

Peer-delivered point-of-care testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* within an urban community setting: a cross-sectional analysis

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Abstract. **Background:** The advent of fully automated nucleic acid amplification test (NAAT) technology brings new public health opportunities to provide *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) point-of-care testing (POCT) in non-traditional settings. **Methods:** This pilot study evaluated the integration of the CT/NG Xpert diagnostic assay into an urban peer-led community setting providing HIV and syphilis POCT. A comprehensive protocol of testing, result notification, referral and follow up, managed by peer test facilitators, was undertaken. **Results:** Over 67 weeks, there were 4523 occasions of CT/NG testing using urine, oropharyngeal and anorectal samples with 25.7% (803) of the 3123 unique participants returning for repeat testing. The prevalence of CT and NG was 9.5% and 5.4% respectively. Where CT and/or NG infection was detected, 98.4% (604/614) of participants were successfully notified of detected infection and referred for treatment. Evaluation Survey responses (11.4%, 516/4523) indicated a substantial proportion of respondents (27.1%, 140/516) 'would not have tested anywhere else'. Of note, 17.8% (92/516) of participants reported no previous CT/NG test and an additional 17.8% (92/516) reported testing more than 12 months ago. A total of 95.9% (495/516) of participants 'Strongly agreed' or 'Agreed' to being satisfied with the service. **Conclusion:** The project successfully demonstrated an acceptable and feasible model for a peer-delivered community-led service to provide targeted molecular CT/NG POCT. This model offers capacity to move beyond the traditional pathology and STI testing services and establish community-led models that build trust and increase testing rates for key populations of epidemiological significance.

Additional keywords: Australia, chlamydia, GeneXpert, gonorrhoea, men who have sex with men, peer testing, point-of-care testing.

Received 6 January 2020, accepted 11 June 2020, published online 31 July 2020

Introduction

The importance of incorporating testing for other sexually transmissible infections (STI) when testing for HIV has been reaffirmed¹ in the push to achieve United Nations HIV/AIDS

90–90–90 goals.² Comprehensive testing is an effective prevention strategy in response to the significant effect of STI as facilitators for HIV transmission and acquisition.³ More recently, integration of STI and HIV testing has been

prioritised among men who have sex with men (MSM) and other at-risk populations seeking to use pre-exposure prophylaxis (PrEP) for the prevention of HIV, acknowledging that PrEP may afford greater opportunities for instances of condomless sex and an increase in STI infection rates.^{4,5}

The availability of rapid POCT for HIV and syphilis within community settings has enabled a variety of innovative, MSM peer-based services for the early detection of infection.⁶⁻⁹ Recent developments in nucleic acid amplification tests (NAAT), such as automated molecular technologies¹⁰ for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG), facilitates greater breadth of STI testing within community settings.^{10,11} It also creates compelling opportunities for enhancing an integrated primary sexual healthcare approach that promises greater accessibility and equity to comprehensive STI testing for those most at risk. These new technologies can facilitate reduced time to diagnosis and treatment, minimise loss to follow up^{9,12} and reduce economic outlay by integrating testing and treatment into a single occasion of service.¹³⁻¹⁵

The Xpert CT/NG assay (Cepheid AB, Solna, Sweden) was registered for use to detect urogenital CT/NG infection by the Therapeutic Goods Administration (TGA) in 2013.¹⁶ The GeneXpert system (Cepheid, Sunnyvale, CA, USA) is regarded as being suitable for POCT,¹⁷ and Australian studies indicate high acceptance by clinical staff.¹⁸ Previous studies found the performance of the Xpert CT/NG assay compares favourably to established laboratory assays,¹⁷⁻¹⁹ including testing of anorectal specimens.²⁰ The GeneXpert system is fully automated and delivers a clear positive or negative test result (within 90 min). Each test cartridge can be added individually to the system as they become available, providing flexibility of use.

The Test, Treat and Go (TTANGO) trial demonstrated that using the Xpert CT/NG assay was accessible, acceptable and reliable when operated by health workers without tertiary- or laboratory-based training in 12 remote Indigenous communities across Australia.¹⁷ Given the successful effect of TTANGO in rural settings, an urban-based POCT trial in a community-based, non-clinical context was considered timely. This urban trial using the Xpert CT/NG assay was conducted at a peer-based community testing site called RAPID and through three outreach programs at sex-on-premises venues (SOPV) in Brisbane, Queensland.

The RAPID testing service, operated by Queensland Positive People, has provided HIV and syphilis POCT delivered by peer test facilitators to mostly at-risk MSM since 2014.⁸ The service operates a 'no questions asked' approach that prioritises peer-to-peer engagement within an informal, open, non-judgemental 'sex positive' community setting that promotes acceptance of sexual diversity and behaviour choices.^{21,22} RAPID seeks to engage at-risk MSM who have not previously tested or test infrequently for HIV. These men may be reluctant to access mainstream clinical services²³⁻²⁵ and may not have had an opportunity for full STI testing. In 2016, RAPID reported 3770 occasions of service for HIV and syphilis POCT,²⁶ and this has steadily

risen to nearly 6000 in 2018.²⁷ Key service staff identified the absence of CT/NG testing as a significant testing gap for this ever-increasing cohort of at-risk MSM.²⁶

Two factors prohibited the use of routine CT/NG laboratory testing. First, the absence of an approved on-site clinical provider at the RAPID service meant the service was unable to access Medicare (Australia's universal health insurance scheme) rebated pathology services and, second, there was insufficient organisational funding available to cover pathology costs. External grant funding was secured for an innovative service delivery project and evaluation. As such, the focus of this project was to develop a more comprehensive 'one-stop shop' POCT screening service. The GeneXpert system and Xpert CT/NG assay are ideally suited for this purpose. Governance supported the established referral pathway model for clients with positive screening tests. The trial of this molecular POCT diagnostic system for CT/NG within an urban community peer-led setting is, we believe, the first such application in Australia. This paper reports on the profile of participants accepting CT/NG rapid POCT, their clinical outcomes, uptake and perception of the expanded testing options at RAPID.

Methods

Study aim

The primary aim of the study was to establish and evaluate a system of CT/NG molecular POCT, delivered by peer test facilitators in an urban community clinic offering HIV and syphilis POCT to MSM since 2014.

Recruitment

This study undertook prospective consecutive sampling and recruitment of participants presenting at four locations (one main clinic and three nearby SOPV where RAPID staff conducted regular outreach testing services) from 3 March 2017 to 14 June 2018 (67 weeks). All individuals, aged ≥ 16 years, presenting to the main clinic or one of the regular SOPV outreach clinics were asked if they wanted CT/NG testing in addition to HIV and/or syphilis POCT. Written consent was obtained before specimen collection, including the client's permission for telephone follow up by a peer test facilitator in the event CT/NG was detected on screening. In accordance with RAPID's Standard Operating Procedures (SOP), clients who reported symptoms of an STI or a potential HIV exposure within the past 72 h were excluded and advised to seek clinical care rather than undergo screening. Sample size calculations were not performed. RAPID staff envisaged most clients accessing services for HIV and syphilis POCT would opt for additional CT/NG testing, so sample size was determined by interest and restricted based on funding and staffing availability.

Procedure

At the time of recruitment at all testing sites, participants were verbally advised by the peer test facilitators of the process of self-collection. Participants were asked to provide a first void urine specimen in a sterile container and an oropharyngeal and anorectal specimen using a separate flocked swab for each site

collection. After self-collection, participants placed each swab into the respective specimen transport tube provided in the swab kit, which contained 2.3 mL of Cepheid universal transport medium (UTM). All collected specimens were promptly returned to a peer test facilitator. The peer test facilitator added 7 mL of neat urine specimen to a separate specimen collection tube containing UTM within 2 h of collection to preserve DNA, in accordance with manufacturer recommendations.²⁸

The only variation in the procedure for the different recruitment points was the transportation of all specimens collected at SOPV outreach settings back to the main clinic where the GeneXpert system was located. Specimens were transported in insulated containers for CT/NG POCT and processed at the end of each SOPV outreach shift or the following day.

As oropharyngeal and anorectal specimen preparation occurred 'off label', the manufacturer's recommended method for vaginal specimen preparation and processing was used,²⁹ whereby 1 mL of UTM from the swab tube was aliquoted by disposable pipette into an Xpert CT/NG assay cartridge specimen chamber before testing.

Participants who provided three individual specimens (urine, oropharyngeal swab and anorectal swab) had specimens pooled in accordance with the methodology developed by Speers *et al.* 2018.¹⁹ It should be noted that the use of pooled specimens from different anatomical sites from the same individual is considered an 'off label' use of the Xpert CT/NG assay, but has been previously validated.³⁰

The RAPID project team implemented quality assurance and control processes within the service allowing for continual quality improvement activities. This included implementation of nightly and monthly audits of clinical records to improve the standard data recording and subsequent data reporting. Additionally, regular internal and external CT/NG quality assurance activities of the GeneXpert system occurred to ensure accurate test and operator performance.

Reporting results

The Xpert test results for CT/NG took ~90 min. Participants were invited to leave the premises and be contacted via Short Message Service (SMS) or phone call once the CT/NG results were ready. This protocol has been in use for several years at RAPID for communicating HIV and syphilis results by telephone to clients, and peer test facilitators were very familiar and confident with the use of this system.

Interpretation of results through the GeneXpert system is clear, with a non-ambiguous 'Detected' or 'Not detected' result provided for test operators. All results were documented in the secure software package designed for primary care use at the clinic as per the RAPID SOP. The client database can only be accessed by RAPID staff with a user-specific password. Client files were not shared with members of the research team who were not RAPID employees. All CT/NG results and study-related data were de-identified before being transferred directly into a password-protected Research Data Manager file hosted in Australia by the University of Queensland (UQ) to which only the

dedicated UQ researchers and RAPID staff identified in the study protocol had access.

Participant follow up

As per study consent, participants were contacted by the peer test facilitators at two different time points following the initial clinical visit. Participants were informed of their Xpert CT/NG results by telephone or SMS within 24 h. Those with no infection detected were informed by SMS. The SMS stated: 'Hi. Your STI test results for gonorrhoea and chlamydia are negative. No action is required. RAPID 3013 5566'. Peer test facilitators, guided by a script, directly called participants with detected infection to advise of the positive result. These participants were offered the option of a referral to the local public Sexual Health & HIV Service, their preferred general practitioner (GP) or another Sexual Health Clinic of their choice. Where requested, the peer test facilitator would make an appointment at the participant's preferred clinic on their behalf. With participant consent, peer test facilitators at RAPID would email or fax an introductory letter to the referral clinic, explaining the nature of the pilot study being conducted at RAPID, the Xpert test results for that individual and the need for confirmatory testing for notification purposes and treatment. If the participant did not agree to this information being forwarded to a clinical service, the information was provided to the participant for self-referral to a clinical service.

Participants with CT/NG detected were also sent an SMS as a point-of-contact to show to the treating referral service. The detailed SMS provided a link for clinicians to the Australian STI Management Guidelines³¹ with advice on contact tracing. This SMS also included clear instructions for the treating referral service to undertake confirmatory testing. The Xpert CT/NG assay does not routinely require confirmatory testing due to TGA accepted sensitivity and specificity performance.³² However, as part of this trial, confirmatory testing of all detected infections was required to ensure notification of a detected infection was completed according to public health requirements in Queensland and due to the off-label use of the Xpert CT/NG assay in this study setting. The follow-up confirmatory tests were processed through the standard pathology laboratory services utilised by the treating clinical service.

A second follow up occurred when the peer test facilitators attempted telephone contact with all participants who had an infection detected 2 weeks after referral for retesting and treatment. The follow-up telephone interview conducted by the peer test facilitators followed a structured 'Interview Guide' assessing the participant's attendance at a referral service, provision of retesting and treatment and whether contact tracing had been addressed. Verbal consent for a Uniform Resource Locator (URL) or web address to the online 'Participant Post Referral Survey' to be sent via SMS was also obtained. The telephone call also provided an opportunity to assess the participant's experience of the Xpert CT/NG testing and referral process; however, the main aim of these calls was to assess linkage to care and support participants, as per SOP.

In those cases where the participant had not accessed the referral pathway, peer test facilitators assisted the participant in this process. The process of follow up via telephone was repeated 2 weeks later. If the participant did not respond to the initial 2-week post-testing phone call, three subsequent attempts were made to contact the participant by phone. Where this was not successful, the participant was considered lost to follow up. Participants were also offered the opportunity to register for 3-monthly testing reminders to be sent to their mobile and or email.

Data collection

Demographic data were collected on enrolment from the participants consenting to the CT/NG test via standard RAPID client registration forms and service satisfaction surveys already in use for the HIV and syphilis testing service. An online CT/NG specific 'Evaluation Survey' was completed post-testing, either on a tablet at the clinic appointment or by accessing the survey URL sent by SMS to the client at the conclusion of their clinic appointment. The Evaluation Survey explored participants' HIV and STI testing history; STI diagnoses in the previous 12 months; factors influencing their choice to accept CT/NG screening; the acceptability of and satisfaction with the CT/NG screening process; and alternative CT/NG testing services they may have attended if CT/NG screening was not offered at RAPID.

Follow-up data were collected by an online 'Post-Referral Survey', accessed via the survey URL sent via SMS to all participants with a detected infection at the time of the 2-week post-testing follow-up interview phone call. The Post Referral Survey explored the type of service the client attended for follow-up, STI testing undertaken at the referral service, the results of follow-up testing and the type and duration of treatment if received. Individual patient-level contact tracing outcome data were collected. Acceptability and satisfaction questions were asked with Likert scale responses. The Post-Referral Survey gave participants the opportunity to provide anonymous feedback about their experiences that they may not have been willing to share during the brief 2-week follow-up phone interview with the peer test facilitators.

Data analysis

The primary outcome of the study, to assess the acceptability and feasibility of providing molecular POCT within the community setting, was measured through de-identified, quantitative data obtained from clinical data management software and survey responses gathered after initial CT/NG testing and 2 weeks post referral of detected infection. Descriptive univariate and bivariate analysis of participant demographic characteristics was undertaken to identify the reach of POCT to users of the RAPID service, specifically MSM populations and infrequent and non-STI testers. χ^2 test (Yates values) and odds ratios were used to compare differences between two groups with a binomial outcome using analytic software (IBM Corp. Released 2016, IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY, USA. *P*-values <0.05 were considered significant.

Ethics approval

The study was granted ethics approval by The University of Queensland Human Research Ethics Committee (UQHREC 2016001764) and was conducted under the Therapeutic Goods Administration Clinical Trial Notification (CTN) Scheme (CTN 00812-1).

Results

The CT/NG POCT was accepted on 93.4% (4523/4843) occasions of service for HIV and syphilis POCT over the 67-week study period by 3123 unique participants. At the participants' first visit, when CT/NG POCT was accepted (*n* = 3123), the majority identified as male (82.8%, 2587), MSM (61.7%, 1926), aged 20–29 years (48.7%, 1520), Australian born (48.2%, 1504), having a Medicare card (71.0%, 2217) and had testing at the main RAPID clinic (88.1%, 2750). Thirty-five participants identified as Aboriginal and or Torres Strait Islander peoples (1.1%) (Table 1).

Of the participants accepting CT/NG POCT, 99.3% (3100/3123) did so on their first visit. One-quarter of the participants accepting CT/NG POCT (25.7%, 803/3123) attended on more

Table 1. Descriptive data of unique study participant characteristics by first attendance for CT/NG testing, repeat attenders for CT/NG testing and participants with CT/NG detected during the study period

CT, *Chlamydia trachomatis*; NG, *Neisseria gonorrhoeae*; MSM, men who have sex with men

Demographic characteristic	First attendance for CT/NG testing (<i>n</i> = 3123)		Repeat attenders for CT/NG testing (<i>n</i> = 1400)		Unique participants with CT/NG detected during study period (<i>n</i> = 548)	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Male	2587	82.8	1266	90.4	468	85.4
MSM	1926	61.7	1082	77.3	394	71.9
Aged 20–29 years	1520	48.7	606	43.3	301	54.9
Australian born	1504	48.2	753	53.8	288	52.6
Aboriginal and or Torres Strait Islander people	35	1.1	23	1.6	13	2.4
Medicare eligible	2217	71	1117	79.8	408	74.5

than one occasion, with 4.5% (140) of participants testing on four or more occasions over the study duration.

Uptake of CT/NG POCT varied by the setting at which testing was offered. Overall, 93.8% (4051/4318) of occasions of service at RAPID undertook CT/NG testing compared with 89.9% (472/525) from the three SOPV outreach settings combined (χ^2 10.98, $P < 0.001$). There was a greater proportion of first occasions of service including CT/NG testing at RAPID compared with SOPV outreach settings; 93.7% (2734/2917) and 90.2% (369/409), respectively ($\chi^2 = 6.50$, $P < 0.01$). Similarly, a greater proportion of participants attending RAPID had repeat CT/NG testing compared with those testing at SOPV outreach settings; 94.0% (1317/1401) and 88.8% (103/116), respectively ($\chi^2 = 4.03$, $P = 0.045$). Most participants accessed CT/NG testing only at RAPID (87.8%, 2743/3123), with a smaller proportion testing solely at the SOPV outreach settings (10.6%, 330/3123). Few participants accessed CT/NG testing at both settings (1.6%, 50/3123).

Over the study period, 429 CT and 244 NG infections were identified from the 4523 CT/NG tests, representing an overall point prevalence of 9.5% and 5.4% for CT and NG, respectively. No statistically significant difference was observed for CT or NG prevalence by setting of testing ($P = 0.647$ and $P = 0.512$, respectively); however, diagnosis of co-infection with CT and NG was more than twice as likely for those testing at an SOPV outreach setting (odds ratio = 2.224, 95% confidence interval (CI) 1.17–4.22, $P = 0.0219$).

The CT/NG detection was more likely on the first than on the second visit (χ^2 Yates = 5.25, $P = 0.0219$). A non-significant upward trend in CT/NG positivity was observed between the second and eighth visits (Fig. 1).

Of the 614 occasions of service where CT and/or NG infection was detected, 604 (98.4%) participants were successfully notified of a detected infection within 24 h of testing and referred for treatment. Ten (1.6%) participants were classified as 'lost to follow up'. Most referrals were to public Sexual Health Clinics (60.4%, 365/604) followed by General Practice services (39.4%, 238/604).

Of the 516 participants completing the Evaluation Survey (response rate 11.4%, 516/4523), 27.1% (140/516) reported they 'would not have gone anywhere else for STI testing' if it were not offered at RAPID or the SOPV outreach settings. More than 1 in 6 participants (17.8%, 92/516) who accepted CT/NG testing reported never having tested for CT/NG, and a further 17.8% (92/516) tested more than 12 months previously. Given a prevalence of 9.5% and 5.4% for CT and NG, respectively and the rate of those who reported their unwillingness to use traditional STI screening services, we estimate that 117 CT infections and 66 NG infections would not have been identified if the RAPID service was not offering CT/NG testing. Among males identifying as gay or bisexual (306), only 35.3% (108) reported testing within the past 3 months, as recommended by National STI testing guidelines for asymptomatic MSM.³³

The trial protocol recommended referral services retest the study participant at the time of appointment before treatment

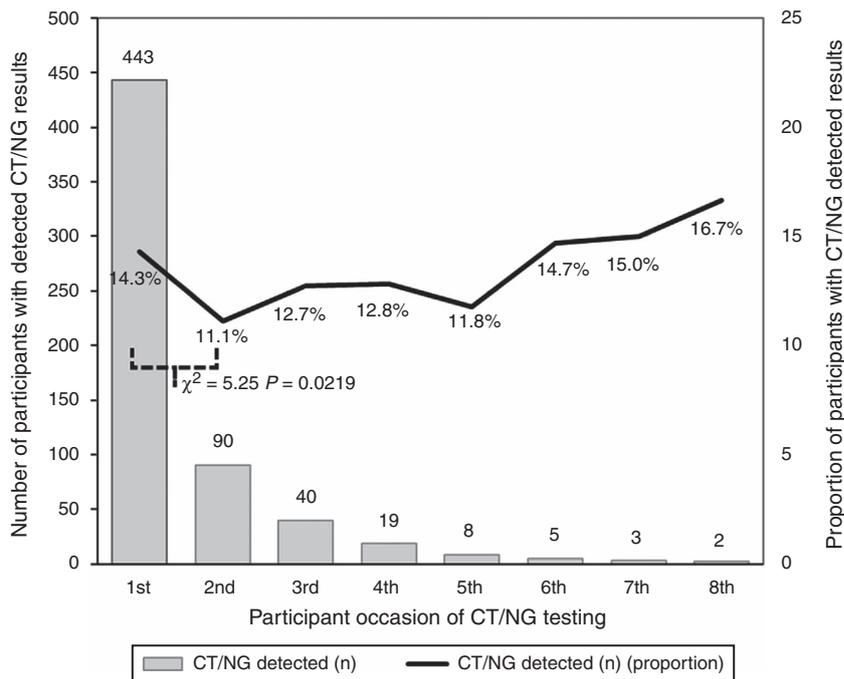


Fig. 1. *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (CT/NG) detection (count and percentage) by participant CT/NG testing visit. *A low number of participants attended on more than eight CT/NG testing occasions. Of the seven participants testing on a ninth occasion, no tests detected CT/NG, three of the five CT/NG tests done on a participant's 10th testing occasion detected CT/NG and one of two participants testing on an 11th occasion had CT/NG detected. Data not shown in Fig. 1.

for STI notification purposes. Of the Post-Referral Survey respondents ($n = 78$), only 51.3% (40/78) reported being retested. Reported retesting varied by referral service type. Participants who attended community-based services, sexual health services, regular GP and non-regular GP reported retesting at 60.0% (3/5), 57.4% (27/47), 43.8% (7/16) and 30.0% (3/10) of occasions, respectively. Nine in 10 participants (89.7%, 70/78) 'received treatment'. Post-referral, 64.1% (50/78) of participants reported having no remaining contacts to inform. The most frequently used methods to contact sexual partners were SMS (51.5%, 34), in person (31.8%, 21) and telephone call (21.2%, 14). Most (56.4%, 44/78) reported no difficulties notifying partners. Of those identifying barriers to notification ($n = 19$), reasons included anonymous partners (42.1%, 8), no contact details (31.6%, 6), anxiety about informing partners (10.5%, 2) and partners refusing to test (10.5%, 2). Most participants (52.6%, 41/78) were aware at least one partner had been tested, and 32.1% (25/78) of participants were aware at least one partner had received treatment. One participant reported having the assistance of referral services to contact partners. Participants referred for testing and management at another service, who completed the satisfaction questions on the Post-Referral Survey ($n = 64$) 'Strongly agreed' or 'Agreed' they were satisfied with the service received from RAPID (98.4%, 63), the Xpert testing technology (93.8%, 60) and would recommend RAPID STI testing services to people they know (95.3%, 61). Fewer participants 'Strongly agreed' or 'Agreed' they were satisfied with having to go to another service to get treatment (64.1%, 41).

With respect to overall service evaluation, reported in the Evaluation Survey ($n = 516$), participants perceived this community testing model as highly acceptable and accessible. The value of being able to test for CT/NG alongside testing for HIV and syphilis was considered very valuable or valuable by 94.2% (486/516) of participants. The ability to receive a result within 24 h (90.1%, 465), the quality of care received (88.6%, 457), the provision of a free service (87.8%, 453), the convenient location (82.0%, 423) and the provision of testing outside of business hours (82.2%, 424) were considered 'Very important' or 'Important' for participants. Of participants who provided a specimen from selected anatomical sites, ease of self-collection was rated as 'Very easy' or 'Easy' by 91.2% (465/510), 79.8% (402/504) and 73.9% (281/380) of participants providing urine, oropharyngeal, and anorectal specimens, respectively. Comfort of collecting specimens was rated as 'Very high' or 'High' by 89.2% (455/510), 75.6% (381/504) and 71.8% (273/380) of participants providing urine, oropharyngeal, and anorectal specimens, respectively.

Discussion

As a result of the project, 429 CT infections and 245 NG infections were detected in 614 participants at one or more anatomical sites. A substantial proportion of evaluation survey respondents (27.1%) reported they 'would not have gone anywhere else for STI testing' if it was not available at the RAPID service or one of the SOPV outreach settings. Addition

of CT/NG testing to the testing options offered at the RAPID service may have identified 117 CT and 66 NG episodes of infection that would have been otherwise undiagnosed. Over 96% of participants with infection detected were referred to services for treatment. The project successfully demonstrated the capacity for a peer-delivered community health service to deliver CT/NG POCT with responsive follow-up strategies in a manner acceptable and accessible to its clientele, many of whom had never been tested.

Through the use of GeneXpert, participants received pathology results for CT/NG the same or following day compared with longer time to results for conventional laboratory testing results. The rapid availability of test results at a single visit could improve outcomes for prompt treatment and partner notification, minimising the risk of onward transmission and serious sequelae.^{9,12} Being male,³⁴ having multiple partners³⁴ and issues navigating appointment bookings,³⁵ have been identified as risk factors for loss to follow up. Subject to appointment availability at referral services, the linking of the RAPID service for predominantly MSM, with clinical follow up via educational support, established referral networks and clear governance structures possibly contributed to low rates of loss to follow up (1.6%) and was critical in facilitating pathways to care.

Providing CT/NG testing, alongside HIV and syphilis testing for MSM and other at-risk populations, is a key HIV prevention strategy and will take on greater prominence as part of standard care management for those receiving PrEP.³⁶ An acknowledged limitation of the RAPID service before commencement of this project was the provision of HIV and syphilis testing only. Management and staff of the RAPID service were easily able to adapt their SOP to incorporate CT/NG POCT. The introduction of CT/NG testing at the RAPID service resulted in an increase in attendance. The peer test facilitators suggested that this resulted in an increase in waiting time to consultation at peak times. However, they felt that the addition of CT/NG testing had no demonstrable effect on clinic consultation duration, as participants collected specimens for CT/NG testing during the 20-min HIV and syphilis POCT development time. Peer test facilitators noted the additional wait time did not appear to be overly burdensome to participants and that if CT/NG testing were no longer available, client attendance would decline. This could suggest the benefits to clients in accessing CT/NG testing in a community setting outweigh an increase in waiting time. The workload requirements needed to make CT/NG testing available were greater than envisaged. This included time taken to contact participants with detected infection, liaison with referral services and additional clinical record and data management activities.

The GeneXpert system has allowed for accurate, relatively inexpensive testing for CT/NG infections without laboratory services and has provided for a more complete suite of STI testing within a non-clinical setting.

The benefits of molecular POCT technology are many. The establishment of a network of community testing sites offering CT/NG POCT should ease demand placed on public sexual health services, as well as increase outreach capacity at SOPV

and other community settings through partnerships. MSM accessing the peer-based service at RAPID for HIV testing, many who had never accessed another service or previously tested for HIV, are for the first time accessing testing for CT/NG, the two most prevalent bacterial STI. Participants reported ease and comfort in performing the self-collected samples. The ability to provide the combination of HIV, syphilis and CT/NG POCT has increased the effectiveness of the peer-based service at RAPID to detect STI, and reduced the need for testing across multiple services.

The GeneXpert system does not require specialist operation and can potentially be delivered by trained generalist health or community workers in a variety of settings. It is widely accepted internationally that trained lay providers, such as the peer test facilitators employed at RAPID, can provide safe and cost-effective POCT and that these community services address disparity in service access for key priority populations.^{37,38} POCT in a community setting may also reduce costs and clinician time.^{39,40}

Participant responses to the Evaluation Survey regarding previous STI testing indicated 17.8% had never had an STI test (other than HIV), with a further 17.8% not testing within the previous 12 months. Survey responses also indicate that had CT/NG testing not been available, 50.0% of the STI testing naïve and 31.5% of those who tested more than 12 months prior would 'probably not have tested elsewhere', suggesting first that some Brisbane MSM continue to engage in STI testing less frequently than recommended and second, other existing STI services do not meet the needs of this cohort.

The degree of success of this project demonstrates a clear community demand for rapid peer-based testing of this kind and is a significant contribution to improving both HIV and STI testing rates among high-risk populations targeted by the RAPID service. Other trials of peer-delivered STI testing or rapid POCT (for HIV) have demonstrated high levels of client satisfaction, acceptability, accessibility and receptivity to health-promoting information.^{6,41} This study provides further evidence supporting the key role peer-led services, such as RAPID, play in increasing access to testing, particularly among higher-risk populations.

Limitations

Survey responses and clinical data were not linked. As a result, it was not possible to establish the change in testing frequency of clients. Additionally, clients could choose from a variety of services to be tested for CT/NG; therefore, RAPID testing data alone provides limited insight into the effect of the project on an individual's testing frequency. However, the uptake of testing by those with an infrequent and naïve testing history demonstrates an increase in the frequency of testing by these two groups.

Limited information acquired from clients and from those referral services responsible for follow-up care, restricted our capacity to conduct a full evaluation of outcomes relating to testing frequency and client management and follow up, including the effect of POCT technologies on ongoing testing behaviour and time to treatment. Studies have found

mean time to treatment in urban Australian settings ranging from 4⁴² to 8 days.⁴³ Waiting for laboratory reporting of results to clinicians accounted for between 1 and 3 days, but the greatest variance in the time-to-treatment pathway was often due to a delay in the individual receiving treatment following notification by the clinician.⁴³ There are scant Australian data reporting time-to-treatment in outreach settings of any kind⁴⁴ or MSM peer-led testing services. However, a peer-led testing service in the UK has demonstrated POCT for CT/NG can reduce the time-to-treatment compared with routine laboratory-based testing.⁴⁵ Wingrove *et al.*⁴⁵ found no reduction in the time-to-treatment following clients being notified of their infection, but rather attributed the reduced time-to-treatment with the introduction of CT/NG POCT and its associated reduced time to notification of the results. Although our study was unable to determine accurate time-to-treatment, these studies suggest reducing the time-to-notification of results is a key step in reducing the time-to-treatment. However, future research is needed to assess the relative contribution of 'time-to-notification' in reducing onward transmission of infection alongside 'time-to-treatment'. We hypothesise the rapid receipt of a positive test result, as provided in this model, may reduce the window of transmission through sexual behaviour modification before treatment at the referral service in addition to its contribution to quickening access to treatment.⁹

On-site treatment was not available as part of RAPID standard practice at the time of the study, requiring referral of all detected infections to external treatment services. Future work should consider improved communication pathways and mechanisms between community testing services and referral treatment services to enable the monitoring of client referral outcomes and timely access to treatment. Alternatively, exploring options for delivery of on-site treatment would be highly desirable.

Conclusion

This study has demonstrated the feasibility, acceptability and effectiveness of incorporating CT/NG POCT through a peer-delivered community testing service providing HIV and syphilis POCT. The flexibility and ease of use of the GeneXpert system and Xpert CT/NG assay enabled innovative service delivery in an urban setting, which increased client engagement in STI testing. This model offers capacity to move beyond the traditional pathology and STI testing services and establish community-led models that build trust and increase testing rates for populations of epidemiological significance.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Acknowledgements

The authors would like to acknowledge the time and contribution of the participants who took part in this research. We would also like to thank Queensland Positive People staff for their invaluable contribution and acknowledge the collaborative involvement of sexual health and GP services to which participants were referred. We acknowledge the

members of the Urban GeneXpert Trial Advisory Committee, Dr Diane Rowling and Dr Julian Langton-Lockton (Metro North Sexual Health and HIV Service), Rayden Rivett (Cepheid, Australia), Cassio Oliveira (Queensland Positive People), Melissa Warner (Queensland Positive People) and Professor Rebecca Guy (Kirby Institute, UNSW, Sydney). Funding was provided by Metro North Hospital and Health Service and the HIV Foundation Queensland. Cepheid provided the 16-module GeneXpert-XVI instrument and some Xpert CT/NG assay cartridges free of charge. This study was conducted with support and under the auspices of the Queensland Professorial Chair in blood-borne virus (BBV) and STI.

References

- Bekker L-G, Alleyne G, Baral S, Cepeda J, Daskalakis D, Dowdy D, *et al.* Advancing global health and strengthening the HIV response in the era of the Sustainable Development Goals: the International AIDS Society-Lancet Commission. *Lancet* 2018; 392: 312–58. doi:10.1016/S0140-6736(18)31070-5
- The Joint United Nations Programme on HIV/AIDS (UNAIDS). 90–90 On the right track towards the global target. Geneva: UNAIDS; 2016.
- Kalichman SC, Pellowski J, Turner C. Prevalence of sexually transmitted co-infections in people living with HIV/AIDS: systematic review with implications for using HIV treatments for prevention. *Sex Transm Infect* 2011; 87: 183–90. doi:10.1136/sti.2010.047514
- Holt M, Draper BL, Pedrana AE, Wilkinson AL, Stoové M. Comfort relying on HIV pre-exposure prophylaxis and treatment as prevention for condomless sex: results of an online survey of Australian gay and bisexual men. *AIDS Behav* 2018; 22: 3617–26. doi:10.1007/s10461-018-2097-2
- Hughes AJ, Chen Y-H, Scheer S. Condomless anal sex among HIV-positive men who have sex with men: biomedical context matters. *AIDS Behav* 2017; 21: 2886–94. doi:10.1007/s10461-017-1852-0
- Leitinger D, Ryan KE, Brown G, Pedrana A, Wilkinson AL, Ryan C, *et al.* Acceptability and HIV prevention benefits of a peer-based model of rapid point of care HIV testing for Australian gay, bisexual and other men who have sex with men. *AIDS Behav* 2018; 22: 178–89. doi:10.1007/s10461-017-1888-1
- Mullens AB, Duyker J, Brownlow C, Lemoire J, Daken K, Gow J. Point-of-care testing (POCT) for HIV/STI targeting MSM in regional Australia at community ‘beat’ locations. *BMC Health Serv Res* 2019; 19: 93. doi:10.1186/s12913-019-3899-2
- Mutch AJ, Lui C-W, Dean J, Mao L, Lemoire J, Debattista J, *et al.* Increasing HIV testing among hard-to-reach groups: examination of RAPID, a community-based testing service in Queensland, Australia. *BMC Health Serv Res* 2017; 17: 310. doi:10.1186/s12913-017-2249-5
- Whitlock GG, Gibbons DC, Longford N, Harvey MJ, McOwan A, Adams EJ. Rapid testing and treatment for sexually transmitted infections improve patient care and yield public health benefits. *Int J STD AIDS* 2018; 29: 474–82. doi:10.1177/0956462417736431
- Kelly H, Coltart CEM, Pant Pai N, Klausner JD, Unemo M, Toskin I, *et al.* Systematic reviews of point-of-care tests for the diagnosis of urogenital *Chlamydia trachomatis* infections. *Sex Transm Infect* 2017; 93: S22–30. doi:10.1136/sextrans-2016-053067
- Tucker JD, Bien CH, Peeling RW. Point-of-care testing for sexually transmitted infections: recent advances and implications for disease control. *Curr Opin Infect Dis* 2013; 26: 73–9. doi:10.1097/QCO.0b013e32835c21b0
- Turner KME, Round J, Horner P, Macleod J, Goldenberg S, Deol A, *et al.* An early evaluation of clinical and economic costs and benefits of implementing point of care NAAT tests for *Chlamydia trachomatis* and *Neisseria gonorrhoea* in genitourinary medicine clinics in England. *Sex Transm Infect* 2014; 90: 104–11. doi:10.1136/sextrans-2013-051147
- Vickerman P, Watts C, Peeling R, Mabey D, Alary M. Modelling the cost effectiveness of rapid point of care diagnostic tests for the control of HIV and other sexually transmitted infections among female sex workers. *Sex Transm Infect* 2006; 82: 403–12. doi:10.1136/sti.2006.020107
- Huang W, Gaydos CA, Barnes MR, Jett-Goheen M, Blake DR. Comparative effectiveness of a rapid point-of-care test for detection of *Chlamydia trachomatis* among women in a clinical setting. *Sex Transm Infect* 2013; 89: 108–14. doi:10.1136/sextrans-2011-050355
- Samarawickrama A, Alexander S, Ison C. A laboratory-based evaluation of the BioStar Optical ImmunoAssay point-of-care test for diagnosing *Neisseria gonorrhoeae* infection. *J Med Microbiol* 2011; 60: 1779–81. doi:10.1099/jmm.0.034116-0
- Therapeutic Goods Administration. Public Summary 207540 Cepheid Holdings Pty Ltd – CT774 Multiple-bacteria IVDs Class 3 -CT/NG Assay. Canberra: Department of Health, Australian Government; 2013.
- Guy RJ, Natoli L, Ward J, Causer L, Hengel B, Whitley D, *et al.* A randomised trial of point-of-care tests for chlamydia and gonorrhoea infections in remote Aboriginal communities: Test, Treat AND GO - the “TTANGO” trial protocol. *BMC Infect Dis* 2013; 13: 485. doi:10.1186/1471-2334-13-485
- Natoli L, Guy RJ, Shephard M, Causer L, Badman SB, Hengel B, *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: e0145993. doi:10.1371/journal.pone.0145993
- Speers DJ, Chua ILJ, Manuel J, Marshall L. Detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* from pooled rectal, pharyngeal and urine specimens in men who have sex with men. *Sex Transm Infect* 2018; 94: 293–7. doi:10.1136/sextrans-2017-053303
- Badman SG, Willie B, Narokobi R, Gabuzzi J, Pekon S, Amos-Kuma A, *et al.* A diagnostic evaluation of a molecular assay used for testing and treating anorectal chlamydia and gonorrhoea infections at the point-of-care in Papua New Guinea. *Clin Microbiol Infect* 2019; 25: 623–7. doi:10.1016/j.cmi.2018.08.001
- Burnes TR, Sungh AA, Witherspoon RG. Sex positivity and counseling psychology: an introduction to the major contribution. *Couns Psychol* 2017; 45: 470–86. doi:10.1177/0011000017710216
- Ivanski C, Kohut T. Exploring definitions of sex positivity through thematic analysis. *Can J Hum Sex* 2017; 26: 216–25. doi:10.3138/cjhs.2017-0017
- Thornton AC, Delpech V, Kall MM, Nardone A. HIV testing in community settings in resource-rich countries: a systematic review of the evidence. *HIV Med* 2012; 13: 416–26. doi:10.1111/j.1468-1293.2012.00992.x
- Pottie K, Medu O, Welch V, Dahal GP, Tyndall M, Rader T, *et al.* Effect of rapid HIV testing on HIV incidence and services in populations at high risk for HIV exposure: an equity-focused systematic review. *BMJ Open* 2014. 4: e006859. doi:10.1136/bmjopen-2014-006859
- Knight V, Wand H, Gray J, Keen P, McNulty A, Guy R. Convenient HIV testing service models are attracting previously untested gay and bisexual men: a cross-sectional study. *J Acquir Immune Defic Syndr* 2015; 69: e147–55. doi:10.1097/QAI.0000000000000688
- Queensland Positive People. Annual Report 2016–2017. Brisbane: Queensland Positive People; 2017.
- Queensland Positive People. Annual Report 2018–2019. Brisbane: Queensland Positive People; 2019.

- 28 Cepheid. Xpert CT/NG urine specimen collection (first catch). Sunnyvale, CA: Cepheid; 2012.
- 29 Cepheid. Xpert CT/NG patient collected vaginal swab specimen collection. Sunnyvale, CA: Cepheid; 2012.
- 30 Badman SG, Bell SFE, Dean JA, Lemoire J, Coffey L, Debattista J, *et al.* Reduced sensitivity from pooled urine, pharyngeal and rectal specimens when using a molecular assay for the detection of chlamydia and gonorrhoea near the point-of-care. *Sex Health* 2020; 17: 15–21. doi:10.1071/SH19028
- 31 Australasian Sexual Health Alliance. Australian STI management guidelines. Sydney: Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM); 2017.
- 32 Goldenberg SD, Finn J, Sedudzi E, White J, Tong C. Performance of the GeneXpert CT/NG assay compared to that of the Aptima AC2 assay for detection of rectal *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by use of residual Aptima samples. *J Clin Microbiol* 2012; 50: 3867–9. doi:10.1128/JCM.01930-12
- 33 STIs in Gay Men Action Group. Australian Sexually Transmitted Infection & HIV Testing Guidelines 2019 for asymptomatic men who have sex with men. Surry Hills: NSWSTI Programs Unit.; 2019.
- 34 Kim YK, Jeoung JW, Park KH. Understanding the reasons for loss to follow-up in patients with glaucoma at a tertiary referral teaching hospital in Korea. *Br J Ophthalmol* 2017; 101: 1059–65. doi:10.1136/bjophthalmol-2016-309103
- 35 Tsadik M, Berhane Y, Worku A, Terefe W. The magnitude of, and factors associated with, loss to follow-up among patients treated for sexually transmitted infections: a multilevel analysis. *BMJ Open* 2017. 7: e016864. doi:10.1136/bmjopen-2017-016864
- 36 Volk JE, Marcus JL, Phengrasamy T, Blechinger D, Nguyen DP, Follansbee S, *et al.* No new HIV infections with increasing use of HIV preexposure prophylaxis in a clinical practice setting. *Clin Infect Dis* 2015; 61: 1601–3. doi:10.1093/cid/civ778
- 37 Kennedy CE, Yeh P, Johnson C, Baggaley R. Should trained lay providers perform HIV testing? A systematic review to inform World Health Organization guidelines. *AIDS Care* 2017; 29: 1473–9. doi:10.1080/09540121.2017.1317710
- 38 Flynn DE, Johnson C, Sands A, Wong V, Figueroa C, Baggaley R. Can trained lay providers perform HIV testing services? A review of national HIV testing policies. *BMC Res Notes* 2017; 10: 20. doi:10.1186/s13104-016-2339-1
- 39 Adams EJ, Ehrlich A, Turner KME, Shah K, Macleod J, Goldenberg S, *et al.* Mapping patient pathways and estimating resource use for point of care versus standard testing and treatment of chlamydia and gonorrhoea in genitourinary medicine clinics in the UK. *BMJ Open* 2014. 4: e005322. doi:10.1136/bmjopen-2014-005322
- 40 Brook G. The performance of non-NAAT point-of-care (POC) tests and rapid NAAT tests for chlamydia and gonorrhoea infections. An assessment of currently available assays. *Sex Transm Infect* 2015; 91: 539–44. doi:10.1136/sextrans-2014-051997
- 41 Minas BC, Giele CM, Laing SC, Bastian L, Burry AW, Sales KJ, *et al.* Early diagnosis of HIV among men who have sex with men in Western Australia: impact of a peer-led sexually transmissible infection testing service. *Sex Health* 2015; 12: 360–3. doi:10.1071/SH14214
- 42 Chen MY, Ryder N, Donovan B. Completeness and timeliness of treatment for chlamydia within a sexual health service. *Int J STD AIDS* 2004; 15: 762–4. doi:10.1258/0956462042395113
- 43 Foster R, Ali H, Crowley M, Dyer R, Grant K, Lenton J, *et al.* Does living outside of a major city impact on the timeliness of chlamydia treatment? A multicenter cross-sectional analysis. *Sex Transm Dis* 2016; 43: 506–12. doi:10.1097/OLQ.0000000000000496
- 44 Natoli L, Guy RJ, Shephard M, Donovan B, Fairley CK, Ward J, *et al.* Chlamydia and gonorrhoea point-of-care testing in Australia: where should it be used? *Sex Health* 2015; 12: 51–8. doi:10.1071/SH14213
- 45 Wingrove I, McOwan A, Nwokolo N, Whitlock G. Diagnostics within the clinic to test for gonorrhoea and chlamydia reduces the time to treatment: a service evaluation. *Sex Transm Infect* 2014; 90: 474. doi:10.1136/sextrans-2014-051580