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**Novel Approaches to Non-Clinic-Based  
*Chlamydia trachomatis* Testing**

Thesis submitted by

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**in August 2011**

as partial requirement for the Degree of Doctor of Public Health  
in the School of Public Health, Tropical Medicine & Rehabilitation Sciences  
James Cook University

## **DEDICATION**

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## **ACKNOWLEDGEMENTS OF OTHER CONTRIBUTORS**

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## **SYNOPSIS**

### ***Introduction***

My daily work as a clinical nurse in a regional sexual health clinic regularly incorporated consultations with clients being tested and diagnosed with Chlamydia trachomatis (chlamydia) infection. Chlamydia infections are predominately diagnosed in the younger, sexually active segments of the population and are mostly asymptomatic, with the potential to progress to severe sequelae such as pelvic inflammatory disease (PID) (Westrom 1995). The current recommended treatment is azithromycin 1 gram orally as a single dose (British Association for Sexual Health and HIV (BASHH) 2002; Workowski and Levine 2002; The Royal Australasian College of Physicians, Australasian Chapter of Sexual Health Medicine et al. 2004). The challenge for health service providers/public health agencies is, therefore, the identification of those asymptomatic cases by testing, and the provision of timely and effective treatment.

Reliable information on chlamydia testing rates or even numbers of tests performed is sparse, thus not allowing the calculation of prevalences or incidences. However, most health systems in developed countries have notification systems and population data that allow the calculation of notification rates. Notification rates in developed countries have been steadily increasing over recent years; for example, in the United States of America (US) notification rates per 100,000 population increased from 304 in 1999 to 392 in 2004, in the United Kingdom (UK) from 101 to 180, and in Sweden from 188 to 355, respectively. The situation seems especially dramatic in Australia, where notification rates between 1999 and 2004 more than doubled from 73 to 177 (Low 2004; Australian Government Department of Health and Ageing 2005; Centers for Disease Control and Prevention 2005). A more detailed analysis of the Australian notification rates reveals distinct differences between states. Notification rates are highest in the Northern Territory (437 in 1999 and 782 in 2004), followed by Queensland (125 in 1999 and 222 in 2004), where they are still well above the national average. A further breakdown of the Queensland data by Health Service District shows higher notification rates still for the northern districts, with the Townsville Health Service District notification rates also doubling over this five-year period – 213 in 1999 and 456 in 2004 – albeit on a considerably higher level than the overall Queensland rates. While the increase in notification rates may be due to many factors, including

more sensitive tests, improvements in notification processes and more testing, and repeat testing it is very likely that they also reflect an increase in real infection rates in the community (Gotz, Lindback et al. 2002; Australian Government Department of Health and Ageing 2005; Chen and Donovan 2005).

Attempts to manage the evident chlamydia epidemic in developed countries differ by jurisdiction. They include recommendations to opportunistically screen high-risk populations, systems to follow up positive cases, changes of legislation to make partner notification compulsory and plans for a systematic screening program. However, all these attempts seem to have had very limited success, as evidenced by the ever-increasing notification rates.

In Australia, attempts to curb this epidemic by means of more or less well-organised health promotion campaigns, relying on testing or screening by the general primary healthcare sector or the 'Well Persons' Health Check' in Indigenous communities between 1998 and 2000, were apparently without measurable success. None of the implemented measures have resulted in a sustained reduction in notification rates (Miller, McDermott et al. 2002; Miller, McDermott et al. 2003; Australian Government Department of Health and Ageing 2005).

Some reasons for the failure of the measures undertaken in Australia relate to a lack of clear government commitment, with low resource allocation and the lack of a well-coordinated approach. The situation is further hampered by the mainly 'passive' methods undertaken; that is, relying on the initiative of the people at risk to get tested as opposed to actively approaching them. A further major general impediment, especially when only 'passive' approaches are employed, is the widespread nature of the population in Australia. The availability of health services decreases substantially in regional centres and even more so in remote areas.

## *Aims*

Novel approaches to *Chlamydia trachomatis* testing that take the specific situation in Australia, and especially Queensland, into account are urgently needed in order to make an inexpensive, reliable and accurate test, together with an inexpensive and effective treatment, acceptable and available to asymptomatic people, especially in non-metropolitan areas.

The main aim was to develop, implement and evaluate such novel testing and management regimes for chlamydia infection. The development of such an approach formed the centrepiece of my doctoral studies.

The specific aims, that is, the specific requirements, for such much-needed and timely novel approaches can be summarised as being:

- 1.) Based on an ‘active’ approach, that is, actively educating and informing the target population and promoting chlamydia testing;
- 2.) Available independent from the place of residence;
- 3.) Available independent of operation times of health services, especially in more regional areas where a health service may only be available a day a week or less;
- 4.) Centrally managed to guarantee access to qualified health professionals who are knowledgeable about follow-up (successful treatment, partner notification, retesting, further testing);
- 5.) Available outside the local social sphere to assure confidentiality;
- 6.) Available independent of the general primary healthcare sector (STIs are generally low on the priority list of general practitioners);
- 7.) ‘Low tech’ (i.e. not requiring complicated procedures, instructions, accommodating low literacy skills); and
- 8.) Connected to existing infrastructure, including communication systems.

## **PROJECTS**

As I was working in a sexual health clinic that is the biggest notifier of chlamydia infection in a regional area of Queensland with high notification rates, I decided to start addressing the problem at the local level.

### ***Local Outreach Clinics***

In consultation with management and the team at the sexual health clinic, a series of outreach clinics was developed as a novel ‘active’ approach to chlamydia testing. Initially, different segments of the local population were targeted to 1.) evaluate the general feasibility of the outreach clinic concept and, if found feasible, 2.) create the evidence base necessary to optimise those clinics, in other words, identify those segments of the target population (i.e. those at high risk of infection) who would most benefit from outreach clinics (i.e. being accessible). At the same time, the outreach clinics were conceptualised in a way so as not to require additional funding in order to be sustainable beyond the lifetime of the project.

***Finance:*** I successfully applied for a grant of **A\$10,000** under the Queensland Nursing Research Scheme to study the feasibility of outreach clinics as a novel approach to chlamydia testing.

***My responsibilities*** in this project were the development of the study design, ethics approvals, sample size calculation, questionnaire design, liaison with partner organisations, instruction of clinical staff, promotion of outreach clinics, conduct and support of outreach clinics, data management, database design, data analysis and communication of results, including the preparation of a manuscript for publication and a conference.

***The main results*** of this local outreach clinic study proved that the general approach was feasible and that the outreach clinics could be conducted within the operating budget of the health service. Additionally, several accessible high-risk segments of the general target population were identified. They provided a valuable evidence base for optimising future outreach clinics, which subsequently were incorporated into and are still being conducted within the routine health service provision. Details of this study and the respective results are provided in Chapter 3.

However, while improving access to testing for many persons at risk of chlamydia infection, there are still some limitations inherent in this outreach clinic approach. The possible frequency of outreach clinics is limited by resources and practicalities. Hence, the offer of such clinics is restricted to areas in the vicinity of the main clinic, which means that access is restricted to those people who can attend them at a fixed place and point in time.

Therefore, a more flexible test delivery mode was needed, independent of place and time, facilitating testing of persons who cannot or would not access conventional testing venues.

## **KIT DEVELOPMENT**

The concept of self-collected and mailed samples for chlamydia testing had been trialled in other countries but had not been possible in Australia due to Australia Post regulations restricting the mailing of liquid biological specimens. Hence, a plan was developed to enable the self-collection of specimens at home, making use of the existing pathology specimen transport infrastructure by allowing participants to drop off their specimen at existing pathology collection points.

***Finance:*** I successfully applied for two grants (**A\$25,000** under the Queensland Nursing Research Scheme and **A\$40,000** from the Queensland Health Communicable Diseases Branch) to develop and evaluate a self-collection drop-off kit for chlamydia testing and an accompanying management system.

***My responsibilities*** in this project were the development of the study design, ethics approvals, development and production of the self-collection kit, development of a management system, development and production of promotion materials, questionnaire design, recruitment of and liaison with partner organisations (QHPS, pharmacies, youth organisations, health service providers, tertiary education providers, non-government organisations, funding bodies), data entry and data management, as well as the clinical management of participants.

***Main results:*** The self-collection kit was developed to the field testing stage.

## **OVERVIEW OF MAIN PROJECT**

At this point in my studies, contact was made with researchers from the University of Queensland, who had developed a process that allowed a liquid to be absorbed into a dry gel and then reconstituted for testing. Their preliminary studies had shown promise for this mechanism to work with urine samples destined for polymerase chain reaction (PCR) testing.

This opened up whole new avenues to explore, especially the prospect of being able to mail a urine specimen while complying with Australia Post regulations.

Thus, my original project plan was adjusted to 1.) encompass this new means of specimen transport and 2.) widen the project to encompass other Health Service Districts.

A collaborative partnership was formed between myself, the Communicable Diseases Branch at Queensland Health, the University of Queensland, Family Planning Queensland, and the Albert Sakzweski Viral Research Laboratory.

***Finance:*** Together with this collaboration, I was successful in securing a major competitive grant of **A\$340,000** from the Australian Government Department of Health and Ageing ‘Targeted Chlamydia Grants Program’ to develop and evaluate a self-collection kit mailed through Australia Post.

This grant thus allowed the expansion of my doctoral studies to not only cover major health districts all over Queensland but also to develop and evaluate a completely new approach to chlamydia testing in Queensland. Chiefly, this grant formed the basis for the transformation of the kit into a self-collection mailing kit in compliance with Australia Post regulations and allowed me to fully evaluate the feasibility and acceptance of this novel non-clinic-based approach to chlamydia testing, completely independent of place and time, and the centralised management of testing, result notification, treatment, partner notification and retesting.

***My responsibilities:*** In my central role in this project, I designed the respective studies, coordinated the development of the promotional materials, wrote the necessary ethics applications and correspondence. I also conducted the sample size calculations, designed the questionnaires, set up the databases, organised and controlled the self-

collection kit production and distribution, data collection and clinical management of participants, and liaised with partner organisations. In addition, I trained staff.

I conducted all analyses, wrote the main reports, communicated the findings at several conferences and wrote up the results in a total of six publications and eleven conference presentations.

## ***Components of Main Project:***

### ***A. Urine Transport Gel (UTG) Development and Evaluation***

While the team at the University of Queensland (UQ) had developed the urine transport gel (UTG) composition and reconstitution process, they had only conducted preliminary testing of the UTG's suitability for chlamydia PCR testing. Subsequently, the diagnostic qualities of the PCR testing method were evaluated using the transformed urine specimen against the gold standard of neat urine, as described in Chapter 4. The results proved that the sensitivity and specificity are comparable to the neat urine method, making the UTG a suitable transport medium for urine, which, in addition to appropriate packaging, rendered the kit compliant with Australia Post regulations.

### ***B. Development of Health Promotion Materials***

In collaboration with health promotion specialists from Queensland Health and James Cook University, I coordinated the development of the health promotion materials for chlamydia education and chlamydia testing using the self-collection kit, including a poster, pocket-sized leaflet and a website. All materials were developed using focus groups of the target population. A project officer was employed to conduct the focus groups and liaise with the artist commissioned to produce the materials. Details of the development process are described in Chapter 5 and more material can be found in Appendix 1.

### ***C. Kit Development and Evaluation, and Establishment of Central Management System***

The inclusion of the UTG as a transport medium and the intended mailing of the kit required a modification of the original drop-off kit and central management system (CMS). The risk management plan approved by Australia Post required the specimen to be contained in several layers of packaging, some of which were not readily available

on the market and needed development. In my role as project coordinator, I was responsible for the sourcing of those additional materials or for their development in collaboration with industry. A field test was conducted to evaluate the functionality and reliability of the entire system, including the tracking of each self-collection kit, the tracking of each returned sample, clinical management of results, and the operation of the integrated reminder system prior to roll-out on a bigger scale. The field test showed that 99% of samples were correctly packaged and that 94% of participants provided contact details, indicating that participants did not have concerns about privacy. The field test also showed that the management system was reliable, as evidenced by a very high percentage of participants contacted for results, follow-up managed, treatment confirmed and partner notification initiated or completed. Further details on the findings of this study are described in Chapter 6. As the field testing showed that all parts of the system were working, with no loss of samples and no complaints from participants or partner organisations, I then proceeded to the next stage of feasibility studies in different segments of the target population.

#### ***D. Feasibility Studies in Asymptomatic People and People with Previous Infections***

Following a successful field testing and final approval by Australia Post, a series of seven feasibility studies were conducted to investigate different strategies for reducing the barriers to chlamydia testing for the target populations of under 26 year olds (young), men who have sex with men (MSM), people with previous chlamydia infection, Indigenous people, and people who are socially or geographically isolated. In five of the studies, the self-collection kit was distributed to asymptomatic people through partner organisations, such as community-based pharmacies, tertiary education facilities, and non-government organisations servicing MSM. In two of the studies, the self-collection kits were distributed by the CMS directly to people requesting a kit through the website or by phone or at a sexual health clinic for the purpose of retesting three months after treatment.

A total of 2,918 self-collection kits were distributed, of which 423 were used by 397 individuals, resulting in an adjusted return rate of 13.8% overall, ranging from 4.7% in Indigenous communities to 66.6% for contact tracing. Higher return rates were achieved in the studies investigating the use of the self-collection kit for retesting and contact tracing than in those in which the self-collection kit was distributed opportunistically

through partner organisations. This finding could indicate that the motivation to test needs to precede the opportunity to test. Thus, health promotion activities and educating the target population prior to the distribution of self-collection kits are required. Unfortunately, data on non-participants is limited; however, such data indicates that age and gender are not indicators for returning a kit. A comparison with standard practice indicated a more than fivefold higher retesting rate when using the self-collection kit. The conduct and findings of these seven studies are detailed in Chapters 7 and 8.

### ***E. Aggregate Analysis – Descriptives***

In addition to the analysis of each separate study, I conducted an aggregate analysis of all self-collection kits, which revealed that the kits were indeed distributed to and returned from a wide geographical area. The median age of participants was 22.6 years (interquartile range (IQR) = [19.8; 28.3]), with 31.6% being male and 8.8% identifying as Indigenous. On their first test, 39 people tested positive, with another two testing positive on subsequent occasions; thus representing incident cases. Overall, 22 people used the self-collection kit more than once (excluding retesting). Treatment was ascertained for 40 of the 41 infections, indicating an effective process for follow-up. Return rates were higher for requested self-collection kits (27.4%) than for those distributed by partner organisations (9.7%). With respect to access to testing, two different groups emerged: 1.) one smaller group used the self-collection kit in preference to accessing mainstream services, thus diverting testing away from those services and possibly alleviating workloads; 2.) a second larger group of participants indicated that they would not have accessed health services for the purpose of chlamydia testing. This latter group can, therefore, be regarded as a new population accessed for testing. Overall, 76 contactable partners of positive cases were identified. Contact tracing was initiated by index cases for 44 contacts and confirmed for 12, while contact tracing was initiated by the CMS for 18 contacts and confirmed for 17. Detailed methods and results are presented in Chapter 9.

### ***F. Aggregate Analysis – Stratified to SEIFA and ARIA***

As the health status of individuals is not only influenced by their personal behaviour but also by socio-economic factors and remoteness, I analysed the aggregate data further to identify whether these factors were associated with the use of the self-collection kit (Australian Institute of Health and Welfare (AIHW) 2003). The first main finding was

that return rates of the self-collection kit did not differ with increased levels of remoteness. The second main finding was that participants from the highest quartile of the Socio-Economic Indexes for Areas (SEIFA) economic resources category had the highest return rate. Details are presented in Chapter 10.

### ***G. Consumer Satisfaction Evaluation***

Consumer satisfaction with the self-collection kit and the testing process was assessed by a questionnaire and phone interview, each with eight items. Additionally, repeat participant behaviour was observed as a measure of the acceptability of the testing process.

The main finding of the questionnaire survey was that all 332 respondents stated they would use the kit again. Additionally, 99.4% would recommend the self-collection kit to a friend. The results from the phone survey were similar. During the twelve month study period, 22 of the 397 participants returned for further testing, excluding those who returned for retesting following a positive result. The details of these studies are described in Chapter 11.

### ***Outcome/Significance***

The discussed novel approaches to *Chlamydia trachomatis* testing take account of the specific situation in Australia, and especially Queensland, and provide a new avenue for making an inexpensive and accurate test, together with an effective and inexpensive treatment, acceptable and readily available to asymptomatic people, particularly in non-metropolitan areas.

The evaluation of local approaches demonstrated that outreach clinics targeting high-risk segments of the population can provide a valuable supplement to routine clinic-based services if their conduct is evidence-based.

The developed and evaluated new methods for accessing testing services fulfil all requirements outlined previously in ‘aims’.

They should be accompanied by education and information campaigns to ‘actively’ promote chlamydia testing in the relevant segments of the target population.

The described self-collection kit can be requested and mailed to any location throughout the Australian Post network and is, thus, absolutely independent of the place of residence.

The self-collection kit is also available independent of any operation times of health services; this feature is especially important in more regional or remote areas where health service availability is notoriously limited.

The operation of the CMS by a qualified health professional provides access to a high level of quality of care with respect to information, follow-up, treatment, partner notification, retesting and further testing, even for those who live in remote areas.

A further advantage of the CMS is the assurance of confidentiality with testing, as a result of enabling access to testing outside the local social sphere. This avoids potentially perceived issues with confidentiality that are especially prevalent in the smaller communities found in rural or remote areas.

The developed system is independent of the general primary healthcare sector, therefore providing an additional and new avenue to testing that might also reach some segments of the target population, especially young men, who are usually only in rare contact with the primary healthcare system.

The presented approach of requesting a self-collection kit and preparing a sample for testing does not require any complicated procedures or instructions and, thus, can be understood and followed by people with limited English language or low literacy skills.

By using the existing infrastructure (standard Australia Post) as well as modern communication systems (mobile phones, emails), the assessed approach further facilitates inexpensive specimen transport, communication and follow-up.

***The outcome*** of my doctoral projects not only demonstrated feasible and inexpensive ways of how improved chlamydia testing can be conducted in Australia but has also found its place in routine health service provisions within Queensland Health.

The Townsville Sexual Health Service now routinely conducts outreach clinics in segments of the target population identified using the methodology developed and the segments identified during these doctoral studies.

On a wider scale, the research version of the self-collection kit was further developed to a standard self-collection kit for non-clinic based testing and was adopted by Queensland Health into their standard health service delivery. That is, the mailing kit is now routinely available through the internet (the research web page was adapted and relocated to the Queensland Sexual Health website) or by phone request.

Further exploration of the self-collection kit for retesting and contact tracing are still underway and other projects currently examine the general feasibility of the self-collection kit as an alternative testing method for asymptomatic people in lieu of clinic-based testing, as well as its suitability for gonorrhoea testing.

Whether the findings and implications of the studies conducted will actually result in declining numbers of chlamydia infections needs to be studied in future projects. However, it already seems clear that the doctoral studies conducted and their results modified the general service provision and have enabled increased access to services, case finding, successful follow-up (treatment) and retesting by successfully overcoming the main identified obstacles to testing as a result of being independent of place and time.

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## LIST OF ABBREVIATIONS

ATSI	Aboriginal/ Torres Strait Islander
ARIA	Accessibility/Remoteness Indicator of Australia
ABS	Australian Bureau of Statistics
ACT	Australian Capital Territory
ADF	Australian Defence Force
AIHW	Australian Institute of Health and Welfare
CDC	Centers for Disease Control and Prevention
CMS	Central management system
CMS	Central management system
CTT	Chlamydia testing trial
<i>C. trachomatis</i> or chlamydia	<i>Chlamydia trachomatis</i>
CSW	Commercial sex worker
CI	Confidence interval
DFA	Direct fluorescent antibody
DIF	Direct immunofluorescence
EB	Elementary body
EIA	Enzyme immunoassay
ELISA	Enzyme-linked immunoassay
GP	General Practitioner
GUM	Genito-urinary medicine
GCSHC	Gold Coast Sexual Health Clinic
HIC	Health Insurance Commission
Ind	Indigenous
IPHAC	Institute of Primary Health and Ambulatory Care
IQR	Interquartile range
IMB	Intramenstrual bleeding
JCU	James Cook University
LCR	Ligase chain reaction
MSM	Men who have sex with men
MIF	Micro immunofluorescence
<i>N. gonorrhoea</i> or gonorrhoea	<i>Neisseria gonorrhoea</i>
NSW	New South Wales
NI	Non-Indigenous
NAAT	Nuclear acid amplification test
OCP	Oral contraceptive pill
PID	Pelvic inflammatory disease
PY	Person-year
PCR	Polymerase chain reaction
P	Prevalence

QHPS	Queensland Health Pathology Service
rtPCR	Real time polymerase chain reaction
RB	Reticulate body
RH FPQ	Rockhampton Family Planning Clinic
SHS	Sexual health service
STI	Sexually transmissible infection
Sig	Significant
SEIFA	Socio-Economic Indexes for Areas
SD	Standard deviation
SDA	Strand displacement assay
TOP	Termination of pregnancy
TNSH	Townsville Sexual Health Clinic
TMA	Transcription mediated amplification
UK	United Kingdom
US	United States of America
UQ	University of Queensland
USQ	University of Southern Queensland
UTG	Urine transport gel
CDC	US Centers for Disease Control
WA	Western Australia
WHO	World Health Organization
<i>C. trachomatis</i> or chlamydia	<i>Chlamydia trachomatis</i>
STI	Sexually Transmissible Infection
SHS	Sexual Health Service
<i>N. gonorrhoea</i>	<i>Neisseria gonorrhoea</i>
UTG	Urine Transport Gel