

### A laboratorian's experience of implementing multiple point-of-care testing in HIV antiretroviral treatment clinics in South Africa

**To the Editor:** Point-of-care testing (POCT) is a top agenda item for healthcare providers. What, where, when and how to implement it is under investigation, and a current focus of my research: 'To determine the feasibility of implementing multiple POCT in clinics for HIV ART initiation.'

I left the safe laboratory environment where anonymous specimens were tested within a rigid quality structure, governed by a framework of good clinical laboratory practice principles

(GCLP),<sup>[1]</sup> and entered the clinic environment of smiling faces, cute children and what appeared to me to be total chaos. The SEAD report<sup>[2]</sup> was not encouraging, but I took the plunge and went on a road trip with my team.

We visited 12 clinics in Gauteng, North-West and Free State Provinces, and just the poor road infrastructure in many places was realisation enough of the difficulties that patients and laboratory specimen couriers face. There was great variation across clinics, in terms of suitable space for POCT testing; all sites required some renovation that ranged from installing a bench and security gate, to erecting pre-fabricated structures. All clinic staff welcomed our presence. Not one refused the idea of POCT, but all claimed that they had no time to perform POCT and that this function would require a dedicated 'lab person'. Our research showed that performing multiple POCT (CD4, Hb, ALT, creatinine, lactate and TB GeneXpert (Cepheid, Sunnysvale, CA)) requires about 22 additional tasks. Removing a nurse from her current NIMART<sup>[3]</sup> duties for POCT seems extreme and costly. We showed that counsellors easily performed POCT. However, in South Africa (owing to HPCSA, SANAS, etc. regulations), these personnel are currently unable to perform phlebotomies. 'Ah, don't worry, all the POCT we needed could be performed on finger-stick'. Problem solved ... or is it? For implementing these numerous POCTs means that patients require >3 finger-stick procedures/visit after HIV counselling and testing (HCT). We obtained ethics approval to perform several finger-stick procedures on patients. To our surprise, all patients preferred finger-sticks over venepuncture. We remain cautious because research shows that performing CD4 cell-based assays with capillary testing (such as PIMA (Alere Healthcare)) increased variability<sup>[4]</sup> and was associated with high error rates.

Can nurses perform multiple POCT and be trained in GCLP? The answer is 'Yes', but there are issues concerning computer literacy for using GeneXpert. The other issue with computers is secure data recording. The IT engineer who travelled with us reminded us constantly that, without connectivity, we would not be able to manage POCT data. This means that without a 'laboratory information system' (LIS) through which the National Health Laboratory Service (NHLS) links their testing platforms to a central data warehouse, POCT results would not be collected. Even if we did have a connectivity solution, several POCT platforms would not be able to connect.

Another hurdle for POCT is throughput: Clinic staff told us that the 'magic patient number for ART initiation/day' is 5, which fits with POCTs, but many more would have to be tested each day to select those 5.

One aspect I had not appreciated was that clinics were less busy, or even empty, in the afternoons. This seemed great for clinic staff and patients, but a shame for the POCTs that are especially time-consuming: Each PIMA CD4 test takes 20 minutes; but adding 3 other POCTs takes >1 hour. Not to mention the GeneXpert test at POC: If the clinic has a Gx4, 4 results take about 2½ hours; so if you are the 5th patient, it takes 5 hours for a result. One of our studies also showed that successful use of GeneXpert requires 2½ personnel to ensure that 15 patients receive same-day treatment.<sup>[5]</sup>

Sadly, we also experienced high clinic staff turnover, HCT kit shortages, the occasional clinic where ART initiation was only conducted once per week, and the usual unstable power supply. All contribute to disruption of services, both clinical and POCT. When patients heard we were providing POCT for a research project, patient numbers increased and further strained services.

If POCT is to be provided for **all** in the massive national HIV programme in South Africa (~2 million HIV viral loads and ~4 million CD4 tests performed by NHLS in 2012), and if equity is to prevail, POCT will need to be placed in ~3 500 clinics. The dilemma for POCT providers is 'scale up or go home'. Experience with the National Department of Health and NHLS's GeneXpert programme in 2011 showed that a phased implementation plan was required to manage the pace of technical and clinical training, site readiness and instrument installation. Even this was affected by stock-outs of kits.

So back to the road trip. We started to appreciate the enormous task that nurses face in caring for large numbers of patients. We learned to appreciate clinic workflow and that it is not just about turnaround time, since we showed that 72% of laboratory results were returned to the clinics within a day. Why then does it take weeks to initiate ART; and will same-day POCT really hasten this process, while appreciating that patient counselling, to assure acceptance and adherence, is also necessary?

As a laboratory scientist, I actually enjoy the clinic environment. I realise that POCT will require partnerships between laboratories and clinics. I value even more the multidisciplinary team approach to improving South Africa's healthcare, especially in view of the coming NHI. There is much work to be done, and perhaps laboratories need to consider providing POCT 'mini-labs' to service hard-to-

reach places. Clinics could modify their workflow to decrease ART initiation times. Both should work on connectivity to improve current paper-based systems and introduce the much promised 'unique identifier' to link the two.

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