the TTANGO Trial

Test, Treat and Go
FINAL REPORT TO HEALTH SERVICES

Executive Summary

This report summarises the key findings of the TTANGO (Test, Treat and Go) trial. This trial was funded by the NHMRC and evaluated the differences between conventional laboratory testing versus point-of-care (POC) testing for chlamydia (CT) and gonorrhoea (NG). The trial specifically looked at

- Acceptability and feasibility of POC testing to staff and clients
- Operational performance/accuracy of the POC test
- Uptake and time to treatment for those with a positive POC test result

The POC test used in TTANGO was a new, molecular test - the GeneXpert CT/NG (manufactured by Cepheid) - which uses a similar technology to laboratories to test for CT and NG. The trial was the first time the GeneXpert CT/NG had been used in primary care health services anywhere in the world.

TTANGO was a collaboration between researchers, peak Aboriginal Health organisations, State Government Departments of Health, pathology providers, health service clinical staff and the communities with which they work.

The trial was implemented through 2013-2015 at 12 remote and regional health services reporting a significant burden of STIs. We used qualitative and quantitative methods to assess standard STI diagnosis and management using conventional laboratory-based testing (standard care) compared with POC testing with the GeneXpert (intervention). During the trial, almost 7000 CT/NG tests were done in 16-29 year olds, with similar positivity in both the standard care (405/3432; 12%) and intervention (455/3241; 13%) periods.

TRIAL FINDINGS DEMONSTRATED:

- **Stakeholders, clinical staff and clients indicated POC testing for STIs was highly acceptable in remote and regional settings and made suggestions for future programs**
- **The GeneXpert CT/NG test used by clinical staff at the point-of-care in these settings was as accurate as conventional laboratory-based tests for CT and NG**
- **POC testing and use of these results to guide clinical management was associated with more timely treatment, reducing delays on average by 9 days**
- **Retesting rates (3 weeks to 3 months following a positive test) were low**

NEXT STEPS INCLUDE:

- **Programmatic expansion of POC testing (including enhanced continuous quality improvement, increased testing and retesting) across WA, SA, QLD and NT (TTANGO2) with additional NHMRC, WA Health and Australian Government funding**
- **Introduction of GeneXpert TV POC test for trichomonas**
- **Seamless connectivity between GeneXpert POC test and clinic patient management systems to allow test results to be sent directly and securely into the patient record, just like conventional laboratory test results**
- **Submission to Medicare for rebate for GeneXpert POC test to ensure the program is sustainable beyond the end of TTANGO2**

Key Finding 1

POC TESTING IS ACCEPTABLE

FINDING: POC testing for STIs is highly acceptable to staff and patients in regional and remote primary health services in Australia.

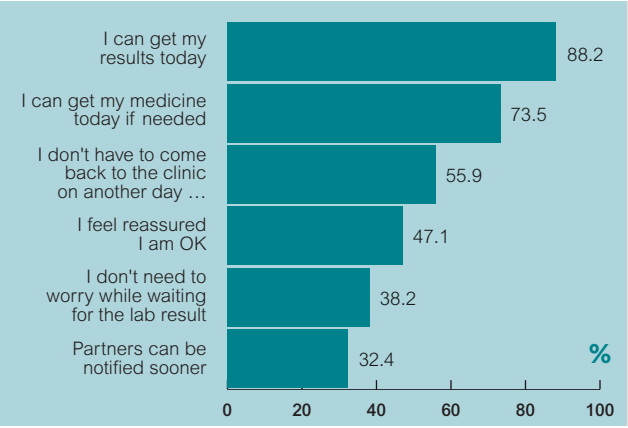
Staff and stakeholders

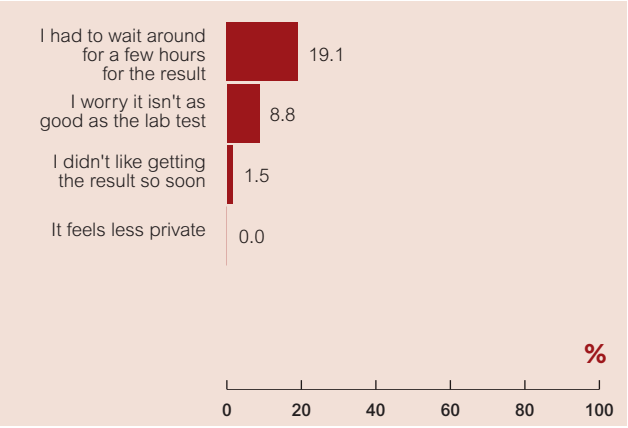
In-depth interviews were conducted with 16 staff (registered or enrolled nurses and Aboriginal Health Workers/Practitioners) who were trained and experienced with GeneXpert testing. These interviews aimed to explore the acceptability of the GeneXpert to primary care staff in regional and remote health services in Australia. Staff overwhelmingly reported a very high level of acceptability with POC testing, but also identified some key challenges to the integration of this POC testing strategy in remote settings.

BENEFITS	CHALLENGES
Useful	Management support
Easy to use and interpret	Staff turnover
Improved management	Connectivity, public health surveillance
Reduced follow-up efforts	Adapting clinic practice – no more presumptive treatment?
Confidence in results	Cost/sustainability
Greater job satisfaction	

Patient Likes and Dislikes

Brief acceptability surveys were completed by patients (n=80) who experienced the POC testing process. The survey included questions exploring patient 'likes' and 'dislikes' about the POC test process. Overall, most patients liked the new POC test and didn't mind waiting for the result.





Findings reported in:

- Natoli L, Maher L, Shephard M, et al. Point-of-care testing for chlamydia and gonorrhoea: implications for clinical practice. PLoS One. 2014; 9(6): e100518.
- Natoli L, Guy RJ, Shephard M, et al. "I Do Feel Like a Scientist at Times": A Qualitative Study of the Acceptability of Molecular Point-Of-Care Testing for Chlamydia and Gonorrhoea to Primary Care Professionals in a Remote High STI Burden Setting. PLoS One. 2015; 10(12): e0145993.

Key Finding 2

GENEXPERT CT/NG POC TEST IS AS ACCURATE AS CURRENTLY AVAILABLE LABORATORY TESTS

FINDING: Compared to the usual laboratory reference tests for CT and NG (NAATs), the GeneXpert CT/NG POC test was highly accurate. Among almost 2500 tests, the GeneXpert test agreed with the laboratory tests almost all of the time (99.4% agreement for CT and 99.9% agreement for NG).

There were only 16 results that did not agree (14 CT and 2 NG). These were most likely the result of relatively low organism loads at the limit of test detection.

Figure 1: *2x2 table showing agreement of results (green) and disagreement of results (red) for CT and NG respectively*

GeneXpert (Gx) test	NAAT+	NAAT-	Total
Gx CT +	209	11	220
Gx CT -	3	2263	2266
Total	212	2274	2486

GeneXpert (Gx) test	NAAT+	NAAT-	Total
Gx NG +	145	2	147
Gx NG -	0	2339	2339
Total	145	2341	2486

Findings reported in:

- Causer LM, Guy RJ, Tabrizi SN, et al. Molecular test for chlamydia and gonorrhoea used at point-of-care in remote primary healthcare settings: a diagnostic test evaluation. *Sex Transm Infect* 2018.

Key Finding 3

POC TESTING REDUCED TIME TO TREATMENT

FINDING: Based on clinical audits conducted at services, of the 16-29 year olds with a positive test in the POC testing arm (n=455), three quarters were treated within 7 days compared with less than half in the standard care arm. There were similar differences in 16-29 year olds for treatment within 2 days (Figure 2). Figure 3 shows this difference in proportion treated within 2 days by health service.

More patients with a positive result on the POC test were treated overall, and those patients also received their treatment much sooner than those having a traditional laboratory test (on average, 9 days earlier).

Figure 2: *Overall treatment intervals in the intention-to-treat population (16-29 year olds), by study arm*

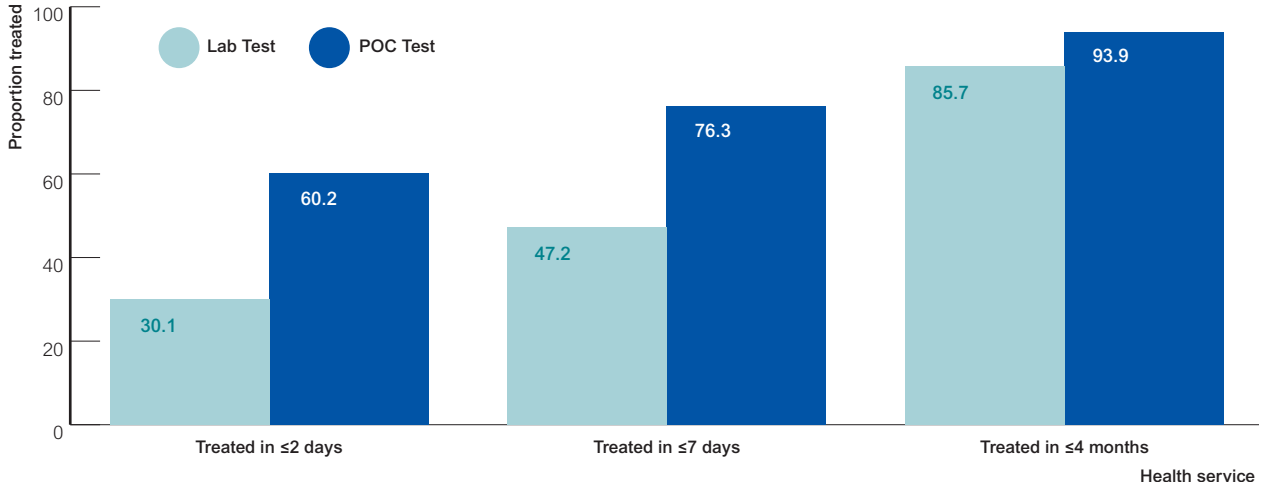
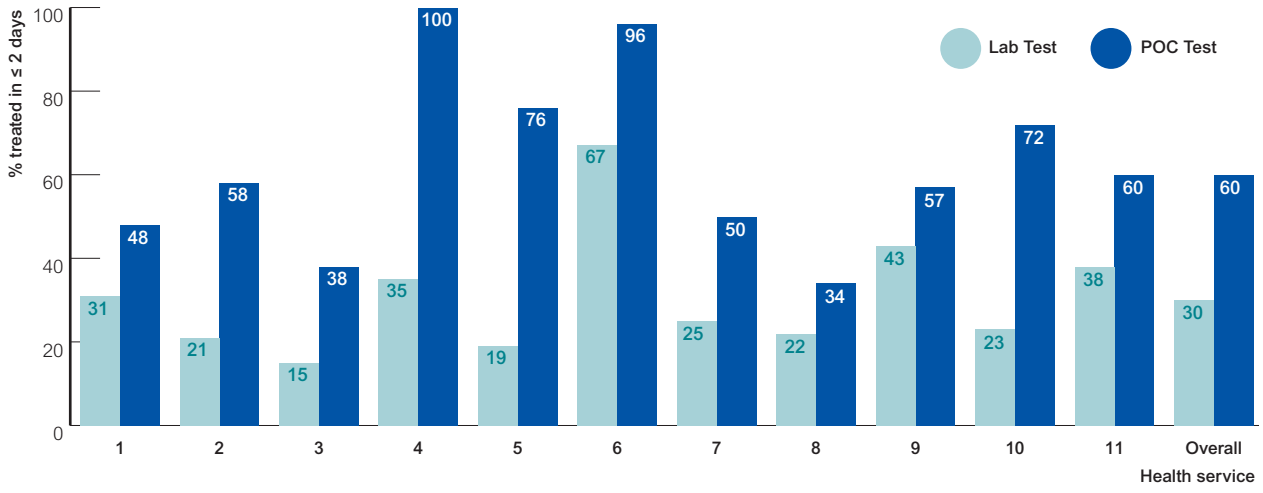


Figure 3: *The proportion of positive CT/NG tests treated in ≤2 days in the intention-to-treat population, 16-29 year olds, by study arm and service**



* data unavailable for one service

Findings reported in:

- Guy RJ, Kaldor JM, Causer LM, et al. A cluster trial of molecular point-of-care tests for sexually transmissible infections: treatment outcomes from TTANGO. Australasian Sexual Health Conference. Adelaide; 2016.

Key Finding 4

RETESTING AND REPEAT POSITIVE TESTS

FINDING: Among 16-29 year olds, retesting rates for those with a positive CT and/or NG result within 3 weeks to 3 months following treatment was low, in both the standard care and intervention periods (16% vs 14%).

Among those retested, between 16-20% had a repeat positive test. There was no difference between the standard care and intervention periods (see fig 4a and 4b below).

Since retesting rates were so low, we cannot draw any final conclusions about this finding.

Figure 4a: *Intervention period (n=455 positive CT/NG tests)*

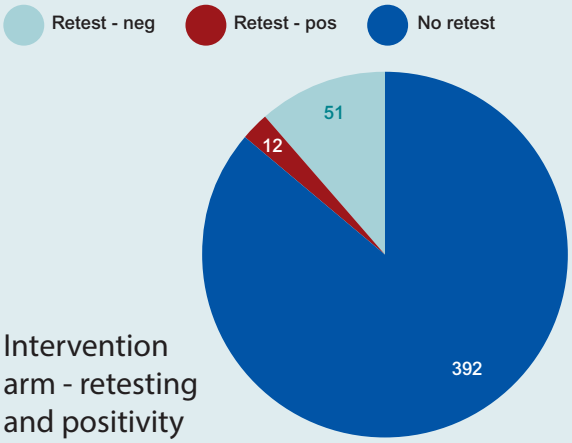
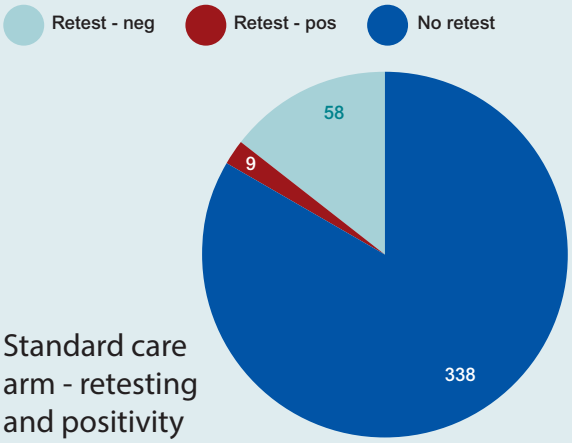


Figure 4b: *Standard care period (n=405 positive CT/NG tests)*



5. Summary

The TTANGO trial provides the first evidence that molecular POC tests for CT/NG diagnosis in regional and remote primary health services with a high burden of STIs improves time to treatment and treatment completion.

This POC technology may lead to other benefits, including reduced re-infection rates, but the evidence will need to come from future studies, which should also explore the sustainability of using this technology and assess operational and cost effectiveness in a range of settings.

Acknowledgements

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Ngaanyatjarra Health Service

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West Australian Country Health Service

PathWest Laboratory Medicine

Western Diagnostics Pathology

Clinipath Pathology

Queensland Health Pathology

Sullivan Nicolaides Pathology

SA Pathology

TTANGO Reference Group

Kirby Institute, UNSW

South Australian Health and Medical Research Institute

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The University of Queensland

Flinders University

University of Melbourne

National Reference Laboratory

Medical Communication Associates

Cepheid

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THANK YOU TO EVERYONE INVOLVED!