

# 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

## Authors:

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## Background:

Following a world-first cluster-randomised controlled trial, molecular point-of-care testing (POCT) for detection of chlamydia (CT)/gonorrhoea (NG) (and later trichomoniasis, TV) was scaled-up to regional and remote primary health clinics across Australia (31 clinics by 2019; 58 by 2022). Clinics could offer molecular POCT or laboratory testing or both. We evaluated the clinical effectiveness, sustainability, and quality of POCT.

## Methods:

Using routinely collected clinic and program data, we (i) measured trends in monthly POCT; (ii) compared proportions of patients with positive results treated in  $\leq 2$ , 7 and 120 days by test type, using risk ratios (adjusted for clinic and patient characteristics, aRR); and (iii) calculated concordance of POCT with laboratory testing.

## Results:

From January 2016 to December 2022, 39463 POCT were performed (31024 CT/NG; 8439 TV). Among clinics contributing data in first 4 years, the median number of monthly POCTs was 408 (IQR:294-538) with an increasing trend over time (10.52 tests per month,  $p < 0.001$ ). Of 3217 positive CT/NG tests, a greater proportion received timely treatment following POCT compared to laboratory testing ( $\leq 2$  days: 61% vs 31% [aRR1.97];  $\leq 7$  days: 64% vs 43% [aRR2.06];  $\leq 120$  days: 80% vs 73% [aRR1.10]), representing 91330 infective days averted (2839 days per 100 positive tests). Differences were greater for the 1155 positive TV tests ( $\leq 2$  days: 32% vs 10% [aRR3.2];  $\leq 7$  days: 45% vs 20% [aRR2.25];  $\leq 120$  days: 65% vs 73% [aRR1.2]), representing 34245 infective days averted (2965 per 100 positive tests). Of 4111 CT/NG and 2371 TV POCT with parallel laboratory tests, result concordance was CT:99.0%, NG:99.3% and TV:98.9%.

## Findings:

Molecular STI POCT was scaled-up and sustained as part of a routinely implemented program with clinical effectiveness similar to that observed under trial

conditions. In addition to individual health benefits, the reductions in number of infective days could contribute to a lower reproductive number and reduced transmissions in the community.

**Disclosure of Interest Statement:**

TTANGO2 program has received reduced price consumables from Cepheid. SB was employed at the Kirby Institute, UNSW when contributing to the work outlined in this abstract. Since January 2022, he has been the Director of Medical and Scientific Affairs for Cepheid (ANZ/APAC). All other authors declare no competing interests.

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