Clinical effectiveness, sustainability and quality of a large, decentralised molecular point-of-care testing network for STIs in regional and remote primary care clinics in Australia

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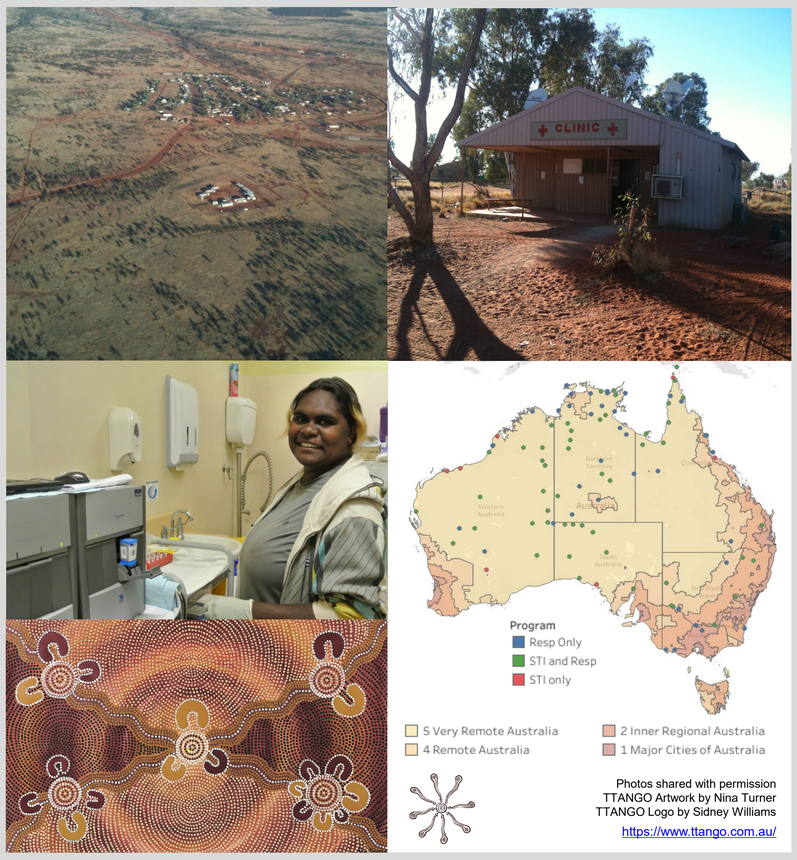
Introduction

- Delays in diagnosis and treatment of STIs occur frequently in remote communities in Australia
- A randomized trial (Test Treat and Go, TTANGO; 2013-2015) in remote clinics demonstrated molecular point-of-care testing (POCT) for chlamydia (CT) and gonorrhoea (NG) improved time to treatment, was accurate, acceptable to stakeholders and cost effective[1-4]
- Since 2016, molecular CT/NG POCT and later trichomoniasis (TV) POCT, has been translated and scaled up to 49 clinics as the national STI POCT program (TTANGO2 and TTANGO3)
- From 2020, molecular detection of SARS-CoV-2 was co-implemented at 105 clinics (Respiratory POCT program),[5] leveraging existing STI POCT infrastructure

[1]Guy et al. Lancet ID 2018 , [2]Causer et al STI 2018, [3]Natoli et al. PLoS One 2015, [4]Watts et al. IHEA 2021, [5]Hengel at al. Lancet ID 2020



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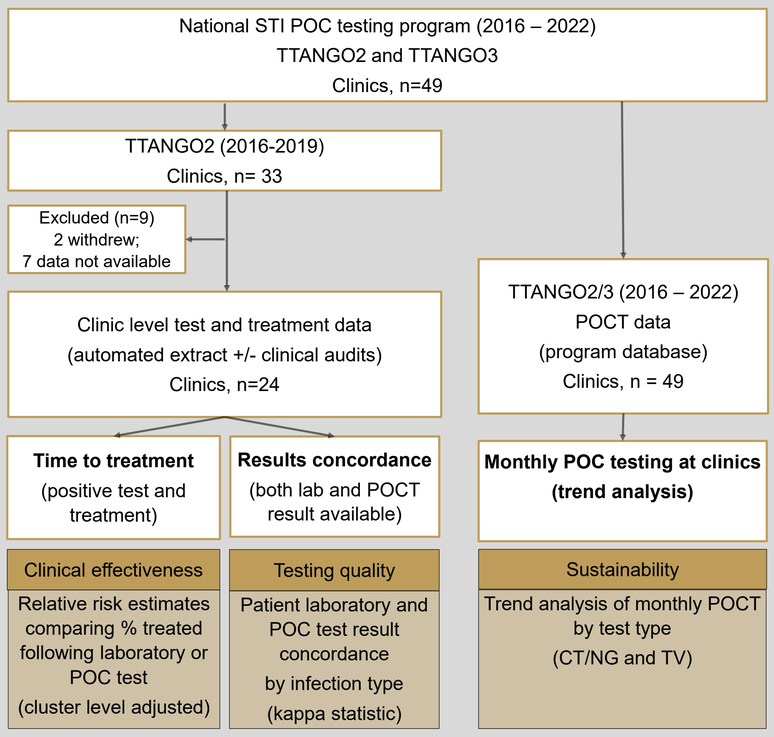
Aim

- To evaluate the clinical effectiveness, sustainability, and quality of STI POCT

Methods

- Using routinely collected clinic and programmatic testing data:
  - i. Measure trend in monthly patient POCT
  - ii. Compare the proportions of patients with positive test results treated in ≤ 2, ≤7 and ≤120 days by test type (POCT vs laboratory)
  - iii. Calculate concordance of patient POC tests with laboratory test results



Positive STI test characteristics (2016 – 2019)

CT/NG	Total	Lab test	POC test	P value
Sex				<0.001
Male (%)	1290 (40.3%)	889 (38.2%)	401 (45.9%)	
Female (%)	1910 (59.7%)	1437 (61.8%)	473 (54.1%)	
Age (years)				0.78 §
Mean (SD)	24.1 (8.3)	24.1 (8.4)	24.0 (8.1)	
Age group				0.44
16-29 years (%)	2514 (78.9%)	1843 (79.2%)	671 (77.9%)	
≥30 years (%)	674 (21.1%)	484 (20.8%)	190 (22.1%)	

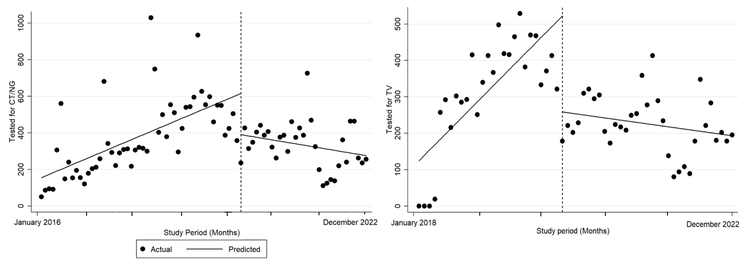
§ t-test

*Overall median age is 22 [interquartile range (IQR) 18-28] years; no difference was found in the median age between laboratory and POC test (p>0.05).

Results

i. Program POCT trends (2016 – 2022)

- 46153 patient POC tests performed



	Mean number observed POC tests per month (tests/months) (SD)	Estimated regression coefficient (95% CI)
CT/NG POC tests		
January 2016 - March 2020§	381 (19,413/51) (211)	9.02 (5.74, 12.31)
April 2020* – December 2022§§	336 (10,747/32) (128)	-3.58 (-7.51, 0.35)
TV POC tests		
January 2018 - March 2020¶	316 (8,535/27) (154)	14.73 (7.17, 22.29)
April 2020 – December 2022¶¶	226 (7458/32) (79)	-2.04 (-4.70, 0.63)

§ 32 clinics; §§ 44 clinics; ¶ 28 clinics; ¶¶45 clinics contributing

Note: Dotted line (April 2020) coincides with Australian public health response to COVID-19 and rapid scale-up and implementation of SARS-COV-2 POCT across the network

ii. Time to treatment (2016 – 2019)

CT/NG positive			Estimated Risk Ratio*	
	Laboratory test P_0	POC test P_1	RR=P_1 /P_0 (95% CI)	p-value
Number of clusters	23	23		
% treated same day				
Overall proportions	30% (696/2327)	65% (579/891)		
Mean of cluster proportions (SD§)	0.27 (0.16)	0.60 (0.29)	2.22(1.61, 3.07)	0.0041
% treated ≤2 days				
Overall proportions	31% (721/2327)	68% (609/891)		
Mean of cluster proportions (SD§)	0.31 (0.15)	0.61 (0.28)	1.97(1.48, 2.62)	0.005
% treated ≤7 days				
Overall proportions	41% (953/2327)	78% (695/890)		
Mean of cluster proportions (SD§)	0.39 (0.17)	0.64 (0.32)	1.64 (1.24, 2.18)	0.02
% treated ≤120 days				
Overall proportions	77% (1781/2327)	88% (787/890)		
Mean of cluster proportions (SD§)	0.73 (0.25)	0.80 (0.29)	1.10 (0.89, 1.36)	0.3845
TV positive				
% treated same day				
Overall proportions (%)	11% (94/872)	35% (99/283)		
Mean of cluster proportions (SD§)	0.10 (0.12)	0.34 (0.32)	3.4 (1.79, 6.47)	0.0145
% treated ≤2 days				
Overall proportions	11% (100/872)	39% (110/283)		
Mean of cluster proportions (SD§)	0.10 (0.13)	0.32 (0.28)	3.20 (1.63, 6.29)	0.0218
% treated ≤7 days				
Overall proportions	19% (169/872)	51% (145/283)		
Mean of cluster proportions (SD§)	0.20 (0.17)	0.45 (0.33)	2.25 (1.41, 3.58)	0.020
% treated ≤120 days				
Overall proportions	51% (452/872)	76% (216/283)		
Mean of cluster proportions (SD§)	0.52 (0.31)	0.62 (0.38)	1.20 (0.83, 1.70)	0.334

iii. Result concordance (2016 – 2019)

	Laboratory test			Kappa statistic, p-value
POC test	Negative	Positive	Total	
Chlamydia trachomatis (CT)				0.94, p<0.001
Negative	3726	17	3743	
Positive	23	345	368	
Total	3749	362	4111 (99.0%)	
Neisseria gonorrhoea (NG)				0.95, p<0.001
Negative	3773	8	3781	
Positive	20	309	329	
Total	3793	317	4110 (99.3%)	
Trichomonas vaginalis (TV)				0.95, p<0.001
Negative	2046	25	2071	
Positive	2	298	300	
Total	2048	323	2371 (99.1%)	

Conclusions

- Molecular POCT for STIs is sustainable and scalable in primary care as part of a routinely implemented program
- Clinical effectiveness (2-3 fold increase in % treated ≤ 2 days) and quality (concordance >99%) of POCT was maintained
- In addition to the individual health benefits of earlier treatment (reduced reproductive morbidities), fewer infective days following POCT could contribute to reduced community transmissions and lower prevalence
- Additional support (workforce and sustained funding) will be critical to ensure clinic capacity to deliver STI POCT alongside other priority services

TTANGO2/3 is collaboration between academic research institutions, Aboriginal and government health organisations, pathology providers, health services, communities and industry: The Kirby Institute UNSW Sydney, Flinders University International Centre for Point-of-Care Testing, South Australian Health and Medical Research Institute, Monash University, Deakin University, The Burnet Institute, University of Queensland Centre for Clinical Research, Aboriginal Health Council of WA, Aboriginal Health Council of SA, Kimberley Aboriginal Medical Services Council, Ngaanyatjarra Health Service, Aboriginal Medical Services Alliance of the Northern Territory, Queensland Aboriginal and Islander Health Council, Apunipima Cape York Health Council, WA Country Health Service, WA Health, SA Health, QLD Health, NT Health, PathWest, Westerns Diagnostics, CliniPath, SA Pathology, Pathology Queensland, NRL, Aboriginal Community Controlled and government health services in each jurisdiction, Medical Communication Associates, and Cepheid Inc. We also thank all staff and patients who participated in this program. We acknowledge the contribution of the TTANGO2 Executive and Investigator groups who guided the implementation of the program. We thank and acknowledge the support of Dr Ye Zhang and Dr Lucy Watchirs-Smith from the Kirby Institute who assisted in the data analyses.

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