A decentralised point-of-care testing model to address inequities in the COVID-19 response

Belinda Hengel, Louise Causer, Susan Matthews, Kirsty Smith, Kelly Andrewartha, Steven Badman, Brooke Spaeth, Annie Tangey, Phillip Cunningham, Amit Saha, Emily Phillips, James Ward, Caroline Watts, Jonathan King, Tanya Applegate, Mark Shephard, Rebecca Guy

The COVID-19 pandemic is growing rapidly, with over 37 million cases and more than 1 million deaths reported by mid-October, 2020, with true numbers likely to be much higher in the many countries with low testing rates. Many communities are highly vulnerable to the devastating effects of COVID-19 because of overcrowding in domestic settings, high burden of comorbidities, and scarce access to health care. Access to testing is crucial to globally recommended control strategies, but many communities do not have adequate access to timely laboratory services. Geographic dispersion of small populations across islands and other rural and remote settings presents a key barrier to testing access. In this Personal View, we describe a model for the implementation of decentralised COVID-19 point-of-care testing in remote locations by use of the GeneXpert platform, which has been successfully scaled up in remote Aboriginal and Torres Strait Islander communities across Australia. Implementation of the decentralised point-of-care testing model should be considered for communities in need, especially those that are undertested and socially vulnerable. The decentralised testing model should be part of the core global response towards suppressing COVID-19.

Introduction

By mid-October, 2020, more than 37 million cases of COVID-19 had been diagnosed in over 215 countries, and over 1 million deaths.[1] The highest rate of cases per 1 million population has been reported in the USA at 48 526 cases per 1 million, followed closely by Brazil.[2] In Australia, daily case counts rose sharply in March, 2020, with a trajectory similar to the outbreaks experienced in China, Europe, and the USA;[3] however, rapid public health control measures led to a steady decrease, with many jurisdictions now observing few or no cases per day, except for a major resurgence in one jurisdiction from June to September.[4] Overall in Australia, the case rate of 1099 cases per 1 million population is much lower than that of the USA, UK, and Europe.[2]

A close examination of the epidemiology shows that, in many countries, COVID-19 has disproportionately affected vulnerable people in society, including Indigenous people.[5] In the USA, non-Hispanic American Indian, Alaska Native, and non-Hispanic Black people are over-represented in the number of diagnoses and hospitalisations.[6] In Brazil, Indigenous populations (many located remotely) have higher case fatality rates than do the rest of the population.[7,8] In Australia, Aboriginal and Torres Strait Islanders (hereafter respectfully referred to as Aboriginal people), particularly individuals living in remote areas, were identified as a vulnerable population early in the pandemic.[9] Fortunately, to date, Aboriginal people account for a low proportion of cases (0·5%) relative to the proportion of Aboriginal people in Australia (3%), and very few cases have been reported in individuals living in remote communities.[4] However, ongoing strategies are needed to protect Aboriginal people in Australia, who are vulnerable to the effects of COVID-19 for many reasons.

First, Aboriginal people have high rates of comorbidities, such as diabetes and cardiovascular disease, with individuals living in remote or very remote areas of Australia having 1·4 times the burden of disease compared with the general population living in major cities. Therefore, these individuals are at increased risk of morbidity and mortality related to COVID-19,[10] as evidenced by the 2009 H1N1 influenza pandemic, in which Aboriginal people comprised 2·5% of the Australian population but accounted for 16·0% of hospitalisations and 9·7% of intensive care unit admissions.[11] Second, many remote Australian communities have housing shortages and overcrowding, with the average household size reported as 11 people per house in some areas, compared with the Australian average of 2·6,[12] making physical distancing virtually impossible and increasing the risk of rapid transmission. Mathematical modelling for the Australian Government's COVID-19 response showed that an undetected case in a remote Aboriginal community in Australia would spread rapidly via overcrowded housing and mixing between households.[13] Third, nearly 20% of Aboriginal people live in remote areas of Australia,[14] where there is usually only one primary care clinic staffed by small teams of registered nurses and Aboriginal health practitioners, supported by resident or fly-in-fly-out doctors and specialists.[15] Emergency care frequently requires medical evacuation to tertiary care,[16] and there are lengthy delays in access to pathology results due to distances between the health centres and laboratories.[17]

Early in the COVID-19 pandemic, specific guidelines were developed for remote Aboriginal communities. These guidelines recognised that although self-isolation is recommended while people wait for their test results, it is often impractical in remote communities characterised by large families living in close proximity. For these reasons, the guidelines recommend that any suspect COVID-19 case in a remote Aboriginal community should be air-lifted out of the community while waiting for test results.

Kirby Institute, University of New South Wales, Sydney, NSW, Australia (B Hengel PhD, L Causer PhD, K Smith PhD, S Badman PhD, A Tangey MPH, P Cunningham PhD, C Watts PhD, J King MEpi, T Applegate PhD, Prof R Guy PhD, A Saha PhD); **International Centre for Point-of-Care Testing, Flinders University, Adelaide, SA, Australia** (S Matthews PhD, K Andrewartha BSc, B Spaeth PhD, E Phillips BMedSci, Prof M Shephard PhD); **NSW State Reference Laboratory for HIV, St Vincent's Hospital, Sydney, NSW, Australia** (P Cunningham); **Poche Centre for Indigenous Health, The University of Queensland, St Lucia, QLD, Australia** (Prof J Ward PhD); **School of Population and Global Health, University of Melbourne, Melbourne, VIC, Australia** (B Hengel)

Correspondence to:
Dr Belinda Hengel, Kirby Institute, University of New South Wales, Sydney, NSW 2052, Australia
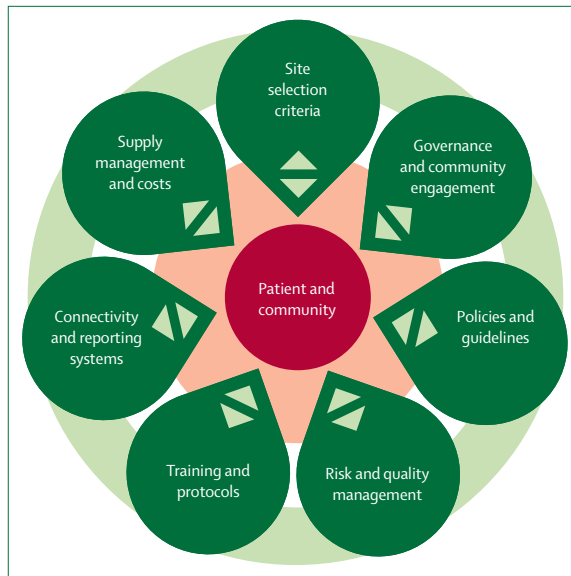bhengel@kirby.unsw.edu.au

Figure 1: Programme framework for the COVID-19 point-of-care testing model

Additionally, if cases are detected, any community action is agreed on in partnership with community members. Possible actions include relocating older or sick residents, restricting movement, and testing all community residents (including asymptomatic individuals).[18] Air-lifting individuals out of the community while waiting on test results is a resource-intensive process, which can be avoided with access to rapid test results.

Globally, there is an urgent need for new testing models to improve access to rapid test results. In many countries, people live in rural and remote areas where access to COVID-19 testing requires several hours or days' travel to the primary health centre, whereby specimens are then transferred to a centralised laboratory for testing, creating substantial barriers to timely results. In this Personal View, we describe a framework for the implementation of decentralised point-of-care (POC) PCR testing in Aboriginal and Torres Strait Islander communities in Australia, using and expanding an existing network of GeneXpert platforms introduced for the diagnosis of sexually transmitted infections, to improve access to timely COVID-19 testing in remote communities. A formal evaluation of the programme is planned and will be reported elsewhere. We are unaware of any other similar models implemented in remote primary care clinics.

Framework for the implementation of the decentralised COVID-19 POC testing model

Since April, 2020, we have developed and implemented the COVID-19 POC testing programme for Aboriginal and Torres Strait Islander people (hereafter referred to as the programme), in partnership with jurisdictional government health departments, the Aboriginal community-controlled health sector, industry, and laboratories. The framework

that supported the programme involved site selection criteria, governance and community engagement, policies and guidelines, risk and quality management, training and protocols, connectivity and reporting systems, and supply management and costs (figure 1).

The GeneXpert platform was selected for the programme because a network of decentralised primary care facilities was already operating a GeneXpert platform for testing of sexually transmitted infections.[19] In addition, the Xpert Xpress severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) assay for use on the GeneXpert platform was regulatory approved in March, 2020, and was the only PCR that could be used at the POC.[20] The Xpert Xpress SARS-CoV-2 assay (Cepheid, CA, USA) is an in-vitro SARS-CoV-2 diagnostic test with results available in 45 mins,[21] and is authorised for use outside of the laboratory setting in Australia and elsewhere.[20,22] Single-use disposable cartridges hold the PCR reagents and host the PCR process for testing purposes.[21] The GeneXpert system consists of a GeneXpert platform, barcode scanner, laptop computer, and integrated Xpert DX software for running tests and viewing results. The test cartridges are self-contained, reducing the risk of cross-contamination and operator risk at the testing site. Each cartridge requires a testing kit consisting of a swab and viral transport medium, and any viral transport medium can be used. During the programme, we changed from using a universal viral transport medium to a molecular transport medium (Longhorn, TX, USA), which preserves the integrity of the RNA,[23] is useful for transport of specimens, and inactivates the virus, rendering the sample non-infectious,[24] thereby increasing POC test operator safety.

Site selection criteria

With more than 150 remote Aboriginal communities in Australia, and a global shortage in Xpert Xpress SARS-CoV-2 cartridges, site inclusion criteria were developed to identify priority health services for the programme (panel 1). Participating services were agreed on by a series of jurisdictional and national governance committees. To optimise coverage and benefits of POC testing, a so-called hub-and-spoke model was established, in which a health service designated as a testing hub had the GeneXpert platform installed, and small, nearby community spokes collected specimens and transported them to the hub services for COVID-19 testing on the GeneXpert platform. By October, 2020, 86 health services were participating in the programme across six jurisdictions (figure 2). A further 67 services are planned to act as spoke sites, increasing the reach of the programme to over 150 remote communities.

Governance and community engagement

The programme was established with a governance model that ensured national and community ownership of outcomes. The programme was funded by the Australian

Figure 2: COVID-19 testing locations
COVID-19 point-of-care testing health services (circles) and spoke sites (triangles) are shown across Australia.

Government and overseen by the National Aboriginal and Torres Strait Islander COVID-19 Advisory Group, a sub-committee of the Australian Health Protection Principal Committee that provides leadership on health issues related to COVID-19 for Aboriginal people. The Australian Health Protection Principal Committee is the key national decision making committee for health emergencies. Additionally, a Programme Clinical Advisory Group was established to provide ongoing guidance on clinical and cultural safety, test quality, data and privacy, and training and integration.

In each jurisdiction, committees were formed, including representatives from the Department of Health, reference laboratories, state and local Aboriginal community-controlled health services and their peak bodies, government health services, and programme staff. Key issues arising from the jurisdictional meetings were raised at the National Aboriginal and Torres Strait Islander COVID-19 Advisory Group and this group also approved the final selection of participating services. Each jurisdiction adapted the programme framework to suit their local structures.

Policies and guidelines

The development of programme governance, training, competency, quality and risk management, and infection control procedures were aligned with the current National Pathology Accreditation Advisory Council guidelines for POC testing in Australia and its associated advisory notes (April, 2020).[25] Additionally, the programme aligned with evolving recommendations from the Public Health Laboratory Network, a group of expert public health microbiologists in Australian and New Zealand laboratories,[26] and with the series of national guidelines on COVID-19 produced by the Communicable Diseases Network Australia.[27]

Early in the COVID-19 response, national and international guidance was developed on laboratory-based SARS-CoV-2 PCR testing, including that respiratory samples should be handled and processed within a biosafety cabinet due to the risk of aerosol generation.[26]
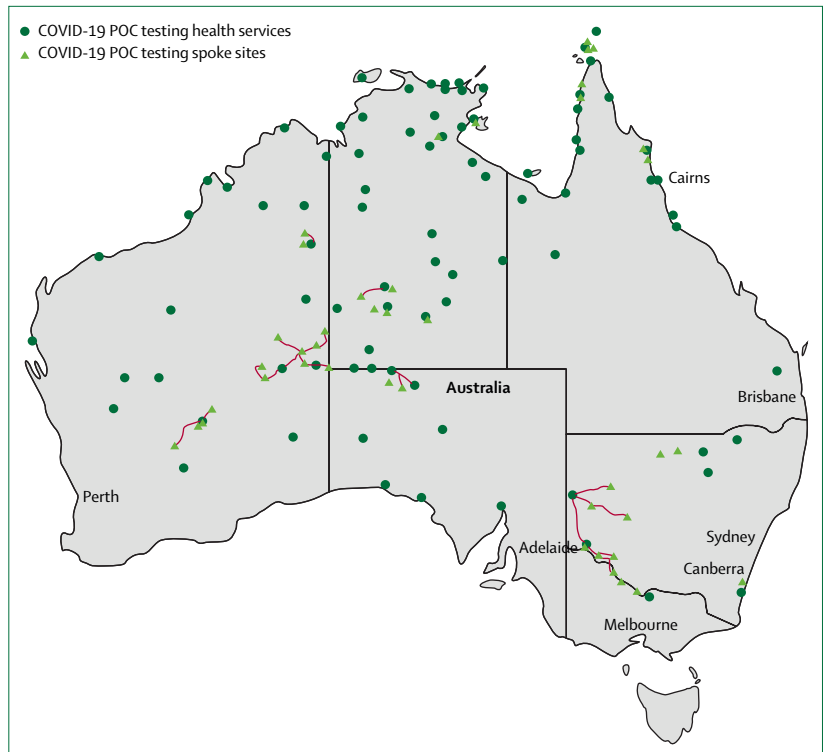
However, by April, 2020, there was no specific guidance on the use of POC PCR assays outside of a laboratory, despite GeneXpert and other assays being approved by regulatory bodies in many countries. Use of biosafety cabinets or other containment devices in primary care facilities is not feasible or affordable, and the Xpress SARS-CoV-2 testing process minimises the risk of infectious aerosols given that it involves a few sample manipulation steps and that the PCR procedures are completed within a closed, single-use cartridge.[21]

Therefore, the programme requested specific guidance from the Public Health Laboratory Network on SARS-CoV-2 POC PCR testing outside of a biosafety cabinet, and the network requested guidance from WHO. On April 15, 2020, the Public Health Laboratory Network released a statement recognising the difference between traditional laboratory-based testing and POC testing.[26] On May 13, 2020, WHO released a statement confirming that molecular POC testing assays, such as GeneXpert, "can be performed on a bench without employing a biosafety cabinet, when the local risk assessment so dictates and proper precautions are in place".[28]

New guidelines were also required on the use of POC testing, whereby a working group, convened by the Australian Government, developed recommendations on the rational use of POC testing in primary care settings (panel 2).[29]

Risk and quality management

A standard risk assessment matrix was adapted by use of the most reasonable consequence and likelihood of the consequence (ie, COVID-19 infection) occurring without risk mitigation strategies in place. Following this assessment, risk mitigation strategies for each task were identified and ranked according to the local relevant legislation. These processes guided the site suitability assessment and training procedures. These mitigation strategies led to the residual risk rating for the programme processes to be categorised as low.

Analytical quality for the programme was managed by regular internal quality control and external quality assurance tests. To be consistent with routine specimen types, positive and negative internal quality control swabs were prepared by the University of Queensland Centre for Clinical Research (Herston, QLD, Australia) by use of sequenced SARS-CoV-2 clinical viral isolate (POW004)[30] and permissive Vero E6 cells in culture (immortalised African monkey kidney cells, ATCC CRL-1586) sourced from the Doherty Institute (Melbourne, VIC, Australia). Heat inactivated stocks were then diluted to reach 1×10^6 $TCID_{50}$/mL viral titre before use. The quality control swabs were transported with routine postal services and refrigerated on arrival, overcoming a key barrier related to maintaining cold chain in transportation to geographically remote settings.[31] Health services were required to test one positive and one

See **Online** for appendix

negative quality control sample per month. If quality control results were not concordant with expected results, the operator contacted the programme help desk for troubleshooting. Internal quality control results were collated and monitored by the programme's quality management scientific team.

External quality assurance (proficiency testing) specimens were manufactured specifically for this POC programme by the Royal College of Pathologists of Australasia Quality Assurance Program (Sydney, NSW, Australia). Two external quality assurance deactivated respiratory specimens were dispatched to each participating service 5 months apart. Testing was done by competent GeneXpert operators with a blind sample format, and results were returned and reviewed for acceptable test results by the programme's scientific team on quality management.

Training and protocols

Informed by the standard risk assessment matrix, a formal site assessment was done at each eligible health service. Programme staff worked with each health service to ensure the service's suitability for participating in the programme. Key site requirements included: having a room to place the device that was well ventilated, away from high throughput areas, and had access to infection control supplies (eg, personal protective equipment [PPE], alcohol solution, and bleach); adequate health service staff and COVID-19 pandemic management plans in place; electricity and internet connectivity; and on-site operators who were required to complete prerequisite training in COVID-19 infection control practices, PPE training, and hand hygiene before attending POC testing training. Following successful site assessment, each service was able to formally register by completion of programme registration forms that outlined training, quality assurance, and reporting requirements to enable participation in the programme.

A comprehensive training resource package developed for the programme consisted of standard operating procedures, Microsoft PowerPoint presentations, associated reference posters, and quality management documents, among other documents (appendix p 1). These programme documents can be requested through the programme. The training aimed to provide test operators with the following skills that relate to SARS-CoV-2 testing: infection control measures; documentation; operation of the GeneXpert device; how to prepare and test patient samples; quality management; how to prepare and test quality control and external quality assurance samples; and general maintenance, cleaning, and disinfection procedures.

Health service staff completing POC operator training were required to complete theory and practical components. For theory training, operators were required to successfully complete a multiple-choice written assessment following the theoretical presentation. Practical competency was assessed by successful completion of

two tests on the GeneXpert platform with a positive and negative quality control sample. Once completed successfully, unique operator identifications and certificates of competency were issued for a period of 2 years.

Due to COVID-19 travel restrictions, training could not be provided face to face. Instead, training was delivered virtually by a desktop sharing programme. For the practical component of training, the trainer used a video application to view the trainee completing a quality control test in real time and, in most cases, this occurred via a mobile phone (eg, on FaceTime or WhatsApp).

A technical support help desk, operating during business hours, was established to enable POC operators to telephone or email queries about device operation and troubleshooting. Additionally, a 24 h on-call telephone hotline was provided and staffed by a senior medical scientist, to whom any positive or presumptive positive patient test results were referred. On receipt of a call, the scientist would immediately (remotely) log in to the device on which the positive or presumptive test was

done to collate details regarding recent quality testing results and information on cycle threshold values for the positive sample, so that an assessment of the analytical validity of the result could be reviewed. Consultation with the relevant clinical staff and a jurisdictional public health representative would then take place to establish the follow-up actions regarding the positive result.

Connectivity and reporting systems

A multifaceted, adaptable connectivity framework was developed to meet the clinical and public health data requirements of each jurisdiction, and to provide crucial data to monitor programme implementation and quality assurance (figure 3). It is envisaged that these systems will be used for POC testing of other infectious diseases.

A set of public health and key performance indicators were developed for the programme. With data from the programme's centralised database, two reporting dashboards were created with Tableau Desktop software: a public-facing dashboard, hosted on Tableau Public, and
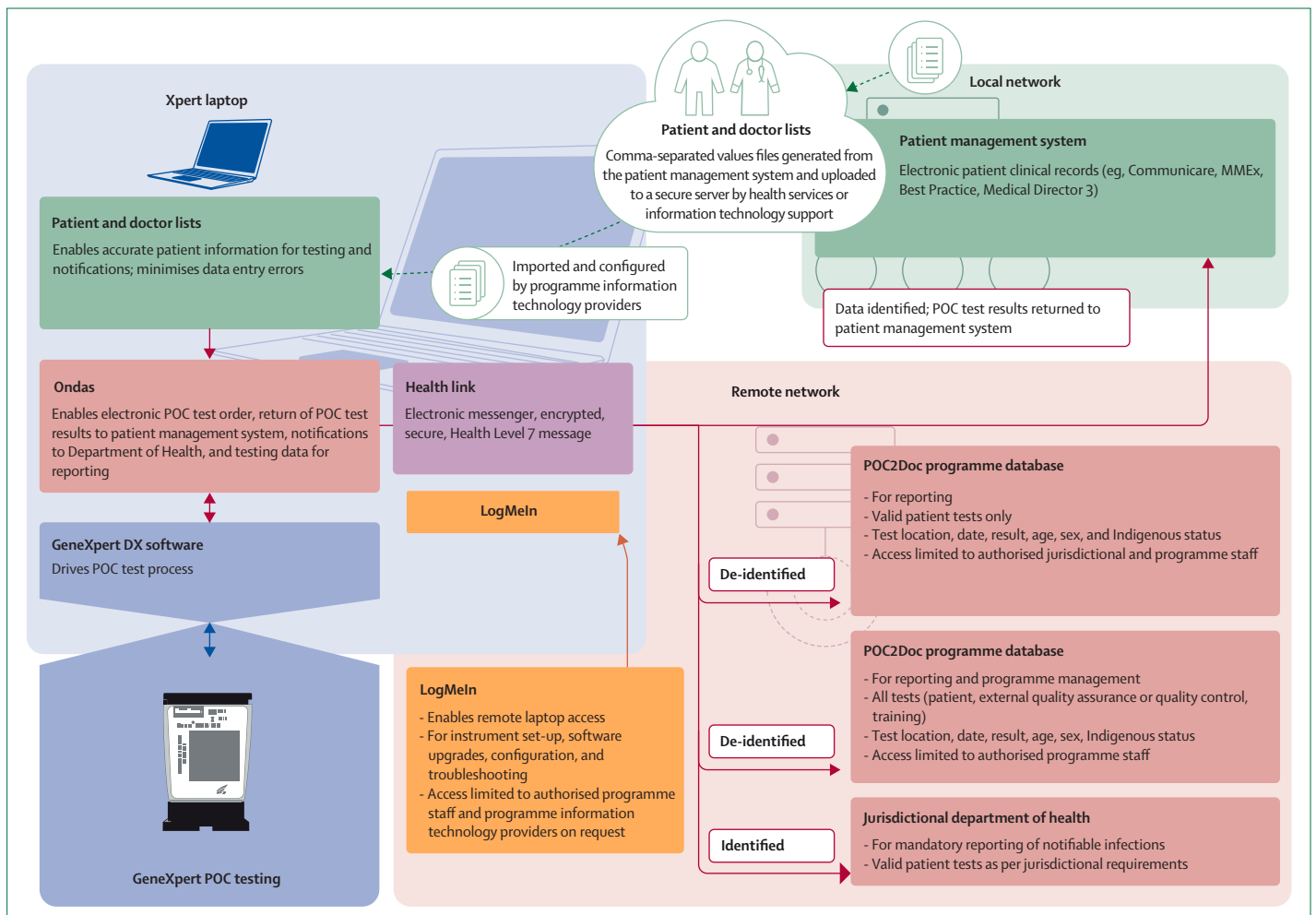
For **Tableau Desktop software** see https://www.tableau.com

Figure 3: **The programme's connectivity framework**
POC=point-of-care.

an internal-facing dashboard, hosted on Tableau Online. The public-facing dashboard was designed to provide national and local health authorities, participating health services, and key stakeholders with data relating to the POC testing programme, such as the number of active services and testing rates, with indicators agreed on by the Australian Government Department of Health and the National Aboriginal and Torres Strait Islander COVID-19 Advisory Group. By Oct 20, 2020, 5342 SARS-CoV-2 POC tests had been completed across six jurisdictions, with over 300 health service staff trained as POC operators. The internal-facing dashboard was designed to report indicators relating to the management of the programme, such as the proportion of POC tests with an error, invalid result, or no result, as well as SARS-CoV-2 assay supply and use at the health service. To date, only 1·8% of tests gave an error.

Supply management and costs

Due to the fluctuating international supply of Xpert Xpress SARS-CoV-2 assays, a dynamic supply model was established, in which supply numbers were regularly adjusted with smaller and more frequent deliveries (3–6 week cycles) than usual circumstances. However, this model allowed for the flexibility to respond to an outbreak. In addition to regular use, the supply model provided health services with an additional internal surge capacity, in case SARS-CoV-2 assays were needed during outbreaks. Test deployment and usage were monitored in real time with connectivity systems to ensure that no stockouts occurred. A central surge capacity was also established, whereby SARS-CoV-2 assays were held in centralised urban or regional-based locations to enable rapid deployment, along with a surge capacity team to respond to outbreaks and test contacts. Additionally, jurisdictions have also agreed to provide a supply, if needed, during an outbreak.

Excluding programme management and set-up costs, the main drivers of cost per test in this setting were staff time for sample preparation and processing, followed by the SARS-CoV-2 cartridges, collection kits, and PPE. A formal cost-effectiveness analysis is underway.

Conclusion

The implementation of a decentralised POC testing model is feasible in some of the remotest lands of Australia to enhance access to testing and to reduce time to results, and we have identified a series of enablers and challenges that should be considered when implementing elsewhere (panel 3). The framework could be adapted for use in other high-income countries to enhance the response for Indigenous communities. The framework could also be used in low-income and middle-income countries, where many people live in rural and remote areas with limited or no access to laboratory testing. In many low-income and middle-income countries, GeneXpert platforms are already located within provincial and regional hospitals for tuberculosis management[32] but are often not used at full capacity, providing an opportunity to leverage existing infrastructure in response to the COVID-19 pandemic. Outside of hospitals, the framework could be used at large rural health facilities, hub-and-spoke models, or mobile outreach models to

rapidly deploy to locations of epidemiological concern. Decentralised use of platforms capable of detection of multiple pathogens might also enhance capacity and autonomy in infectious disease testing.[33]

Many of the protocols and systems established are also relevant for high-performing antigen-based rapid diagnostic tests. Although registered by several health authorities, many tests are less sensitive than PCR, ranging from 0% to 94% (average 56%).[34,35] However, a test with a sensitivity of 90% is better than no test at all, particularly if it can be scaled up. Two new funding initiatives (WHO's Access to COVID-19 Tools Accelerator and the National Institutes of Health's Rapid Acceleration of Diagnostics) aim to accelerate equitable access to POC PCR tests and high-performing rapid diagnostic tests.[36,37] In October, 2020, WHO listed two rapid diagnostic tests as emergency use for detecting SARS-CoV-2, and announced a partnership to ensure that 120 million of these tests are available for low-income and middle-income countries.[38]

Overall, decentralised POC testing models could enable rapid public health responses, minimise further transmission and adverse patient outcomes, and reduce the burden on secondary and tertiary health facilities. Further investment to maximise the supply of POC tests and associated consumables is urgently needed.

References
1 WHO. Coronavirus disease (COVID-19) weekly epidemiological update. Oct 12, 2020. https://www.who.int/publications/m/item/weekly-epidemiological-update---12-october-2020 (accessed Dec 14, 2020).

2 Our World in Data. Cumulative confirmed COVID-19 cases per million people. https://ourworldindata.org/coronavirus-data-explorer?country=USA~GBR~CAN~BRA~AUS~IND~ESP~DEU~FRA&region=World&casesMetric=true&interval=total&perCapita=true&smoothing=0&pickerMetric=location&pickerSort=asc (accessed Dec 14, 2020).

3 Price DJ, Shearer FM, Meehan MT, et al. Early analysis of the Australian COVID-19 epidemic. *eLife* 2020; **9:** e58785.

4 Australian Government Department of Health. COVID-19 Australia: epidemiology report 26. *Commun Dis Intell* 2020; **44.**

5 Curtice K, Choo E. Indigenous populations: left behind in the COVID-19 response. *Lancet* 2020; **395:** 1753.

6 Centres for Disease Control and Prevention. COVIDView. A weekly surveillance summary of U.S. COVID-19 activity. Oct 16, 2020. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html#mortality (accessed Oct 19, 2020).

7 Palamim CVC, Ortega MM, Marson FAL. COVID-19 in the Indigenous population of Brazil. *J Racial Ethn Health Disparities* 2020; published online Oct 6. https://doi.org/10.1007/s40615-020-00885-6.

8 Santos VS, Souza Araújo AA, de Oliveira JR, Quintans-Júnior LJ, Martins-Filho PR. COVID-19 mortality among Indigenous people in Brazil: a nationwide register-based study. *J Public Health (Oxf)* 2020; published online Oct 12. https://doi.org/10.1093/pubmed/fdaa176.

9 Eades S, Eades F, McCaullay D, Nelson L, Phelan P, Stanley F. Australia's First Nations' response to the COVID-19 pandemic. *Lancet* 2020; **396:** 237–38.

10 Australian Government Australian Institute of Health and Welfare. Australian Burden of Disease Study: impact and causes of illness and death in Australia 2015. June 13, 2019. https://www.aihw.gov.au/reports/burden-of-disease/burden-disease-study-illness-death-2015-summary/contents/table-of-contents (accessed Dec 14, 2020).

11 Flint SM, Davis JS, Su JY, et al. Disproportionate impact of pandemic (H1N1) 2009 influenza on Indigenous people in the top end of Australia's Northern Territory. *Med J Aust* 2010; **192:** 617–22.

12 Bailie RS, Wayte KJ. Housing and health in Indigenous communities: key issues for housing and health improvement in remote Aboriginal and Torres Strait Islander communities. *Aust J Rural Health* 2006; **14:** 178–83.

13 Australian Government Department of Health. Impact of COVID-19 in remote and regional settings. Aug 21, 2020. https://www.health.gov.au/resources/publications/impact-of-covid-19-in-remote-and-regional-settings (accessed Aug 25, 2020).

14 Australian Bureau of Statistics. Estimates of Aboriginal and Torres Strait Islander Australians. Aug 31, 2018. https://www.abs.gov.au/statistics/people/aboriginal-and-torres-strait-islander-peoples/estimates-aboriginal-and-torres-strait-islander-australians/jun-2016 (accessed July 29. 2020).

15 Russell DJ, Zhao Y, Guthridge S, et al. Patterns of resident health workforce turnover and retention in remote communities of the Northern Territory of Australia, 2013-2015. *Hum Resour Health* 2017; **15:** 52.

16 Spaeth BA, Shephard MD, Schatz S, Shephard M. Point-of-care testing for haemoglobin A1c in remote Australian Indigenous communities improves timeliness of diabetes care. *Rural Remote Health* 2014; **14:** 2849.

17 Hengel B, Maher L, Garton L, et al. Reasons for delays in treatment of bacterial sexually transmissible infections in remote Aboriginal communities in Australia: a qualitative study of healthcentre staff. *Sex Health* 2015; **12:** 341–47.

18 Australian Government Department of Health. National Guidance for remote Aboriginal and Torres Strait Islander communities for COVID-19. https://www.health.gov.au/resources/publications/cdna-national-guidance-for-remote-aboriginal-and-torres-strait-islander-communities-for-covid-19 (accessed Oct 20, 2020).

19 Guy RJ, Ward J, Causer LM, et al. Molecular point-of-care testing for chlamydia and gonorrhoea in Indigenous Australians attending remote primary health services (TTANGO): a cluster-randomised, controlled, crossover trial. *Lancet Infect Dis* 2018; **18:** 1117–26.

20 Australian Government Department of Health: Therapeutic Goods Administration. COVID-19 test kits included on the ARTG for legal supply in Australia. April 24, 2020. https://www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia (accessed April 28, 2020).

21 Cepheid. Xpert Xpress SARS-CoV-2: instructions for use. For use with GeneXpert Xpress System (point of care system). Sunnyvale, CA: Cepheid, 2020.

22 US Food and Drug Administration. Coronavirus (COVID-19) update: FDA issues first emergency use authorization for point of care diagnostic. March 21, 2020. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-first-emergency-use-authorization-point-care-diagnostic (accessed July 30, 2020).

23 Longhorn Vaccines and Diagnostics. PrimeStore Molecular Transport Medium (MTM): product information. https://biotrading.com/wp-content/uploads/2020/08/Product-insert-MTM-Primestore.pdf (accessed Dec 14, 2020).

24 van Bockel D, Munier CML, Turville S, et al. Evaluation of commercially available viral transport medium (VTM) for SARS-CoV-2 inactivation and use in point-of-care (POC) testing. *Viruses* 2020; **12:** 1208.

25 National Pathology Accreditation Advisory Council. National pathology accreditation advisory council (NPAAC) guidance for point of care testing. https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-poctguid (accessed July 30, 2020).

26 Public Health Laboratory Network. PHLN guidance on laboratory testing for SARS-CoV-2 (the virus that causes COVID-19). March 14, 2020. https://www.health.gov.au/resources/publications/phln-guidance-on-laboratory-testing-for-sars-cov-2-the-virus-that-causes-covid-19 (accessed Aug 31, 2020).

27 Communicable Disease Network Australia. Coronavirus disease 2019 (COVID-19). CDNA national guidelines for public health units. https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdna-song-novel-coronavirus.htm (accessed Aug 14, 2020).

28 WHO. Laboratory biosafety guidance related to coronavirus disease (COVID-19). Interim guidance. May 13, 2020. https://www.who.int/publications/i/item/laboratory-biosafety-guidance-related-to-coronavirus-disease-(covid-19) (accessed May 28, 2020).

29 Australian Government. COVID-19 primary care response: guidance for the rational use of point-of-care testing in primary care. https://www.health.gov.au/resources/publications/cdna-national-guidance-for-remote-aboriginal-and-torres-strait-islander-communities-for-covid-19 (accessed Dec 14, 2020).

30 Walker GJ, Clifford V, Bansal N, et al. SARS-CoV-2 in human milk is inactivated by Holder pasteurization but not cold storage. *J Paediatr Child Health* 2020; published online Aug 7. https://doi.org/10.1111/jpc.15065.

31 Dimech W, Vincini G, Davies K, et al. Validation of dried tube sample format quality controls for the monitoring of viral load and blood screening assays. *J Virol Methods* 2020; **285:** 113957.

32 Cazabon D, Pande T, Kik S, et al. Market penetration of Xpert MTB/RIF in high tuberculosis burden countries: a trend analysis from 2014–2016. *Gates Open Res* 2018; **2:** 35.

33 Ndlovu Z, Fajardo E, Mbofana E, et al. Multidisease testing for HIV and TB using the GeneXpert platform: a feasibility study in rural Zimbabwe. *PLoS One* 2018; **13:** e0193577.

34 La Marca A, Capuzzo M, Paglia T, Roli L, Trenti T, Nelson SM. Testing for SARS-CoV-2 (COVID-19): a systematic review and clinical guide to molecular and serological in-vitro diagnostic assays. *Reprod Biomed Online* 2020; **41:** 483–99.

35 Dinnes J, Deeks JJ, Adriano A, et al. Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. *Cochrane Database Syst Rev* 2020; **8:** CD013705.

36 Tromberg BJ, Schwetz TA, Pérez-Stable EJ, et al. Rapid scaling up of COVID-19 diagnostic testing in the United States–the NIH RADx Initiative. *N Engl J Med* 2020; **383:** 1071–77.

37 WHO. The access to COVID-19 tools (ACT) accelerator. https://www.who.int/initiatives/act-accelerator (accessed Aug 26, 2020).

38 WHO. Global partnership to make available 120 million affordable, quality COVID-19 rapid tests for low- and middle-income countries. Sept 28, 2020. https://www.who.int/news/item/28-09-2020-global-partnership-to-make-available-120-million-affordable-quality-covid-19-rapid-tests-for-low--and-middle-income-countries (accessed Dec 14, 2020).