods Administration's (TGA's) Approved Rapid Antigen Tests

RAT results are less accurate than PCR results reported from approved COVID-19 testing sites. The Australian Department of Health provides information on RAT self-testing and the Australian Public Health Laboratory Network provides more detailed information on using and interpreting results from RATs.

The TGA has approved some 22 rapid antigen self-test kits (at time of writing). This means there is information available on the sensitivity, specificity and external validation of these tests. RAT manufacturers report the accuracy of a test through two measurements: sensitivity and specificity.

- Sensitivity represents how well the test registers the presence of virus (viral proteins) when they are present. High sensitivity reduces the chance of false-negatives (a negative result from a sample that does contain viral antigens). **Put simply – if a test has high sensitivity a person who has a positive test is highly likely to <u>have</u> the infection.**
- Specificity indicates how accurately the test reports a negative if there is no virus present. High specificity reduces the chance of false-positives (a positive result when the disease is not present). **Put simply if a test has a high specificity, a person who has a negative test is highly likely <u>not to have</u> the infection.**

When community transmission was low, say one case per 200 people or so, the PCR testing capacities were not stretched and the potential for false positives was a major limitation for RATs to be able to contribute to the public health response. Nevertheless, they were appropriate in certain workplaces and high-risk settings to screen asymptomatic workers as an additional layer of security, when matched with access to confirmatory PCR testing. In these settings, tests with the highest specificity were appropriate for use.

However, in the current setting of high community transmission, with much of Australia reporting PCR test positivity of more than 30%, there is a very low likelihood that a positive result, in someone who would otherwise seek a PCR test (through symptoms or case contact) will be a false positive, and the relative sensitivity of the tests is more important than their specificity. As such, positive RAT results should be accepted as confirming a case with a high degree of confidence. Systems must be established to capture the numbers of these cases, and to initiate the appropriate public health responses such as isolation, hospitalisation or support at home, and PCR confirmation where this will affect high risk settings such as healthcare, aged and disability care.

The Therapeutic Goods Administration lists approved RAT and the public can consider the sensitivity of the various tests to select for purchase.

Disclaimer

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