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How to Set Up and Manage a POCT Service

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Various point-of-care testing (POCT) models for early detection and/or management of chronic diseases in rural Aboriginal communities were discussed earlier in this issue of The Clinical Biochemist Newsletter.[1] In this paper these models are used to provide practical examples of how to set up and manage a viable and sustainable point-of-care testing (POCT) service, whether it be in a general medical practice (GP) clinic, Aboriginal health service, or hospital service or clinic. The general principles are shown in Figure 1 and are aligned very closely with the national Interim Standards for Point of Care Testing in General Practice in Australia[2], as well as other international guidelines.[3-4]

1. BEFORE INTRODUCING A POCT SERVICE

Identify the Clinical Need

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Select a suitable POCT Instrument
(a) Survey the range of available POCT Instruments
(b) Establish the analytical expectations of the POCT Instrument
(c) Validate the technology prior to purchase
(d) Establish the impact on organisation and infrastructure of the practice

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Economic Considerations
- Weighing up the Cost versus Benefits

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2. ORGANISATION AND MANAGEMENT OF THE POCT SERVICE

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Clinical Governance/Organisation and Accountability

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Staff Training and (On-going) Competency Assessment

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Documentation of Policies and Procedures
- The Standard Operating Procedure manual

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Implementation of the Routine POCT Service

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Maintaining Total Quality Assurance and Assessing Quality Outcomes

Figure 1. General Principles in Establishing a Point-of-Care Testing Service.

Planning a POCT Service

The Needs Assessment

The key principles behind establishing a POCT service include:

- A defined clinical purpose and identifiable benefits, with the ultimate goal of providing optimal quality of care for the patient.
- The provision of an equivalent, if not better, clinical service than is currently available through the laboratory.
- A service that is tailored to local needs.

Practical examples from our own experiences include the Western Australian site (Kalgoorlie) in the POC in Aboriginal Hands Program, where the POCT service was needed because there was an identified significant burden of chronic disease in this region. The clinical purpose for introducing the service was for the risk assessment and management of patients referred to or attending the diabetes and heart clinic at the health practice. The intended benefits of introducing POCT were as follows: Clinically, the practice doctors wanted to decrease the time to initiate or change treatment and provide more timely counselling for patients. POCT would potentially provide a more readily accessible, convenient service for patients that would improve their self-motivation and compliance with medication. From the health practice's perspective, being in control of this improved POCT service was crucial.

With the Umoona Kidney Project, the POCT service was needed because there was community concern (particularly among elders) at the number of community members undergoing dialysis at Alice Springs, Port Augusta and Adelaide, with their subsequent dislocation from the community. The clinical purpose for introducing the POCT service focused around the community's desire to stem the tide of renal disease through an early detection and prevention program of which they were in control. The community also had very limited access to laboratory pathology. Clinically, POCT would enable early identification of renal disease leading to more rapid initiation of treatment to prevent or delay the onset of the disease and its complications. Community members would also have access to a previously unavailable preventative renal disease service for which there was an identifiable need.

Selecting a Suitable POCT Instrument/System

Having established the need for a POCT service, the next step is to select a suitable POCT instrument. Key principles are[2]:

- Survey the range of currently available POCT devices that can perform the tests needed but be aware that the choice may often be very limited.
- Establish the analytical expectations of the POCT instrument.
- Validate the technology prior to its introduction to routine practice.
- Establish the impact of the introduction of POCT on practice organisation and infrastructure.

Extensive material exists in the peer-reviewed literature to assist with determining all these principles, including an internationally recognised, multi-tiered hierarchical pproach to setting desirable performance standards based on clinical outcome studies, biological variation, opinions of professional groups and data from proficiency testing programs and the general literature.[5] Searching the literature should always be supplemented with discussions with professional colleagues who have hands-on, practical field experience and knowledge of POCT systems.

Such discussions often reveal that POCT systems do not necessarily always meet expectations and there is a need to undertake your own internal validation, as the following example from our own experience shows.

One of the sites in our Point-of-Care in Aboriginal Hands program wanted to introduce a POCT system to measure a common blood marker of renal function to improve the service provided as part of their monthly renal clinic (conducted by a visiting renal specialist from Perth, Western Australia). The system was initially evaluated in the laboratory by one of our Community Point-of-Care Service scientists. The candidate POC instrument showed an unacceptable 20% positive bias in our patient comparison with the laboratory method (Figure 2). Poor precision (CV 8%) was also observed at a critical decision level for patient management and an unacceptably high (17%)

Figure 2. An example of a POCT device that did not meet analytical expectations.

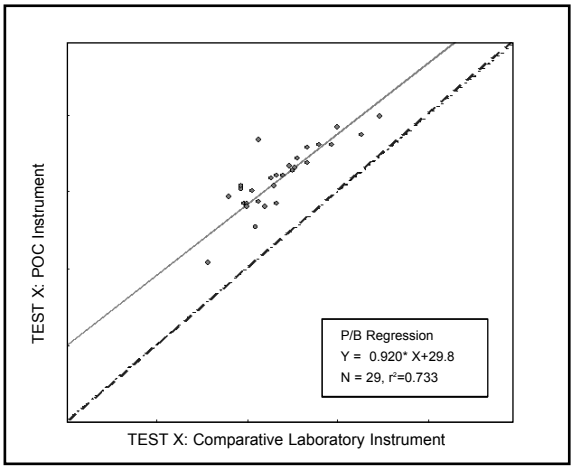
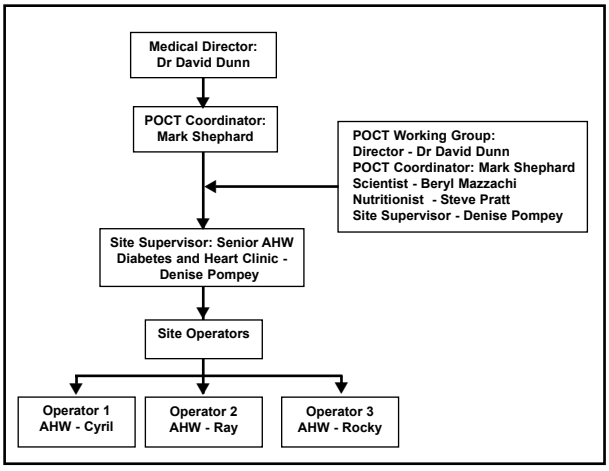


Figure 3. Organisational Structure used in one of our sites in the Point-of-Care in Aboriginal Hands Program.



cartridge error rate was found, indicating the system was not robust. A trained operator from the Aboriginal health service then conducted an on-site evaluation of the technology. Poor agreement was found between the marker measured in the clinic and the local laboratory (confirming the accuracy problem) and there was a one-in-five cartridge error rate in the clinic (verifying its unreliability). In this case, the POCT instrument was not introduced routinely. Results of our laboratory and field investigations were reported back to the manufacturer who subsequently took appropriate action (through calibration and software modification) to improve the analytical specifications of the analyser.

As well as analytical performance, consideration needs to be given to the impact of the introduction of the POCT service on the organisation and infrastructure of the health practice. This involves an assessment of some or all of the following factors[2]:

- Physical (non-analytical) attributes of the POCT instrument
- Expectations of the staff
- Projected future work-loads and/or patterns of testing
- Spatial requirements
- Health and safety aspects

Economic Considerations - Weighing Up Cost Versus Benefits

One of the greatest challenges of POCT is to determine the costs of setting up the service versus the defined benefits, given that there are many hidden costs that need to be taken into account when determining the 'true' or total costs of POCT.

Fixed capital costs include some or all of the following[2]: the instrument itself, an annual fee for participation in external quality assurance (EQA) programs, an annual service contract fee with the vendor, fees for accreditation compliance and/or licensing, an external quality management service fee (where a practice may be paying a laboratory or a consultant group to assist in managing their POCT service for them), and ancillary infrastructure (for example site alterations such as new plumbing, power outlets, fridges, centrifuges and computers).

Variable costs (those dependent on workload) include[2]: reagents (allowance needs to be made for wastage due to actual usage not meeting expected workload and cartridge errors), consumables, quality control materials, calibrators, staff time (that is, time required to perform the total testing process - not just analytical - and time required for training/retraining and maintenance of professional competency), personal protective equipment (gloves, gowns, eye protection and face masks), waste disposal and infection control.

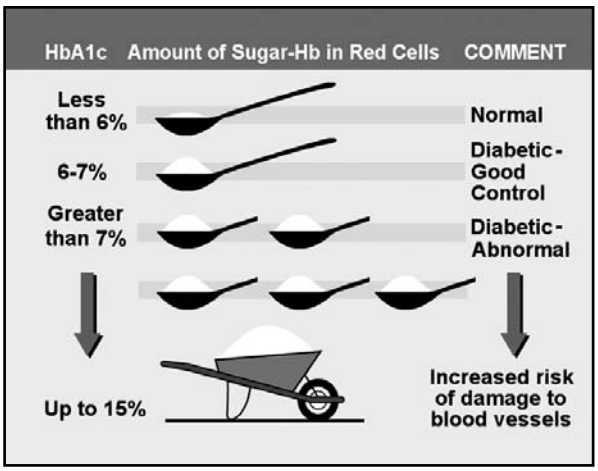
Don't be surprised if the initial cost of setting up POCT is higher than that of the equivalent laboratory service where economies of scale can be factored in. Although much more difficult to quantify, the most appropriate assessment of the cost-benefits of POCT needs to take into consideration the 'total episode of care' - where the potential longer term benefits of POCT such as future reduced length of hospital stay, reduced readmissions, and reduced complications of a disease process are taken into account.

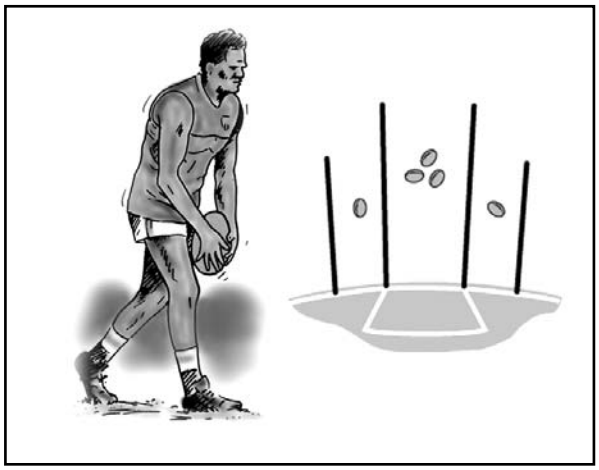
Organisation and Management of the POCT Service

Clinical Governance/Organisation and Accountability

The organisational structure behind one of the sites in the POC in Aboriginal Hands program (Kalgoorlie, WA) demonstrates all the key principles and features required for POCT governance and accountability[2] (Figure 3).

Figures 4a and 4b. Examples of how to translate complex medical and scientific concepts into readily understandable messages for non-laboratory staff using POCT.





Clinical governance and ultimate responsibility for the POCT service lies with Dr David Dunn, the Medical Director at the practice. The author is the POCT Coordinator (working externally from nearly 2000 kilometres away). My responsibilities include overall supervision and management of the POCT service and ensuring compliance with the policies and quality standards required by the practice.

Our POCT Working Group comprises the Medical Director, the POCT Co-ordinator, a supporting scientist from the Community Point-of-Care Services unit (again external to the field site), the practice's nutritionist who doubles as their IT support person, and the Senior Health Worker responsible for the service's diabetes and heart clinic. There are as many as three Aboriginal Health Workers acting as Site Operators at any one time.

If the POCT Co-ordinator is not located on-site, then the importance of regular site visits by this person cannot be overemphasised. It is critical to develop a rapport with the health professionals with whom you are working and with the broader community during (and between) site visits.

During field visits to sites in our POC in Aboriginal Hands Program, training is reinforced, interesting cases are discussed, the latest QC/EQA results are reviewed, reagent audits conducted, updated summaries of results are presented to the POCT Working Group and formal presentations to the Board of the Health Service are made when appropriate. We have also prepared community posters that are used to promote local ownership. We regularly give presentations (and feedback) to the local community members to raise awareness of our programs and services and attend community functions and health promotion activities (such as the Kalgoorlie Show, the Port Lincoln Aboriginal Women's Centre's nutrition day and a chronic disease cultural awareness day at the Coober Pedy Area School).

Staff Training and On-going Competency Assessment

A fundamental principle of POCT is that testing should only be carried out by staff who have undergone appropriate initial training (by the POCT Co-ordinator), who have their competency levels regularly assessed (certified), and who participate in regular retraining sessions. [2]

Our experience shows that important points to consider when designing and delivering a training program include:

- Keep the key messages simple (bearing in mind non-laboratory staff may not be the least interested in intricate scientific or medical detail).
- Pitch training at a level that is appropriate for the group being trained
- Ideally, train people in small groups to enable each person to experience using the POCT technology in a 'hands-on' sense and gain confidence. Do not let staff sit back and say 'they'll do it later'!
- Encourage a representative from the manufacturer of the POCT device to be involved in supporting training.

With our working POC models, we have been presented with the challenge of translating complex scientific, medical or laboratory concepts into culturally appropriate images that can be readily understood by an Aboriginal health professional team. The importance of such a translation is even more important when one considers that the transfer of information in Aboriginal culture is based on the spoken word and visual images.

Using examples from our work, the relationship between Haemoglobin A1c (HbA1c) and control of diabetes has been portrayed by using spoonfuls and wheelbarrows of sugar (Figure 4a). HbA1c has been described simply as sugar that is attached to haemoglobin in the red cells of the body. In discussing the concept of accuracy and precision, the analogy of an Australian Rules footballer having kicks for goal has been used (Figure 4b).

Highly visual laminated posters with simple step-by-step instructions to consolidate detailed information into a practical, workable format have also been used to show how to perform a POC test and how to conduct quality-testing procedures.

Two critical factors learnt from our working POCT models are that:

- Retraining and continuing education are the keys to a successful and sustainable POCT service.
- The biggest challenge for the sustainability of a POCT service is unquestionably the high rate of staff turnover across the lifetime of the program.

As an example from our national 'QAAMS' Program for point-of-care HbA1c testing on the Bayer DCA 2000, Service 19 was ranked number one in the program for their precision and accuracy base in Cycle 5 (July to December 2001). One particular female Aboriginal Health Worker who was the key operator at this site achieved this sustained level of excellence. However, she was absent from the service across Cycle 6 (January to July 2002). Another health worker who had less experience with the DCA 2000 and who did not attend our annual QAAMS Training Workshop that year took responsibility for QAAMS testing during Cycle 6. Participation rate fell, while the service's precision and accuracy ranking deteriorated significantly (Table 1).

Table 1. The effect of training on POCT performance, when a trained and highly skilled Site Operator (Cycle 5) was replaced with a less skilled Site Operator (Cycle 6).

Cycle	Participation Rate (%)	Precision Base		Accuracy Base	
		CV%	Rank	Bias	Rank
5	100	1.5	1	0.08	1
6	66	3.7	41	0.11	20

Documentation of Point-of-Care Policies and Procedures

The Interim Standards for POCT in general practice state that a Standard Operating Procedure (SOP) Manual (in hard copy or electronic form) should be kept as an accessible and logically organised primary source for describing policy, organisation and management, procedures for training and retraining, and every aspect of the total POCT process.[2] It should be used as the reference point against which the quality of the POCT service can be assessed.[2]

In adopting the above principles for our fieldwork, we have made the maximum use of diagrams and flow charts in order to simplify written information because, in an Aboriginal setting, a 200-page blandly written Standard Operating Procedure manual simply won't be read or used effectively.

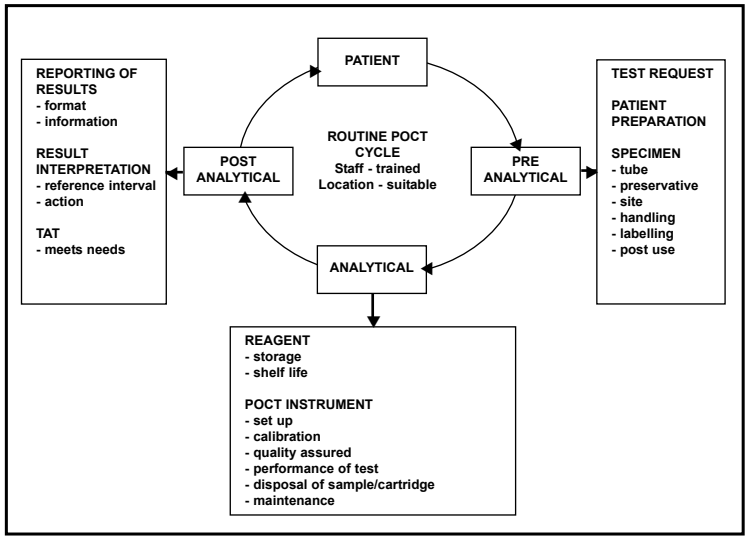
Implementation of Routine POCT Service

Following the extensive planning process described above, routine POCT can now proceed, following the manufacturer's instructions as closely as possible in relation to the device and addressing all the pre-analytical, analytical and post-analytical aspects of the routine POC testing cycle[2] (Figure 5). It is critical for staff to understand the importance of pre-analytical and post-analytical factors on the effectiveness of a POCT service.

An example of how quality of POC results can be affected by pre-analytical factors was observed in a recent evaluation by our group of the HemoCue (HemoCue AB, Sweden) point-of-care analyser for whole blood haemoglobin measurement. In our hands, this POCT instrument demonstrated excellent accuracy and precision when both horizontal and vertical inversion of the whole blood sample prior to analysis was undertaken in accordance with the manufacturer's instructions.[6] However, if mixing was performed by horizontal rotation only (that is, without vertical inversion and not according to manufacturer's instructions), then the perceived accuracy base of the test suffered and the specificity and positive predictive value of the test for anaemia fell from 100% in both cases to 86% and 73% respectively. This was not the fault of the instrument per se but rather it was due purely to pre-analytical error.

In terms of post analytical factors, a POCT device may provide very rapid results but the overall POCT service will be flawed if result reporting and delivery to the doctor does not occur in a timely fashion. Results should be stored accurately, ensuring continuity of the patient record, and be readily accessible in accordance with a well-defined result audit trail.[2]

Figure 5. The total point- of- care testing cycle.



Maintaining Total Quality Assurance and Assessing Quality Outomes

All POCT services should be monitored and evaluated regularly to ensure the program is complying with POCT policies and procedures (as documented in the SOP Manual) and meeting the needs of both providers, patients and the practice overall.[2] This requires internal quality control testing and participation in external quality assurance (or proficiency testing) programs, which enables a practice's POCT system to be subjected to peer review assessment by comparing their POC results with those from other sites using the same technology.[2] Participation in external quality assurance is considered a mandatory requirement for general practices in Australia wanting to take up POC testing.[7]

Conclusions

There are many challenges to establishing a viable POCT service and clinical scientists might feel daunted by the task. However a final example from one of the POCT sites in the national QAAMS program for HbA1c testing shows what is possible with good planning and support. The site in question is located in a very remote desert region of the Western Australian outback, 700 kilometres from the nearest town. It receives mail delivery by plane once a week, is connected to the outside world by a satellite phone link that regularly breaks down and strands the service from outside communication for days at a time, experiences regular power fluctuations, and has only one POCT Site Operator at the practice, who is required to look after the health of nearly a thousand Aboriginal people. Despite the overwhelming disadvantages of distance and lack of resources, this site has maintained a 90% participation rate since the QAAMS program began in June 1999 and is regularly ranked in the top 25% for its analytical performance base.

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