

## Rapid point-of-care tests for HIV and sexually transmissible infection control in remote Australia: can they improve Aboriginal people's and Torres Strait Islanders' health?

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Point-of-care (POC) diagnostic tests conducted at the time of the patient visit have the potential to improve treatment and management of curable sexually transmissible infections (STI) such as chlamydia, gonorrhoea and trichomoniasis. For Aboriginal and Torres Strait Islander remote communities, STI remain an important and long-standing public health issue. They are associated with serious sequelae including pelvic inflammatory disease, infertility and systemic disease,<sup>1</sup> and are particularly prevalent in remote communities.<sup>2</sup> In 2009, chlamydia and gonorrhoea notification rates for Aboriginal and Torres Strait Islander peoples were very high at 2620 and 2252 per 100 000 population,<sup>2</sup> respectively, equating to chlamydia and gonorrhoea prevalence above 10% in many remote communities. HIV diagnosis rates in the same communities remain low at 1 per 100 000 population in 2009.<sup>2</sup>

STI management and prevention in remote communities is predominantly the responsibility of primary healthcare services with numerous competing priorities such as child and maternal health, chronic disease and acute emergencies. In this setting, optimal STI care is hampered by delays in receiving laboratory results and recalling patients for treatment, with previously reported time to treatment of 21 days.<sup>3</sup> Seldom has success been achieved in remote areas in reducing community prevalence of STI. One long-term STI program that reduced the community prevalence of STI achieved treatment rates of 94% with an average time to treatment of just under 2 weeks.<sup>4</sup>

Currently, several POC tests are commercially available for the detection of STI and HIV but are not currently approved as screening tests by the Therapeutic Goods Administration

(TGA). As technological advances occur in chlamydia and gonorrhoea POC tests, there is the potential to improve STI management outcomes without presenting an unacceptable burden to clinicians. In this paper, we describe the rationale, benefits and risks of introducing POC tests for STI and HIV in remote Aboriginal or Torres Strait Islander communities.

A precedent is already established for the use of POC tests in Aboriginal and Torres Strait Islander communities through the Quality Assurance Aboriginal Medical Service program. This program involves more than 100 health services using POC testing for diabetes management, and has shown that POC testing is clinically effective and culturally appropriate, and has enabled Aboriginal health workers to have a greater role in treating diabetes.<sup>5,6</sup>

Globally, the use of POC tests for STI and HIV is increasing. HIV POC tests are the standard of care in many developing countries, and are used for screening high-risk groups in some developed countries. Syphilis POC tests are gaining momentum in developing countries, and chlamydia, gonorrhoea and trichomoniasis POC tests have also been developed and are being refined.<sup>7</sup>

The POC tests vary in regard to their ease of use, recommended specimens, procedures and accuracy. In regards to chlamydia, the Chlamydia Rapid Test appears the most promising, with a recent meta-analysis demonstrating a pooled sensitivity estimate of 80% for vaginal swab specimens and 77% for centrifuged urine specimens, and a specificity of 99%.<sup>8</sup> There have also been a number of PCR-based STI POC tests recently developed which detect multiple

infections. Evaluations are underway on their performance. The Determine HIV1/2 Ag/Ab Combo 4th generation POC test has been reported to have a very high sensitivity of 100% in established infections and a specificity of 99.5%.<sup>8</sup> A few POC tests for detection of gonorrhoea have been evaluated with sensitivity estimates ranging from 53% to 94%.<sup>9,10</sup> New syphilis POC tests are now able to differentiate recent and past infection with high sensitivity and specificity estimates of >95%.<sup>11</sup> However, these tests are unable to provide the rapid plasma reagin titre required to track the serological response to treatment. None of these HIV and STI POC tests have been evaluated in Australian settings, although some trials are underway.

Test characteristics which make a POC test particularly suitable for use in remote Australian communities would closely follow the requirements of the 'ASSURED' criteria of the World Health Organization STD Diagnostic Initiative: affordable, sensitive, highly specific, user friendly, rapid and robust, equipment free, and deliverable to end users.<sup>12</sup> Ideally, a POC test for use in this setting should have the ability to diagnose chlamydia, gonorrhoea and trichomoniasis from a single specimen, and a multiplex single test would be highly beneficial.

There are many potential benefits related to the use of chlamydia and gonorrhoea POC tests. The tests could provide an almost immediate result in clinic settings, enabling clinicians to offer treatment and begin the process of partner notification at the same consultation.<sup>13</sup> This process could reduce the time to treatment of positive cases and their contacts, which may, in turn, reduce re-infections and ongoing transmission. The POC tests may also alleviate the need for a second consultation and staff time consumed by recalling patients. The POC tests may also minimise the extent of over-treatment due to syndromic management, which is recommended current practice in many regions.

However, STI POC testing would lengthen the consultation due to the need to centrifuge urine to maximise sensitivity and wait 10–20 min for the result, which could impact on patient flow. This time could be accommodated by other health educational activities but would result in other opportunity costs. There would also be a need to develop protocols for the communication of 'positive' or 'preliminary positive' results, when contact tracing should be initiated, and for the management of false-positives and negative results (evident when polymerase chain reaction (PCR) results are returned); and more resources would be required to counsel patients about the new 'preliminary' test. Although the positive predictive value of the POC test is much better in remote communities than urban settings because prevalence is higher (Table 1), use of the POC tests would miss more infections (20%) compared with PCR (<10%). From a cost-effectiveness point of view, it might be better to use only a POC in these remote settings or, as shown by Gift *et al.* in settings where chlamydia prevalence is high, a two-test algorithm involving a rapid POC test followed by a more sensitive PCR laboratory test may be still be cost-effective<sup>13</sup> despite the additional resources required. These calculations are influenced by the loss to follow-up rate and other factors, so local cost studies would be required.

HIV POC tests have the potential to reduce the time required for a preliminary positive result, and could have a limited role in populations of known high incidence or prevalence with minimal infrastructure. However, any positive HIV POC results would still need to be confirmed by standard HIV serology and Western blot. Even with high specificity, the use of HIV POC tests in a low HIV prevalence population such as remote communities will result in a high proportion of positive tests being false-positives, which could erode confidence in the POC test and inflict harm on individuals and communities. For example, in a large health service in a

**Table 1. Hypothetical performance of the use of chlamydia point-of-care (POC) tests in a remote Aboriginal community compared with a young, urban heterosexual population**

Note: This assumes that the chlamydia POC test has a specificity of 99% and a sensitivity of 80%, and that polymerase chain reaction (PCR) has a specificity of 99% and a sensitivity of 95%

	Testing strategy	Expected chlamydia incidence (%)	Ratio of true-positive to false-positives POC results	Positive predictive value of a reactive POC test (%)	% infections missed
Remote Aboriginal community	POC	10 <sup>2</sup>	8.9 : 1	89.9	20
Young urban non-Aboriginal heterosexual population	PCR	4.5 <sup>14</sup>	4.5 : 1	81.8	5

**Table 2. Hypothetical performance of the use of HIV point-of-care (POC) tests in a remote Aboriginal community compared with an urban population of gay men**

Note: HIV POC test is assumed to have a specificity of 99.5% and a sensitivity of 100%

	Expected HIV incidence (%)	Ratio of true-positive to false-positives	Positive predictive value of a reactive HIV POC test (%)
Remote Aboriginal community	0.001 <sup>2</sup>	1 : 500	0.2
Urban gay male population	1.24 <sup>15</sup>	3 : 1	71.5

remote Aboriginal community conducting 1000 HIV tests per year, none or one HIV infection would be diagnosed in 10 years, and for each true HIV infection, there would be 500 false reactive results, equating to a positive predictive value of 0.2% (i.e. a reactive HIV POC would have a 0.2% chance of being a true infection (see Table 2)). This compares with testing gay men in an urban setting where the HIV incidence is 1.24%, where a reactive HIV POC would have a 72% chance of being a true infection (Table 2).

There is also some doubt that a slightly earlier preliminary diagnosis of HIV using POC tests will lead to reduced risk of onward transmission. The major factors in reducing ongoing transmission are likely to be a firm diagnosis and adequate counselling, along with establishing a trusting, ongoing therapeutic relationship with appropriate healthcare providers. Rapid tests afford little or no advantage over standard HIV serology in this regard.

The use of HIV POC tests would also require resources and training for staff to manage false reactive results, post-test support and referral pathways. Given the enormous challenges in providing confidential, long-term care to HIV-positive clients in remote community settings, secure management of patient results early in the diagnosis is critical. In recognition of this, some health services already have processes in place to maximise confidentiality in HIV testing, but rapid testing could compromise these.

Overall, any POC test displaces the burden of administering the test from the laboratory to the health service, so cost-benefit analyses should examine the potential to improve care and patient outcomes against the burden placed onto the remote health service. POC tests are not currently covered by a Medicare rebate, so purchase costs would need to be met from elsewhere or a Medicare rebate sought. Lastly, use of POC tests would require quality assurance systems to be implemented and monitored.

In Australia, there remains considerable question about the role of POC tests in terms of clinician workload, quality assurance requirements and costs associated with these tests. Appropriate further evaluation, particularly of POC testing for STI other than HIV would involve:

- (i) Performance testing of the POC tests (sensitivity, specificity, positive and negative predictive values) and operational characteristics (ease of use, equipment, time to result) in the laboratory and relevant field settings;
- (ii) Assessment of the impact of the POC test on re-infection and disease prevalence rates;
- (iii) A process evaluation in settings where they are likely to be used (patient flow, time to conduct the test, costs incurred etc);
- (iv) Qualitative interviews with clinical staff and patients about acceptability of the POC testing process; and
- (v) Cost-benefit analysis.

It is likely that the degree to which test characteristics conform to many of the ASSURED criteria will ultimately determine their usefulness in remote settings. If cost-benefit analyses suggest an overall advantage to proceeding with STI POC testing as an adjunct to conventional testing, it would be appropriate to pilot the intervention in several

communities, and consider pathways to sustainably fund wider implementation.

The use of STI POC tests for chlamydia, gonorrhoea and trichomoniasis should be a research priority in remote settings to help address the unacceptably high rates of STI rates affecting Aboriginal peoples and Torres Strait Islanders, and the resultant morbidity. Research programs should assess the accuracy of the technology especially sensitivity and positive predictive values in different population prevalence settings, as well the acceptability of these tests from both community and clinician perspectives. The use of HIV POC tests in remote settings cannot currently be recommended due to the low levels of infection and potential harm associated with false-positive results.

### Conflicts of interest

None declared.

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This paper reflects the viewpoints of the authors but not necessarily the communities or health services they are associated with.

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