Chapter

# Pathology Testing at the Point of Patient Care: Transformational Change for Rural Communities

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## Abstract

Point-of-care (POC) testing is an innovative and revolutionary *in vitro* diagnostic (IVD) technology that enables the real-time conduct of pathology testing during a patient consultation, facilitating immediate clinical action. When conducted under a quality-assured framework, POC testing is an essential diagnostic tool, and is now well embedded, in primary health care settings in rural communities around the world. POC testing helps bridge the gap in health equity access that exists in geographically isolated rural communities and empowers patients to invest in understanding and improving their own health literacy. Using POC testing networks for chronic, acute and infectious diseases that are currently operating in rural and remote Australia, this chapter explores the operational, clinical and economic benefits that POC testing can deliver, and the lessons learned that have contributed to continuously improved quality of POC testing service delivery. Investment in POC testing and infrastructure by Australian governments, both federal and state, has reaped significant rewards for patients in rural communities. Additionally, translational research in this field has provided insight into how POC testing can be successfully scaled up for broad application in low- and middle-income countries.

**Keywords:** point-of-care testing, equity of access, patient-centered care, translational research, scalability

## 1. Introduction

Point-of-care (POC) testing enables pathology testing to be conducted during a patient consultation in a primary care setting and facilitates timely clinical review and action for the patient. POC testing is the fastest growing sector of the pathology industry, with the global POC testing market worth US $45 billion in 2022 and expecting to reach around US $103 billion by 2030, with a compound annual growth

rate of 10.9% [1]. As such, POC testing is referred to as a 'disruptive technology' [2], having transformed the way pathology testing is delivered for the care of patients with non-communicable (NCD) and infectious (ID) diseases, particularly in rural and remote primary care settings. This was particularly evident during the COVID-19 pandemic, where nucleic acid amplification, and later rapid antigen POC testing enabled rapid diagnosis and swift public health action and treatment [3]. Patient-centered care, with specimen collection, POC testing and informed treatment taking place during the consultation, is not only convenient and reduces loss to follow-up, but also enables the patient to become empowered and engaged in understanding and improving their own health and health literacy [4].

POC testing networks within remote Australia have demonstrated that when governments have the political will and are prepared to invest in POC testing and required infrastructure then clinical, operational, cultural and economic benefits can be derived for both the patient and healthcare system [5]. This is particularly evident for remote communities and marginalised populations, where access to centralised pathology laboratories is limited and loss to follow-up is high [6].

Following the rapid expansion of POC testing during the pandemic, current global research discussion in the field of POC testing is now focused on building high-quality, sustainable POC testing networks with the capacity to be scaled up to, for example, a national level; scale-up is defined by the World Health Organisation (WHO) as "the deliberate efforts to increase the impact of successfully tested health interventions [such as POC testing] so as to benefit more people and to foster policy and programme development on a lasting basis" [7]. This chapter explores the evolution of POC testing in rural and remote Australia using both qualitative and quantitative translational research, and highlights lessons learned, from established selected, working POC testing networks in this country. Commentary focuses particularly on the key quality and resource elements that must be embedded into POC testing to enable successful field translation, clinical utility and scale-up.

## 2. Investment by government in funding POC testing networks in Australia

The Flinders University International Centre for Point-of-Care Testing (ICPOCT) is a specialist POC testing network provider that currently supports eight different NCD and ID POC testing models in primary care settings in Australia; five of these networks are managed solely by the Centre and three are managed in partnership with the Kirby Institute, University of New South Wales. A summary of these networks is provided (**Table 1**). All these networks are funded by either the Australian Government Department of Health and Aged Care or State/Territory governments within Australia. Funding is generally provided for a fixed time period, with re-contracting occurring multiple times for many models, providing key performance indicators set by the government are met.

To illustrate how these models have been established and managed and to discuss the continuous quality improvements that have been made towards the goal of optimisation for scale-up, examples will be drawn from three specific models—one with a chronic disease focus (Quality Assurance for Aboriginal and Torres Strait Islander Medical Services [QAAMS] Program), one with acute care testing as

| POC testing program | Funder | Year started | POC device | POC test/s performed & time to result | No. of services | No. of operators[@] |
|---|---|---|---|---|---|---|
| QAAMS | Aust. Govt. | 1999 | Siemens DCA Vantage | HbA1c[^] *(6 mins)* Urine ACR[#] *(7 mins)* | 238 | 3233 |
| NT i-STAT | NT Govt. | 2008 | Abbott i-STAT | • Sodium, potassium, glucose, Hb[~], urea, creatinine *(2 mins)* | 86 | 2104 |
| | | | | • Cardiac troponin I *(10 mins)* | | |
| | | | | • Blood gases—pH, pO2, pCO2, base excess; lactate *(2 mins)* | | |
| | | | | • PT/INR[*] *(5 mins)* | | |
| TTANGO (Test, Treat and Go)[**] | Aust. Govt. | 2013 | Cepheid GeneXpert | Chlamydia, Gonorrhoea and Trichomonas *(60–90 mins)* | 51 | 795 |
| Enhanced Syphilis Response (ESR) | Aust. Govt. | 2018 | Abbott Determine™ Syphilis TP | Syphilis *(15 mins)* | 112 | 1043 |
| Syphilis WA | WA Govt. | 2020 | Abbott Determine™ Syphilis TP | Syphilis *(15 mins)* | 44 | 369 |
| COVID-19[**] | Aust. Govt. | 2020 | Cepheid GeneXpert | SARS-CoV-2[+] *(45 mins)* | 101 | 733 |
| NT WBC DIFF | NT Govt. | 2020 | Radiometer HemoCue® WBC DIFF | Total WBC count plus five-part differential *(5 mins)* | 20 | 175 |
| National Hepatitis C[**] | Aust. Govt. | 2021 | Cepheid GeneXpert | Hepatitis C *(58 mins)* | 48 | 103 |

*Aust. Govt. = Australian Government, NT Govt. = Northern Territory Government, WA Govt. = Western Australian Government.[@]Number of new operator certifications to November 30, 2022.*
*[^]Haemoglobin A1c.*
*[#]albumin: creatinine ratio.*
*[~]Haemoglobin.*
*[*]International Normalised Ratio.*
*[**]POC testing program managed in partnership with the Kirby Institute, University of New South Wales.*
*[+]Severe Acute Respiratory Syndrome Coronavirus 2.*

**Table 1.**
*Summary of primary care POC testing networks managed by the ICPOCT (Flinders University) alone, or in collaborative partnership with the Kirby Institute (UNSW).*

its core activity (the Northern Territory [NT] Acute Care POC Testing Program) and one concerning infectious disease (the National Enhanced Syphilis Response [ESR] Program). Each of these models operates in rural and remote Australia and supports mainly Aboriginal and Torres Strait Islander peoples living in those geographically isolated areas. The lessons learned from these models have been important for, and have shaped, the development of government policy for POC testing in Australia [8].

## 3. Evolution of POC testing models: Building blocks underpinning POC testing and associated translational research

### 3.1 The Quality Assurance for Aboriginal and Torres Strait Islander Medical Services (QAAMS) Program

The Quality Assurance for Aboriginal and Torres Strait Islander Medical Services (QAAMS) Program was Australia's first national POC testing network in the primary care sector. The program emerged from a recommendation from the National Diabetes Strategy in 1998, which supported a trial of the Siemens (then Bayer) DCA 2000 POC testing device for haemoglobin A1c (HbA1c) in Aboriginal and Torres Strait Islander people with established diabetes [9]. Diabetes and associated renal disease were at the time, and continue to be, a major contemporary health problem for Aboriginal and Torres Strait Islander peoples who experience rates of diabetes that are three times the national average and up to 12% in remote areas [10, 11]. In these latter geographically isolated areas, testing through traditional pathology laboratories was characterised by long delays for turnaround of pathology results and high rates of patient loss to follow-up. Through funding provided by the (then) Australian Government's Office for Aboriginal and Torres Strait Islander Health, in partnership with the National Aboriginal Community Controlled Health Organisation (NACCHO)—the peak body representing the health of Aboriginal and Torres Strait Islander communities in Australia—the QAAMS Program began as a pilot in 45 Aboriginal and Torres Strait Islander health services across Australia in 1999; more than 80% of these services were in rural or remote Australia.

Since that time, the program has been scaled up to reach almost 200 health services at 238 testing sites across Australia and is now fully embedded in the mainstream diabetes diagnosis, monitoring and care of Aboriginal and Torres Strait Islander people.

#### *3.1.1 Surveillance of analytical quality*

In 1999, POC testing was in its infancy in Australia. The principal focus of the Australian Government in funding QAAMS was to establish that POC testing in primary health care services, which was conducted principally by Aboriginal Health Workers who were trained by ICPOCT scientists, could meet analytical performance standards expected of a pathology laboratory. Aboriginal Health Workers are health professionals of Aboriginal and Torres Strait Islander descent who live in the community and have a qualification in primary health care. The importance of high quality, robust and culturally safe training for POC testing operators and the surveillance of analytical quality became the initial core elements of this pioneering POC testing model.

Analytical quality in QAAMS was assessed by trained operators regularly testing both commercially available quality control (QC) and blinded external quality assurance (EQA, also known as proficiency testing) samples. Both QC and EQA testing processes form part of mandatory medical testing requirements for pathology laboratories accredited to international standards but had never been implemented in an Aboriginal and Torres Strait Islander primary care setting, nor conducted by non-laboratory trained health professionals. In QAAMS, the QC material was supplied by Siemens and the EQA samples were provided by the Royal College of Australasia's Quality Assurance Programs (RCPAQAP), an accredited global EQA provider; the EQA samples for QAAMS POC testing were identical to those tested

by 250 Australasian laboratories (employing 21 different analytical methods) in a separate national laboratory based EQA Program provided by the RCPAQAP. This has enabled a direct comparison of the analytical performance for HbA1c (as measured by imprecision, expressed as a coefficient of variation, CV), in the QAAMS Program versus Australasian laboratories. To enable clinically significant changes in serial patient HbA1c measurements to be detected and not be masked by poor-quality test performance, imprecision goals of 3% (desired) and 2% (optimal) have been set by professional bodies and expert panels [12, 13].

Twenty years of data (from 2002 to 2022) is now available on the comparative imprecision for HbA1c testing in QAAMS and laboratories, with 49,169 EQA samples having been tested in QAAMS (**Figure 1**). In a remarkable achievement, imprecision has continued to improve across time and there has been no significant difference in the imprecision for HbA1c testing observed in the QAAMS Program (mean 2.75% SD 0.46) versus Australasian laboratories (mean 2.68% SD 0.39) over this 20-year period ($p = 0.435$ on a two-tailed p test).

A major improvement to the QAAMS quality system involved the development of real-time entry of QC test results (in 2016) and blinded EQA test results (in 2020) by test operators on the QAAMS website (www.qaams.org.au). This initiative has allowed operators to receive immediate feedback on the results of the quality testing performed at their health service. Once a quality result is entered, operators receive an instant message as to whether their test performance (a) meets analytical standards,

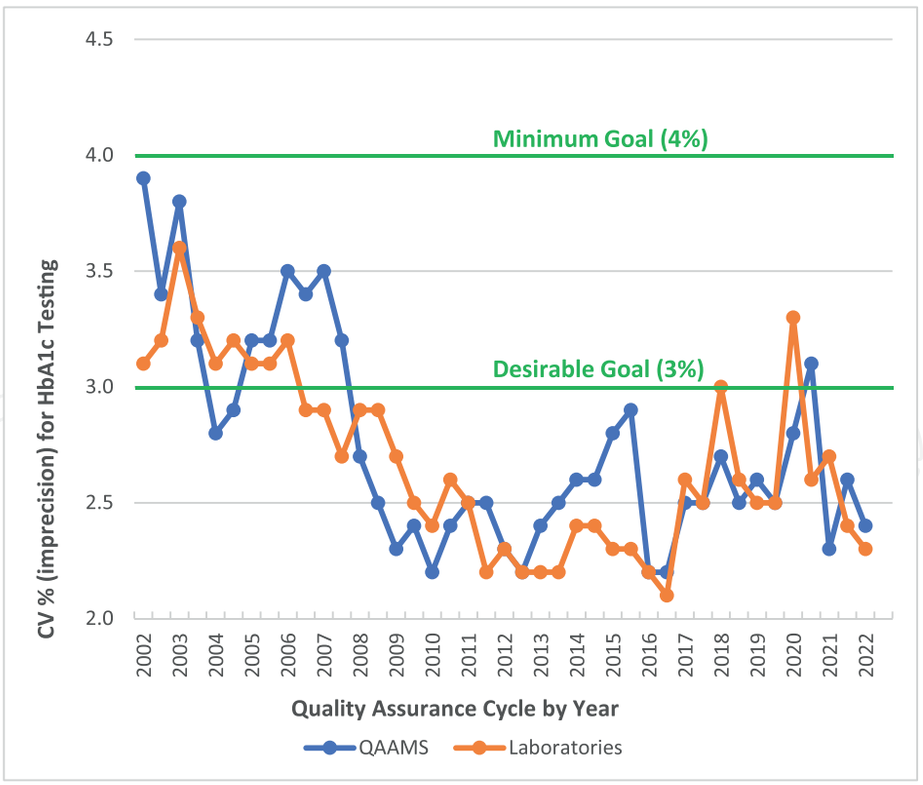


**Figure 1.**
*Comparative imprecision (median CV%) observed for HbA1c quality assurance testing in QAAMS (by POC testing) and Australasian laboratories (all methods) from 2002 to 2022. *QAAMS sites and Australasian laboratories tested the same EQA material from 2002 to 2020, after which the supplier of EQA material for QAAMS changed (to an Australian-based rather than an international supplier). Three levels of analytical goals for imprecision have generally been recognised for HbA1c testing over the past 20 years—A minimum goal of 4%, a desired goal of 3% and an optimal goal of 2% [12].*

enabling them to continue to test patients, or (b) falls outside acceptable limits for quality, in which case patient testing should be ceased until the reason for poor performance can be identified and rectified through consultation between the operator and the ICPOCT scientific support team.

### *3.1.2 Training for POC operators*

The sound and sustained analytical quality observed in QAAMS is underpinned by a culturally safe training program, which provides flexible modes of training delivery and training resources. Across the 20-year-plus lifespan of QAAMS, variable training formats have been developed and expanded to include face-to-face training for individual services and at regional or annual training workshops; self-directed/self-paced e-learning modules through password-protected access via the QAAMS website; and tele-, video- or now web-conference training sessions (formerly using videocassette, DVD and USB). ICPOCT considers face-to-face training to be the most effective means of training, as it provides an opportunity for operators and training staff to meet and form relationships which then enhance future communication when device troubleshooting, for example, is required. The annual training workshop, which offers attendance support via travel scholarships for remote POC operators from across Australia to meet centrally, is also highly valuable, as it provides a forum for cultural education, operator networking and fosters a sense of inclusion rather than having operators feel they are working in isolation. The training resource package for QAAMS includes a hard copy training manual in full-colour A3 format; a set of posters which provides simple step-by-step visual instructions for operators to conduct patient, QC and EQA testing; training aids on how to interpret patient and quality test results; training videos on the QAAMS website; and a PowerPoint presentation delivered by ICPOCT scientists. Once training is completed, all operators undertake a written and practical competency assessment to formally obtain a competency certificate as a qualified operator in the program. Competency certification lasts for a specified period, currently 2 years, after which a training update and renewal of competency is required. These core learnings from QAAMS training have been invaluable in shaping POC testing policy in Australia [7, 8].

Through this process, a significant workforce for conducting POC testing for chronic disease care has been built in rural and remote Australia, with more than 3200 operators having been trained and/or renewed their competency in the program over 20 years. Further aspects of training will be discussed later in this chapter.

There have been many key time points/significant events that have occurred in the optimisation and scale-up of the QAAMS Program over its lifespan. These will be described in chronological order and provide an insight into how the building blocks of this pioneering POC testing model were established.

### *3.1.3 Independent evaluation of the program*

The program has undergone two independent evaluations—by NACCHO in 2001 and by the Government-commissioned external consultancy company, Campbell Research and Consulting, in 2008. The major impact of the QAAMS Program reported from these evaluations included themes of improved community-based diabetes management, health worker empowerment and appropriate cultural sensitivity (**Table 2**). Continuing evaluation is an important component of a POC testing network and provides an insight into whether the program is fit for clinical purpose,

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|---|
| 2002: Evaluation by the National Aboriginal Community Controlled Health Organisation (NACCHO). |
| "This new point of care technology [the DCA 2000] seems to represent a 'major opportunity' to better care for and manage clients with diabetes and for the clients themselves to better understand its impact on their health." … |
| "The machine served as a catalyst for communication to enhance self-management through the speedy return of results and its overall ease of use which led to health workers generally demonstrating a high level of acceptance of this new 'point of care technology'." … |
| "A key finding was that nearly two-thirds of services expressed … [that the DCA] had the effect of raising the esteem of health workers in their community contexts. That is, health worker competence in using this relatively sophisticated piece of technology and the subsequent opportunity this presented for health workers and clients to work together to deal with the multiple effects of diabetes, demonstrated their communities' capacity to take control of the management of [diabetes]." … |
| "… a sense of community control was enhanced as a result of the way in which the management of persons with diabetes became more focused within most services." |
| 2008: Campbell, Research and Consulting |
| "The QAAMS model is firmly rooted in accepted approaches to Aboriginal healthcare. QAAMS has consistently maintained a high level of cultural appropriateness and acceptability …" |
| "Aboriginal health professionals and clients alike hold QAAMS in high esteem." |
| "The program has always been very consultative and culturally sensitive and empowering; those are the things that have made it such a success." |
| "All sources of evidence suggest that QAAMS is meeting best practice standards in the areas of Indigenous healthcare, diabetes management and Point of Care testing." |
| "QAAMS is one of the few programs to successfully navigate the cultural complexities and potential pitfalls of chronic disease management in Indigenous communities." |

**Table 2.**
*Summary of findings from independent evaluations of QAAMS.*

how the program is viewed by its stakeholders, in what areas improvement to the program can be made, and where the program may be failing.

### *3.1.4 Validation of test performance*

Urine ACR POC testing was added to the program in 2003, following the test's approval for use in Australia, demonstration of its clinical use for the detection of microalbuminuria in peer-reviewed international literature, and an independent evaluation of its analytical performance both in the laboratory [14] and the field [15]. Indeed, ICPOCT have maintained the philosophy consistent with best practice that, where possible, laboratory and field evaluations of new POC tests and devices should be conducted before their introduction into a new network [16, 17]. Similar to HbA1c, sound long-term analytical performance has been observed with urine ACR testing in the QAAMS Program [18].

### *3.1.5 Integration of POC testing into clinical pathways*

It is critical that POC testing is not performed in isolation but is integrated formally to improve clinical pathways for the care of patients, who are focus of the program. In QAAMS, POC test frequency was aligned with established Australian clinical guidelines for the use of the tests concerned; for HbA1c, up to four tests per annum are conducted for the management of patients with diabetes while, for urine ACR, tests

are performed three- to six-monthly depending on clinical need for those patients with microalbuminuria and annually on patients without microalbuminuria [19, 20]. A new clinical pathway incorporating the use of the HbA1c test for the diagnosis of diabetes was developed and approved by the Australian Government in 2015 [21].

*3.1.6 Assessment of clinical effectiveness*

The clinical effectiveness of POC testing in facilitating improvements in the glycaemic control of patients with established diabetes was confirmed early in the evolution of the QAAMS Program [22]. Later, a statistically significant reduction in HbA1c of 2.7% was observed in a cohort of 40 diabetes patients across the NT who had access to POC testing in QAAMS for 15 months, while no significant reduction in HbA1c was seen in these patients when laboratory testing was used as part of their care for the 15 months prior to POC testing. In addition, the mean turnaround time for HbA1c test results was 42 hours when laboratory services were used and less than 10 minutes for POC testing, while the mean time for patient follow-up and clinical consultation was 24 days following laboratory testing and less than 15 minutes post the implementation of POC testing [23].

*3.1.7 Ensuring POC testing is cost effective*

Significantly, in 2002, the QAAMS Program was the first POC testing program outside an accredited laboratory in Australia to be granted a rebate under the Australian Government's Medical Benefits Scheme (MBS). The rebate was approved directly by the Federal Health Minister and enabled services in the QAAMS Program to claim for a POC HbA1c test conducted for the management of established diabetes. (Medicare rebates are usually restricted to medical testing in pathology laboratories accredited to international quality standards by the National Association of Testing Authorities [NATA]). The QAAMS rebate has ensured that the HbA1c POC test is paid for through the national public health system in Australia and not by the health services participating in the network. Subsequently, MBS rebates have also been approved in QAAMS for the ACR test for detection of microalbuminuria in 2006 and for HbA1c for the diagnosis of diabetes in 2015. These rebates have ensured sustainability and growth of the program, as the cost remains neutral for participants. **Figure 2** summarises the numbers of MBS claims for the three item numbers currently available in QAAMS.

Outside of QAAMS, processes for supporting MBS rebates for POC tests remains a significant barrier for the field in Australia and more support and flexibility is required by Governments in this area, particularly if there is a strong clinical need and evidence base to support the clinical, cultural, operational and cost benefits of utilising POC testing in rural and remote environments. The demonstration of the cost benefit of POC testing is now a critical area of research for the field, as predictive cost savings from mathematical modelling for diagnosis and intervention and evidence-based value propositions of diagnostic tests are essential tools for incentivising government investment [24].

*3.1.8 Acceptability of POC testing by stakeholder groups*

Surveying the views and satisfaction levels of key stakeholder groups such as clinical staff, POC test operators, and patients who are the consumers of the POC service

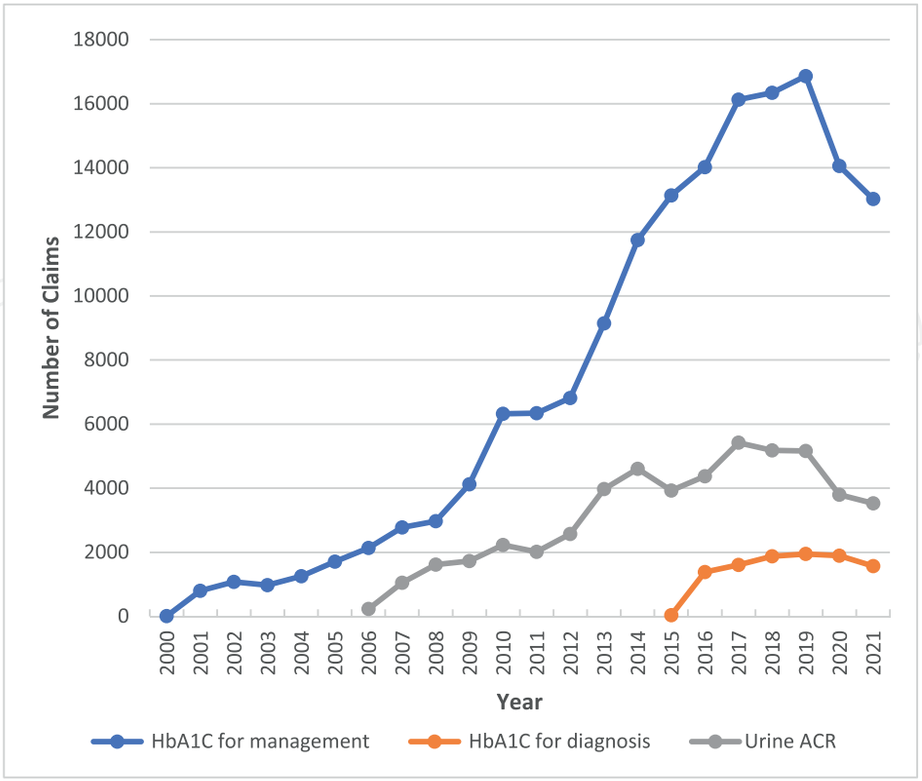


**Figure 2.**
*Total number of MBS items claimed per year by services enrolled in the QAAMS Program—For the HbA1c items for the management of established diabetes and for the diagnosis of diabetes, as well as for the UACR item for microalbuminuria.*

is an important component of assessing a model's acceptability, cultural safety and suitability to scale-up.

Surveys has been regularly conducted through the lifespan of QAAMS (as early as 2004 and as recently as 2016) [22, 25]. Ideally, stakeholder satisfaction should be embedded as a core element at the initiation of a new network where, ideally, acceptability can be assessed for example prior to, during and post implementation of a model.

### *3.1.9 Clinical governance of a network*

The governance of the QAAMS Program was initially administered by a small management committee comprising the QAAMS Program Manager and QAAMS Training Coordinator, reporting directly to the Government. However, a more multidisciplinary and inclusive governance structure was implemented in QAAMS in 2006, which included representatives from the following stakeholder groups: RCPA QAP (responsible for EQA support), Medicare Australia (to support services with MBS rebate claims) and Siemens (as an industry representative responsible for logistical supply of devices, cartridges and QC material). A Clinical Support Officer role was also created at this time to provide clinical advice and support to doctors and allied health professionals from participating sites on the appropriate clinical use of the HbA1c and urine ACR tests, as well as interpretation of POC testing results for these analytes. While this was a pioneering appointment in QAAMS at the time, the importance of systematic and integrated clinical governance is now considered paramount for all large-scale POC testing networks in Australia. The clinical governance portfolio can be assigned to a single individual (such as with QAAMS [and the NT POC

Testing network—see next section]) where the Clinical Support Officer is a member of the program's management committee or to a Clinical Advisory Group which act as an advisory panel that sits separate to, and hierarchically above, a management committee. The importance of clinical governance for POC testing networks, with designated and accountable clinical responsibility, is now embedded within the latest *Requirements for POC Testing in Australia* and will become an integral component of future accreditation frameworks for POC testing in this country [8].

### *3.1.10 Indigenous leadership for QAAMS*

In 2006, a QAAMS Indigenous Leadership Team was established. This initiative recognised the ongoing contribution of Aboriginal Health Workers (now also known as Practitioners in some parts of Australia) and their commitment to the success and viability of the program. One representative from each State/Territory of Australia was appointed to the initial leadership team. The Leaders Team act as cultural ambassadors for the program, provide an ongoing Indigenous voice and viewpoint on all aspects of QAAMS, advise on the cultural safety of program's training resource package and, increasingly, participate in training workshops and the development of training resources. The national leader of this group was also appointed to the program's expanded management committee. This initiative has proven one of the most important success stories for the program and continues to the present day, with the group renamed the QAAMS National Leadership Forum in 2021. There is no doubt that any POC testing network that supports the health of Aboriginal and Torres Strait Islander people must include strong Indigenous leadership, co-designed programs, and community engagement.

### *3.1.11 Connectivity and the electronic capture of POC test results*

Most early models of POC testing devices had the capacity to print out a set of POC test results that could be manually placed in a patient's clinical record. However, the importance of connectivity—the capacity to electronically capture POC test results and securely store them in the patient's electronic medical record—has now become an essential post-analytical component of a modern POC testing network.

In the past, connectivity has been a challenge for QAAMS due to issues with individual services' firewalls and different patient management systems used by different groups of health services. Connectivity was first trialled and established in QAAMS in 2010, when a group of 40 new POC testing devices were introduced into the state of Queensland (Qld), following the receipt of a grant from the Queensland government (an initiative approved by the Australian Government at the time). The transition from the Siemens DCA to the Atellica (see Section 3.1.13), which offer improved connectivity functionality combined with the current range of open POC testing middleware solutions available on the market, may enable full connectivity of QAAMS devices to be realised in the future. However, the costs associated with connectivity software implementation, device driver development and licencing for large scale networks remain prohibitive.

For some of our Centre's ID networks, the connectivity system also extends to remote access of the POC device for troubleshooting, real-time POC test dashboard and alert systems, and jurisdictional electronic notification of encrypted positive test results [3].

### *3.1.12 Scale-up of QAAMS achieved after 11 years*

Following the sequential implementation of the building blocks outlined, QAAMS had been systematically scaled up to almost 150 sites by 2010. It had taken the best part of 11 years to achieve what was considered an optimised POC testing chronic disease model. Given QAAMS had been a pioneering, best practice model for POC testing outside the laboratory in Australia and acknowledging the quantitative and qualitative translational research conducted, the quality improvements continually made, and the lessons learned along the journey, this time frame was not unexpected.

However, with an accumulated knowledge of the building blocks required for a POC testing network to be scaled-up, the growth and optimisation of future models (as later outlined) could now be facilitated in shorter time frames.

Before concluding the section on QAAMS, two other aspects deserve brief commentary.

### *3.1.13 Transitioning to new/updated models of POCT devices*

With QAAMS operational across a 23-year period, it was inevitable that changes/upgrades to the POC technology used in the program would occur. For the first 9 years of operation, the Siemens DCA 2000 was used in the program. In 2008, Siemens introduced a newer model known as the DCA Vantage. Fortunately, the method principle did not change, only the external appearance and electronic display features were modified. This facilitated a smooth transition to the new device over the ensuing three-year period, when the existing DCA 2000 devices were systematically exchanged for the Vantage model. Before introducing the Vantage, an independent evaluation of the new device's analytical performance was conducted by ICPOCT scientists. Support from both the industry vendor (where discounted prices were offered in flexible changeover packages) and government (who facilitated the purchase of new devices for nearly half of the enrolled participants) greatly enhanced the transition to the new device. In 2021, Siemens announced the approval of the Atellica® DCA Analyser by the Therapeutics Goods Administration (TGA)—the peak regulatory agency for IVDs, medicines and therapeutics—and availability to the Australian IVD market. A similar transition to the new device has commenced. The method principle has again not changed, albeit there is a reduction in time for result for the HbA1c test from 6 to 4 minutes and progression to a more versatile and smaller device. A further analytical evaluation of this new device has also been completed by ICPOCT scientists. The introduction of both these new devices 13 years apart has necessitated the redevelopment of updated training resource packages, a process which requires co-design and time to complete.

### *3.1.14 Impact of COVID-19 on test usage in QAAMS*

The world has been grappling with the spread of the SARS-CoV-2 virus since late 2019. The COVID-19 pandemic has resulted in severe disruption to the provision of basic health services in many communities, with a focus on isolation of patients with COVID and prioritisation given to the testing for this new disease, especially prior to widespread vaccination. Australia (and QAAMS) have been no exception [26, 27]. As described above, the quality of testing in QAAMS has not been impacted but the number of POC tests performed on diabetes patients has. In the year before the pandemic struck (2019), there were approximately 16,864 MBS claims for HbA1c

POC testing for the management of diabetes. At the end of the first full year of the pandemic (2020), MBS claims for this item had fallen to 14,053 (a decrease of 17%) while, by the end of 2021, only 13,030 tests were conducted (a total reduction in test numbers from pre-pandemic levels of 23%). Similarly, a 32% reduction in MBS claims for ACR testing was seen from 2019 to 2021, while there was a 19% decrease in MBS claims for the HbA1c diagnosis item over the same period.

Across the pandemic, the role of Aboriginal Health Workers changed significantly with a range of other COVID-related tasks preoccupying their role; these included contact tracing; swabbing patients for laboratory COVID testing and/or in some cases conducting molecular-based POC testing for SARS-CoV-2 in remote communities (through the Flinders-Kirby COVID POC Testing network—see **Table 1**); conducting telephone follow-ups and welfare checks; issuing COVID-19 vaccinations (when available), delivering medications, COVID isolation packs and food supplies; promoting COVID-safe health messages and explaining isolation/quarantine requirements. These conflicting roles no doubt contributed to decline in testing rates in remote Indigenous communities.

QAAMS continues to be a landmark and ground-breaking POC testing network in Australia. The fact that QAAMS has operated sustainably for more than 23 years is a testament to the commitment of Government, the National Indigenous Leadership Forum, the QAAMS governance and operational teams, and the Aboriginal and Torres Strait Islander health professionals who deliver the program at the rural and remote coalface.

### 3.2 The Northern Territory acute care POC testing program

The Northern Territory (NT) of Australia covers an area of 1.3 million square kilometres (km) and represents the third largest state/territory in Australia. It comprises some of the most challenging environments for conducting POC testing in Australia. The landscape is harsh and environmental extremes of soaring temperatures, excessive humidity and tropical monsoonal rains make living and working conditions difficult. Outside of three major towns (Darwin, Katherine and Alice Springs), the vast majority of communities in the Territory are geographically isolated and classified as remote or very remote by the Australian Statistical Geography Standard (ASGS) Remoteness Area Structure [28]. Health services are often spartan, with large road and air distances (often hundreds of kilometres) to reach the nearest regional hospital facilities. Health professional staff (notably remote area nurses) are often transient and overworked. The nature of health care delivery is mainly opportunistic, with multiple daily medical emergencies being a common occurrence among the predominantly Aboriginal and Torres Strait Islander peoples that live in these remote communities.

The NT Acute Care POCT program began in 2008, after the collapse of NT medical retrieval air services meant that pathology tests were unable to be transported to either of the two main pathology laboratories in the Territory. The NT Government investigated POC testing as a possible solution to address the issue and engaged ICPOCT to establish and manage a POCT service, initially in 33 remote health services administered by the Government. The Abbott i-STAT® device was employed due to its capacity to perform a range of acute care tests, notably sodium, potassium, creatinine, glucose, haemoglobin (on a test cartridge known a CHEM8+); blood gases and lactate (CG4+ cartridge), and troponin I. In addition, the i-STAT could test for Prothrombin Time (PT)/International Normalised Ration (INR) on a separate cartridge. The PT/INR test had specific clinical application in the Territory, as Aboriginal

and Torres Strait Islander people living in the Territory have one of the highest rates of rheumatic heart disease (RHD) in the world and INR is used routinely to monitor warfarin levels, an anticoagulant used to treat RHD [29]. By placing the i-STAT into a downloading cradle, patient and quality test results can be instantaneously transferred to a central data repository. A more detailed and recent review of the NT POCT program has been published elsewhere [30].

Through lessons learned from the research conducted in QAAMS, the NT program was established using the same core building blocks which had proven successful in QAAMS.

In terms of governance, a NT POC Testing Management Committee was initially established which comprised scientific representatives from ICPOCT (including the chair of the Committee and senior scientist overseeing the program), a clinical support officer (the District Medical Officer for the NT Government's Remote Health Branch), regional POC testing supervisors from Central Australia and the Top End [the northern half of the Territory] (both professional practice nurses), and representatives from the Remote Health Branch's quality and safety committee. Over time, this structure has been modified with more scientific representatives from ICPOCT and a representative from the Aboriginal Medical Services Alliance NT (AMSANT), the peak body representing the Aboriginal community controlled health service sector in the NT, now part of the Committee.

### *3.2.1 Integration into clinical pathways*

Emphasis on clinical aspects of governance has included specified clinical uses for each test measured and the development of NT-based paediatric reference intervals for each test. The integration of POC testing into clinical pathways has been continuously enhanced with POC testing protocols now embedded within the NT Remote Primary Care Manuals, a series of four clinic manuals for primary health care practitioners and allied health professionals in remote and Indigenous health services in central and northern Australia [31].

### *3.2.2 Growth of the program towards scale-up*

The program has undergone rapid growth across the past 14 years. The number of health service enrolled in the program remained between 30 and 35 from 2008 until 2014. However, following the initial success of the program and after a coroner's case found that a patient death may have been avoided if an i-STAT device had been available, the NT Government purchased sufficient i-STAT devices to service every remote NT community in 2015, effectively doubling the size of the program to a total of 72 devices. Since then, and with the support of the NT Government, the program has extended across the NT border into additional remote health services in the Ngaanyatjarra (Ng) Lands, which comprise an approximate 250,000 $km^2$ area of Western Australia (WA) adjoining the NT and South Australian (SA) borders, bringing the current number of enrolled services to 86 (**Figure 3**).

The total number of operators trained (mainly remote area nurses) has steadily increased across the lifespan of the program to now reach 2104, of which 1340 have undergone at least one competency recertification (**Figure 4**). More than 253,000 POC tests have been performed, rising from just 700 in 2008 to 36,675 in 2021 (**Figure 5**). The CHEM8+ and PT/INR cartridges are the most frequently performed test types (**Figure 6**).

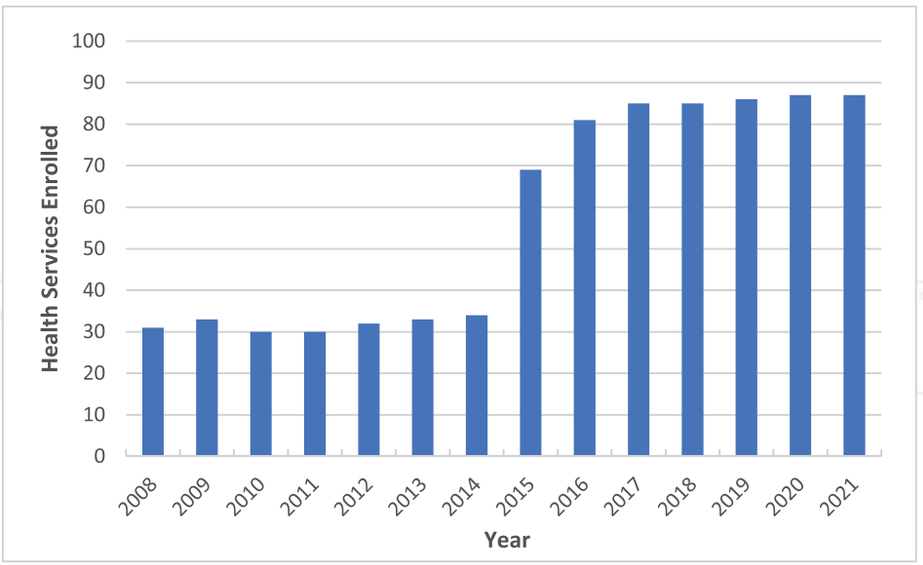


**Figure 3.**
*Number of remote health services enrolled per year in the NT acute care POC testing program using the i-STAT device.*

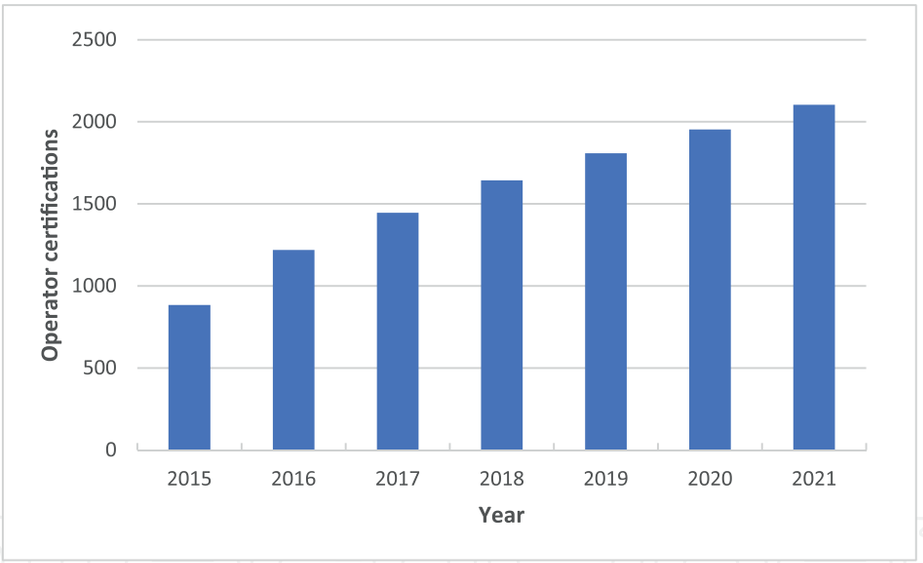


**Figure 4.**
*Cumulative growth in the number of operators trained (new and recertifications) in the NT acute care POC testing program using the i-STAT device.*

### *3.2.3 Analytical quality (and evaluation of test performance)*

Quality testing has underpinned the program since its inception. Participation in QC testing has averaged 90% since 2009, and 95% or better for the past 7 years since 2015. The imprecision for QC testing for a representative selection of critical i-STAT analytes–sodium, potassium, creatinine and pH—is shown in **Figure 7**. The average imprecision across the past 6 years for each analyte was: sodium 0.6%, potassium 1.0%, creatinine 3.5% and pH 0.2%, with each analyte meeting or being close to the imprecision goals currently achieved by participants in the RCPAQAP condensed POC testing program, survey 6, 2022 (of 0.5, 1.0, 4.6 and 0.2%, respectively) [30].

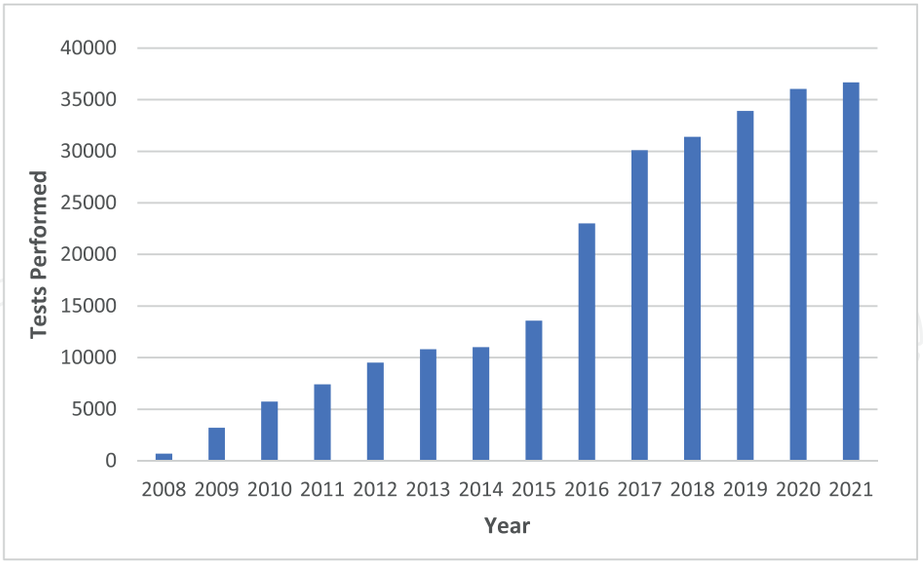


**Figure 5.**
*Total number of tests performed on the i-STAT per annum in the NT acute care POC testing program.*

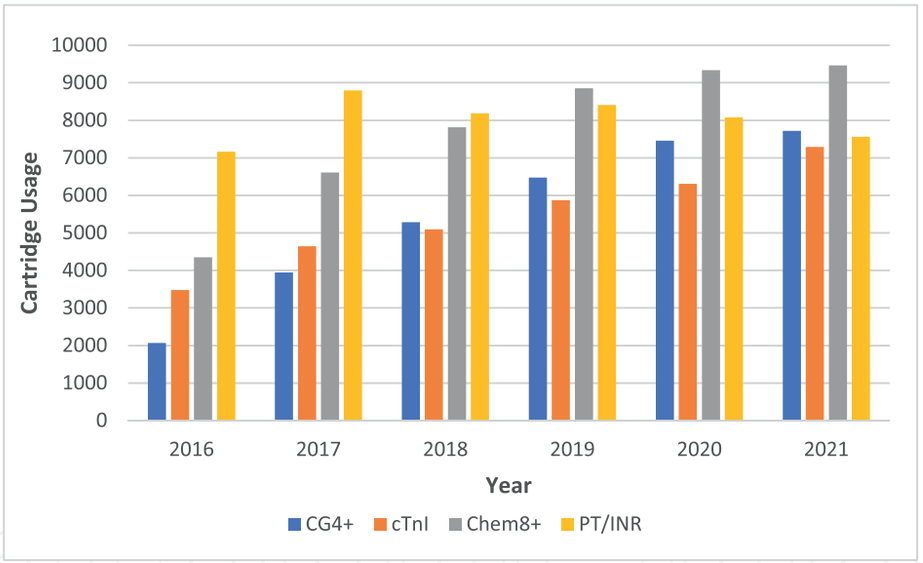


**Figure 6.**
*The number of patient tests performed in the NT acute care POC testing program using i-STAT blood gas (CG4+), cardiac troponin I (cTnI), basic chemistry (CHEM8+), or prothrombin time/international normalised ratio (PT/INR) cartridge types, differentiated by year of test.*

This data highlights the remarkably consistent and analytically sound performance of these tests in the hands of remote area POC testing operators.

There have also been continuing evaluations of the analytical performance of the test analytes as part of the broader research and surveillance undertaken across the lifespan of the program [32, 33].

### *3.2.4 Clinical effectiveness*

During the early years of the program, a log of clinical cases where POC testing had resulted in beneficial clinical outcomes was developed. Among these was the case

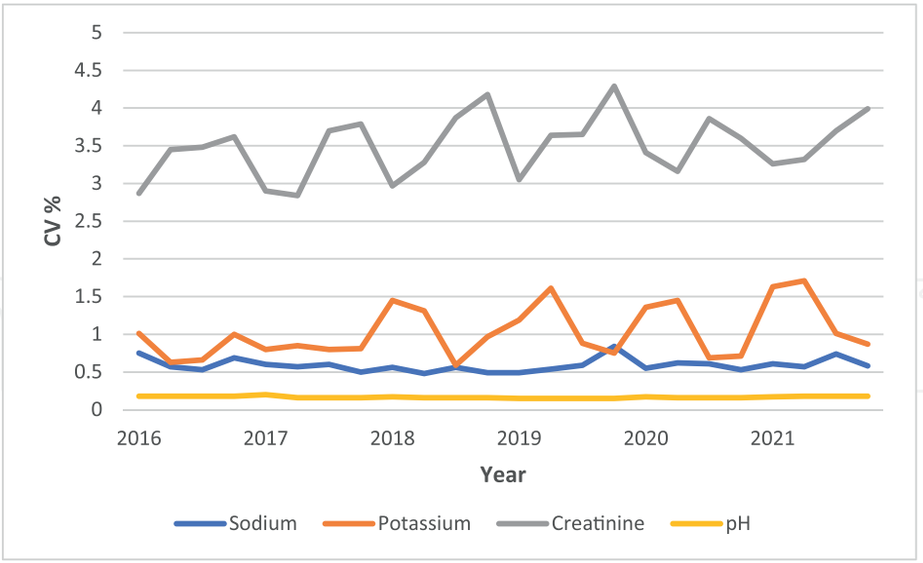


**Figure 7.**
*The average between-site imprecision for selected i-STAT analytes in the NT acute care POC testing program from 2016 to 2021, as assessed by QC testing.*

of a 46-year-old male with a history of RHD who had a coronary bypass surgery and was on warfarin to reduce his risk of stroke. In the year prior to the introduction of POCT, the average time between PT/INR tests was 67 days and time in therapeutic range (TTR) was 31% (well below the desired TTR of 60–70%). However, in the year post the introduction of POC testing, the average time between tests was 14 days and his TTR was 74% [29].

In 2015, the ICPOCT was awarded a research grant to investigate the clinical and economic effectiveness of POC testing in the NT. The study investigated 200 patient cases with three acute medical presentations at six remote health services: patients with acute chest pain (n = 147), patients with acute diarrhoea (n = 25) and patients with acute exacerbation of renal failure due to a missed dialysis session (n = 21). POC testing enabled more informed triaging of acutely ill patients requiring evacuation to a tertiary hospital as well as ruling out the need for evacuation for patients who could remain in the community and be stabilised [34].

### *3.2.5 Cost effectiveness*

Perhaps the most compelling evidence for the benefits of acute POC testing came from a cost-benefit analysis that was conducted as part of the 2015 research study. POC testing prevented 60 unnecessary medical retrievals from the cohort of 200 patients. The cost savings for the Northern Territory Government were (AUD) $13.7 million per annum (for chest pain patients), $6.45 million per annum (missed dialysis) and $1.57 million per annum (diarrhoea), translating to an annual total saving of ($21.75 million) for the NT health system [35].

### *3.2.6 Scale-up complete in 7 years*

Applying previous research conducted and lessons learned in QAAMS, the NT acute care POC testing program had been optimised and scaled up to a Territory-wide program in effectively 7 years.

Since 2015, the program has continued to grow in terms of number of services, tests and operators. Despite doubling the size of the program, the robustness and resilience of this optimised model has been sustained, with no diminution of analytical quality (see **Figure 7**). Indeed, in 2021, the NT Acute Care POC Testing program received an Engagement Australia Award in the category of 'outstanding engagement for research impact'.

### *3.2.7 White blood cell count and differential (WBC DIFF) POC testing network*

The success of this program led the NT Government to expand the suite of POC testing devices available to support other acute care presentations by introducing POC testing for white blood cell count (WBC) (including a 5-part differential (DIFF)) on the HemoCue WBC DIFF® device.

An extensive pre-evaluation of both the analytical performance and clinical utility of the WBC DIFF device was initially undertaken. Analytical performance was sound [36], while the clinical effectiveness study demonstrated the WBC DIFF device positively influenced decision making; enhanced patient safety for a range of clinical presentations, including undifferentiated sepsis, appendicitis and meningitis; and produced positive economic benefits (cost savings of approximately $5 million per annum) through reducing numbers of unnecessary aeromedical evacuations [37].

Based on this evidence-based research, the NT Government supported and funded a WBC DIFF network of 20 remote health services in the Top End of the NT in 2020.

Services were prioritised for recruitment by NT Health's Top End Quality and Safety Team, with input from senior District Medical Officers and the Care Flight air service, based on how useful the tests would be for decision-making regarding medical retrieval and which sites would benefit the most from this decision-making capability.

A Primary Health Care Remote Guideline was developed for the clinical use of the device and its operation. This document is an NT Health Policy Guidelines Centre (PGC) Approved and Controlled document.

A workforce of over 175 trained and competent operators has been established, while approximately 1160 WBC DIFF tests have been conducted in just over 2 years (547 in 2021 and 611 to date in 2022).

This albeit smaller POC testing network has been scaled up in a two-year window (having been based on learnings and translational research from the NT Acute Care model). The 20-site program has recently been extended in duration to mid-2024 by the NT Department of Health.

In a more recent development (2021), ICPOCT, in partnership with the NT Government and other researchers, was the lead organisation in a successful Medical Research Future Fund (MRFF) grant awarded by the National Health and Medical Research Council (NHMRC) (Application ID 2016006). This 5-year research grant will investigate whether the availability of a full blood examination (measuring both red and white cell parameters using the HemoScreen [Pixcell Medical] POC device), can further enhance the clinical benefits of conducting acute care POC testing in the Territory, notably for patients with sepsis. The grant will research the analytical quality, clinical, operational, cost and cultural effectiveness of this new technology as well as build an Indigenous workforce competent in using this device before, if successful, making an evidence-based decision to supersede the WBC DIFF device.

### 3.3 The national Enhanced Syphilis Response program involving POC testing

An outbreak of infectious syphilis (*Treponema pallidum*) has been progressively spreading across Qld, the NT, WA and SA, disproportionately affecting young Aboriginal and Torres Strait Islander peoples predominantly aged between 15 and 29 years [38]. In response to the outbreak, an Australian Government-commissioned working group was established to develop effective community-based strategies to tackle and mitigate the outbreak. The subsequent Enhanced Syphilis Response (ESR) program was established in 2018. Using a co-design approach, NACCHO were engaged to provide advocacy and leadership in the design and delivery of the ESR program, to establish and strengthen partner and stakeholder relationships, to support the enrolment of ACCHOs, to build a 'community of practice', and to increase the uptake of POC testing for syphilis by ACCHOs [38]. The ICPOCT was separately contracted by the Australian Government to establish and deliver a training and quality management system to support safe and accurate syphilis POC testing, as a screening tool, for the ESR program in affected communities. In terms of logistics, NACCHO is responsible for the distribution and stock management of syphilis POC test strips for their participating services. A complimentary program was later initiated by the WA Department of Health in 2020 to expand the reach of syphilis POC testing beyond ACCHOs, and into peri-urban maternal health services and community outreach screening in that state.

#### *3.3.1 The POC test used to screen for syphilis*

The Abbott Determine™ Syphilis TP immunochromatographic test strip was chosen as the rapid, screening test of choice for the ESR (and WA) program, as it was (and remains) the only POC test approved by the TGA and has a clinical sensitivity and specificity of at least 96% in a capillary (fingerstick) sample type [39]. The Abbott Determine™ Syphilis TP test detects antibodies to *Treponema pallidum*.

The syphilis screening test is one of simple complexity (being suitable since 2021 as a syphilis self-test) and differs from the moderate complexity POC testing devices used in the QAAMS and NT Programs. The syphilis test provides a qualitative test result ('non-reactive' or 'reactive') rather than a quantitative (numerical) result. Being a manual test (where the operator loads 50 µL of capillary or venous whole blood on to the test strip), electronic capture of test results can only be recorded via digital photographs or imaging software. As such, many participating ACCHOs have created specific clinical items in their patient management systems for the POC syphilis test, with results able to be entered manually. Results can also be incorporated into other general health check data sets that are available for Aboriginal and Torres Strait Islander people in Australia. Nonetheless, these differences between the POC testing technologies used in the three networks outlined in this chapter highlight the broad methodological diversity of POC testing devices and applications which are now available on the global market. Following the advent, wide global usage and eventual definitive case identification of COVID-19 by rapid antigen testing, there is now a broader public awareness, competence and inclusion of lateral flow POC tests for sexually transmitted infections within a self-testing and broader policy environment [40].

A limitation of the Determine™ Syphilis TP test strip is that it is unable to distinguish between an active infection and a past, treated infection, infectious activity or progression of associated complications. Operators are made aware of this limitation as part of their extensive training delivered by ICPOCT scientists for the program.

Patients with 'reactive' POC test results for syphilis antibodies are checked against syphilis registers (available in most jurisdictions) and a serology sample is then sent to the laboratory for confirmation of positivity. The jurisdictional registers and laboratory testing therefore enable services to assess whether an infection is active or not.

In order to respond to the outbreak and build capacity for ACCHO engagement and support, there have been five phases in the rollout of the ESR program since its inception. The first phase commenced in June 2018 in Darwin (NT) and Townsville and Cairns (Qld). The second phase started in October 2018 in the Katherine Region, Nhulunbuy (NT) and the East Kimberley Region (WA). The third phase commenced in April 2019 in West Arnhem Land (NT), Western, Eyre, Far North and Adelaide Regions (SA), and the Pilbara and Western Kimberley Regions (WA). The fourth phase began in May 2020 in Mt. Isa (Qld) and Tennant Creek (NT). A fifth phase commenced in July 2021. In total, 111 services have been engaged in the rollout (**Figure 8**).

### *3.3.2 Training for syphilis POC testing*

The simplicity of the syphilis POC screening test enabled a new model of training to be adopted for the ESR program—that of 'advanced operator training', where local experienced 'POC testing champions' were identified and took part in a higher level of training from the ICPOCT primary training team and were then able to on-train other operators at their health service or surrounding regions. This was particularly advantageous during the initial phases of the COVID-19 pandemic, where face-to-face training sessions delivered by ICPOCT were not possible due to jurisdictional border closures and community lockdowns enforced in many participating services. The use of advanced operators enabled the workforce capacity for syphilis POC testing to be scaled up quicker as part of this emergency response program. Up to November 2022, a total of 872 operators have achieved basic operator certification since the ESR program commenced, while 171 advanced operators (representing 20% of the workforce on the ground) have been certified during this period (**Figure 9**, top). In the WA Syphilis

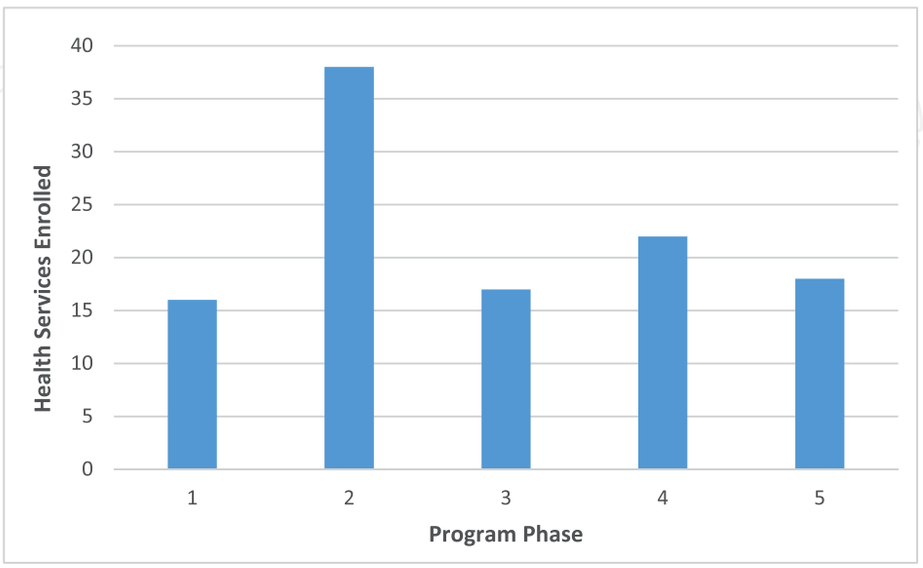


**Figure 8.**
*The number of health services enrolled in the enhanced syphilis POC testing program during the five phases of recruitment from 2018 to 2021.*

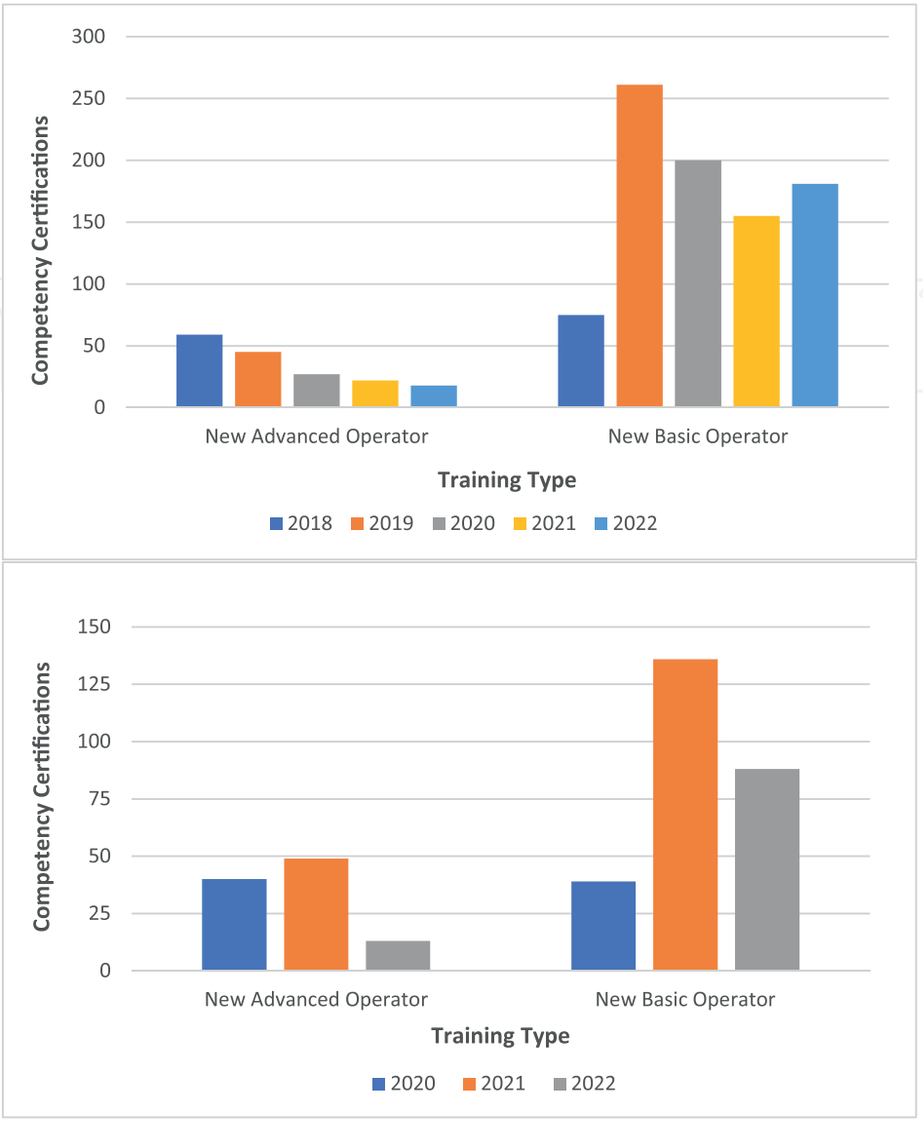


**Figure 9.**
*The number of operators undertaking advanced and basic training in the enhanced syphilis POC testing program (top) and Western Australian syphilis POC testing program (bottom) since the inception of these programs.*

program, 263 healthcare staff have obtained basic operator certification, while 106 (39%) have obtained advanced operator certification (**Figure 9**, bottom).

### *3.3.3 Use of advanced operator training depends on test complexity and patient risk*

A critical distinction needs to be made regarding the usefulness of the advanced operator training or 'train-the-trainer' approach. Syphilis POC testing is a relatively simple POC test of low technical complexity (i.e. suitability for a self-test) and relatively low patient risk if analytical performance characteristics are satisfactory. For this type of test, advanced operator training is appropriate, particularly when other forms of training may be limited or rapid scale-up of such a simple test is needed. However, advanced operator training is not appropriate for other POC test methodologies which are more complex and have higher patient and/or operator risk; for example, devices using molecular-based technologies that involve thermal cycling and have associated software packages (both for test ordering and result

interpretation). In relation to our ICPOCT networks, the latter category includes tests such as Hepatitis C performed on the GeneXpert device, with the test being classified as Class IV IVD by the TGA, which carries the highest level of patient risk; and the Class III IVD, the SARS-CoV-2 and/or multiplex SARS-CoV-2, Flu A/B and RSV tests, also conducted on the GeneXpert system (in the Australian Government's national respiratory infection program), where operators are required to wear full personal protective equipment and risks of pre-analytical, analytical and post-analytical errors causing false positives or false negatives are high.

*3.3.4 What elements of training are not negotiable and which can be consumer driven?*

In terms of developing a training framework for POC testing that is compliant with Australian POC testing requirements [8], ICPOCT have identified key elements of POC operator training which are mandatory and thus non-negotiable. These include, but are not limited to, work health and safety requirements which may be specific to the disease type, method or device; clinical governance requirements; competency registers; quality system compliance; and cultural co-design. The only negotiable elements of training are those relating to different modes or formats of training resources and delivery (i.e. allowing advanced operator training), but these should be applied specifically with the POC test and device complexity and thus patient risk at the forefront. Quantitative metrics, including error rates, error types, QC and EQA performance data and comprehensive, embedded qualitative end-user training surveys may be interdependent on training format offered and provide an evidence base for continual quality improvement of POC operator training. Continual quality improvement strategies should be adopted where possible; however, patient safety considerations, international standards and best-practice requirements may not be able to facilitate all end-user training feedback or change requests (**Figure 10**).

*3.3.5 Analytical quality of syphilis POC testing*

Since late 2018, services enrolled in the ESR program have participated in 17 EQA testing events, with four events per year and two samples tested per event. The EQA material is prepared and distributed by the RCPAQAP (as part of their serology program) and contains both non-reactive and reactive samples with varying concentrations of syphilis antibodies and therefore degrees of reactivity. Concordance with the expected EQA result has averaged 98% (range 93–100%) in the ESR program. For the WA program, which commenced in late 2020, concordance (using the same EQA material and event sequence) has averaged 96% (range 80% during the initial set up of the program to 100%).

Similar to elements of training and competency (described above), assessment of POC test performance via specific requirements for QC and EQA are non-negotiable. Robust quality systems, capable of detecting false negatives or false positives (or quantitative performance at clinically important decision points) underpin POC test result quality and patient safety.

Important to ID POC testing models, where disease prevalence can change from low to high in geographical populations over time, is consideration of the monitoring of QC performance and adoption of individualised QC plans (IQCP) [41]; these plans provide flexibility with changing patient risk (i.e. false negatives and false positives) and permit the customisation of QC plans according to test method and

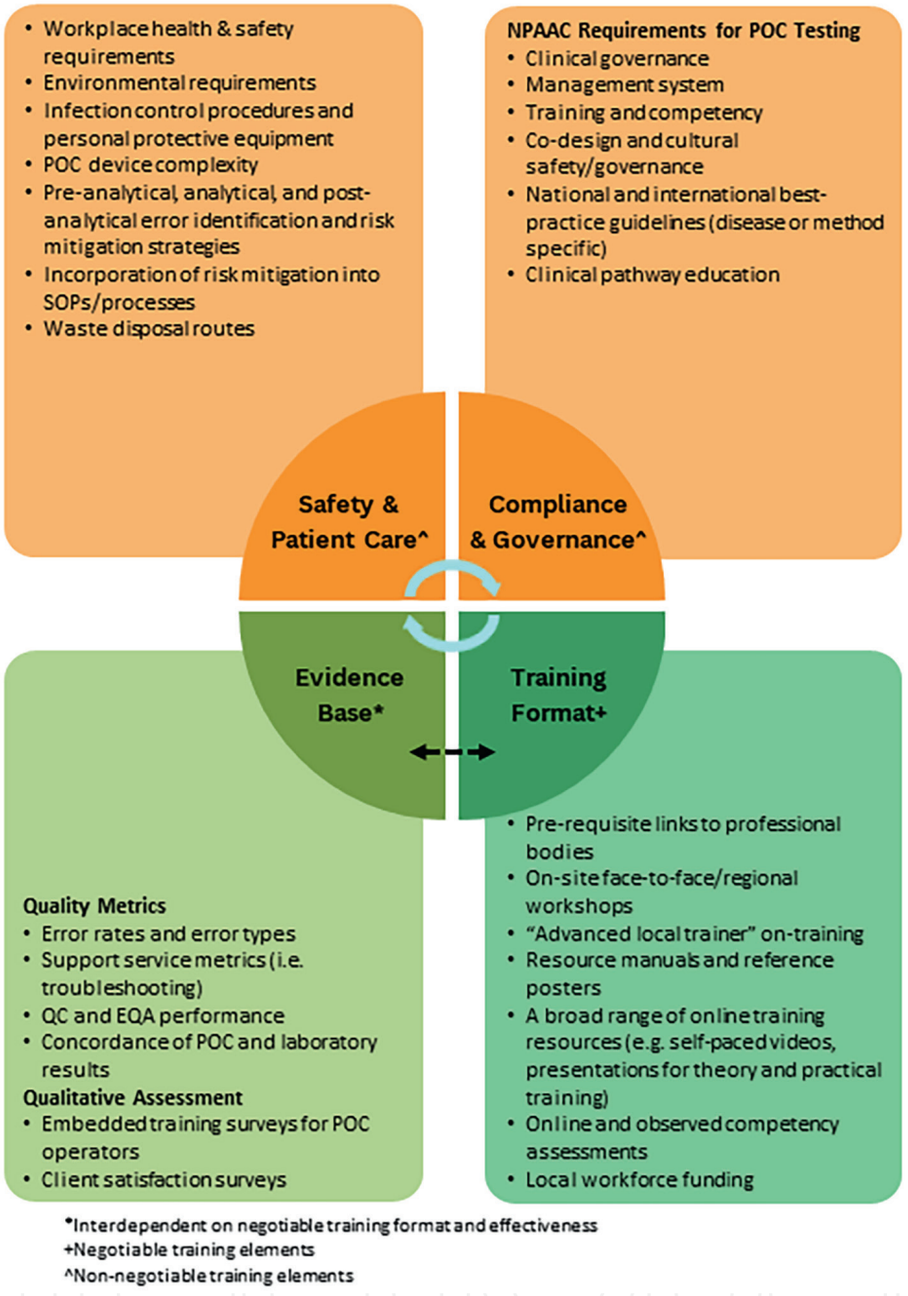


**Figure 10.**
*A framework for the design and continual quality improvement of POC operator training, with elements that should be considered as negotiable, non-negotiable and interdependent.*

use, environment, and personnel competency while providing for equivalent quality testing. IQCP could potentially be considered as an additional regulatory option for POC testing in Australia.

### 3.4 Concluding remarks: implications for POC testing moving forward

Many lessons have been learned from 25 years of implementing POC testing networks in rural and remote Australia. The building blocks to optimise a POC testing network have come together in somewhat of a jigsaw (**Figure 11**) but are now well established following a strong evidence-base of original research and quality improvements carried out along the journey. The optimisation and scale-up of POC


**Figure 11.**
*Building blocks for the development, implementation and ultimate scale-up of a POC testing network—Compiled from lessons learned from ICPOCT experience over nearly 25 years.*

testing models remains a 'hot topic' in research conducted around the world in the field [42–44].

Where possible, POC testing scale-up should be accelerated to meet the time frame deemed necessary for the model—depending for example on whether it is a test for NCD versus an ID test that may be required for a disease outbreak or global emergency response. In this regard, ICPOCT remains at the cutting edge of this field through (a) its partnership with the Kirby Institute in an NHMRC-funded Centre for Research Excellence looking at scale-up of POC testing systems (now known as RAPID) and (b) its designation as a World Health Organisation (WHO) Collaborating Centre working *inter alia* on POC testing for sexually transmitted diseases and current gaps in health literacy for NCDs.

There remains considerable blue sky for methodological advancement, technological miniturisation, personalised scope and application of POC testing systems, particularly in rural and remote settings of the world and to service disadvantaged populations. But, as mentioned in the opening remarks for this chapter, success is dependent on policy change and support from governments. Our Australian models have benefitted from continuous funding from governments, albeit with contractual agreements needing to be negotiated repeatedly in time frames as short as 6 months. Ideally, successful models which can demonstrate clinical, operational, economic and cultural benefits as well as sustained analytical quality equivalent to a laboratory, should be underpinned by long-term, integrated funding where possible. This includes ongoing support for the cost of POC testing devices and cartridges; in this regard within Australia, MBS rebates to cover costs of these essential consumables should be in place for models where clinical need is high and laboratory services are lacking. Until recently the QAAMS Program was the only POC testing network with its own rebates. Recently, an MBS item was approved for the performance of POC HbA1c testing in the general practice (family doctor) sector in Australia. The rebate took effect after many years of negotiation with, and repeated submissions to, the main Government authority responsible for approving new rebate items (the Medical Services Advisory Committee, MSAC). When there is an overwhelming evidence-base to support the need for and quality of POC testing, the discipline of POC testing should be expeditiously supported with sustainable funding models.

## Acknowledgements

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## Conflict of interest

The authors have no conflict of interest to declare.

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