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

Thesis submitted by

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DEDICATION

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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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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

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
C. trachomatis or chlamydia	*Chlamydia trachomatis*
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
N. gonorrhoea or gonorrhoea	*Neisseria gonorrhoea*
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	Retuculate 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
C. trachomatis or chlamydia	*Chlamydia trachomatis*
STI	Sexually Transmissible Infection
SHS	Sexual Health Service
N. gonorrhoea	*Neisseria gonorrhoea*
UTG	Urine Transport Gel

CHAPTER 1 AIMS AND SCOPE OF PROJECT

1.1 Background

Chlamydia trachomatis (chlamydia) infection is the most commonly notified sexually transmissible bacterial infection in the developed world (World Health Organization 2001; Centers for Disease Control and Prevention 2005; Cassell, Mercer et al. 2006). 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 prevalence or incidence. 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 (Low 2004; Centers for Disease Control and Prevention 2005).

The situation seems especially dramatic in Australia, where notification rates between 1999 and 2004 more than doubled from 73 to 177. Here, total notifications of chlamydia infections as well as notification rates per 100,000 population in Australia have been increasing by up to 20% per annum over the past 10 years, peaking at a total of 62,657 cases of chlamydia and resulting in a notification rate of 286.4 per 100,000 inhabitants in 2009 (Australian Government Department of Health and Ageing 2005).

Previous research has shown that the general population and, in particular, the high-risk younger age groups know little about chlamydia and do not perceive themselves at risk (Grulich, de Visser et al. 2003; Skinner and Hickey 2003; Lim, Hellard et al. 2007). Additionally, many infected or at-risk people do not actively seek healthcare due to the predominantly asymptomatic nature of chlamydial infections (Schachter 1999). Consequently, most people infected with chlamydia will not seek healthcare and will, therefore, be at risk of the sequelae of the infection, including severe long-term effects on the sexual and reproductive health of males and females (Westrom 1995). No vaccine is available for protection against chlamydia infections; thus, infection and disease control must be achieved through education and primary and secondary prevention initiatives (Scholes, Stergachis et al. 1996; Australian Government Department of Health and Ageing 2005a).

Usually, chlamydia testing is conducted in primary healthcare settings. In Australia, most testing for chlamydia is conducted in general practitioner (GP) practices and sexual health services as opportunistic, on-demand or symptomatic screening. However, an Australian study found that more than 80% of 16 to 24 year old women presented to a primary healthcare provider at least once in 2004, but only 7% were tested for Chlamydia (Fairley, Hocking et al. 2005). More recently, a study found that chlamydia testing rates according to Health Insurance Commission (HIC) data were about 6.3% for females and 1.6% for males in the 16 to 24 age groups (Kong, Guy et al. 2008). In addition, men who have sex with men (MSM) might not disclose their sexual preferences to their healthcare provider and are, therefore, unlikely to be tested for chlamydia (Andersen, Olesen et al. 2002; Chen and Donovan 2003; Meckler, Elliott et al. 2006). Opportunistic screening for chlamydia in GP practices might be hampered by an already heavy workload, especially in rural and remote parts of Australia (Schattner and Coman 1998; Humphreys, Jones et al. 2003), and the over 80 specialist sexual health clinics in Australia are mostly located in the larger centres along the coast (Australasian Chapter of Sexual Health Medicine (ASHM) 2007). These centres are out of reach for many potential clients given the vast distances of the country, which is of particular concern for the high-risk Aboriginal and Torres Strait Islander (ATSI) population located in remote areas (Miller, McDermott et al. 2003).

The advent of nucleic acid amplification test (NAAT) methods with high sensitivity and specificity allowed detection of chlamydia in samples with low bacterial counts, thus making self-administered swabs or urine samples a testing option (Johnson, Newhall et al. 2002).

A promising approach to improve screening lies with programs that specifically target high-risk groups (Gotz, van Bergen et al. 2005; Hocking and Fairley 2005). Previously, studies conducted in Sweden and the US used self-collecting kits of urine and swabs, with specimens being sent directly through the normal mail service. However, some loss of specimens was experienced due to leakage, which also resulted in an associated risk of potential exposure of postal workers (Novak, Edman et al. 2003; Gaydos, Dwyer et al. 2006; Novak and Karlsson 2006). Novak et al. (2003) sent a self-collection kit to all 22 year old male residents of a Swedish city. Liquid urine samples were returned and results were available via the internet. In a further study, Novak et al. (2006) offered self-collection kits to the entire population of a Swedish county using the internet (Novak and Karlsson 2006). These studies reported successfully attracting younger people to chlamydia testing. The Swedish study had, thus, achieved the highest published male response rate for chlamydia testing (Novak, Edman et al. 2003).

A more detailed analysis of 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 (Australian Government Department of Health and Ageing 2005). A further breakdown of Queensland data by Health Service District shows higher notification rates for the northern districts, with the Townsville Health Service District notification rates doubling over this five-year period – 213 in 1999 and 456 in 2004 – albeit on a considerably higher level than the overall Queensland rates (Pugh 2001; Sweeny and Beard 2009). While the increase in notification rates may be due to many factors, including more sensitive tests, improvements in notification processes and more 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 and the 'Well Persons' Health Check' from 1998 to 2000 in Indigenous communities, 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 no 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.

Thus, 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, available to asymptomatic people, especially in non-metropolitan areas.

1.2 **Aims**

The aim of my studies was to develop, implement and evaluate novel approaches to chlamydia testing and the management of test results. Such novel approaches were to be non-clinic based, user friendly, non-invasive and cost-effective.

The development of such approaches 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.) Outside the local social sphere to assure confidentiality;

6.) Available independent of the general primary healthcare sector (sexually transmissible infections 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.

1.3 **Funding of Research**

I successfully applied for a total of four competitive grants totalling an overall sum of **A$415,000** to fund the research for my doctoral studies. These were:

1.) A grant of **A$10,000** from the Queensland Nursing Research Scheme to study the feasibility of outreach clinics as a novel approach to chlamydia testing (Grant number 0035-3033-012-001);

2.) A grant of **A$25,000** under the Queensland Nursing Research Scheme (Grant number 4122-0023-002); and

3.) A grant of **A$40,000** from the Queensland Health Communicable Diseases Branch (10/ 2005).

These were used to develop and evaluate a self-collection drop-off kit for chlamydia testing and an accompanying management system.

4.) A collaborative partnership grant between me, Queensland Health, the University of Queensland, Family Planning Queensland, and the Albert Sakzweski Viral Research Laboratory of **A$340,000** from the Federal government 'Targeted Chlamydia Grants Program' to develop and evaluate a self-collection kit mailed through Australia Post.

All my studies were organised from one location hosted by the Townsville Health Service District at the Institute of Primary Health and Ambulatory Care (IPHAC). The work was, at times, supported by part-time research officers.

Ethical clearances

Ethical clearance for all studies was applied for and granted by the relevant ethics committees. All ethics approvals are listed in detail in APPENDIX 2.

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CHAPTER 2 INTRODUCTION TO CHLAMYDIA TRACHOMATIS AND LITERATURE REVIEW

2.1 Background

Chlamydia trachomatis (chlamydia) infection is frequently asymptomatic in both males and females (Biro, Reising et al. 1994; Stamm 1999; McKay, Clery et al. 2003; Williams, Tabrizi et al. 2003; Solomon, Peeling et al. 2004). These asymptomatic individuals will consequently not seek healthcare for the management of chlamydia infection and, thus, will possibly be at risk of the sequelae of this infection, which include salpingitis, pelvic inflammatory disease (PID) and epididymitis (Stamm 1999; Westrom and Eschenbach 1999). In women, PID and salpingitis lead to an increased risk of ectopic pregnancy and tubal infertility (Westrom 1975; Scholes, Stergachis et al. 1996; Bush and Everett 2001). Repeat infections contribute to the likelihood of sequelae occurring (Hillis, Owens et al. 1997; Westrom and Eschenbach 1999), which have been found to occur in between 10% and 50% of women (Burstein, Gaydos et al. 1998; Orr, Johnston et al. 2001; Whittington, Kent et al. 2001; Rietmeijer, Van Bemmelen et al. 2002).

Chlamydia infection also has to be seen in the context of HIV infection, as being infected with one sexually transmissible infection (STI) increases the risk of acquiring another (Royce, Sena et al. 1997; Fleming and Wasserheit 1999).

Due to the asymptomatic nature of chlamydia infection and the lack of suitable animal models, much of the natural history of chlamydia is unresearched. It is, however, thought that chlamydia infection can persist for months or years if left untreated (Schachter 1999; Stamm 1999; Morre, van den Brule et al. 2002; van den Brule, Munk et al. 2002; Molano, Meijer et al. 2005).

Chlamydia is of serious public health concern. For 1999, the World Health Organization (WHO) estimated the annual incidence of curable STIs to be in the range of 340 million worldwide, of which 90 million are genital chlamydia infections (World Health Organization 2001). The United States of America (US) reported an increase in chlamydia infection rates from 78.5 per 100,000 population in 1987 to 407 per100,000 in 2005, with a total of nearly 800,000 reported infections (Centers for Disease Control

and Prevention 2005). This increase is due to several factors, including improved testing methods, increased testing and also a real increase in infection rates (Centers for Disease Control and Prevention 2002). Trends in chlamydia infection rates in Canada and the United Kingdom (UK) are similar to that in the US (Patrick 1997; Fenton, Korovessis et al. 2001; Wright, Chippindale et al. 2002). In Australia, genital chlamydia infection is the most common bacterial STI, with 41,295 notifications in 2005. This is 14% up on the 36,186 notifications in the previous year and an increase of 144% during the five-year period from 2000 to 2005 (Australian Government Department of Health and Ageing 2005).

Screening guidelines for chlamydia have been available since 1984 in Canada, since 1985 in the US, and since 2007 in the UK (Canadian Task Force on the Periodic Health Examination 1984; Centers for Disease Control and Prevention 1985; Centers for Disease Control and Prevention 2005; Lamontagne, Baster et al. 2007; Low 2007). However, a coordinated national screening program was not available in any of these countries in 2004. In the UK, a national screening program was only fully implemented by 2007 (Lamontagne, Baster et al. 2007). In Sweden, free screening for chlamydia through the primary care sector was implemented in the early 1980s and, as a consequence, screening rates are high (Ripa 1990). The Swedish system, which is conducted on a county level and is not nationally organised, has a registry-based follow-up program with compulsory contact tracing for patient and provider (Ripa 1990; Herrmann and Egger 1995). In Australia, the first national STI strategy was launched in 2005; however, no systematic screening programs exist on a national or State-wide level (Australian Government Department of Health and Ageing 2005a).

This chapter will introduce in some detail the taxonomy, biology and general management of genital chlamydia infection.

This introduction is followed by a literature review, which is presented in three sections:

1.) Prevalence and incidence of chlamydia in developed countries;

2.) Risk factors for chlamydia infection; and

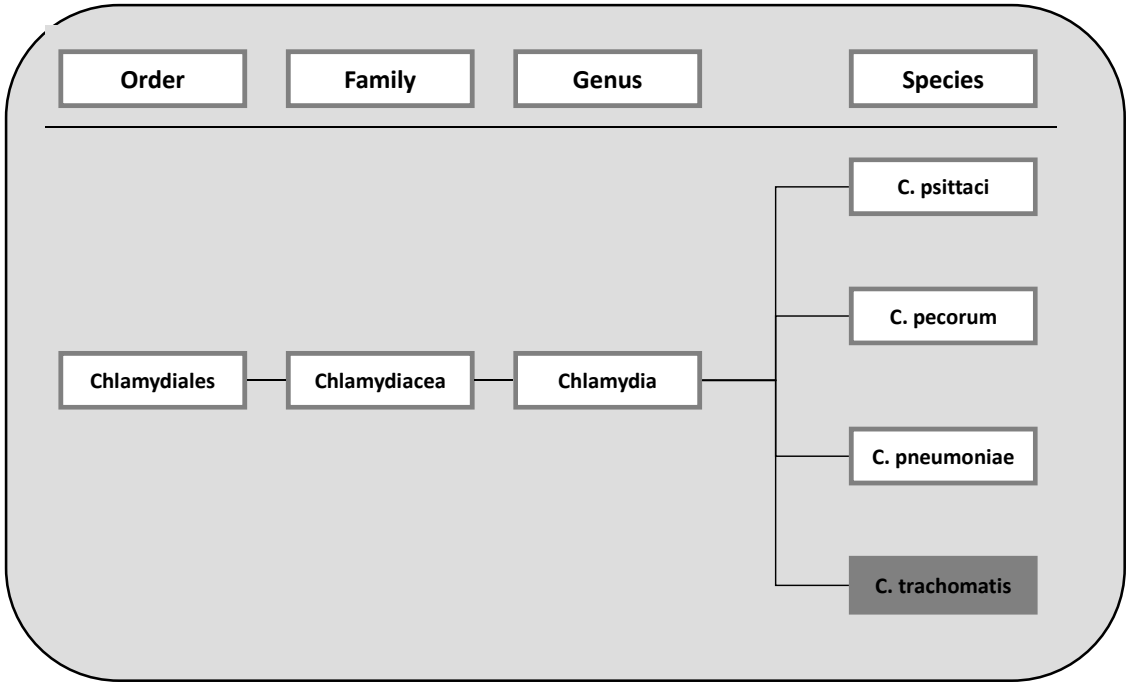
3.) Interventions studies to increase participation in screening for chlamydia in primary care and non-clinical settings.

2.2 Introduction

2.2.1 Taxonomy of *Chlamydia trachomatis*

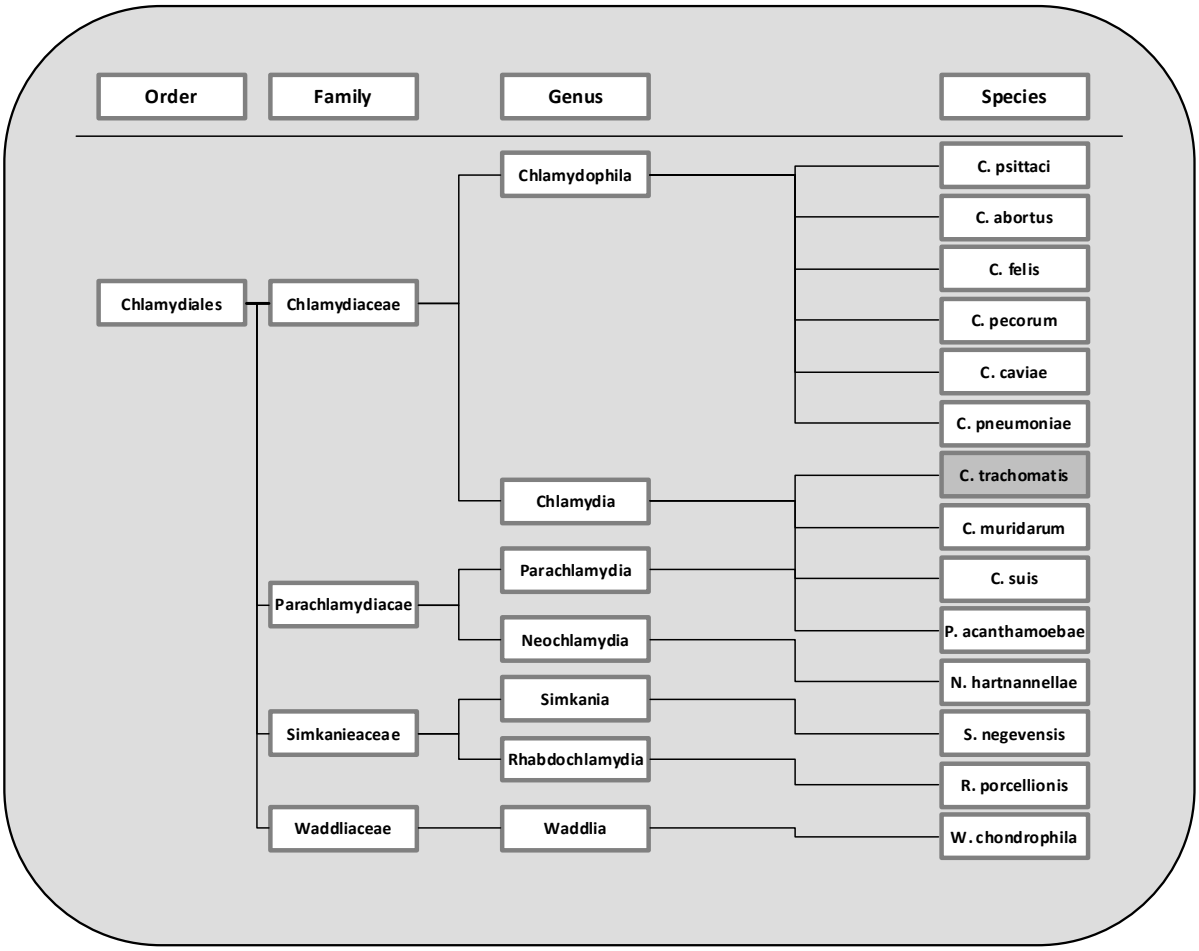
The taxonomy of the Chlamydiae has gone through some major and, at first controversial, reclassification over the past decades. In 1999, Everett et al. published an article proposing a reclassification, which has now been generally accepted (Everett, Bush et al. 1999). The species *Chlamydia trachomatis* is one of three species belonging to the genus *Chlamydia*, which is part of the family Chlamdyiaceae in the order Chlamydiales. The order Chlamydiales is the only member of the class Chlamydiae, which is again the only member of the phylum Chlamydiae, which belong to the domain/kingdom Bacteria. The major reclassification has occurred from the level of 'order' downwards, now comprising four families (Figures 2.1 and 2.2).

Figure 2.1'Old' taxonomic classification of *Chlamydia trachomatis*



(Schachter 1999; Bush and Everett 2001)

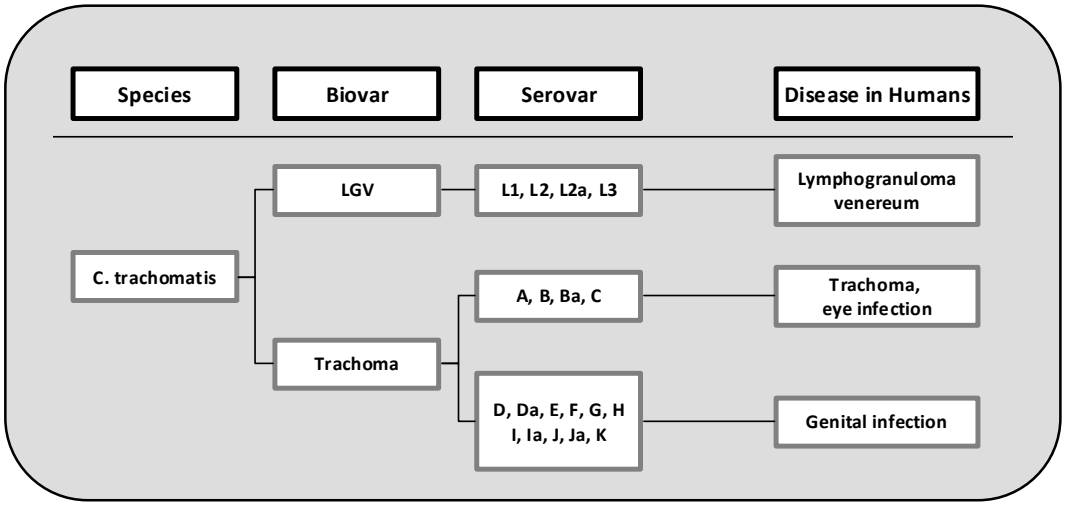
Figure 2.2 New taxonomic classification of *Chlamydia trachomatis*



(Everett, Bush et al. 1999; Schachter 1999; Bush and Everett 2001; Garrity, Lilburn et al. 2007)

The species *C. trachomatis* can be further differentiated into the two biovars lymphogranuloma venereum (LGV) and trachoma. Both biovars affect humans (see Figure 2.3)

Figure 2.3 *Chlamydia trachomatis* biovars and serovars



(Everett, Bush et al. 1999; Solomon, Peeling et al. 2004)

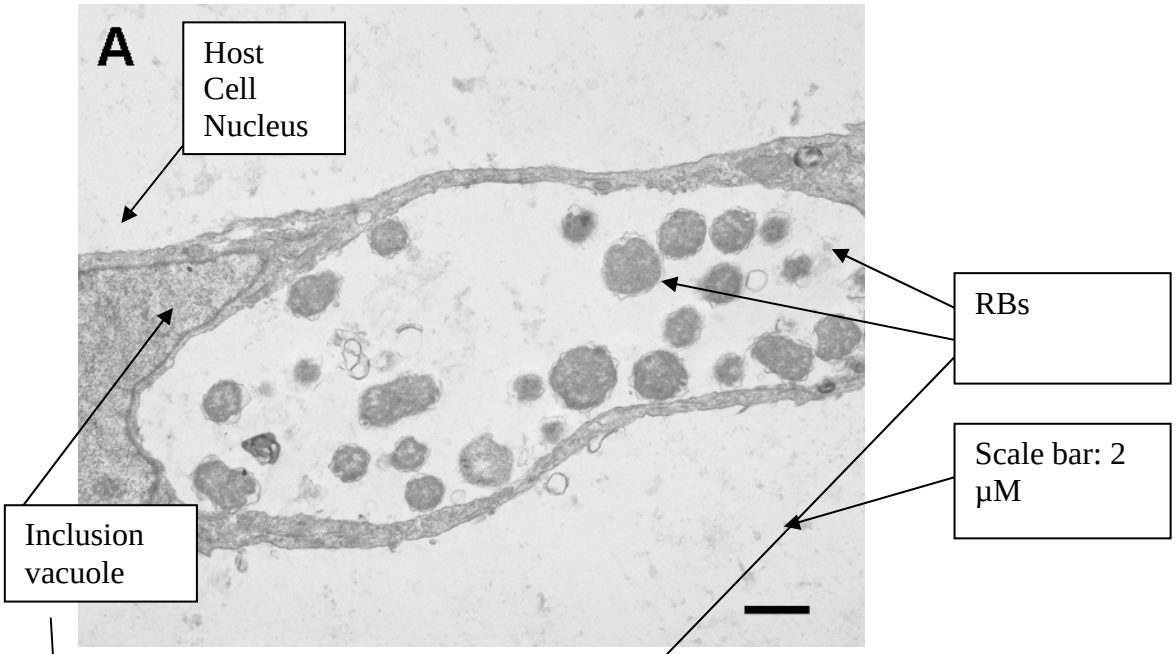
Genital chlamydia infection, caused by *C. trachomatis* serovars D–K, is an STI causing acute and chronic genital tract inflammation in males and females (Schaechter, Medoff et al. 1993; Schachter 1999). My thesis focuses on genital *Chlamydia trachomatis* infection.

2.2.2 The biology of Chlamydia trachomatis

Chlamydiae are Gram-negative, compulsory intracellular bacteria which cannot be cultured on artificial growth media. They have a unique life cycle that involves two stages and two distinct morphological forms: 1.) an intracellular stage represented by the reticulate body (RB) (see Figures 2.4 and 2.5); and 2.) an extracellular stage represented by the elementary body (EB) (Schachter 1999; Bush and Everett 2001; Everett and Andersen 2001; Corsaro, Valassina et al. 2003).

In the intracellular stage, the bacterium is metabolically active and non-infectious, while in the extracellular stage it is metabolically inactive but infectious. Chlamydia does not have the ability to synthesise high-energy compounds (e.g. ATP), amino acids, vitamins and other vital compounds (Schachter 2008). The reproductive cycle of Chlamydiae is common to all and is usually completed between 36 and 96 hours.

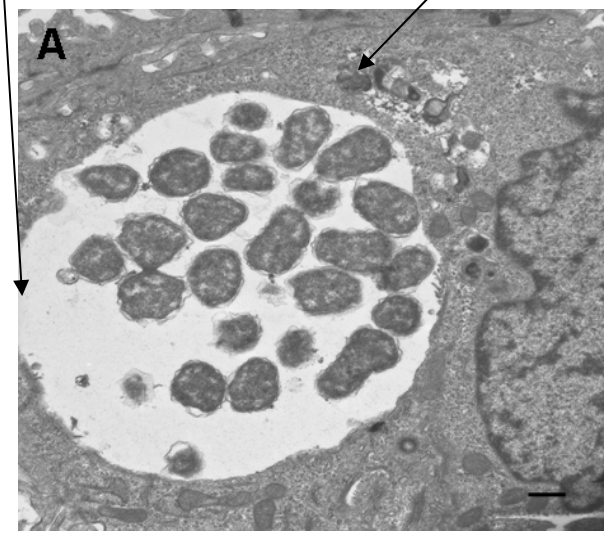
Figure 2.4 TEM* showing chlamydia RBs inside a host cell's inclusion vacuole



***Transmission electron micrograph (TEM)**

TEM courtesy of Wilhelmina Huston.

Figure 2.5 TEM* showing chlamydia RBs inside a host cell's inclusion vacuole



***Transmission electron micrograph (TEM)**

TEM courtesy of Wilhelmina Huston.

2.2.3 Management of *Chlamydia trachomatis*

Treatment for chlamydia is effective and includes a single dose of azithromycin or longer courses of doxycycline, erythromycin or roxithromycin.

Management guidelines in the US, the UK and Australia recommend a single dose of 1 gram of azithromycin orally as the first line of treatment (The Royal Australasian College of Physicians, Australasian Chapter of Sexual Health Medicine et al. 2004; British Association for Sexual Health and HIV (BASHH) 2006; Centers for Disease Control and Prevention, Workowski et al. 2006). The recorded side effects of azithromycin are usually minor and include allergy, nausea, rarely vomiting, and interaction with other drugs but not with oral contraceptives. Alternatively, doxycycline can be considered first-line treatment; however, compliance with the drug-taking regimen could be an issue (British Association for Sexual Health and HIV (BASHH) 2006).

The guidelines provide little guidance on best-practice treatment intervals, that is, the time between diagnoses of the infection and treatment; however, it would seem appropriate to treat an infected person as soon as possible. Positive cases are likely to be at high risk of repeat infection and, indeed, re-infection rates have been found to be between 10% and 15% (Whittington, Kent et al. 2001; Rietmeijer, Van Bemmelen et al. 2002; Peterman, Tian et al. 2006). Therefore, retesting after treatment is recommended after 3 to 6 months (The Royal Australasian College of Physicians, Australasian Chapter of Sexual Health Medicine et al. 2004; British Association for Sexual Health and HIV (BASHH) 2006; Centers for Disease Control and Prevention, Workowski et al. 2006). All guidelines recommend partner notification; however, contact tracing is only compulsory in Sweden (Ripa 1990; Herrmann and Egger 1995). In contrast to retesting rates, which are available from multiple sources, data about contact tracing is scarce. Only one review study from the UK has evaluated contact tracing, showing that partner notification rates were about 0.43 contacts per case for STI clinics and 0.64 contacts per case for community settings (Low, Welch et al. 2004). These results show that the management of positive cases leaves room for improvement.

2.3 Literature review on the frequency of occurrence of *Chlamydia trachomatis* in developed countries

2.3.1 Scope and limitations of this review

As *Chlamydia trachomatis* is an intracellular organism, the traditional method of diagnosing chlamydia involved cell culturing samples of the cervix. Samples needed to be fresh and had to have high bacterial load for the diagnostic test to have reasonable sensitivity and specificity. Obtaining a sample was invasive and expensive and was, therefore, restricted to symptomatic patients and the clinical setting. The laboratory methodology of cell culture was highly specialised and larger scale screening for chlamydia was not feasible (Gordon, Harper et al. 1969; Watson, Templeton et al. 2002).

This situation changed notably in the mid 1990s with the advent of DNA-based testing methods, including polymerase chain reaction (PCR), ligase chain reaction (LCR), DNA strand displacement, and other methods based on nucleic acid amplification tests (NAAT). These new methods have several advantages. They have allowed non-invasive sampling, for example, using urine or self-administered swabs, in both non-specialised clinical and non-clinical settings. The PCR testing methods are standard and do not require much specialisation. Additionally, these new methods are less expensive and have allowed screening to be conducted (Cook, Hutchison et al. 2005).

During the 1990s, these DNA-based methods of chlamydia testing were refined and introduced as routine laboratory practice throughout the developed world and are now regarded as gold standard. As a consequence, testing rates, as well as notification rates, have increased dramatically; in Australia notification rates have increased from about 55 per 100,000 inhabitants in the mid 1990s to 200 per 100,000 in 2005 (Australian Government Department of Health and Ageing 2005). This increase most likely reflects a combination of intensified testing, especially in high-risk populations, improved test sensitivity, and possibly also a real increase in infection (Centers for Disease Control and Prevention 2002). The latter is difficult to judge because no population-based prevalence or incidence studies have been repeatedly conducted in a standardised manner.

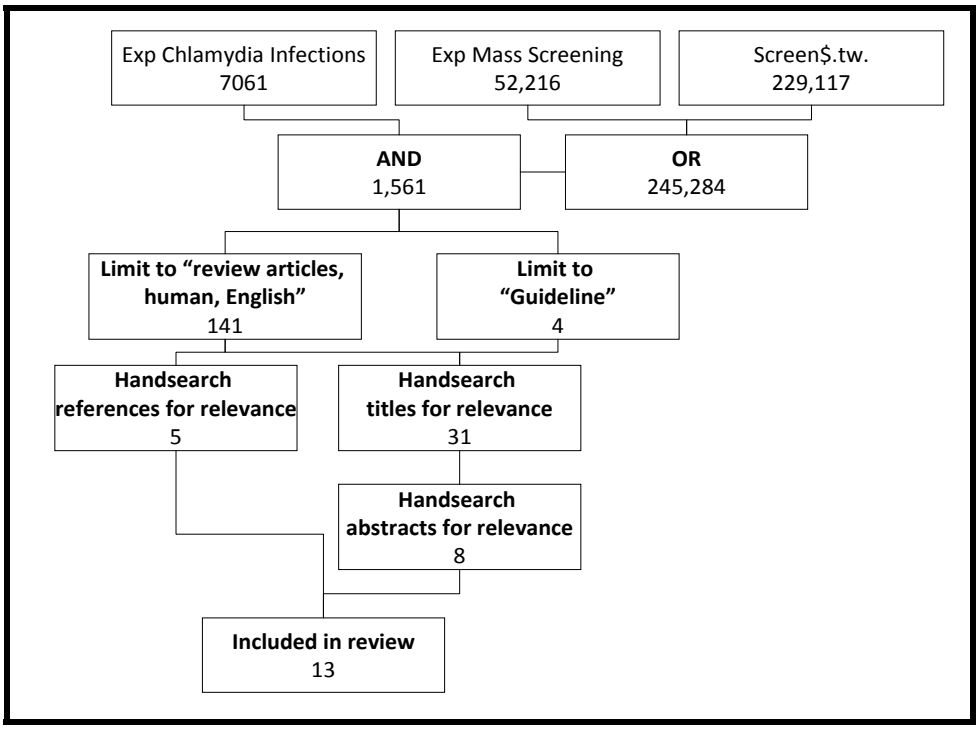
Because of the above-mentioned changes to chlamydia testing and their profound effects on the availability of data, I have focused my literature review on prevalence and

incidence to studies that utilised DNA-based testing methods and to reviews of the respective literature. I also focused my literature review on developed countries comparable to the Australian context. Only articles published up to the beginning of 2005 (in print in 2004) were included as my own studies commenced in 2004.

I used the following search engines for this literature review: PubMed, OvidSP, Embase, Cochrane databases, Google and CINAHL (Plus). Additionally, the reference lists of articles were searched for relevant publications. I used the MeSH search terms – 'chlamydia', 'Chlamydia trachomatis', 'mass screening', 'risk', 'review literature' and 'review' – in order to identify the articles. Articles were deemed relevant if they were reporting on risk factors for chlamydia infection in either men or women, or if they reported screening criteria, and demographic information about the study population. All non-English articles were excluded.

The articles identified were filtered by relevance (e.g. excluding *Chlamydia pneumonia*), and references already included in the identified reviews were excluded. A total of 13 articles, including eight review articles and five original articles, were used for the review (see Figure 2.6).

Figure 2.6 Overview of literature search for studies on occurrence of chlamydia



Articles were selected for abstract review if they were about genital chlamydia infection excluding trachoma. The abstract was then reviewed. The full article was reviewed if the abstract indicated that the study was about prevalence or incidence in a population-based sample or sub-population. Comprehensive reviews were conducted to determine policy in several countries, including the US, Canada, Scotland and the UK. These review articles were included and only articles that reported results not covered by the included reviews were added if they fitted the selection criteria.

The review articles included in this literature review were comprehensive and not systematic, as too many smaller studies had been published on chlamydia. To be included, all review articles were assessed based on strict inclusion and exclusion criteria: adequate sample size; clear definition of study population; and type of diagnostic test used, thereby excluding non-NAAT-based studies. In addition, articles that were not part of previous reviews because of timing or geography were included. Similar inclusion and exclusion criteria were used to assess these articles.

2.3.2 Frequency of occurrence of Chlamydia trachomatis in developed countries

Figure 2.7 depicts the development of notification rates for chlamydia per 100,000 population for selected developed countries: those with national guidelines for screening for chlamydia; those with active screening programs for chlamydia; the Netherlands, which currently conduct numerous studies investigating the feasibility of national screening; and Australia, where the Australian Government Department of Health and Ageing is in the process of commissioning studies in all States and Territories to investigate the feasibility of a national screening program for Australia (Abbott 2005). Figure 2.7 show a clear trend of increased notification rates from the late 1990s onwards for all selected countries, except the Netherlands where chlamydia has only been notifiable since 2003.

Figure 2.8 shows notification rates per 100,000 inhabitants for all States and Territories in Australia between 1994 and 2005. Again, there was a general trend to increased notification in all States and Territories from the late 1990s onwards. In addition, the graph shows that notification rates were substantially higher for the Northern Territory. In Figure 2.9, notification rates per 100,000 inhabitants are plotted for Queensland and for Australia between 1994 and 2005. The figure clearly shows that notification rates in Queensland exceeded the national average in the designated time frame. Figure 2.10 provides notification rates stratified by Indigenous status and by States for the period from 1994 to 2004. This figure shows that notification rates were much higher for Indigenous Australians and, in particular, in the Northern Territory (National Centre in HIV Epidemiology and Clinical Research 2000; National Centre in HIV Epidemiology and Clinical Research 2005). The geographical differences in notification rates in Australia for 2004 were substantial and are depicted in Figure 2.11.

A total of 13 articles, including eight reviews, were identified for this literature review (Table 2.1). The eight reviews included between 14 and 90 studies pertaining to the incidence and prevalence of chlamydia. Given the similarities of the topics addressed by the eight reviews, it is not surprising that there was considerable overlap in the reviewed articles.

My literature review included three review articles in which traditional diagnostic methods were used as well as NAAT-based methods (Davies and Wang 1996; Henry-

Suchet, Sluzhinska et al. 1996; Wilson, Honey et al. 2002) (Table 2.1). These three reviews included reports from all over the world (Davies and Wang 1996; Henry-Suchet, Sluzhinska et al. 1996) (Davies and Wang 1996; Henry-Suchet, Sluzhinska et al. 1996) and Europe only (Wilson, Honey et al. 2002) (Wilson, Honey et al. 2002). In addition, I am aware that previously there was a report published by the Scottish Intercollegiate Guidelines Network in 2000, which was available online (http://www.sign.ac.uk/guidelines/published/index.html). However, the network updated its guidelines in 2009 and the old version is no longer available. Davies and Wang (1996) did not mention sample sizes; however, the other two reviews had included studies with sample sizes ranging between 95 and 72,831 participants. The target populations of the three review articles included young males and females, as well as women attending services for reproductive health. Wilson, Honey et al. (2002) included only female-based studies. The three reviews found prevalences for chlamydia ranging between 1% and 21% for men and between 0% and 86% for females, although prevalences markedly above 25% were found in women attending infertility clinics or presenting with ectopic pregnancies.

Another three reviews included studies that had predominantly applied NAAT-based diagnostic tests for chlamydia (Nelson and Helfand 2001; Kohl, Markowitz et al. 2003; Adams, Charlett et al. 2004) (Table 2.1). These three reviews included reports from all over the world (Nelson and Helfand 2001; Kohl, Markowitz et al. 2003) and the UK and Ireland only (Adams, Charlett et al., 2004). Reviewed articles included studies with sample sizes ranging between 20 and 148,650 participants. The target populations of these three review articles again included young males and females, but also people who attended community and primary care facilities. Prevalences ranged between 0% and 33% for men and between 1.6% and 45% for women (Nelson and Helfand 2001; Kohl, Markowitz et al. 2003; Adams, Charlett et al. 2004). Kohl et al. (2003) also provided results relating to the number of tests performed rather than the number of people who were tested positive, with prevalences ranging between 2.7% and 29.1%.

Two Australian reviews were included in my literature review (Chen and Donovan 2004; Vajdic, Middleton et al. 2005) (Table 2.1). Both Australian reviews included studies that had predominantly applied NAAT-based diagnostic tests for chlamydia. Chen and Donovan (2004) included only articles with 100 or more participants. They

reviewed 18 different populations, including a total of 21,640 diagnosed specimens. Vajdic, Middleton et al. (2005) reviewed 50 different populations of all sizes, with a total of 40,587 individuals. The single studies ranged between 48 participants and 6,199 specimens (Vajdic, Middleton et al. 2005). The target populations of the two reviews included people attending STI clinics and family planning clinics, Australian Indigenous communities and a random selection of 657 Victorian women aged 18 to 35 years (Hocking, Willis et al. 2006). The review by Chen and Donovan (2004) found prevalences ranging between 0% and 12.9% for men and between 0.9% and 19.7% for women. For Indigenous Australians prevalences ranged overall between 6.5% and 11%. The study by Vajdic, Middleton et al. (2005) found a mean overall prevalence of 4.6%, while the mean prevalence for community-based Indigenous men was 7.5% and for women was 8.7%, and 1.5% and 1.4% for non-Indigenous men and women, respectively. The population-based study by Hocking, Willis et al. (2006), which was included in Vajdic's review, found a prevalence of 3.1% for Victorian women aged 18 to 24 years and 0.2% for women aged 25 to 35 years. The latter result was the lowest reported prevalence in Vajdic's review. Further in this review, the highest prevalence of chlamydia infection (27%) was reported for 92 pregnant adolescents aged 13 to 17 years who intended to deliver (Quinlivan et al., 1998). Thirty-three percent of women in this study were Indigenous. Debattista et al. (2002) reported a prevalence of 19.7% for 249 female Queensland disadvantaged youth who were detached from formal schooling.

My literature review on the prevalence of chlamydia included another five single articles that were published between 1995 and 2005 (Table 2.1). These studies were included because they were not part of any of the previously described review articles. I included these studies into my review because they were either population-based or substantial. However, the prevalence rates found in those studies were not markedly different from the results reported in the reviews. The Australian study by Hocking and Fairley (2005) was an audit of the Melbourne Sexual Health Centre, which is frequently attended by men who have sex with men (MSM). The study analysed data collected between 2002 and 2003, and included a total of 4,726 participants. Twenty-three percent of the 2,642 male clients were MSM. Prevalence for female sex workers was 3.3% and for female non-sex workers was 4.0%; prevalence in MSM was 9.1% and in other men was 6.8% (Hocking and Fairley 2005).

2.3.3 Risk factors for Chlamydia trachomatis

Studies agree that the risk of chlamydia infection is highest in the 15 to 19 year age group followed by the 20 to 24 year age group (Figure 2.12; Table 2.2a). Studies were more frequently conducted in female populations. A comparison of prevalence or notification rates of men and women (Table 2.1) showed that frequency of disease was similar for both genders. Female rates were higher in studies investigating risk settings such as ectopic pregnancy or reproductive health clinics (Davies and Wang 1996; Henry-Suchet, Sluzhinska et al. 1996). A large Australian review of 50 populations, including 40,587 participants, found very similar prevalences for men (non-Indigenous, 1.4%; Indigenous, 8.7%) and women (non-Indigenous, 1.5%; Indigenous, 7.5%) (Vajdic, Middleton et al. 2005) (Table 2.1).

Non-white Americans and non-white residents in the UK had increased rates of chlamydia (Nelson et al., 2001; Turner et al., 2002; Lamontagne et al., 2004) (Table 2.2a). Turner and co-workers (2002) noted prevalence rates of 21.4% for black female Americans in comparison to 1.3% for non-black female Americans, and 7.5% and 5.2% for respective male groups. Similarly, Lamontagne and co-workers noted that both men and women of black Caribbean, black British and mixed ethnicity were significantly more likely to be infected with chlamydia compared to white British people (Lamontagne, Fenton et al. 2004). Both Australian reviews noted that infection rates were increased for Indigenous people compared to non-Indigenous participants (Chen and Donovan 2004; Vajdic, Middleton et al. 2005) (Table 2.2a; Figure 2.10). Two reviews mentioned low income as a risk marker for chlamydia infection (Davies and Wang 1996; Nelson and Helfand 2001) (Table 2.2a).

Noted behavioural risk factors for chlamydia infection included the number of sexual partners or partner change during the past 3 to 12 months (Table 2.2a). Number of sexual partners was identified by all review articles, including the two Australian reviews, which had access to respective information (Davies and Wang 1996; Henry-Suchet, Sluzhinska et al. 1996; Nelson and Helfand 2001; Kohl, Markowitz et al. 2003; Chen and Donovan 2004; Vajdic, Middleton et al. 2005). The Swedish study by Jonsson et al. (1995) noted the lifetime number of partners and age at sexual debut as risk factors for infection (Jonsson, Karlsson et al. 1995). Most of the review articles identified not using a condom as a risk factor for chlamydia infection (Davies and Wang 1996; Henry-

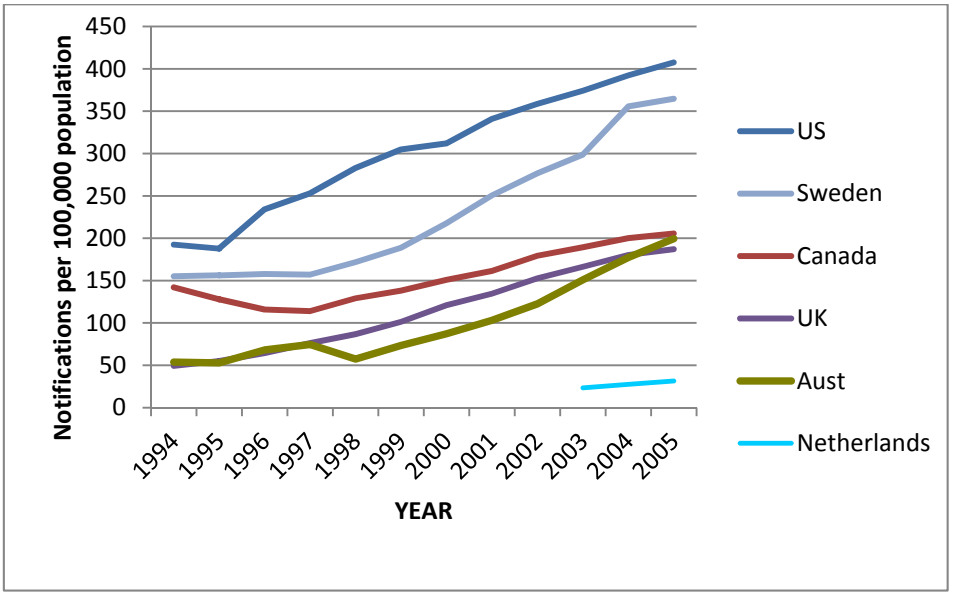
Suchet, Sluzhinska et al. 1996; Nelson and Helfand 2001; Kohl, Markowitz et al. 2003; Chen and Donovan 2004) (Table 2.2a). Hocking and Fairley (2005) reported higher rates of infection in MSM. These authors found that in non-MSM Victorian men, the risk of infection was 1.5 times higher when condoms were used less often than 50% of the time during sexual encounters in the past 3 months. In contrast for MSM, the risk of infection remained unchanged with decreased use of condoms but was significantly reduced when no anal sex had been practised during the previous 3 months (Hocking and Fairley 2005). The same study showed that women who had reported a condom use of less than 50% during the previous 3 months had a significantly increased risk of chlamydia infection (adjusted odds-ratio of 2.5) (Hocking and Fairley 2005). In addition, two of the review articles and an original Finnish study noted the use of oral contraceptives or intrauterine devices (IUDs) as risk markers for infection (Henry-Suchet, Sluzhinska et al. 1996; Hiltunen-Back, Haikala et al. 2001; Nelson and Helfand 2001) (Table 2.2a).

Several published reviews and original articles identified a history of STIs as well as a history of PID as risk markers for increased risk of current infection with chlamydia (Jonsson, Karlsson et al. 1995; Davies and Wang 1996; Hiltunen-Back, Haikala et al. 2001; Nelson and Helfand 2001; Kohl, Markowitz et al. 2003) (Table 2.2b). In addition, Davies and Wang (1996) and Nelson and Helfand (2001) identified current STI infection other than chlamydia as a risk marker (Table 2.2b). Henry-Suchet, Sluzhinska et al. (1996) as well as Nelson and Helfand(2001) noted that women who attended pregnancy clinics were more likely to be infected with chlamydia (Table 2.2b). Henry-Suchet and co-workers noted that women younger than 20 years of age who were seeking termination of pregnancy (TOP) were three to four times more likely to be infected (Henry-Suchet, Sluzhinska et al. 1996). In addition, Jonsson, Karlsson et al. (1995) reported that women who had a history of TOP had a higher likelihood of infection (Table 2.2b).

Symptoms for chlamydial or gonorrhoeal infections, including inter-menstrual bleeding (IMB) and dysuria and/or discharge, were mentioned as risk factors by several authors (Davies and Wang 1996; Henry-Suchet, Sluzhinska et al. 1996; Nelson and Helfand 2001; Kohl, Markowitz et al. 2003; Hocking and Fairley 2005). Two reviews noted that the setting of a study was of relevance (Adams, Charlett et al. 2004; Vajdic, Middleton

et al. 2005). Clinic-based studies tended to report higher infection rates than community-based studies (Table 2.2b). Turner et al. (2002) noted that participants who reported the use of antibiotics in the previous 6 months were at a lower risk of infection (Table 2.2b).

Figure 2.7 Trends in chlamydia notification rates per 100,000 population in selected developed countries 1994 to 2005



(Australian Government Department of Health and Ageing 2009; US Department of Health and Human Services, Centers for Disease Control and Prevention et al. 2009; World Health Organization and Regional Office for Europe 2010).

Figure 2.8 Trends in chlamydia notification rates per 100,000 population in Australia, States and Territories 1994 to 2005

(Australian Government Department of Health and Ageing 2009)

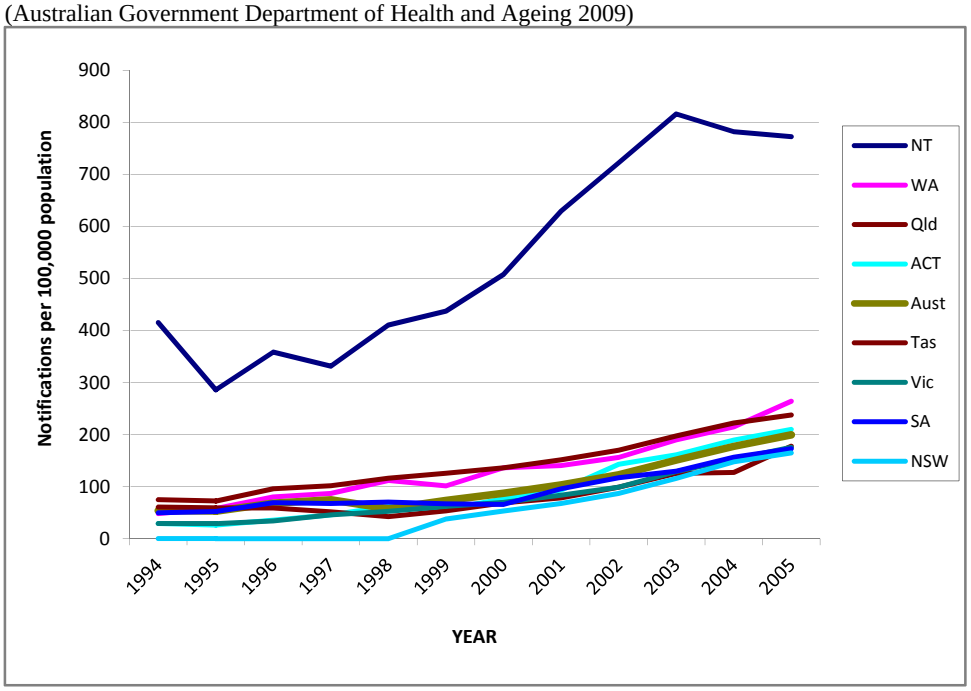
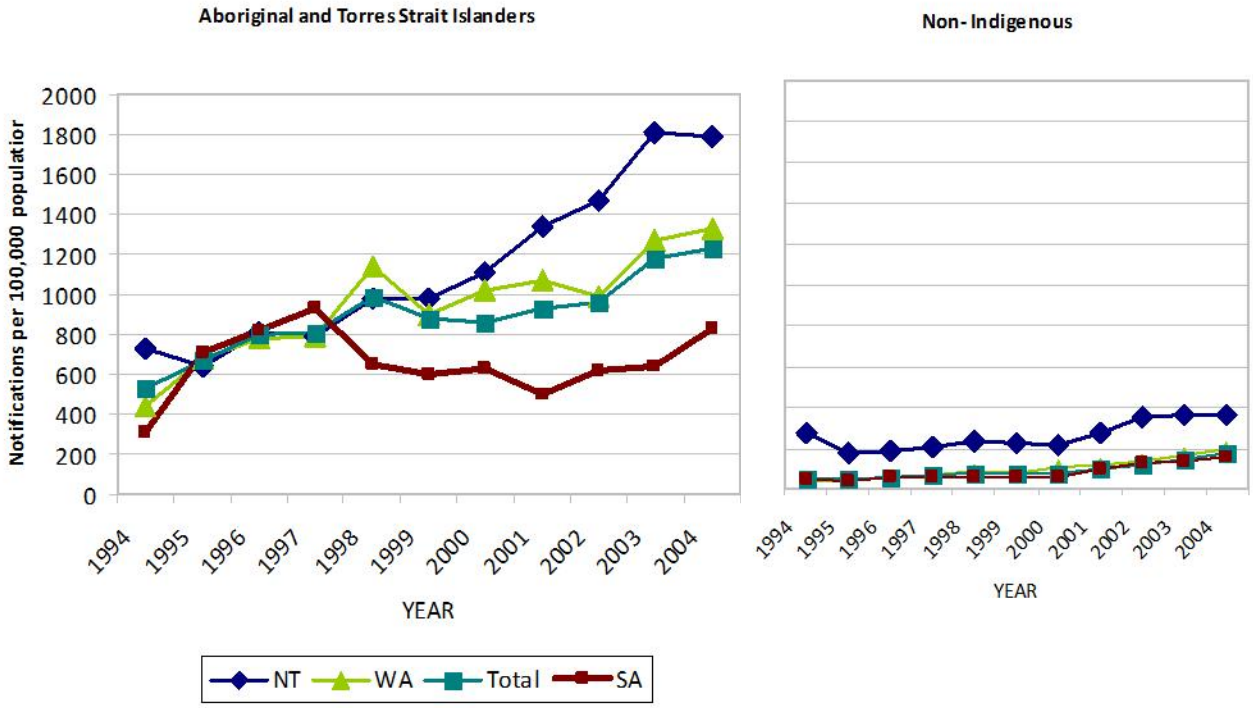
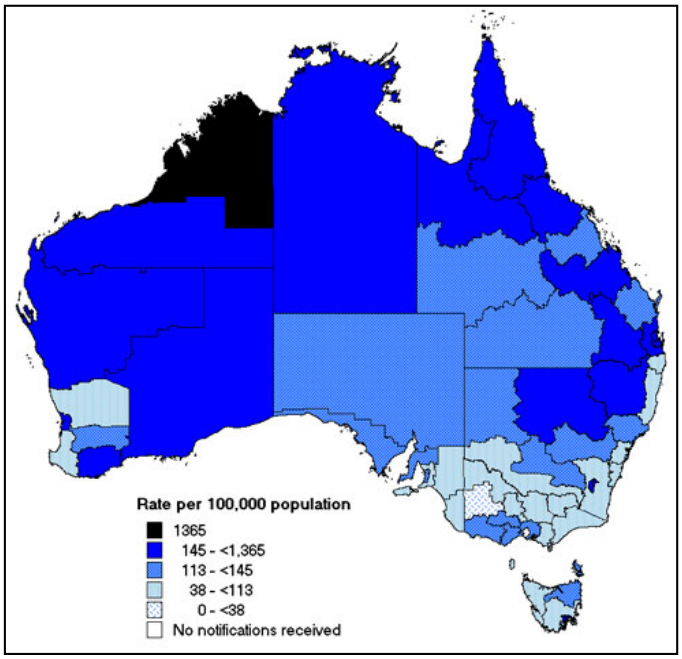


Figure 2.9 Trends in chlamydia notification rates per 100,000 population by Indigenous status and State 1994 to 2004



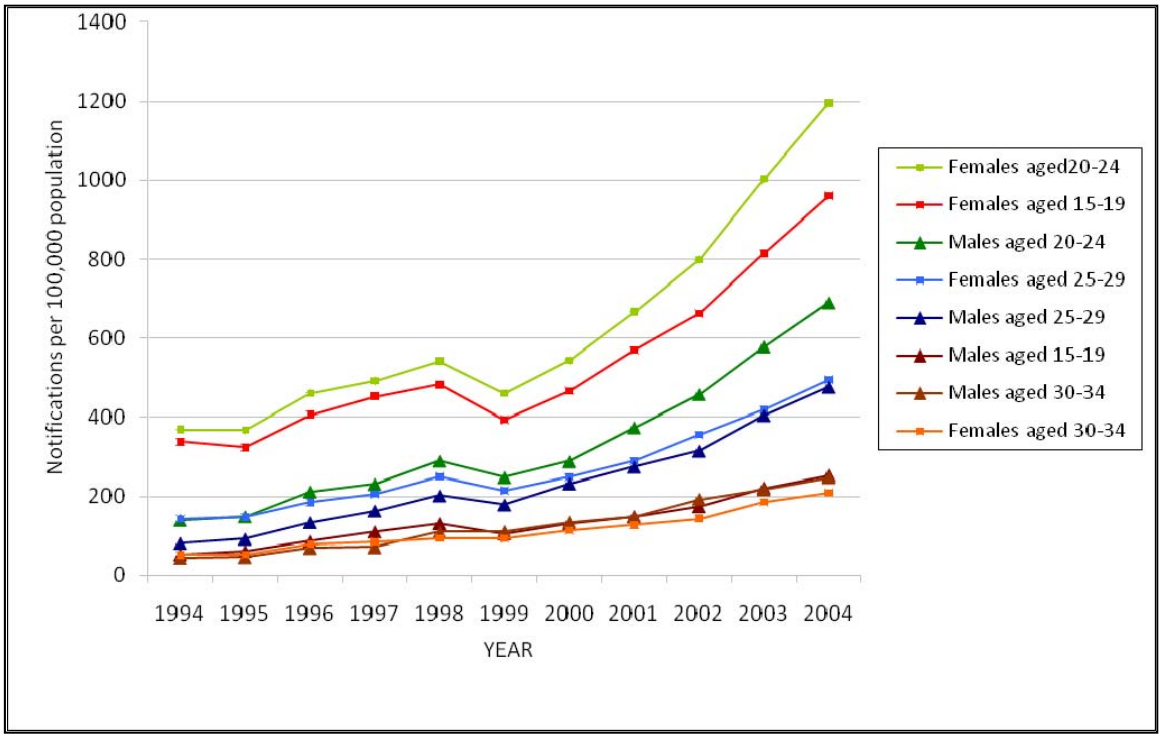
(National Centre in HIV Epidemiology and Clinical Research (Australia) 2000; National Centre in HIV Epidemiology and Clinical Research (Australia) 2005)

Figure 2.10 Notification rates of chlamydial infection, Australia, 2003, by Statistical Division of residence



(Miller, Roche et al. 2005)

Figure 2.11 Notification rates of chlamydial infection by age group and year



(Australian Government Department of Health and Ageing 2005)

Table 2.1 Review articles and selected articles describing prevalence and incidence of *Chlamydia trachomatis* from the mid 1990s to 2005 in developed countries

Author, year, country	Design; time frame; number of articles related to prevalence and incidence or location	Population and sample size	Testing methods used	Prevalence/ incidence overall	Men	Women
REVIEW Mainly traditional methodology						
Davies, H. D. and Wang, E. E., 1996, Canada	Review of articles from Canada and worldwide; 1983–1995; 23 articles	Adolescents, college students, women attending services related to reproductive health	DFA[1], ELISA[2], PCR, culture		Young Canadians: *P*[*]: 1% to 21%	Young Canadians & reproductive health: *P*: 1% to 25% Infertility: *P*: 11% to 86% Ectopic pregnancy: *P*: 0% to 82%
Henry-Suchet, J. et al., 1996, France	Review of articles worldwide; 1985–1996; 31 articles	Military recruits, young women, reproductive health services; between 146 and 72,831 participants	Culture, EIA[3], PCR, DIF[4]		Military service: *P*: 1.3% to 12.2%	Military service: *P*: 8.2% to 10.0% Young women: *P*: 3.5% to 25.0% Pregnant women: *P*: 2.0% to 26.7% Reproductive health services: *P*: 4.0% to 17.0%
Wilson, J.S. et al., 2002, Europe	Review of articles Europe; 1980 to 2000; UK, Sweden, Netherlands, Bulgaria, France Finland, Hungary, Italy , Spain; 14 articles	Women, reproductive health services, schools, GP practices, 14,794 participants, between 95 and 6,161	Culture, DFA, EIA, PCR, LCR, Pace 2,			*P:*1.7% to 17%
REVIEW Predominately DNA-based methodology						
Nelson, H.D. et al., 2001, USA	Review of articles worldwide; 1994–2000; 18 articles	Men, military recruits, non-pregnant women, community and primary care, STI clinics, reproductive health services; 141,549 participants , range 211 to 28,000 participants	EIA, DFA, culture, PCR and LCR		*P*: 1.2% to 15.4%	Non-pregnant women: *P*: 2.3% to 21.5% Pregnant women: *P*: 2.0% to 31.0%

Author, year, country	Design; time frame; number of articles related to prevalence and incidence or location	Population and sample size	Testing methods used	Prevalence/ incidence overall	Men	Women
Kohl, K.S. et al., 2003, USA	Review of articles worldwide; 1996–2003; 15 articles	Reproductive health services, STI clinics, education facilities; 256 to 148,650 participants	EIA, DFA, culture, PCR, DNA probe, LCR	*P*: 2.0% to 45.0% Positivity: 2.7% to 29.1%		
Adams, E.J. et al., 2004, UK	Review of articles UK, Ireland; 1978–2003; 90 articles	Military recruits, GP surgeries, reproductive health services, STI clinics, postal surveys, 149,430 participants, range 20 to 42,944	NAAT, PCR, LCR, TMA[5], EIA, ELISA, DFA, MIF[6], culture, unknown	*P*: 0% to 33%	*P*: 0% to 33%	*P*: 1.6% to 12.7%
AUSTRALIA						
Chen, M. & Donovan B., 2004	Review of articles Australia and worldwide 1980– 2003, over 100 participants and NAAT testing	18 populations, 21,640 specimens, Indigenous community, population-based, STI clinic	NAAT, non-NAAT in older studies	*P*: 0% to 19.7% *P*: 6.5% to 11% Ind[**].	*P*: 0% to 12.9% *P*:8.6% to 9.1% Ind.	*P*: 0.9% to 19.7% *P*: 6.5% to 11% Ind.
Vajdic, C.M. et al., 2005, Australia	Review of articles Australia; 1997–2004; 40 articles	50 populations; 40,587 participants; population, reproductive health services, community, STI clinics,	NAAT, EIA & NAAT	*P*: 4.6% overall *P*: 8.0% Ind. *P*: 3.2% NI[***],	*P*: 8.7% Ind. *P*: 1.4% NI	*P*:7.5% Ind. *P*: 1.5% NI
ORIGINAL ARTICLES - PCR						
Jonsson, M. et al., 1995, Sweden	Population-based sample, serology and culture, cross-sectional study, not specifically stated when data was collected	611 participants, all women, community in north of Sweden, participation rate 75%, cohorts of 19, 21, 23 and 25 year olds	Culture, cervical samples, serology MIF			*P*: 2.7% culture, 24.7% serology

Author, year, country	Design; time frame; number of articles related to prevalence and incidence or location	Population and sample size	Testing methods used	Prevalence/ incidence overall	Men	Women
Turner, C.F. et al., 2002, US	Population-based sample, Baltimore US	579 participants, 18 to 35 years old, residents of Baltimore	NAAT, LCR	*P*:3.0% [0% to 6.4%]	*P*: 1.1% to 2.4%	*P*: 0% to 6.4%
Hiltunen-Back, E. et al., 2002, Finland	Nationwide sentinel, cross-sectional study, 1995–1997, Finland	35,916 participants, 7 STI clinics, 5 student health clinics, 18,610 men, 13,620 women	LCR, PCR, culture, immunoassay	STI clinic *P*: 8.4% Health clinic *P*: 5.3%	STI clinic *P*: 8.8%	STI clinic *P*: 7.8%
Lamontagne, D. S. et al., 2004, UK	Cross-sectional study, 2003–2004, UK,	16,413 tests, 302 sites, GP clinics	PCR		13.3%	10.1%
Hocking, J. & Fairley, C. K., 2005, Australia	Cross-sectional, audit, Melbourne, Australia, 2002 to 2003	4,726 participants, 2,642 males, 2,084 females, STI clinic	SDA[7]		7.3% [6.3%; 8.4%]	3.9% [3.1%; 4.9%]

Abbreviations: [*]*P*,Prevalence; [**] Ind, Indigenous; [***]NI, non-Indigenous; [1]DFA, direct fluorescent antibody; [2]ELISA, enzyme-linked immunoassay; [3]EIA enzyme immunoassay; [4]DIF direct immunofluorescence; [5]TMA, transcription mediated amplification; [6]MIF, micro immunofluorescence; [7]SDA, strand discplacement assay

Table 2.2a Review articles and articles describing risk factors for *Chlamydia trachomatis* – Part 1

			Socio-demographic risk factors			Behavioural risk factor		
Author, year, country	**Design; time frame; number of articles related to risk factors**	**Population and sample size**	**Age**	**Ethnicity**	**Socio-economic status**	**Partner**	**Sexual practices**	**Contraceptive use**
Worldwide								
Jonsson, M. et al., 1995, Sweden	Population-based sample, serology and culture, cross-sectional study, not specifically stated when data was collected	611 participants, all women, community in north of Sweden, participation rate 75%, cohorts of 19, 21, 23 and 25 year olds	Younger age at coitarche	-	-	Lifetime partners	-	-
Davies, H. D. & Wang, E. E., 1996, Canada	Review of articles from Canada and worldwide; 1983–1995; 23 articles	Adolescents, college students, women attending services related to reproductive health	Male: younger age Female: under 25	-	Low income	Male: multiple partners Female: >2 partners past 12/12, new partner past 12/12	Male: Female: condom use	-
Henry-Suchet, J. et al., 1996, France	Review of articles worldwide; 1985–1996; 31 articles	Military recruits, young women, reproductive health services; between 146 and 72,831 participants	Male: young Female: under 25 and under 20 more	-	-	Male: - Female: >1 or >3 partners past 12/12	Male: Female: condom use	OCP*
Nelson, H.D. et al., 2001, USA	Review of articles worldwide; 1994–2000; 32 articles	Men, military recruits, non-pregnant women, community and primary care, STI clinics, reproductive health services; range to 13,204 participants	Male: under 25 Female: under 25	Male: non-white Female: black or non- white	Low income	Male: >2 partners in 2/12, STI in partner Female: multiple partners, new partner, symptomatic partner, STI in partner	Condom use	OCP

			Socio-demographic risk factors			Behavioural risk factor		
Author, year, country	**Design; time frame; number of articles related to risk factors**	**Population and sample size**	**Age**	**Ethnicity**	**Socio-economic status**	**Partner**	**Sexual practices**	**Contraceptive use**
Turner, C.F. et al., 2002, US	Population-based sample, Baltimore US,	579 participants, 18 to 35 years old, residents of Baltimore	Younger age	Male: black Female: black	-	-	-	-
Hiltunen-Back, E. et al., 2002, Finland	Nationwide sentinel, cross-sectional study, 1995 to 1997, Finland	35,916 participants, 7 STI clinics, 5 student health clinics, 18,610 men, 13,620 women	Younger age	-	-	Higher number of partners Male: casual partner Female: regular partner	-	OCP, IUD
Kohl, K.S. et al., 2003, USA	Review of articles worldwide; 1996–2003; 15 articles	Reproductive health services, STI clinics, education facilities; 256 to 148,650 participants	Male: young age Female: young age, <25,	-	-	Male: > 1 partner Female: new or multiple partners	Condom use	-
Adams, E.J. et al., 2004, UK	Review of articles UK, Ireland; 1978–2003; 90 articles	Military recruits, GP surgeries, reproductive health services, STI clinics, postal surveys, 149,430 participants, range 20 to 42,944	Younger age, <20 highest	-	-	-	-	-
Lamontagne, D. S. et al., 2004, UK	Cross-sectional study, 2003–2004, UK	16,413 tests, 302 sites, GP clinics	Male: <25 Female: <20	Non- white	-	New partner, multiple partners, Male: not sig**. Female: sig.	-	-

			Socio-demographic risk factors			Behavioural risk factor		
Author, year, country	**Design; time frame; number of articles related to risk factors**	**Population and sample size**	**Age**	**Ethnicity**	**Socio-economic status**	**Partner**	**Sexual practices**	**Contraceptive use**
AUSTRALIA								
Chen, M. & Donovan B., 2004	Review of articles Australia and worldwide 1980–2003, over 100 participants and NAAT testing	18 populations, 21,640 specimen, Indigenous community, population-based, STI clinic	Male: younger Female: younger, <25	Indigenous higher than non-Indigenous	-	Higher number of partners, recent change in partner	Condom use	-
Vajdic, C.M. et al., 2005, Australia	Review of articles Australia; 1997–2004; 40 articles	50 populations; 40,587 participants; population, reproductive health services, community, STI clinics	Male:- Female: younger age	Indigenous higher than non-Indigenous	-	Male: - Female: ≥2 partners past 12/12	-	-
Hocking, J. & Fairley, C. K., 2005, Australia	Cross-sectional, audit, Melbourne, Australia, 2002–2003	4,726 participants, 2,642 males, 2,084 females, STI clinic	Male: MSM 30 to 35, non-MSM <25 Female: < 20 non-CSW, <25 CSW	-	-	MSM*** Male: MSM >3 partners past 3/12, symptomatic partner, STI in partner non-MSM: > 4 partners 12/12, STI in partner Female: >2 partners 12/12, STI in partner	Male: non-MSM <50% condom use past 3/12 Female: <50% condom use past 3/12	-

Abbreviations: * OCP, oral contraceptive pill; **sig, significant; ***CSW, commercial sex worker.

Table 2.2b Review articles and articles describing risk factors for *Chlamydia trachomatis* – Part 2

Author, year, country	Design; time frame; number of articles related to risk factors	Population and sample size	History of STI	Other risk factors
WORLDWIDE				
Jonsson, M. et al., 1995, Sweden	Population-based sample, serology and culture, cross-sectional study, not specifically stated when data was collected	611 participants, all women, community in north of Sweden, participation rate 75%, cohorts of 19, 21, 23 and 25 year olds	Past PID	Previous TOP
Davies, H. D. & Wang, E. E., 1996, Canada	Review of articles from Canada and worldwide; 1983–1995; 23 articles	Adolescents, college students, women attending services related to reproductive health	Male: past gonorrhoea infection	Male: nil Female: concurrent gonorrhoea infection; symptoms: IMB
Henry-Suchet, J. et al., 1996, France	Review of articles worldwide; 1985–1996; 31 articles	Military recruits, young women, reproductive health services; between 146 and 72,831 participants	-	TOP, symptoms: dysuria and/or discharge
Nelson, H.D. et al., 2001, USA	Review of articles worldwide; 1994–2000; 32 articles	Men, military recruits, non-pregnant women, community and primary care, STI clinics, reproductive health; range to 13,204 participants	Past STI, PID	Pregnancy, douching, concurrent gonorrhoea infection, symptoms: dysuria and/or discharge
Turner, C.F. et al., 2002, US	Population-based sample, Baltimore, US	579 participants, 18 to 35 years old, residents of Baltimore	-	Antibiotic use in past 6/12 lowers risk
Hiltunen-Back, E. et al., 2002, Finland	Nationwide sentinel, cross-sectional study, 1995–1997, Finland	35,916 participants, 7 STI clinics, 5 student health clinics, 18,610 men, 13,620 women	Past STI	

Author, year, country	Design; time frame; number of articles related to risk factors	Population and sample size	History of STI	Other risk factors
Kohl, K.S. et al., 2003, USA	Review of articles worldwide; 1996–2003; 15 articles	Reproductive health services, STI clinics, education facilities; 256 to 148,650 participants	Past STI	Symptoms: dysuria and/or discharge
Adams, E.J. et al., 2004, UK	Review of articles UK, Ireland; 1978–2003; 90 articles	Military recruits, GP surgeries, reproductive health services, STI clinics, postal surveys, 149,430 participants, range 20 to 42,944	-	Setting of study, population-based lower than clinic-based
Lamontagne, D. S. et al., 2004, UK	Cross-sectional study, 2003–2004, UK	16,413 tests, 302 sites, GP clinics	-	-
Chen, M. & Donovan B., 2004	Review of articles Australia and worldwide 1980–2003, over 100 participants and NAAT testing	18 populations, 21,640 specimens, Indigenous community, population-based, STI clinic	-	-
Vajdic, C.M. et al., 2005, Australia	Review of articles Australia; 1997–2004; 40 articles	50 populations; 40,587 participants; population, reproductive health services, community, STI clinics,	-	Setting, community-based lower than clinic-based for non-Indigenous
Hocking, J. & Fairley, C. K., 2005, Australia	Cross-sectional, audit, Melbourne, Australia, 2002–2003	4,726 participants, 2,642 males, 2,084 females, STI clinic	-	Symptoms: dysuria and/or discharge

2.3.4 Discussion

My review included a total of 13 articles, eight of which were review articles. Some of these review articles were very comprehensive, consisting of numerous original manuscripts. Some reviews were based on data from more than 100,000 people (Kohl, Markowitz et al. 2003; Adams, Charlett et al. 2004). Two reviews were conducted to inform national guidelines for chlamydia screening in Canada (Davies and Wang 1996) and the US (Nelson and Helfand 2001).

Chlamydial notification rates for the US, UK and many European countries, as well as for Australia as a whole and for all States and Territories, showed clear upward trends between the 1990s and 2005. The initial increase from the mid 1990s onwards was not unexpected as at that time NAAT diagnostic testing was introduced and quickly became the expanded gold standard (Watson, Templeton et al. 2002). The change in diagnostic testing enabled healthcare providers to start opportunistic as well as nationally organised screening for chlamydia. For example, the UK introduced a national screening program for chlamydia in late 2002 (Lamontagne, Fenton et al. 2004). NAAT testing is more sensitive than previously used methods, cheaper and allows testing of asymptomatic individuals outside the clinical setting (Genc and Mardh 1996; Dean, Ferrero et al. 1998; Watson, Templeton et al. 2002).

The question remains whether these increases in notification reflect real increases in chlamydia prevalence. In the absence of population-based longitudinal data on chlamydia, this question is, indeed, difficult to answer. One could try to detect changes in rates for severe outcomes of chlamydia infections, such as ectopic pregnancy or PID, as a proxy. However, in the case of PID in Australia, gradual management changes occurred from hospital-based to non-hospital-based treatment. Hence, available hospital separation data for PID will not reflect PID trends adequately. On the other hand, the incidence of ectopic pregnancies decreased from 1990 to 1998 in NSW (Boufous, Quartararo et al. 2001).

In Australia, notifiable disease surveillance is the responsibility of state and local health authorities. Notification and surveillance requirements are regulated in the public health legislation on state and territory level. Therefore a variation exists between states and territories in regards to case definitions, diseases as well as the responsible person/organisation who has to notify (Yohannes, Roche et al. 2006). In Queensland,

South Australia, the Australian Capital Territory (ACT) and the Northern Territory, notification for chlamydia infection is laboratory-based; that is, each positive diagnosis is automatically notified to the registry or the dedicated public health unit. This is not the case in the other states, where a positive diagnosis is notified by the diagnosing healthcare provider. These different notification processes could imply an under-estimation of notification rates for Western Australia (WA), New South Wales (NSW) and Tasmania, and might explain the comparatively high rates for Queensland.

Notification rates for the Northern Territory were extraordinarily high. These extremely high notification rates might be due to the comparably higher proportion of Indigenous Australians; in 2001, 2.2% of all Australians identified as Indigenous in comparison to 25.1% in the Northern Territory (Australian Bureau of Statistics (ABS) 2001). Figure 2.10 showed that Indigenous Australians from the Northern Territory had particularly high notification rates from 2000 onwards, exceeding all other States. The high notification rates may, in part, be a reflection of intensive screening of Indigenous communities. For example, the 'Well Person's Health Check' is a Queensland-based program targeted at Indigenous people living in remote communities of Cape York (Miller, McDermott et al. 2002; Miller, McDermott et al. 2003). During a typical visit the healthcare provider will screen opportunistically for a variety of potentially common health problems. Similarly, in the Northern Territory the 'Tri State' project is conducted in Alice Springs and surrounds, which might result in high notification rates (Willis, Wilson et al. 2004).

Despite all these unknowns, it is obvious that each notification is a positive case. That is, notifications rates will still only provide an under-estimation of the true prevalence of chlamydia because the denominator for the notification rate includes the total population and not just the tested population.

The prevalence of chlamydia varies widely depending on the population tested and the local context. Prevalence studies and reviews of prevalence and incidence studies for chlamydia showed that the infection is prevalent in many sub-populations of developed countries. Published prevalences typically ranged up to 25% or 30%, and even as high as 86% for women who were selected because they potentially experienced consequences of chlamydia infection, such as ectopic pregnancy or infertility (Davies and Wang 1996).

Age was universally identified as the most influential risk factor of chlamydia infection (Table 2.2a). Young people aged between 15 and 25 years form the highest risk group. Young people are likely to engage in sexual activities and are also likely to more frequently change partners, which increases their risk of infection (Skinner and Hickey 2003). This is in comparison to people who have settled in a stable relationship.

The sexual behaviour of people is an obvious risk factor for all STIs and, in particular, for chlamydia. My review of the data showed clearly that studies agreed that higher numbers of recent sexual partners or partner change increased the risk of infection. The literature indicates that people use condoms to prevent pregnancy rather than the transmission of STIs (East, Jackson et al. 2007). However, condoms are an effective protection measure and my review identified a number of articles that cited low condom usage as a risk factor (Davies and Wang 1996; Henry-Suchet, Sluzhinska et al. 1996; Nelson and Helfand 2001; Kohl, Markowitz et al. 2003; Chen and Donovan 2004; Hocking and Fairley 2005). As a consequence, women who use non-barrier methods of contraception are at increased risk of chlamydia infection, which has been identified in my review. Pregnancies are a result of unprotected sex and it is, therefore, not surprising that pregnant women are at increased risk of infection with chlamydia, as noted by Jonsson, Karlsson et al. (1995), Henry-Suchet, Sluzhinska et al. (1996) and Nelson and Helfand (2001).

It was noted that more studies were focused on chlamydia in women than in men. This could possibly be due to the higher morbidity in women as a consequence of chlamydia infection , as well as to the fact that women are, in general, more likely to access the healthcare system ; in particular, women of reproductive age using non-barrier methods of contraception require medical consultation (Fairley, Hocking et al. 2005). The public health focus on females might give the impression that chlamydia infection is a purely female problem, and my own observations when working as a sexual health nurse suggest that many men perceive chlamydia as a female problem. I should note here that my review identified MSM as a high-risk group for chlamydia and other STIs (Hocking and Fairley 2005).

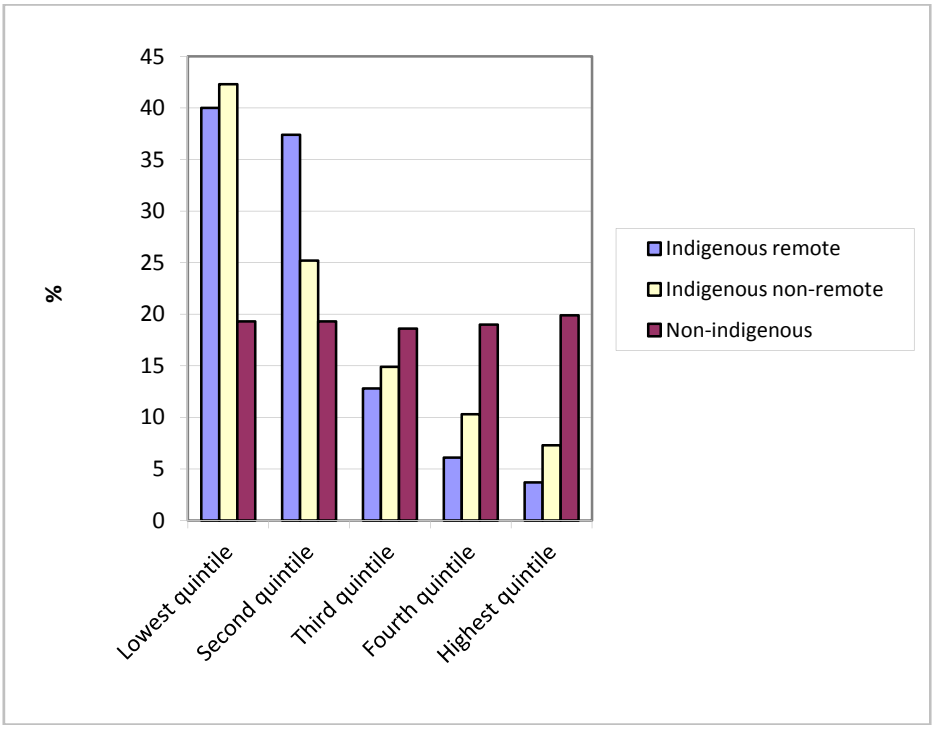
Apart from the notably higher rates in Indigenous Australians, the prevalence of chlamydia in Australia was comparable to that in other developed countries. On the other hand, ethnicity might not be the correct risk indicator as there is no biological

reason for differences in STI rates between ethnic groups. Ethnicity in Australia, as well as in the UK and US, might, however, be a proxy measure for socio-economic status. In Australia in 2002, a majority (70 %) of Indigenous people were in the two lowest quintiles of income indicators and only 6% of Indigenous individuals were in the highest quintile (Australian Bureau of Statistics (ABS) 2004) (Figure 2.13). Income might, as such, explain STI risk differences much better than ethnicity. The reviews by Davies et al. (1996) and Nelson et al. (2001) mentioned low income as a risk marker of infection. However, people might be less inclined to divulge their income and collected information might be misclassified as a consequence. Ethnicity, on the other hand, is often part of the routine data collection set.

Five studies noted a history of STI infection as a risk factor for current chlamydia infection (Jonsson, Karlsson et al. 1995; Davies and Wang 1996; Hiltunen-Back, Haikala et al. 2001; Nelson and Helfand 2001; Kohl, Markowitz et al. 2003). The question arises whether current infection is a persistent infection or, indeed, a new infection. However, this question is difficult to answer. On the other hand, studies showed that between 10% and 15% of previously infected persons had a positive test result after 3 to 6 months (Whittington, Kent et al. 2001; Veldhuijzen, Van Bergen et al. 2005). Hence, current guidelines for the management of chlamydia infection from the US, the UK and Queensland recommend retesting 3 to 6 months after initial treatment (Nelson and Helfand 2001; British Association for Sexual Health and HIV (BASHH) 2002; Queensland Health 2006). In addition, two studies noted a history of PID as a risk marker for current chlamydia infection (Jonsson, Karlsson et al. 1995; Nelson and Helfand 2001). However, PID is a likely consequence of genital STI infection and, therefore, a proxy marker for past infection.

Symptoms including IMB, dysuria and discharge increased the likelihood for chlamydia diagnosis (Davies and Wang 1996; Henry-Suchet, Sluzhinska et al. 1996; Nelson and Helfand 2001; Kohl, Markowitz et al. 2003). These findings are not surprising; however, it is important to bear in mind that the vast majority of chlamydia infections are asymptomatic (Biro, Reising et al. 1994; Stamm 1999; McKay, Clery et al. 2003; Williams, Tabrizi et al. 2003; Solomon, Peeling et al. 2004).

Figure 2.12 Equalised gross household income by Indigenous status 2002



(Australian Bureau of Statistics (ABS) 2004)

2.4 Literature review of intervention studies to increase screening for *Chlamydia trachomatis* in primary care settings

2.4.1 Introduction

So far my literature review showed that chlamydia infection is on the rise in developed countries worldwide, including Australia. The high proportion of asymptomatic infections proposes a particular challenge to management programs. In addition, population-wide screening is out of the question for several reasons, including high costs, high false positive rates and general lack of feasibility. Selective screening in high-risk groups seems to be a much more realistic approach.

As identified above, high-risk groups include young sexually active people aged 15 to 25 years, MSM, people who engage in unprotected sex, and people with a history of STIs. There is broad consensus that young people form the largest risk group for chlamydia infection (Table 2.2a). Therefore, the question remains how to access and successfully engage young people and maybe other risk groups in screening for chlamydia.

One possible option is health promotion campaigns, which increase awareness among the target population about a certain health concern. One of the more famous health promotion campaigns conducted in Australia by the Department of Health and Ageing was the 'Grim Reaper' campaign in 1987 (Abelson, Taylor et al. 2003). This TV campaign targeted the general Australian population and was aimed at raising awareness about HIV. The TV commercial was very controversial, but is still considered highly successful in terms of reaching the population (Myhre and Flora 2000). Despite their successes, health promotion campaigns have several downsides. Money is one of the biggest issues for these campaigns. For example, the 'Grim Reaper' campaign cost about A$3 million in 1987, which is a large sum and requires support from governmental health agencies. In the case of the 'Grim Reaper' campaign, support was granted because of the worldwide increase in HIV/AIDS diagnoses at that time. Therefore, a health promotion campaign to boost screening rates of chlamydia in Australia would require comprehensive coverage and sustained support from State and Federal health authorities.

A second option for improving screening rates could involve outreach clinics. Outreach clinics involve health professionals conducting a clinic in a non-traditional setting. Outreach clinics try to improve access to clinical services by bringing the service to the client rather than expecting the client to come to the service. In Australia, outreach clinics are an attractive option to reach remote communities. Debattista and co-workers (2002a and b) conducted outreach clinics in high schools in the wider Brisbane area and in nightclubs frequented by MSM in order to improve screening rates for chlamydia and *Neisseria gonorrhoea* in these suspected high-risk populations (Debattista, Clementson et al. 2002; Debattista, Martin et al. 2002). Outreach clinics can be highly effective in boosting testing rates in targeted sub-populations. However, each outreach clinic requires dedicated staff and is, therefore, competing with the resources required for standard services. Hence, local outreach clinics often depend on the requirements of the service, as well as compete with other demands on the service. Therefore, implementing outreach clinics to improve screening rates for chlamydia in Australia would not be feasible.

Thus, the focus of my literature review was, firstly, on primary care clinic-based interventions as these are long-term options and, secondly, on non-clinic-based approaches that could be implemented using minimal resources.

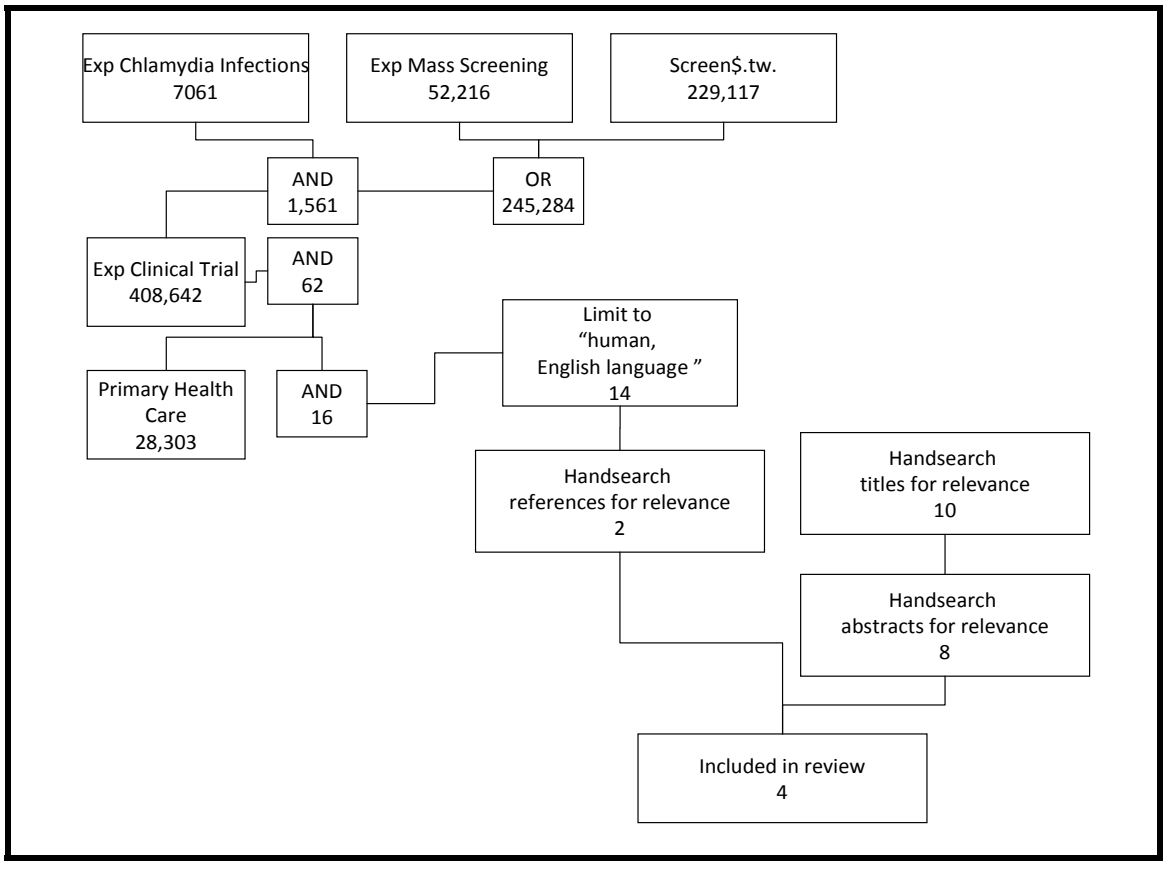
For most developed countries, a possible point of access is provided by the primary care sector, including general practitioners (GP), community health centres and sexual health clinics.

A study by Fairley and co-workers (2005) showed that in Australia in 2004, 81% of 15 to 19 year old women and 89% of 20 to 24 year old women attended a GP at least once in a 12-month period. However, only 7% of women in this age group were tested for chlamydia (Fairley, Hocking et al. 2005). In the US, about 20% of young women aged 15 to 25 years are screened for chlamydia while receiving healthcare by managed care organisations (National Committee for Quality Assurance 2003). A study by Cook and co-workers (2001) found that only one-third of US physicians responded that they would screen asymptomatic, sexually active teenage women for chlamydia during a routine gynaecological examination (Cook, Wiesenfeld et al. 2001). Women in the younger age group are more likely to access healthcare because of reproductive health issues than men and are, therefore, more likely to be screened for STIs than men

(Fairley, Hocking et al. 2005). Australia has the added complication of being a vast country with a 87% urbanisation rate at a few densely populated metropolitan centres (Australian Bureau of Statistics (ABS) 2001). Access to services in rural and remote Australian locations has been an ongoing issue and might be another barrier to screening (Australian Institute of Health and Welfare (AIHW) 1998).

The following literature review focuses on studies that reported interventions to improve screening rates for chlamydia in primary care settings. I conducted this review in the same manner using the same search engines as the review on frequency and risk factors of chlamydia infection.

Figure 2.13 Overview of literature search for intervention studies to increase screening for *Chlamydia trachomatis* in primary care settings



2.4.2 Intervention studies to increase screening for *Chlamydia trachomatis* in primary care settings

The four identified intervention studies were conducted in the US, UK and Belgium (Table 2.3). Two of the studies were cluster randomised controlled trials, with GP clinics and paediatric clinics as the primary sampling units (Shafer, Tebb et al. 2002; Verhoeven, Avonts et al. 2005). One study was a randomised controlled trial randomising GP practices , and one study compared two primary healthcare centres, of which one received an intervention (Armstrong, Kinn et al. 2003; Allison, Kiefe et al. 2005) (Table 2.3).

The intervention designed by Shafer and co-workers (2002) aimed at achieving a cultural change in clinicians towards opportunistic screening for chlamydia using a team development approach. The authors describe their intervention in the following manner: 'the intervention, which required that leadership be engaged by showing the gap between best practice and current practice; a team be assembled to champion the project; barriers be identified and solutions developed through monthly meetings; and progress be monitored with site-specific screening proportions' (Shafer et al., 2001). The intervention was implemented over an 18-month period.

Armstrong and co-workers (2003) used a dedicated health advisor, who worked alongside clinicians in the intervention centre for 6 months. The role of the advisor was to raise awareness of chlamydia among staff and patients and to offer training in general sexual health. The health adviser was available to support staff in managing difficult cases and to advise on administrative systems for effective partner notification work (Armstrong et al., 2003).

Verhoeven et al.'s (2005) intervention aimed to address GPs' reluctance to initiate consultation about sexual health. The intervention consisted of a short video simulating a consultation in which a GP offered testing for chlamydia to a patient. The video was accompanied by a one-page text on communication skills for taking a sexual history (Verhoeven et al., 2005).

Allison and co-workers (2005) implemented a web-based intervention comprising four case-based learning modules for physicians. The learning modules concentrated on: 1.) education about high-risk groups for chlamydia infection; 2.) non-invasive testing

methods; 3.) and treatment options. The intervention also contained printable patient education materials.

Three of the four intervention studies targeted young female patients (Shafer, Tebb et al. 2002; Allison, Kiefe et al. 2005; Verhoeven, Avonts et al. 2005) and one study focused on young patients aged 15 to 24 years (Armstrong, Kinn et al. 2003) (Armstrong, Kinn et al. 2003) (Table 2.3).

Outcome measures of the four studies included the mean number of patients being appropriately tested for chlamydia per GP (Verhoeven, Avonts et al. 2005); the percentage of sexually active females screened (Shafer, Tebb et al. 2002; Allison, Kiefe et al. 2005) (Shafer et al., 2002; Allison et al., 2005); and one study compared the number of requested tests before and after the intervention (Armstrong, Kinn et al. 2003). All four studies reported overall improvements in their outcome measures (Table 2.3).

The study by Verhoeven and co-workers (2005) reported that the pre-intervention mean number of tests was just over two in a 15-week period, similar for both intervention and control groups. This number was increased to six in the intervention group and to 3.2 in the control group ($P = 0.035$) (Table 2.3). The study was able to increase the percentage of patients who were appropriately tested from 67.1% to 85.5%; however, this result was not significant ($P = 0.075$), most likely because of the small sample size (18 GPs in each group). The result was significant ($P = 0.029$) at the patient level ($n = 211$).

The study by Shafer and co-workers (2002) reported median pre-intervention screening rates of 0 (range 0–13) for the intervention group and 19 (range 0–23) for the control group ($P = 0.15$). This result was most likely not significant because of the small sample size of participating clinics (five in each group). Over the entire study period of 18 months, the intervention increased the screening rate to 47% ($n = 1017$), while the respective screening rate in the control group was 17% ($n = 1194$; $P < 0.05$) (Table 2.3). The authors were able to establish a difference between the control and intervention groups, which they monitored over the 18-month period and which was largest at the last assessment (65% versus 21%) (Shafer, Tebb et al. 2002).

The study by Armstrong and co-workers (2003) found that there was an overall increase of 120% in testing at the intervention health centre and an increase of 11% at the control

health centre. In the intervention health centre, 11% of the increase was accounted for by testing of patients aged 15–19 years; 43% was accounted for by testing of patients aged 20–24 years and 46% by testing in patients aged 25 years and over (Table 2.3).

The study by Allison and co-workers (2005) found that the mean screening rates before, during and after the intervention for the control practices were 18.9%, 13.0% and 12.4%, respectively, and for the intervention practices were 16.2%, 13.3% and 15.5%, respectively, (P = 0.044 for post-intervention differences after adjusting for baseline performance). The authors claimed that this web-based intervention was successful in attenuating the general downwards trend in screening rates seen in the control group (Allison, Kiefe et al. 2005) (Table 2.3).

Table 2.3 Review articles and articles describing intervention studies to increase participation in screening for chlamydia

Author, year, country	Design: RCT blinded; cluster; quasi experimental	Sample size control and intervention	Intervention	Patient population	Outcome measure
Shafer, M. et al., 2002, US	Cluster randomised	10 paediatric clinics in North Carolina, US 5 intervention 5 control	Changes to systems of clinical practice to reduce barriers to testing over 18 months	Female patients 14 to 18 years	% of sexually active females screened I*: 47% (*n* = 1,017) C**: 17% (*n* = 1,194)
Armstrong, B. et al., 2003, UK	Two primary health centres chosen; intervention centre was randomly chosen	2 primary health centres in Scotland 1 intervention 1 control	Introduction of personal health advisor to increase chlamydia awareness and training on chlamydia screening guidelines over 6 months	All patients aged 15 to 24	Pre/post number of tests I: 152/335 C: 336/374
Allison, J. et al., 2005, US	RCT	191 GP practices 95 intervention 96 control	Internet-based CE*** to increase chlamydia testing over 2 years	Female patients 16 to 26 years	% pre/during/post screening rates. I: 16.2/13.3/15.5 C: 18.9/ 13.0/ 12.4 *P* = 0.044
Verhoeven, V. et al., 2005, Belgium	Cluster randomised	36 GPs in Antwerp, Belgium 18 intervention, 18 control	Educational package (video & text) on communication skills for sexual history taking (15 weeks)	Female patients <35 years	Mean number of females appropriately tested, (*n* = 211) I: 6 C: 3; *P* = 0.035 Screening rates I: 81.6% C: 56.2%; *P* = 0.02

* I, Intervention; ** C, Control; *** CE, Continuous Education.

2.4.3 Discussion

The four reviewed studies showed that increasing screening rates in a primary care setting is possible. However, only the study by Verhoeven et al. (2005) achieved an adequate screening coverage. On the other hand, the intervention approach taken by Shafer and co-workers (2002) seemed very promising, as a cultural change towards screening practice involving all levels of clinic management will remain as a long-term investment independent of individuals. Future clinicians working in such a changed environment are likely to adopt the practices. Also, as the screening coverage in the intervention group was 65% at the end of the 18-month study period, one can hope for further increases after the study due to the changed environment (Shafer, Tebb et al. 2002).

The results given by Armstrong and co-workers (2003) were, unfortunately, not directly comparable to the other studies, as these authors only provided absolute numbers of tests without relating these numbers to a population size. In addition, the study was not based on individuals but on tests. Armstrong et al. (2003) aimed to increase the number of tests; however, their results showed that the highest increase in testing was in the older age groups and, hence, they failed to increase testing in the main risk group.

The above literature review looked at interventions to increase the level of screening for chlamydia in primary care settings. Limited published research on this topic was available up until 2005. In developed countries, primary care settings are a very attractive vehicle to increase screening coverage because they provide an established, wide-reaching structure. For example, in Sweden, national screening guidelines were implemented in the 1980s (Low 2004) , and screening for chlamydia is covered by the healthcare system and is conducted in primary care settings. In the UK, a national chlamydia screening program was implemented in 2003 utilising the primary care structure (Lamontagne et al., 2004). At the time of this literature review, no Federal guidelines for chlamydia testing existed in Australia. However, the primary care system is predominantly funded by the Federal government. This might, in part, explain why screening is often seen by Australian clinicians as a public health activity that might be in breach of the testing guidelines (Fairley, Hocking et al. 2005) .

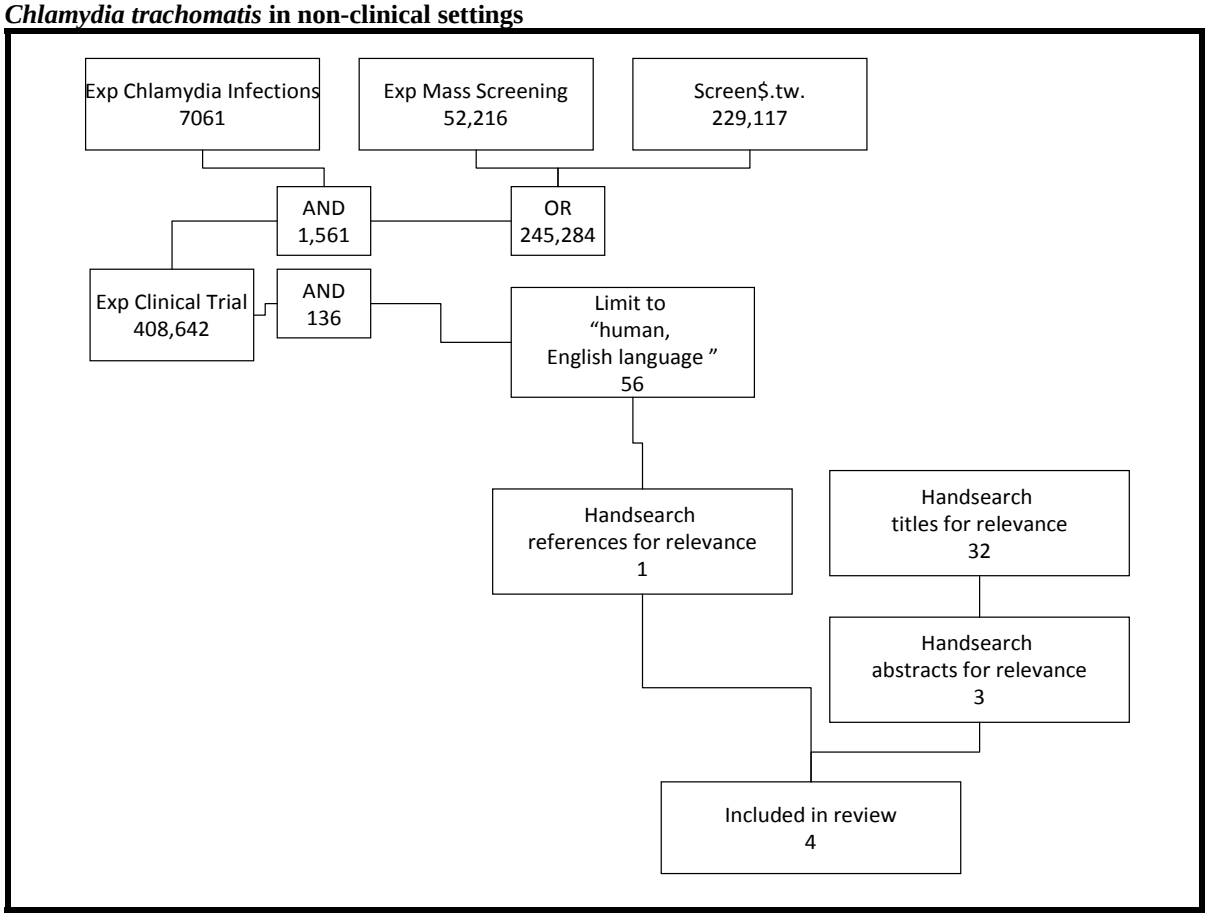
This leads to the question of what alternative options to primary care-based screening for chlamydia are available. The following literature review looks at published articles on non-clinic-based interventions to increase screening rates for chlamydia.

2.5 Literature review of intervention studies to increase screening for *Chlamydia trachomatis* in non-clinical settings

2.5.1 Introduction

The following literature review focuses on studies that reported randomised controlled trials to improve screening rates for chlamydia in non-clinical settings. I conducted this review in the same manner using the same search engines as the review on frequency and risk factors of chlamydia infection.

Figure 2.14 Overview of literature search for intervention studies to increase screening for *Chlamydia trachomatis* in non-clinical settings



A total of four articles were selected. Two of these articles focused directly on my review topic (Ostergaard, Andersen et al. 1998; Andersen, Olesen et al. 2002), while the focus of the other articles was aimed at improving rates of contact tracing (Andersen, Ostergaard et al. 1998) and retesting (Sparks, Helmers et al. 2004). In a more general sense, contact tracing and retesting can also be regarded as screening, albeit in high-risk groups. Another 12 selected articles were feasibility and cost-effectiveness studies but not randomised controlled trials.

2.5.2 Intervention studies to increase screening for *Chlamydia trachomatis* in non-clinical settings

The two studies that assessed the possibility to increase screening rates were both based in Aarhus, Denmark, and were conducted by the same research team (Ostergaard, Andersen et al. 1998; Andersen, Olesen et al. 2002) (Table 2.4). Aarhus County had about 631,000 inhabitants, which formed 12% of the Danish population (Andersen, Olesen et al. 2002). The first study of this team (Ostergaard, Andersen et al. 1998) conducted a cluster randomised controlled trial targeting sexually active high school students. The study randomised all 17 schools in Aarhus County. The total number of participating students was 4,336 in the intervention and 4,573 in the control schools (Ostergaard, Andersen et al. 1998).

The second selected study of this research group randomly selected persons born between 1974 and 1976 who lived in Aarhus in October 1997 (total 30,439) (Andersen, Olesen et al. 2002). The authors mentioned in the methods part: ‘A group of 4000 women and 5000 men was selected randomly from the 15,459 women and 14,980 men. The 4000 women and 5000 men were randomized further into 2 intervention groups of 2000 women and 2500 men. The remaining 11,459 women and 9980 men had the opportunity to visit a physician for usual care.’ (Andersen, Olesen et al. 2002) (Andersen et al., 2002) (Table 2.4).

The school intervention consisted of a mailing kit for chlamydia testing, which was offered to all students in the intervention group. Urine and vaginal samples could be directly mailed back to the laboratory for testing. Test results were sent to home addresses provided by the students. The control group was offered usual testing by doctors or at the local sexual health clinic (Ostergaard, Andersen et al. 1998). Similarly,

the intervention for the random sample of 21 to 23 year olds from Aarhus County consisted of a home sampling kit and samples were sent directly to the laboratory for testing (Andersen, Olesen et al. 2002) . The difference between the two intervention groups in this study was that one group received the mailing kit together with the invitation, while the second group first had to return a pre-stamped and pre-addressed reply card to receive the mailing kit (Andersen, Olesen et al. 2002) (Andersen, Olesen et al. 2002) (Table 2.4).

Both studies successfully increased screening rates in the intervention groups. The high school intervention study increased screening rates for females from 7.6% to 93.4% and for males from 1.6% to 97.3% (P <0.001, respectively) (Ostergaard, Andersen et al. 1998) (Table 2.4). The population-based study increased screening rates for females from 9.4% in the control group to 38.6% in the intervention group to which a sampling kit was automatically sent, and to 33.0% in the intervention group that had to request a sampling kit (P <0.01, respectively) (Andersen, Olesen et al. 2002) . The respective results for males were 1.4% in the control group, 26.8% in the intervention group that directly received the mailing kit and 16.5% in the intervention group that had to request it (P <0.01, respectively) (Table 2.4).

In 1998, the Danish research team also published a randomised controlled trial aimed at increasing contact tracing of partners of positive female index cases (Andersen, Ostergaard et al. 1998) (Table 2.4). The study included 96 women with chlamydia infection who were seen by GPs in Aarhus County, Denmark. The intervention group received a mailing kit for their partner; while the control group received envelopes that included an invitation for their partners to see a GP. The intervention was able to increase rates of contact tracing from 28% (19 of 68 partners) to 68% (44 of 65 partners) (in 1998 P <0.01) (Andersen, Ostergaard et al. 1998) (Table 2.4).

The fourth study in this review was conducted in Seattle, US (Sparks, Helmers et al. 2004) (Table 2.4). This randomised controlled trial aimed to increase retesting rates for genital infection with *C. trachomatis* or *N. gonorrhoea* in patients who were diagnosed at an urban STI clinic or hospital emergency department. Of the 122 participating patients, 60 were randomised into the intervention group. Patients in the control group were contacted by phone or letter and invited to attend the clinic for retesting. Patients in the intervention group were given the option of either mailing a specimen for testing

of going to a clinic for retesting (Sparks, Helmers et al. 2004) (Table 2.4). The study found an increase in the retesting rate within 28 days of the reminder from 32% (20 of 62 patients) in the control group to 45% (27 of 60 patients) in the intervention group; however, this result was not statistically significant (Sparks, Helmers et al. 2004) (Table 2.4).

Table 2.4 Articles describing interventions to increase chlamydia screening in non-clinical settings

Author, year, country	Design: RCT blinded; cluster; quasi experimental	Sample size control and intervention	Intervention	Patient population	Outcome measures
Andersen, B. et al., 1998, Denmark	RCT	I*: 45 C**: 51 all females	Mailing kit to positive women for partner to test versus invitation to see GP	Women with positive chlamydia test➔ partners	Primary outcome: Contacts who used kit I: 68% C: 28% Secondary outcomes: Contacts testing positive I: 27% C: 39% Time to testing I: 12.6 days C: 17.7 days
Ostergaard, L., et al., 1998 Denmark	Cluster randomised	I: 4,336 total, 2,603 females, 1733 males C: 4,573 total, 2,884 females, 1,689 males	Mailing kit for chlamydia testing	High school students of a county in Denmark, sexually active	Primary outcome: Sexually active students tested: Females: I: 93.4% of 928 C: 7.6% of 833 Males: I: 97.3% C: 1.6% Secondary outcomes: Students testing positive: Females: I: 4.6% C: 0.6% Males: I: 2.5% C: 0.4% Response rate:

Author, year, country	Design: RCT blinded; cluster; quasi experimental	Sample size control and intervention	Intervention	Patient population	Outcome measures
					Females: I: 48% (1,254) C: 38% (1,097) Males: I: 34% (590) C: 19% (316)
Andersen, B., 2002, Denmark	RCT	Total: random sample of 9,000 Females: 4,000 Males: 5,000 Randomisation into two intervention groups of 2,000 and 2,500, 11,459 are the control group with usual care I 1 and 2: Females: 2,000 Males:2,500 each C: Females: 11,459 Males: 9,800	Direct mailing of invitation to test for chlamydia using a home sampling kit I 1: kit was directly mailed I 2: needed to return a card to request the kit Control: usual care; both intervention groups could also receive usual care, no reminders	All persons born 1974 to 1976 who live in county total: 30,439 Females: 15,459 Males: 14,980	Primary outcome: Participation: Females: I 1: 38.6% I 2: 33.0% C: 9.4% Males: I 1: 26.8 I 2: 16.5 C: 1.4 Secondary outcome: Participants testing positive: Females: I 1: 6.5% I 2: 8.0% C: 10.0 Males: I 1: 5.9% I 2: 5.7% C: 19.3%

Author, year, country	Design: RCT blinded; cluster; quasi experimental	Sample size control and intervention	Intervention	Patient population	Outcome measures
Sparks, R. et al., 2004, USA	RCT	Total eligible: 297, participants: 122 I: 60 C: 62 Male: I: 41 (66%) C: 43(72%) Female: I: 19 (34%) C: 17 (28%)	Mailing of testing kit I: either test at clinic or mail sample for retesting C: only offer of clinic retest Reminders after 28 days of not attending, then all were offered mailing kit	Eligible heterosexual positives diagnosed at STI clinic or ED	Primary outcome: Rescreened within 28 days: I: chose clinic: 38%, mail: 61% total: 45% C: 32% Secondary outcome: Rescreened within 100 days with reminders: I: 60% C: 56%

Abbreviations: * I, Intervention; ** C, Control;

2.5.3 Discussion

The few controlled non-clinic-based intervention studies that aimed to improve rates of screening, contact tracing and retesting were all successful. The tested interventions were similar as they all involved mailing kits for chlamydia testing. The results of the high school study by Ostergaard and co-workers (1998) were impressive, with a screening rate of over 90% for both genders. However, the response rate in this study was rather low (females, 43%; males, 26%) and it is difficult to judge the direction of this potential selection bias. The study by Sparks et al. (2004) showed a response rate of 41%. Andersen and co-workers (2002) conducted a survey of the non-responders within their large population-based intervention study. In this survey of 308 people, almost 35% said that they had forgotten to participate in the study; another 25% said that they had been recently tested for chlamydia by a GP, and another 22% of these non-responders reported that they did not feel at risk of infection. On the other hand, 82.8% said that it was a good idea to offer a testing kit by mail (Andersen et al., 2002).

Using a self-mailing kit for testing STIs seems to be very attractive for potential clients, most likely because of ease of access and confidentiality. Self-mailing kits became available only with the advent of NAAT and could be potentially used for boosting screening rates in: 1.) screening programs that are conducted outside a clinic setting, with clients actively requesting a kit and mailing samples back to the laboratory; and 2.) through a population-based registry, with kits mailed to high-risk groups, for example to all people aged 15 to 25.

Self-mailed testing kits are very promising as they potentially increase access to testing in rural or remote locations, or in groups that are difficult to reach, such as MSM, or socially isolated people. The studies above have shown that self-mailed kits are also a feasible option for contact tracing and retesting.

2.6 Conclusions of the conducted literature reviews

Chlamydia trachomatis is an obligatory intracellular, Gram negative bacterium with a two-stage life cycle. With the advent of NAAT diagnostic tests for chlamydia in the mid 1990s, highly sensitive and specific, cheap and uncomplicated testing has become available. The management of chlamydia is straightforward, with a single dose of azithromycin. Nevertheless, chlamydia is of public health relevance as it occurs asymptomatically in the majority of cases. Moreover, untreated genital chlamydia infection is associated with severe reproductive morbidity in both genders.

My literature review showed that chlamydia notification rates for the US, UK and many European countries, as well as for all Australian States and Territories, showed clear upward trends between the 1990s and 2005. There is some doubt as to whether these increases reflected true rises in infection rates or were due to a proliferation in testing, improved test quality and enhanced notification processes. Most researchers would agree that a combination of these factors is the most likely explanation for the rise in notification rates.

The prevalence of chlamydia varies widely depending on the population tested and the local context. In Australia, the highest notification rates were reported in the Northern Territory, followed by Western Australia and Queensland. Rates were particularly high in Indigenous peoples. However, these comparatively higher rates in Indigenous communities might have been, at least in part, a reflection of targeted testing. There is no documented biological reason why ethnicity should influence susceptibility to chlamydia infection. It is much more likely that differences in infection rates by ethnicity are explained through an association between ethnicity and socio-economic status.

Younger age was universally identified as the most important risk factor for chlamydia infection. Sexually active people aged between 15 and 25 years were most at risk. Prevalences were comparable between men and women, although notification rates for women were higher, most likely because of increased testing as a result of more frequent access to healthcare.

The sexual behaviour of people determined the risk of chlamydia infection. High numbers of recent sexual partners and recent partner change were frequently identified

as risk factors for chlamydia infection. Using non-barrier methods for contraception was also found to increase the likelihood of infection, as was a history of STIs.

As noted above, the asymptomatic nature of chlamydia poses a challenge to its control, and this is compounded by the fact that chlamydia mainly affects young people. The issues are: 1.) how to convince seemingly healthy young people to access the health services for chlamydia testing; and 2.) how to convince health service providers to test seemingly healthy young people.

Up to 2005, a small number of intervention studies had been conducted to increase testing rates in primary care settings. My review of these studies showed that increases in opportunistic screening for chlamydia in primary care are possible. However, only one study achieved a screening rate that was above 50%. Turner and co-workers (2002) used mathematical modelling to show the effect of screening on the long-term reduction in prevalence assuming three different strategies: 1.) annual screening of women aged 16 to 44 years; 2.) annual screening of women plus screening after a change in partner; and 3.) annual screening of men and women aged 16 to 44 years. The models resulted in a marked reduction in prevalence of up to about 90%; however, they assumed that 85% of people were accessing primary care and that the acceptance of screening would range between 50% and 70% (Turner, Rogers et al. 2002). These theoretical results highlight the relative weakness of opportunistic screening and argue for systematic screening programs.

Alternatively, one could investigate the option of increasing access to screening in non-clinical settings from the target population's perspective. In this context, I reviewed four randomised controlled trials that were published before 2005 and which all explored the usefulness of mailing screening kits. The studies successfully increased screening rates and showed that mailing screening kits could also be a possible option for contact tracing and retesting.

Australia is a large continent with pockets of high-density population along the southern and eastern coastlines. Australia also does not have a nationally coordinated screening program for chlamydia. Physical access to health services is a well-recognised problem for rural and remote communities, which exacerbates other barriers to testing, including shame, stigma, concerns about confidentiality and privacy, as well as costs. Self-mailing

kits for testing of any disease and, in particular, for STIs, could offer an attractive solution.

Thus, the evidence gathered in my literature review suggested that the target population for my studies should encompass young and sexually active people. However, the literature review also showed that the prevalences differed with the local context.

Therefore, based on the findings of the literature review, my further doctoral studies started with an assessment of the prevalence of chlamydia in different suspected high-risk segments of the population and at the same time an evaluation of the feasibility of outreach clinics as a method to increase access to testing (Chapter 3).

This is followed by a description of the development (Chapters 4, 5, 6), implementation (Chapters 7, 8) and evaluation (Chapters 9, 10, 11) of a self-collection kit for the mailing of specimens for chlamydia testing through the regular Australia Post network.

Chapter 12 summarises my findings and provides general recommendations.

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CHAPTER 3 FEASIBILITY OF OUTREACH CLINICS AS A NOVEL APPROACH TO *CHLAMYDIA TRACHOMATIS* TESTING

3.1 Introduction

As previously stated, notification rates in Australia of *Chlamydia trachomatis* (chlamydia) per 100,000 population averaged 177.6, ranging between 127.1 for Tasmania and 782.6 for the Northern Territory in 2004 (Australian Government Department of Health and Ageing 2005). The notification data is indicative of an overall increase in chlamydia infection, especially in the 16 to 25 year age group and the Indigenous population. This is in agreement with previous studies on chlamydia, suggesting that young and Indigenous Australians are under increased risk. However, it seems that additional local factors define risk groups further (see Chapter 2). For example, commercial sex workers in Sydney were identified as a high-risk group for chlamydia infection, whereas records from the Melbourne Sexual Health Centre showed a low prevalence rate in local sex workers attending for routine health checks (O'Connor, Berry et al. 1996; Lee, Binger et al. 2005).

Attempts to curb this epidemic in Australia by means of health promotion campaigns relying on testing or screening by the general primary healthcare sector and the 'Well Persons' Health Check' in Indigenous communities 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).

One reason for the failure of the measures taken in Australia relates to the mainly 'passive', conventional methods taken; that is, relying on the initiative of the people at risk to get tested as opposed to actively approaching them.

Thus, novel approaches to chlamydia testing that take account of the specific situation in Australia, and especially Queensland, are urgently needed to make an inexpensive, reliable and accurate test, together with an inexpensive and effective treatment, available to asymptomatic people, especially in non-metropolitan areas.

Based on the above motivation, a series of six outreach screening clinics was planned with the aims of: 1.) identifying high-risk groups for chlamydia infection in Townsville,

north Queensland, as the evidence base needed for effectively targeting future outreach clinics; and 2.) to evaluate the feasibility of conducting such outreach clinics.

The records of the Townsville Sexual Health Service were used to identify potential high-risk groups that were accessible, such as high school students, defence force personnel and backpackers.

The six cross-sectional studies directly addressed four of the main aims of my doctoral studies to develop a novel approach to chlamydia testing with the characteristics of being:

- Based on an 'active' approach, that is, actively educating and informing the target population and promoting chlamydia testing;
- Centrally managed to guarantee access to qualified health professionals knowledgeable about follow-up (i.e. successful treatment, partner notification, retesting, further testing);
- Available independent of the general primary healthcare sector (STIs are generally low on the priority list of general practitioners); and
- Low tech (not requiring complicated procedures, instructions, accommodating low literacy skills).

The results of these studies were published as:

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3.2 Publication

Novel approach to an effective community-based chlamydia screening program within the routine operation of a primary healthcare service

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Abstract. ***Background*:** A prospective study was undertaken to develop an evidence-based outreach chlamydia screening program and to assess the viability and efficiency of this complementary approach to Chlamydia testing within the routine operations of a primary healthcare service. ***Methods*:** A primary healthcare service based in Townsville, Queensland, Australia, identified high-prevalence groups for chlamydia in the community. Subsequently, a series of outreach clinics were established and conducted between August 2004 and November 2005 at a defence force unit, a university, high school leavers' festivities, a high school catering for Indigenous students, youth service programs, and backpacker accommodations. ***Results*:** All target groups were easily accessible and yielded high participation. Chlamydia prevalence ranged between 5 and 15% for five of the six groups; high school leavers had no chlamydia. All participants were notified of their results and all positive cases were treated (median treatment interval 7 days). Five of the six assessed groups were identified as viable for screening and form the basis for the ongoing outreach chlamydia screening program. ***Conclusion*:** The present study developed an evidence-based outreach chlamydia screening program and demonstrated its viability as a complementary approach to chlamydia testing within the routine operations of the primary healthcare service, i.e. without the need for additional funding. It contributes to the evidence base necessary for a viable and efficient chlamydia management program. Although the presented particulars may not be directly transferable to other communities or health systems, the general two-step approach of identifying local high risk populations and then collaborating with community groups to access these populations is.

Additional keyword: Australia.

Background

Chlamydia trachomatis (chlamydia) infection is the most commonly notified sexually transmissible bacterial infection in the developed world.[1,2] During 2005 a total of 41 358 cases of chlamydia were notified in Australia resulting in a notification rate of 197 per 100 000 inhabitants.[3] For Australia the true population prevalence of chlamydia remains unknown and only limited data on perceived high-risk groups like the young, minority groups and people attending sexual health or family planning clinics are available with prevalences ranging between 0 and 27% in those populations.[4_7]

Infection with chlamydia is mostly asymptomatic.[8] Consequently, most people infected with chlamydia will not seek healthcare and will therefore be at risk of the sequelae of the infection. Without treatment, infection with chlamydia may be persistent and may have severe long-term effects on the sexual and reproductive health of men and women.[9] The advent of nucleic acid amplification test methods with high sensitivity and specificity allow detection of chlamydia in samples with low bacterial counts, thus making self-administered swabs or urine samples an option.[10]

An abundance of literature describes the conduct of studies on prevalence and incidence of chlamydia in single segments of populations.[11,12] Certain aspects of establishing and conducting large-scale systematic screening programs have been published for the UK.[13_15] Although interagency collaborations facilitating sexual health outreach screening have been described in Australia, very little information is available on how to develop a successful chlamydia screening program within the routine operation of primary healthcare services, without a national program or special funding.[16] A promising approach to improve screening lies with programs that specifically target high-risk groups.[17,18] We therefore propose and evaluate a novel approach to ongoing community based Chlamydia testing in identified high prevalence populations within the routine operation of a primary healthcare service.

A prospective study was undertaken to investigate the feasibility and efficiency of specifically designed outreach chlamydia screening clinics. These clinics would target identified high-prevalence groups as the basis for the development of an evidence-based chlamydia screening program within the routine operation of a primary health service.

The specific aims were to investigate:

- access to identified high-prevalence groups;
- acceptability of chlamydia testing in identified high prevalence groups; and
- chlamydia prevalence and efficiency of Chlamydia management in these settings.

Methods

Setting

The study was conducted between August 2004 and November 2005 in Townsville (160 000 inhabitants; median age 32 years),[19] Australia, as collaborative research between the Anton Breinl Centre for Public Health and Tropical Medicine at James Cook University and the Townsville Sexual Health Service (SHS), a free and confidential community-based primary healthcare service funded by Queensland Health.

Target groups

The SHS records basic demographic and clinical data of people attending the clinic. This data includes information on age, sex, occupation, reason for attendance, pathology test results, diagnosis and treatment. Evaluation of this clinical data identified a series of population groups with relatively high chlamydia prevalence. Out of these, the following groups were expected to be accessible at a defined location and formed the basis of the initial outreach screening program: (1) a defence force unit; (2) a university; (3) high school leavers' festivities; (4) a secondary high school catering to Indigenous students; (5) two youth service programs accessed by youth at risk of disengaging from mainstream education; and (6) budget accommodation providers specialising in backpacker accommodation.

Access to target groups

Following a formal request by the defence force to conduct an outreach clinic, the SHS was invited to participate in a multiservice 'Men's Health Expo', which was organised by the defence force and also provided an opportunity for education on sexually transmissible infections (STI). The student association of the local university organises a market day during orientation week at the beginning of each semester. On three market days two clinicians of SHS staffed a stall, provided information on sexual health and offered chlamydia screening. Two days before the event posters advertising free and confidential screening were placed around the market area.

In Townsville the high school leavers' festivity 'schoolies week' is an organised festivity for predominantly local school leavers. Two clinicians of SHS staffed a tent and provided information on sexual health and offered Chlamydia screening throughout the week.

Two youth-services programs, which provide social back-upfor youth who are at risk of disengaging from mainstream education, were contacted and SHS was invited to provide education and clinical services on a regular basis for both programs.

All 10 budget accommodation providers (backpackers) listed in the Townsville phone directory were contacted and asked for permission to access the premises. The clinics were conducted at three consenting venues in the common area during evenings. Educational posters were placed in the common areas 2 days before a clinic. A presentation with an education program was running continuously, and condoms and educational material on STI were distributed during the clinic.

Ethics

Ethical approval was granted by the Townsville Health Service District Institutional Ethics Committee and the Human Ethics Subcommittee at James Cook University. Participation in the study was completely voluntary and clinical service provision was not dependent on participation in the study. All participants gave written informed consent.

Data collection, chlamydia test

Potential participants were invited by outreach clinic staff to participate in chlamydia screening. All participants filled out a short questionnaire asking for age, sex, symptoms, ethnicity and contact details.

Male participants were asked to supply a specimen of first catch urine (FCU) for testing and women were given a choice between a self-administered vaginal swab (VS) or a FCU. All samples were analysed at the local pathology service using the Roche Cobas AmpLi-Cor test (sensitivity 0.86–1.0; specificity 0.98–1.0).[20]

Financial costs

To ensure sustainability of the outreach screening clinics it was essential that they be manageable within the routine operation of the clinic, i.e. without additional funds. No extra staffing costs were incurred for this project because staff that would usually work in the clinical setting were redirected to conduct the outreach clinics. Transport costs were negligible as the clinic maintains two vehicles.

At the time of writing a standard laboratory chlamydia test cost AU$27.40 for non-Indigenous and AU$13.70 for Indigenous participants (50% subsidy under a federal program).

Follow up

SHS used a variety of strategies (email, short message service (SMS), phone, letter) for contacting all participants to convey the results within 1 week of testing. Participants with a positive test result were offered a full sexual health check and additional STI testing, free treatment, partner notification services (i.e. contact tracing) and retesting after 3 months; those who had moved were referred to their nearest SHS for further management. All positive cases were treated with a single dose of azithromycin 1 g orally.

Data handling
All collected information was de-identified and entered into a spreadsheet (SPSS for Windows, Rel. 14.0; SPSS Inc, Chicago, IL, USA). Exact binomial confidence intervals were calculated.

Results
Overall 358 people were screened for chlamydia at the six outreach clinic locations. Four chlamydia test results were invalid and eight people declined their data being used for research, resulting in an overall consent proportion of 346/ 358 (96.6%). Basic demographics of participants are detailed in Table 1.

Feasibility (acceptability of testing by identified high-prevalence groups)

Defence force unit participation
The 20-min education sessions on STI in general and chlamydia in particular were attended by ~350–400 people of all ranks and ages. Around 80% of the attendees were under 25 years of age. After the session, defence personnel were asked to self-assess their risk of chlamydia infection. Seventy-five men participated in testing.

University participation
The open day was frequented mainly by first-year students; a total of 95 participants were recruited over the three occasions.

High school leavers' festivity participation
Overall, 670 registered school leavers attended the festivity and SHS approached 540 persons. A total of 320 sexually active school leavers were offered screening; 68 participated.

High school catering for Indigenous students participation
Out of a total of 84 students at the high school, 20 students participated in the study during 10 clinical sessions conducted within the study period.

Youth service programs participation
A total of 23 participants were recruited during 10educational sessions conducted within the study period.

Backpackers participation
Chlamydia screening was offered to all sexually active backpackers. A total of 65 backpackers participated during five clinics.

Efficiency (chlamydia prevalence and management)
Chlamydia prevalence and treatment intervals (time from testing to treatment) for the different targeted groups are detailed in Table 2. The highest prevalence was found in the Indigenous high school and youth service populations with 15 and 13%, respectively. All participants were notified of their test results; all positive participants were either treated at the SHS or referred to the nearest SHS for free treatment. Treatment was confirmed for all 21 participants with a positive test result; 12 (57.1%) were treated within 7 days, 81% were treated within a fortnight of being tested. Two people could not be contacted for 3 weeks as they were deployed with the defence force.

Table 1. Demographic details of study participants stratified by targeted group

Identified high-prevalence group	Count	Male (%)	Indigenous[A]		Age (years)	
			n	%	Median	Interquartile range
Defence force unit	75	100	3	4.1	25	22, 28
University	95	55.8	1	1.2	21	20, 25
High school festivities	68	47.1	2	3.4	17	17, 18
High school	20	5.0	20	100.0	15	15, 16
Youth service programs	23	0	4	17.4	16	15, 17
Backpackers	65	44.6	0	0.0	25	22.5, 27.5
Total	346	54.9	30	9.3	21	18, 25

*Indigenous status was not available for 25 participants.

Table 2. Prevalence of *Chlamydia trachomatis* and treatment intervals stratified by targeted group

Identified high-prevalence group	Count	Chlamydia testing positive			Treatment interval (days)	
		n	%	95% confidence interval	Median	Range
Defence force unit	75	5	6.7	2.2, 14.9	5	5–34[A]
University	95	5	5.3	1.7, 11.9	3	3–11
High school festivities	68	0	0.0	0.0, 5.3	Not applicable	Not applicable
High School	20	3	15.0	3.2, 37.9	7	7–28
Youth service programs	23	3	13.0	2.8, 33.6	7	7–10
Backpackers	65	5	7.7	2.6, 17.1	11	6–20
Total	346	21	6.1	3.8, 9.1	7	3–34

*Two participants deployed 3 weeks directly after screening

Discussion

The present study is, to the authors' knowledge, the first study that developed an evidence-based outreach chlamydia screening program and demonstrated its viability as a complementary approach to clinic-based chlamydia testing. It is especially noteworthy that the developed outreach program: (1) can be conducted within the routine operations of the primary healthcare service (i.e. without the need for additional funding) by redirecting clinical services from the clinical setting to an outreach setting; and (2) contributes substantially to the evidence base for an efficient and effective overall chlamydia management program.

Feasibility

Identification of high-prevalence groups by means of routinely available clinical data was easy and access to groups proved uncomplicated with only a few hours spent on preparations. Moreover, the setting up of access to the different groups created persisting structures. SHS has been 'actively' invited back for ongoing education and clinical service provision by several groups that participated in this study.

Identification of high-risk groups is the crucial starting point for the proposed screening approach and requires insight into the community. This, however, might be harder to achieve in major cities where identification of and access to some groups might prove more difficult than in the setting of the present study.

Acceptance of chlamydia testing and participation in the study were generally high. Participation may have been boosted by the fact that screening was always offered in the wider context of STI and often accompanied by short STI education sessions. This is in contrast to many other settings where opportunistic screening is undertaken, as for instance when visiting a general practitioner.[15] In particular, the presented approach yielded a comparatively high number of young male participants – a group which is renowned for being difficult to engage in screening and is therefore often not even targeted.[21,22]

Prevalence

Chlamydia prevalences found for the different groups (Table 2) are similar to those reported in the literature. The low prevalence in high school leavers is in line with the studies from Debattista *et al.* and Bowden *et al.*, which reported a prevalence of just over 1% for a cross-section of almost 2000 Australian high school students.[5,6] The higher prevalence found in Indigenous students is also similar to results published by Miller *et al.*[23]

Follow up

All participants in the present study were notified of their results using their preferred method of contact. Email, SMS and calls to mobile phones were popular choices. This demonstrates the acceptability of these new technologies to participants and therefore the usefulness to clinicians for efficient management of test results – even in transient populations. All individuals diagnosed with chlamydia infection were treated. Treatment proportions in published literature usually refer to clinic-based screening where most clients were presumptively treated and only a small proportion of clients required follow up for treatment.[24–26] Direct comparisons are therefore not possible but a 100% treatment proportion is excellent. In this context it seems especially worth mentioning that even the backpackers, the most challenging group with respect to follow up, were all notified and treated. Treatment intervals were also acceptable with more than half of the positives being treated within 1 week and more than 80% within a fortnight of testing. The only two treatment intervals in excess of a fortnight were caused by a 3-week deployment of two defence force employees directly after screening.

Sophisticated cost–benefit models for clinical settings were beyond the scope of the present study.[27] It should be noted, however, that the whole program was run within the budget of the healthcare service. Crude laboratory costs of the program per test and per positive test were AU$26.20 and AU$431.80, respectively, and therefore higher than the observed laboratory costs for tests observed during routine in-house clinics (AU$25.90 per test; AU$291.60 per positive test). However, the populations tested during the outreach program differed from that of the in-house clinics in several ways: outreach clinic participants were exclusively asymptomatic whereas in-house participants include a high proportion of symptomatic people (as well as contacts of chlamydia cases); in outreach clinics people get tested in a much shorter time period than at regular clinics; and, most importantly, outreach clinics can reach segments of the population that would not be accessible to regular clinic services. Therefore, the higher crude costs per test observed in the outreach setting seem easily offset by the faster testing rate and the gained access to otherwise untested people by outreach clinics.

Outreach clinic program

The prevalence threshold for cost-effective chlamydia screening remains a matter of debate.[28,29] However, there is no doubt that screening for chlamydia and effective management of positive cases will over time lead to improved health and a reduction in adverse health outcomes. All target groups were easily accessible and yielded high participation. In five groups the prevalence of chlamydia was above 5%. These five groups therefore form the basis for the initial evidence-based outreach testing program, which has now been added to the routine operations of SHS improving access to testing for the local community. Future research will be necessary for the program to remain up-to-date and responsive

to the potential dynamics of risk groups in the community.

Limitations

The present study is an operational study and consequently many factors can't be influenced, controlled or accounted for by the researchers. For instance, true participation rates could not be evaluated.

Conclusion

The present study developed an evidence-based outreach chlamydia screening program and was able to demonstrate its viability as a complementary approach to chlamydia testing within the routine operations and the operational budget of a primary healthcare service. This study therefore contributes to the evidence base necessary for an efficient and cost-effective overall chlamydia management program.

Although the presented particulars may not be directly transferable to other communities or health systems because of differences in populations and health systems, the approach as such can be generalised. The first step is to get to know your community and identify potential high-risk groups. Setting up contact and collaboration between healthcare provider and community organisations in order to access these high-risk groups is the next step. The actual screening program should be complemented by educational material on STI, which may not only help to increase participation but also to establish future long-term collaborations with community organisations. Modern communication methods such as mobile phones and email help to optimise the management of participants even in transient groups.

Conflicts of interest

None declared.

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3.3 Summary of results, relevance, and how this project contributes to the overall doctoral studies

The studies showed that students attending an Indigenous high school (15%) and young persons who used the Youth Services (13%) had the highest prevalence of chlamydia. On the other hand, all tested mainstream high school students attending the end of school year festivities ('schoolies week') tested negative for chlamydia. These findings were similar to previously published results from Australia (Debattista, Martin et al. 2002; Miller, McDermott et al. 2003; Bowden, O'Keefe et al. 2005).

This project was the first that developed an evidence-based outreach chlamydia screening program and demonstrated its viability as a complementary approach to clinic-based chlamydia testing. It is especially noteworthy that the developed outreach clinic program:

1.) can be conducted within the routine operations of the primary healthcare service, without the need for additional funding, by actively redirecting clinical services from the clinical setting to an outreach setting;

2.) allows management of results and follow-up through a specialist service;

3.) provides access to chlamydia testing outside the clinical setting; and

4.) uses non- invasive testing methods.

Thus, these studies contributed substantially to the evidence base for a novel, efficient and effective chlamydia management program.

The findings of this project informed the current practice of the Townsville Sexual Health Service; for example, the outreach clinics at the Indigenous high school, Youth Services and the university are continuing. The Australian Defence Force (ADF) outreach clinic continued for several years. Testing for chlamydia in mainstream high school students and backpackers was not feasible and, therefore, discontinued.

Although the results of this project are important, useful and encouraging for conducting outreach clinics in addition to clinic-based testing, the limitations of the outreach clinic approach are clear. Only persons of the defined group are targeted for testing; the outreach clinics are only conducted at specific times; and trained staff is

required for the conduct of the outreach clinic at the location. Thus, access to testing is still restricted for people living in locations without outreach clinics, such as rural and remote areas of the Townsville Health District and all rural and remote areas of Australia.

In order to address this major barrier to testing and in collaboration with the University of Queensland and Queensland Health, a system and process that allows the mailing of specimens using the Australia Post regular mail service was developed. Chapters 4 and 5 describe the development and evaluation of this system.

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CHAPTER 4 GEL DEVELOPMENT AND EVALUATION

4.1 Introduction

The advent of nucleic acid amplification tests, such as real-time polymerase chain reaction (rtPCR) and ligase chain reaction (LCR) assays, have revolutionised the diagnosis of *Chlamydia trachomatis* (chlamydia) infections through their high sensitivity and suitability for non-invasively collected specimens, such as urine (Mahony, Jang et al. 1997; Schachter 1997; Xia, Xu et al. 2007). Despite these advances in diagnostic technology, chlamydia screening and disease control is still limited in some populations due to several factors. These include geographic isolation or an inability or unwillingness to access healthcare centres for diagnostic testing (Humphreys, Jones et al. 2003; Miller, McDermott et al. 2003; Australian Government Department of Health and Ageing 2005a; Kang, Rochford et al. 2006).

The use of self-collected specimens, such as urine, vaginal swabs or tampons, which can be collected by individuals on their own, can help increase the numbers of people using testing for sexually transmissible infections (STIs) (Knox, Tabrizi et al. 2002). Several studies have successfully evaluated the use of self-collected and mailed urine samples for chlamydia screening (Ostergaard, Moller et al. 1996; Morre, van Valkengoed et al. 1999; Gotz, van Bergen et al. 2006); these were reviewed in Chapter 2. Such non-clinic-based methods of specimen collection and transport would be ideal for facilitating the extension of existing chlamydia testing programs (Australian Government Department of Health and Ageing 2005a; Hocking, Walker et al. 2008). However, in Australia the transport of biological specimens, such as urine in a liquid state, is restricted by Australia Post regulations.

Hence, a partnership was formed with Drs Bialasiewicz and Whiley, from the Sir Albert Sakzewski Virus Research Centre at the University of Queensland, who had developed a super-absorbent polymer with a DNA stabilising capacity for the absorption of liquids. The idea was to assess whether this polymer was suitable as a urine absorbent in the context of chlamydia testing.

This part of my doctoral studies evaluated a urine transport gel (UTG) as a means of storage and transport of urine specimens for chlamydia testing. In particular, the sensitivity and specificity of the standard PCR testing method were prospectively

evaluated, using urine samples that were transported at ambient temperatures through the regular mail system.

Thus, these studies contributed substantially to the following aims of my doctoral studies to develop a novel approach to chlamydia testing with the characteristics of being:

- available independent from the place of residence;
- 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;
- centrally managed to guarantee access to qualified health professionals knowledgeable about follow-up (i.e. successful treatment, partner notification, retesting, further testing);
- outside the local social sphere to assure confidentiality;
- available independent of the general primary healthcare sector (STIs are generally low on the priority list of general practitioners);
- low tech (not requiring complicated procedures, instructions, accommodating low literacy skills); and
- connected to existing infrastructure, including communication systems.

While the initial idea to use a modified super-absorbent polymer with DNA stabilising capacity as a transport medium for urine was developed by Drs Bialasiewicz and Whiley, I was responsible for the specific study designs, process of blinding, data collection, analysis and writing up of these components for the resulting publication. The methodology with respect to the gel was authored by Drs Bialasiewicz and Whiley. Further co-authors were responsible for recruiting participants into the study, specimen collection, laboratory work, and general supervision and advice to the project.

This study was published as:

Bialasiewicz S, Whiley DM, **Buhrer-Skinner M,** Bautista C, Barker K, Aitken S, Gordon R, Muller R, Lambert SB, Debattista J, Nissen MD, Sloots TP. A novel gel based method for self collection and ambient temperature postal transport of urine for PCR detection of chlamydia trachomatis. *Sex Transm Infect*, 2009; **85**:102-105.

4.2 Publication

A novel gel-based method for self-collection and ambient temperature postal transport of urine for PCR detection of Chlamydia trachomatis

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ABSTRACT

Objectives: The aim of this study was to develop a novel urine transport method to be used in self-collection-based screening for Chlamydia trachomatis. The method needed to be suitable for C trachomatis PCR detection, be economical and suitable for transport by standard envelope mailing.

Methods: An anhydrous gel composed of super-absorbent polymer and buffering agent was used to desiccate urine into a dry granulous state, which could subsequently be reconstituted upon arrival at a laboratory. DNA was then extracted from the reconstituted solution using the Roche MagNA Pure protocol for the detection of C trachomatis by PCR. Collections of urine specimens from three populations with widely differing chlamydia prevalence (100%,n = 56; 47%, n = 70; 3%, n = 97) were used. We determined the gel method's impact on C trachomatis PCR sensitivity and specificity using neat and gel-processed urine specimens. An equine herpes virus PCR was used to test for assay inhibition.

Results: Overall, the sensitivity of the gel-based method ranged from 94.6–100% compared with neat urine, with a specificity of 100%. No PCR inhibition or decrease in analytical sensitivity was observed using the gel-processed extracts.

Conclusions: The gel-based method was found to be suitable for the detection of C trachomatis by PCR. In addition, its ease of use, effectiveness at ambient temperature and low cost makes it well-suited for self-collection kits used in population-based C trachomatis screening, particularly for geographically and socially isolated individuals.

Despite advances in diagnostic technology, Chlamydia trachomatis screening and disease control is still limited in some populations due to a variety of factors, including geographic isolation or an inability or unwillingness to access healthcare centres for diagnostic testing.[1–4] Unfortunately, this has maximum impact upon the groups most at risk of chlamydial infections, including young people under the age of 25 years, indigenous populations and men who have sex with men.[1–4] Over the past few years, an annual 20% increase in C trachomatis cases has been reported in Australia.[1] In response, the Australian National Sexually Transmitted Infections Strategy 2005–2008 report identified as a priority the need for increased testing of these at-risk populations, prompting the need to investigate alternative collection and testing methodologies.[15]

The use of self-collected specimens, such as urine, vaginal swabs or tampons, which can be collected by individuals in their own homes can help increase the numbers of people using sexually transmitted infections (STIs) testing.[6] Several studies have successfully evaluated the use of home-collected and mailed urines for C trachomatis screening.[7–9] Such non-traditional methods of collection and transport would be ideal for facilitating the extension of existing C trachomatis testing programmes.[15] However, there may be unforeseen obstacles that impair programme implementation and, consequently, need to be overcome, such as a need to refrigerate the sample, complexity of the collection method or additional costs associated with transport and mailing of liquids.

We describe the development and evaluation of a novel super-absorbent polymer-based method for the self-collection and ambient temperature transport of urine, which is economical, easy to use and retains the high sensitivity of C trachomatis real-time polymerase chain reaction (rtPCR) detection.

METHODS

Gel matrix

The gel matrix consisted of two reagents in equal parts: 0.5 g of the super-absorbent polymer Poly(acrylic acid), partial sodium salt-graft-poly(-ethylene oxide) (C5H7NaO3) (Sigma-Aldrich, New South Wales, Australia) and 0.5 g of the buffering agent Tris base (NH2C(CH2OH)3) (Sigma-Aldrich) in equal parts, the whole of which is further referred to as the ''gel''. In this evaluation, 3 ml of each urine specimen was added to a 10 ml tube containing 1 g of dry gel.

In its anhydrous form, the polymer exists as complex folded chains of molecules. When urine is introduced, the water is absorbed to the polymer, expanding and opening up the chains' structures, which results in the gel swelling into a dry granular form while desiccating the urine. Consequently, the cells, proteins and DNA previously suspended within the urine are sequestered within the swollen gel matrix; thus, the transformation of the urine into a dry granular state allows urine samples to be packaged for standard envelope mailing with out fear of leakage.

Reconstitution of urine from the gel was achieved by adding 1.0 ml of 100% isopropanol followed by several vigorous inversions of the tube, which acted to liberate the bound water and resuspend the cells and DNA. After 5 minute

resting, 200 ul of supernatant was drawn off and the DNA extracted by the magnetic-bead-based MagNA Pure automated extraction machine using the MagNA Pure LC Total Nucleic Acid Isolation Kit (Roche Diagnostics, New South Wales, Australia)

Study design and patient specimens
C trachomatis PCR results were compared using de-identified paired samples comprising neat urine and urine processed through the gel. Except where indicated, DNA was extracted from 200 ml of neat urine or 200 ml of urine reconstituted from gel, and detection of C trachomatis was performed at the Molecular Diagnostic Unit, Pathology, Queensland on a Roche COBAS TaqMan 48 rtPCR analyser using the COBAS TaqMan C trachomatis Test (Roche Diagnostics). Following the recommendation by Zhou et al,[10] the evaluation of the new method was performed in three stages: exploratory, challenge testing and clinical evaluation.

Exploratory stage
An initial laboratory-based retrospective evaluation designed to evaluate the principal usefulness of the gel was performed using specimens from Pathology Queensland Central Laboratory (PQCL). Altogether, 56 de-identified urine specimens (32 male, 24 female) previously C trachomatis positive by the TaqMan 48 C trachomatis assay during routine STI diagnostic testing were assessed using the gel-based method. The original urine samples were stored at 4uC for 2 weeks following collection and then at 220uC prior to being divided into aliquots. The fractions were added to gel and incubated at ambient room temperature in the laboratory for approximately 7 days prior to processing and testing in order to simulate the estimated time a sample may take to be delivered by mail to a diagnostic laboratory.

Challenge stage
Paired neat and gel-absorbed urine fractions were collected prospectively from patients attending the Townsville Sexual Health Clinic (TWNSHC). Specimens (36 male, 34 female) were selected on the basis of clinical symptoms and history to ensure a high proportion positive for C trachomatis. The paired samples were blinded prior to being transported to Brisbane by road and air courier where they were processed on arrival.

Clinical evaluation stage
A prospective evaluation was conducted to determine the gel's clinical sensitivity and specificity compared with neat urine as well as with results from the Roche Amplicor C trachomatis diagnostic assay (Roche Diagnostics), which is widely used for routine C trachomatis PCR testing in many pathology laboratories. Aliquots from urine samples of all patients (66 male, 31 female) presenting to the Gold Coast Sexual Health Clinic (GCSHC) for routine C trachomatis testing were collected over a 2-week period. Two de-identified paired aliquots from each patient sample were drawn off prior to the urine sample's transport to the Gold Coast Hospital for routine C trachomatis testing using the Amplicor C trachomatis assay. One aliquot was applied to the anhydrous gel and the second was left as a neat urine fraction. Both fractions were incubated at ambient room temperatures for approximately 7 days before processing and were blinded prior to C trachomatis testing.

Impact of variable temperature
To investigate the effect of increased storage temperatures we incubated five C trachomatis positive PQCL neat and gel urine fractions at 37uC over a period of 8 days prior to processing and testing. To address the impact of freezing temperatures, 10 C trachomatis positive urines from the main evaluation stage were stored overnight, each in three fractions: a neat urine at room temperature, a neat urine at 220uC and a gel urine at 220uC, prior to processing and testing.

Limit of detection
To assess the limit of detection, C trachomatis positive urine was serially diluted 10-fold in C trachomatis negative urine. Each dilution was tested in triplicate using neat and gel-based methods in the TaqMan 48 rtPCR C trachomatis assay.

Inhibition control
An equine herpes virus (EHV) rtPCR method (kindly provided by Dr Gerry Harnett, PathCentre, Western Australia) was used to test for PCR inhibitors. Briefly, DNA extracts from gel fractions were tested in EHV rtPCR reaction mixes spiked with EHV DNA. Using this system, the presence of DNA inhibition is indicated by a significant delay in cycle threshold value. The EHV rtPCR consisted of 10 pmol each primer (EQHSV-330F 59-GATGACACTAGCGACTTCGA-39, EQHSV-410R 59-CAGGGCAGAAACCATAGACA-39), 4 pmol probe (EquHSV360 FAM-59-TTTCGCGTGCCTCCTCCAG-39-BHQ-1), 12.5 ml of Quantitect Probe master mix (Qiagen, Victoria, Australia), 1 ml of cultured EHV DNA in a 25 ml reaction, with 2 ml of gel fraction extract or water acting as the input template. Ten replicates of water and DNA extract from ten gel-processed urines were tested in the EHV rtPCR on a Corbett RotorGene 3000 (Corbett Robotics, Sydney, Australia) under the following conditions: 15 min incubation at 95uC, followed by 45 cycles of 15 s at 95uC and 1 min at 60uC. The cycle threshold values from the water and gel extracts were then compared.

Data analysis
Intercooled Stata (v9.2) software (Stata Corp, Texas, USA) was used to compare groups and calculate CIs.

RESULTS

Main evaluation

Exploratory stage
Of 56 C trachomatis positive urine specimens received from PQCL, 53 were positive results using the gel method (table 1). The three discrepant specimens (2 male, 1 female) were further investigated by retesting fresh DNA extractions of the original neat urine specimens, with two specimens returning positive results.

Challenge stage
Of the TWNSHC paired specimens, 69 of 70 were in agreement (table 1) with one urine sample from a male patient testing C trachomatis positive in the neat urine fraction but negative in the gel fraction.

Clinical evaluation stage
There were no discrepant results in the paired specimens from GCSHC and these matched the routine diagnostic result using the Cobas Amplicor C trachomatis assay (table 1).

Impact of variable temperature
The cycle threshold values from the neat and gel fractions incubated at 37uC were found to be similar, with mean cycle threshold values of 35.9 and 34.9, respectively. Similarly, the

Table 1 Comparison of Chlamydia trachomatis detections in three sample populations of neat urine and the corresponding gel-processed urine

Evaluation stage/location	NU–/GU–	NU+/GU+	NU+/GU–	NU–/GU+	Sensitivity, % (95% CI)	Specificity, % (95% CI)
Exploratory, PQCL (n = 56)	N/A	53	3	0	94.6 (85.1 to 98.9)	N/A
Female (n = 24)	N/A	23	1	0	95.8 (78.9 to 99.9)	N/A
Male (n = 32)	N/A	30	2	0	93.8 (79.0 to 99.2)	N/A
Challenge, TWNSHC (n = 70)	37	32	1	0	96.9 (84.2 to 99.9)	100.0 (90.5 to 100)
Female (n = 34)	15	19	0	0	100.0 (82.4 to 100)	100.0 (78.2 to 100)
Male (n = 36)	23	13	1	0	92.9 (66.1 to 99.8)	100.0 (85.2 to 100)
Clinical, GCSHC (n = 97)	94	3	0	0	100.0 (29.3 to 100)	100.0 (96.2 to 100)
Female (n = 31)	29	2	0	0	100.0 (15.8 to 100)	100.0 (88.1 to 100)
Male (n = 66)	65	1	0	0	100.0 (2.5 to 100)	100.0 (94.5 to 100)

frozen gel samples produced comparable results with both the neat frozen and room temperature urines with mean cycle threshold value differences 0.7 and 0.1, respectively.

Limit of detection

The TaqMan 48 C trachomatis assay detected C trachomatis target DNA to the same 10-fold dilution in both the neat and gel fractions with little cycle threshold value variation (table 2).

Inhibition control

The mean cycle threshold values of the gel-fraction extracts and water templates in the EHV rtPCR were similar: 24.1 and 24.4, respectively.

DISCUSSION

With this study, we demonstrate a simple and sensitive gel-transport method for the PCR detection of C trachomatis, which can be used for self-collected and mailed urine specimens. The gel material is non-hazardous and is widely available and inexpensive, costing approximately AUD$0.13 per specimen. Furthermore, by converting the urine into the solid phase, the method eliminates the possibility of accidental leakage and, thus, preventing both contamination of the sample and limiting the risk of exposure to postal workers. These features make this method ideally suited to self-collected population-based screening using the postal system and should be particularly useful for difficult to reach populations or for follow-up and recall programmes of people previously tested for C trachomatis.

The initial exploratory stage with known positive specimens showed that use of the gel method has limited impact on the sensitivity of C trachomatis PCR. This was supported by the similar high sensitivity and specificity rates obtained in the subsequent challenge and clinical evaluation stages, although due to the small number of positives in the GCSHC population the sensitivity value had a lower confidence limit of 29.3%. The gel method's sensitivity and specificity in the female portion of the study populations was found to be equal or greater than that of the male portion (table 1) suggesting that the method is suitable for use by both genders. Testing 10-fold dilutions of C trachomatis DNA showed that the use of the gel did not appear to impact the analytical sensitivity of the TaqMan 48 CT assay when compared with neat urine. Further, the gel did not introduce PCR inhibitors into the nucleic acid extracts.

A A total of four specimens from the exploratory and challenge stages were negative in the gel fraction but positive in the neat urine fraction suggesting that use of the gel may slightly impact the clinical sensitivity of C trachomatis PCR. However, at least one of these false-negative results may have been due to deterioration of the sample prior to use in this study given the previously positive neat urine in question was negative when re-extracted and retested. Nevertheless, we believe any minor decrease in the sensitivity of the gel method would be outweighed by the increased access to C trachomatis testing provided by this method, particularly to geographically and socially isolated populations. Due to its simplicity, the gel method could also be potentially applied synergistically to other programmes or protocols. For example, Wisniewski et al[11] recently reported development of the FirstBurst urine collection device to collect the first 4–5 ml of first void urine from men, and showed that this approach provided higher organism yields compared with regular urine cup collection and, hence, improved the performance of both point of care and PCR tests for C trachomatis. The volumes used by FirstBurst are compatible with our gel method and so the two approaches could potentially be used in combination to improve clinical sensitivity.

The gel method was shown to provide suitable C trachomatis detection within a 7 day window between collection and testing, which was considered to be a likely maximum time frame for mail handling and processing. In a further limited experiment, we were able to successfully detect C trachomatis in gel fractions that had been left at room temperature for 6 weeks (data not shown). The bulk of the evaluation was performed under ambient room temperatures of approximately 25uC. However, the challenge stage (TWNSHC) neat and gel fractions, coming from a warmer, tropical climate, would have been subjected to a wider variation of temperatures during their road and air transport, with little impact seen on sensitivity. Furthermore, there was no observable impact to the gel's overall

Table 2 Mean Taqman 48 Chlamydia trachomatis assay cycle threshold values of 10-fold C trachomatis positive urine dilutions processed neat or through gel in triplicate

	C trachomatis template dilution				
Urine fraction	1.0E21	1.0E22	1.0E23	1.0E24	1.0E25
Neat	34.60 (34.3 to 34.8)	37.77 (37.3 to 38.3)	40.37 (40.2 to 40.6)	ND	ND
Gel	34.97 (34.8 to 35.1)	37.90 (37.7 to 38.2)	41.80 (41.0 to 42.5)	ND	ND

Replicate threshold ranges are shown in parentheses. ND, not detected.

Key messages

- A novel method was developed that turns self-collected urine into a solid, dry gel, which can then be used to detect chlamydia by PCR.
- The method is cheap, safe, easy to use and does not impact the sensitivity or specificity of the Roche Taqman diagnostic assay.
- This method prevents urine leakage during transport, minimising sample contamination and risk to people handling the package.
- The method is ideally suited for population screening, especially for hard to reach populations since urine samples could be easily sent through the mail.

sensitivity when subject to warmer or below freezing incubation temperatures. This suggests the gel's performance is independent of temperature variations potentially encountered during different modes of transport. Notwithstanding the results of this study, we recommend that the gel method be evaluated in any prospective patient population before routine use to investigate whether differences in local conditions impact upon its performance.

During the course of the evaluation, one sample was identified by routine diagnostic testing as being dually infected with C trachomatis and Neisseria gonorrhoeae, affording an opportunity to test the gel's performance with other target organisms. The original extracts of the sample's neat and gel urine fractions were screened with a previously published N gonorrhoeae rtPCR assay[11] and similar cycle threshold values were obtained (data not shown). The results suggest that the gel may be suited for the PCR detection of N gonorrhoeae as well; however, a comprehensive evaluation would need to be performed to establish the suitability of the gel for use in N gonorrhoeae screening.

We have optimised the gel method, including volumes used, for use with the Roche MagNA Pure extraction and COBAS TaqMan 48 C trachomatis protocols, and so re-evaluation and modification of the gel method may be necessary if alternate nucleic acid extraction and detection protocols are used. The data from this evaluation support the use of the gel for diagnostic purposes; however, a study with larger sample numbers is needed to fully validate diagnostic applicability and performance. Currently, the gel is being evaluated as part of a self-collected and mailed specimen kit used in an Australian government-funded Chlamydia Screening Pilot Trial of at-risk and regional populations.

We have developed a novel method for use in mailing urine that is inexpensive, easy to collect and process, and has been demonstrated to be suitable for C trachomatis detection by PCR. The gel has been created as a supplementary sampling method for situations in which traditional collection and C trachomatis screening cannot be achieved, and is not intended to replace conventional collection and testing protocols. It is our hope that this gel and other novel approaches will facilitate an increase in accessible and widespread C trachomatis screening, with the ultimate aim of reducing C trachomatis prevalence and disease burden within high-risk, isolated or disadvantaged populations.

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Competing interests: None.

Ethics approval: Approved by the Human Research Ethics Committee for the Townsville Health Service District and James Cook University.

Contributors: SB: conceptualisation, study design, sample processing, data collection and analyses, and drafting of manuscript; DMW: conceptualisation, study design and drafting of manuscript; MBS: study design, sample collection, data analyses and drafting of manuscript; CB: sample processing and testing and drafting of manuscript; KB: sample collection and drafting of manuscript; SA: sample collection and drafting of manuscript; RG: study design, sample collection and data analyses; RM: data analyses and drafting of manuscript; SBL: study design, data analyses and drafting of manuscript; JD: study design and drafting of manuscript; MDN: study design and drafting of manuscript; TPS: conceptualisation, study design and drafting of manuscript.

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4.3 Summary of results, relevance, and how this project contributes to the overall doctoral studies

Using Australia Post for transporting neat urine specimens proved to be impossible because of stringent regulations regarding the transport of biological specimens. Within Australia, liquid urine cannot be mailed by ordinary people.

This study demonstrated that a simple and sensitive gel transport method can be used for self-collected and mailed urine specimens that are intended for the detection of chlamydia by PCR. Both the sensitivity and specificity of PCR detection using this system were high and comparable to conventional methods. The gel material is non-hazardous, widely available and inexpensive, costing approximately A$0.13 per specimen. These features make this method ideally suited for population-based screening, particularly for difficult-to-reach populations or for follow-up and recall programs of people previously tested for chlamydia.

Thus, these promising results suggest that the UTG might be suitable for use in testing in Aboriginal and Torres Strait Islander populations, as well as in men having sex with men (MSM), as both those populations are at high risk of chlamydia.

During the course of the evaluation, one sample was identified by routine diagnostic testing as being dually infected with *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (gonorrhoea), affording an opportunity to test the gel's performance with other target organisms. The results suggested that the gel may be suited for the PCR detection of gonorrhoea as well.

The UTG formed an invaluable and crucial part of a self-collection kit as the basis for a novel approach to chlamydia screening/testing. However, other aspects were still missing, namely the development and evaluation of: 1.) promotional materials to raise chlamydia awareness in the target population; and 2.) a system to reliably manage outgoing self-collection kits, incoming samples and management of results.

Chapter 5 describes the development of the promotional materials for chlamydia testing using the self-collection kit, and the establishment and evaluation of a central management system (CMS).

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CHAPTER 5 DEVELOPMENT OF PROMOTIONAL MATERIAL AND CENTRAL MANAGEMENT SYSTEM FOR A SELF-COLLECTION KIT FOR *CHLAMYDIA TRACHOMATIS* TESTING

5.1 Introduction

Several studies have successfully evaluated the use of home-collected and mailed urine samples for *Chlamydia trachomatis* (chlamydia) screening (Ostergaard, Moller et al. 1996; Morre, van Valkengoed et al. 1999; Gotz, van Bergen et al. 2006), and these methods were reviewed in Chapter 2. Such non-traditional methods of specimen collection and transport would be ideal for facilitating the extension of existing chlamydia testing programs (Australian Government Department of Health and Ageing 2005a; Hocking, Walker et al. 2008).

I had previously developed a self-collection kit for chlamydia testing that required participants to drop off a urine sample at a pathology collection point. I now adapted this self-collection kit to allow for mailing the sample through regular mail by using the ultra-absorbent polymer, as described in Chapters 4 and 6.

This chapter describes the specific development of the promotional material and the central management system (CMS) for the mailed self-collection kit.

5.2 Development of promotional material

5.2.1 Introduction

A search for appropriate existing promotional resources was conducted but none could be found. It was, therefore, decided that one set of resources (i.e. poster, leaflet and website) should be developed in a separate study using a best-practice approach. The development of the project website was conducted separately. I established a steering committee for the promotional resources comprising members from the Institute of Primary Health and Ambulatory Care (IPHAC) health promotion unit, Anton Breinl Centre health promotion unit (James Cook University), an Indigenous health worker from the Townsville Sexual Health Service, as well as CMS staff. The role of this group

was to guide best-practice principles in resource design and development and provide expert advice on content and clinical data. The development of the poster and leaflets formed part of the Master of Public Health qualifications of Brooke Ellis, a student from James Cook University. Brooke Ellis was supervised by myself and Ms Sue Devine.

5.2.2 Poster and leaflet

Background

Health promotion materials that would educate the target population about chlamydia as well as provide information on testing for chlamydia using the new self-collection kit did not exist and required development. Options for promoting the self-collection kit included written print materials, as they are the most common instructional tool used by health professionals to educate their clients and target audiences (Griffin, McKenna et al. 2003). This section describes the process of developing and piloting the print resources for the self-collection kit studies (named the Chlamydia Testing Trial or CTT) described later in this thesis. A detailed report written by Brooke Ellis is available as Appendix 1.

Methods

As formative research should dictate and guide the development of resources to ensure that both the topic and target audience are identified and their needs are met, members of the target population were actively involved in the process (Egger, Donovan et al. 1993). Members of the target audience, that is, young Australians aged 16 to 25 years, participated in a series of three focus groups (one with males, one with females and one mixed gender focus group), including between five and six participants. The focus groups informed on the development of the visual appearance, content, slogan and key messages of the educational resources.

Data Analysis

The recordings of the focus groups were transcribed verbatim and reviewed by the project officer, Brooke Ellis, along with the notes provided by the group facilitators and nurses. Manual analysis was undertaken. This data was collated, recurrent themes were identified and ideas highlighted to provide observations and suggestions to the steering committee, and an artist was commissioned to create the educational resources for the project.

Results

All focus groups suggested that it should be possible to order self-collection kits either by phone or over the internet.

The key messages that should be conveyed through the promotional materials as identified by the focus groups are as follows:

- testing should be discrete, confidential and possibly anonymous;
- information should educate on the asymptomatic nature of chlamydia;
- simple statistics (i.e. 1 in 10 people have it) should be provided;
- consequences of untreated chlamydia infection should be emphasised;
- ease of treatment should be explained;
- risk groups should be identified;
- location of kit distribution points should be provided;
- duration of time for the receipt of test results should be included;
- methods of result delivery should be mentioned;
- explanation should be included that the self-collection kit testing method is free, painless and simple (self-explanatory, easy to use).

Based on the findings of the focus groups and the subsequent informed discussions of the steering committee, an artist was employed to create a leaflet and a poster. The result of his work is shown in Figures 5.1 and 5.2.

Discussion

This study demonstrated the value of undertaking formative evaluation processes when developing health education resources. Research in health promotion has shown the effectiveness of using limited-reach media, such as leaflets and pamphlets, to help promote informed choice around screening decisions (Fox 2006). It is important, however, that healthcare professionals and health promotion professionals adhere to best-practice approaches, such as having the target population involved when developing educational materials (Sanson-Fisher 1997; Griffin, McKenna et al. 2003).

Figure 5.1 Poster

Figure 5.2 Pocket-sized leaflet

For the development of the promotion resources intended for the CTT (see following chapters), a number of approaches were applied to ensure the content was evidence-based.

Some interesting themes emerged in this study, which mirror many themes currently being used or which are exemplary of traditional campaigns for sexually transmitted infections (STIs). As STIs can be a sensitive topic, many people tend to find them more palatable if they are presented under the guise of humour. This idea runs concurrent with a recent Australian-based study conducted with Melbourne street youth (Henning, Alice et al. 2007). 'Sex sells' was another prominent theme that was raised by the focus groups. This presents a slight dichotomy, as it can be difficult to promote STI testing with 'sexy', as stated by one study participant, who suggested that 'people could accuse you of promoting risky sexual behaviour'. Chlamydia and gonorrhoea campaigns in West Australia (the 'Could I Have It?' campaign) and the UK (the 'Condom Essential Wear' campaign) have managed to incorporate this approach. The poster and leaflet developed for the CTT included both overt and subtle sexual imagery to identify with this theme.

Using a best-practice participatory approach throughout this project was useful in understanding the perceptions of the target audience. This resulted in the development of a product that is likely to resonate with and appeal to the target audience. Larger images of the poster and the leaflet are provided as Appendices 3 and 4.

Reducing barriers to STI and, specifically, chlamydia testing is a multifaceted social issue. The development of health education resources, such as posters and pamphlets, can be effective tools to raise awareness of the new home sampling kit and increase the uptake of chlamydia testing. The quality of the resources was likely to be enhanced by the active participation of the target group in the development process. Addressing the increasing rates of chlamydia nationwide is an important priority in preventing future, more permanent sequelae of the infection and the costly public health burden.

5.2.3 Website

In addition to the printed promotional resources, a website was developed. The project website (www.health.qld.gov.au/chlamydia, Appendix 5) was and still currently is (but now redeveloped and redirecting to http://www.health.qld.gov.au/sexhealth/chlamydia/) hosted by Queensland Health and contained the same information as the poster, leaflet and information contained in the self-collection kits. Additionally, the website contained information about the distribution sites, such as opening hours and location, and a page from where a kit could be ordered via email. Links to other sexual health websites were included for people seeking further information on either chlamydia or locations and contact details of specialist clinics in their area.

5.2.4 Acknowledgements

Brooke Ellis was employed part time by the CTT as the project officer for developing the promotional materials. She was able to use this work as a contribution towards her Master of Public Health qualification at James Cook University. Brooke worked under my direct supervision. The steering committee for the development of the promotional materials consisted of: Ms Sue Devine, health promotion specialist with James Cook University; Ms Sue Birch, team leader health promotion Queensland Health; Ms Florence Henaway, Indigenous Health Worker, Queensland Health; and Ms Rose Gordon, Clinical Nurse Consultant, Queensland Health. The artist employed was Gavin Ryan. The steering committee met weekly for the duration of the resource development. Brooke Ellis coordinated communication with the artist, while I chaired the committee.

5.3 The Central Management System (CMS)

The CMS formed the 'hub' of the self-collection kit part of the studies and was hosted by the Townsville Health Service District at the Institute of Primary Health and Ambulatory Care (IPHAC). The distribution of the self-collection kits and returned samples were managed through the CMS. The CMS consisted of one full-time position shared by myself and Ms Rose Gordon.

In collaboration with Ms Jana Bender, a medical data management specialist, the previously developed Microsoft Access application for the drop-off kit project was adapted for the recording of the information related to the self-collection kit from the time when the kit left the CMS until the end of an episode of care. The self-collection kit included a questionnaire (see Chapter 6 for more detailed information), which was used to manage the samples and evaluate the kit. Variables were created for each of the questions in the questionnaire plus additional clinical management information, such as the date the kit was received back, the type of sample, date the participant was contacted with the result, referral agency for treatment, type of treatment received, partner notification details and a final satisfaction survey.

The database had built-in queries that accommodated the clinical management of participants. Queries included the production of lists of participants who had returned a sample but for whom the result was still outstanding from pathology, or for those who had not yet received their results, treatment or partner notification. Another feature of the database was the ability to produce lists for reminders for re-testing.

5.4 Summary of results, relevance, and how this project contributes to the overall doctoral studies

The participatory approach to the resource development was satisfying and resulted in attractive products. A leaflet, poster and website were developed to promote the self-collection kit for chlamydia testing. In order to offer chlamydia testing to the target audience by means of the self-collection kit, a management system was required. The central management system (CMS) of the chlamydia project was responsible for running the CTT. Chapter 6 describes in detail the development of the self-collection kit.

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CHAPTER 6 SELF-COLLECTION KIT DEVELOPMENT

6.1 Introduction

All components of the self-collection kit were sourced by the central management system (CMS) in accordance with the requirements of Australia Post and Queensland Health's acquisition guidelines. Parts such as the cardboard box had to be developed in collaboration with industry; other parts such as the tubes had to be sourced from overseas as no suitable product was available in Australia. Some items were available as standard stock through Queensland Health requisitions. Documentation, that is, an information sheet, instructions for taking a sample and a questionnaire, pathology request form, a unique number card and a welcome letter was specifically developed for the study (Appendix 6).

For the purpose of the study it was deemed important to be able to track each kit from leaving the CMS to returning to the CMS with a sample. Therefore, each kit needed to be individually labelled using identification numbers, which were matched on the pathology form, questionnaire and sample containers. The kit packing was contracted out to community organisations. Packers were supplied with all required materials, a demonstration kit, written packing instructions, as well as a practical demonstration. Quality control was conducted by the CMS on all kits returned from packing. Initially, 3,000 unique kits were produced for this project.

The following text describes the contents of the self-collection kit. Initially, Australia Post voiced concerns about the potential of participants incorrectly packaging samples. Therefore, an evaluation of the packaging of the first 100 returned samples was conducted and is also described below.

This chapter addresses the specific means used to achieve the aims of my thesis; that is, to develop, implement and evaluate novel approaches to non-clinic based chlamydia testing and the management of test results.

I developed and/or sourced all parts of the kit, apart from the gel, as well as the documentation. The steering committee approved the kit. The CMS, that is, Ms Rose Gordon and myself, were responsible for the day-to-day running of the study.

This study was published as:

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6.2 Publication

CSIRO PUBLISHING www.publish.csiro.au/journals/sh *Sexual Health*, 2009, **6**, 163–169

The check is in the mail: piloting a novel approach to *Chlamydia trachomatis* testing using self-collected, mailed specimen

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Abstract. *Objectives*: To develop, implement and evaluate the processes of a novel approach to chlamydia testing that is accessible, confidential, free of charge, easy to use, and allows for self-collection of specimens, their transportation by regular mail and the central management of results. *Methods*: A 'self-collection kit' was developed including all items and instructions necessary to obtain a sample. A network of distribution sites at locations frequented by the target population has been established. The 'kits' can be requested via an advertised website and by phone. Specimens are returned via reply paid mail. A centralised system for the management of results and follow up has been established. Test results are conveyed by the participant's method of choice. Treatment is organised via a network of health care providers.
Results: Of the first 100 returned kits 99% were safely packed and 86% were sent back with a completely filled outpathology request form. Ninety-two participants provided contact details; 70.7% indicated mobile phone or SMS as the preferred methods to receive results. Seven positive cases were identified and treatment was confirmed for all within 6 days.
Discussion: These findings provide evidence that the presented approach to chlamydia testing is easy to implement,achieves excellent follow-up and treatment rates, and therefore opens important new channels to otherwise difficult toaccess high-risk populations, such as young people and geographically and socially isolated populations.

Additional keywords: mail, screening, self-collection

Introduction

Chlamydia trachomatis (chlamydia) is the most commonly notified sexually transmissible bacterial infection in the developed world.1 A systematic review of prevalence studies conducted in the UK found chlamydia prevalence as high as 33% depending on the setting and age-group tested.2 Similar prevalence ranging between zero and 27.0%, has been reported in Australian studies.3,4 Chlamydia prevalence was estimated to be 8.2% in a recent American study, which screened more than 51 000 young men enrolled in a national job training program.5 Risk groups consistently identified are the younger age group, the socio-economically disadvantaged, minority groups such as migrants, and military personnel.25 Usually chlamydia testing is conducted in primary health care settings. In Australia, most testing for chlamydia is conducted in general practitioner (GP) practices and sexual health services as opportunistic, on-demand, or symptomatic screening.6 Opportunistic screening for chlamydia in GP practices is hampered by an already heavy workload especially in rural and remote parts of Australia.7,8 There are over 80 specialist sexual health clinics in Australia most of which are located in the larger centres along the coast.9 These centres are out of reach for many potential clients given the vast distances of the country, which is of particular concern for the high-risk

Aboriginal and Torres Strait Islander (ATSI) population located in remote areas.10 Young people are the major risk group for Chlamydia infection.25 However, an Australian study found that although more than 80% of the 16- to 24-year-old women present to a primary health care provider at least once per year, only 7% were tested for chlamydia and it is most probable that this percentage is even smaller in men, especially men who have sex with men (MSM).6,1113 Previous research has shown that the general population and, in particular, the high risk younger age group know little about chlamydia and do

not perceive themselves at risk.1416 Additionally, many infected or at-risk people do not actively seek health care, due to the predominantly asymptomatic nature of chlamydial infections.

In 2006, Gaydos *et al*. targeted females for Chlamydia testing by using the internet and community organisations to advertise a chlamydia testing kit allowing for self-collection of vaginal swabs that were mailed back for testing.17 Novak *et al*. sent a self-collection kit to all 22-year-old male residents of a Swedish city. Liquid urine samples were returned and results were available via the internet.18 In a further study, Novak *et al*. offered self-collection kits to the entire population of a Swedish county using the internet.19 These studies reported successfully attracting younger people to Chlamydia testing. The Swedish study additionally pointed out that they had achieved the highest published male response rate for chlamydia testing.18 Similarly, a Scottish study found that men were responding well to the self-collection postal kits.20 This study concluded that a combination of self-sampling postal kits and continued screening programs in clinical settings would be the most effective way to capture most high-risk groups.20 The present study aimed to address the described issues by developing, implementing and evaluating the processes of a new approach to chlamydia testing based on a novel self-collection kit and management system.

Methods

Ethics

Ethics approvals were granted for all parts of this project by the human research ethics committees of James Cook University (H2614) and by Queensland Health (33/05).

Chlamydia self-collection kit

A multi-disciplinary steering group including sexual health nurses, health promotion specialists, sexual health physicians, epidemiologists, laboratory-based scientists, and consumers developed a self-collection kit for chlamydia testing, which consisted of 15 components (Fig. 1).

(1) A welcome letter.

(2) A leaflet with general information on chlamydia (e.g.aetiology, risk groups, signs and symptoms, prevention), ethical aspects of the study, and a dot-point guide on how to participate.

(3) A leaflet with detailed instructions on how to obtain a suitable sample for chlamydia testing. There are two versions of this instruction sheet, one for heterosexual men and women and one for the MSM community. The instruction sheet contains descriptive as well as pictorial instructions for taking a vaginal or anal swab and a urine sample, as well as the packaging and mailing of the sample.

(4) A slip with the unique number of the kit and contact details of the project management (for those who wish not to give their contact details to receive their results).

(5) A consent form with a structured self-administered questionnaire covering demographics (age, gender, ethnicity) as well as sexual behaviour including number and gender of sexual partners, use of condoms, history of chlamydia testing and diagnosis, and experience of dysuria and discharge. The questionnaire was piloted (n = 60) and refined during this process.

(6) A single wrapped sterile cotton bud for taking either a vaginal or an anal sample for chlamydia testing.

(7) A pre-labelled colour-coded sterile container specifically designed for the transport of the swab.

(8) A sterile 70-mL container required for holding the primary urine sample.

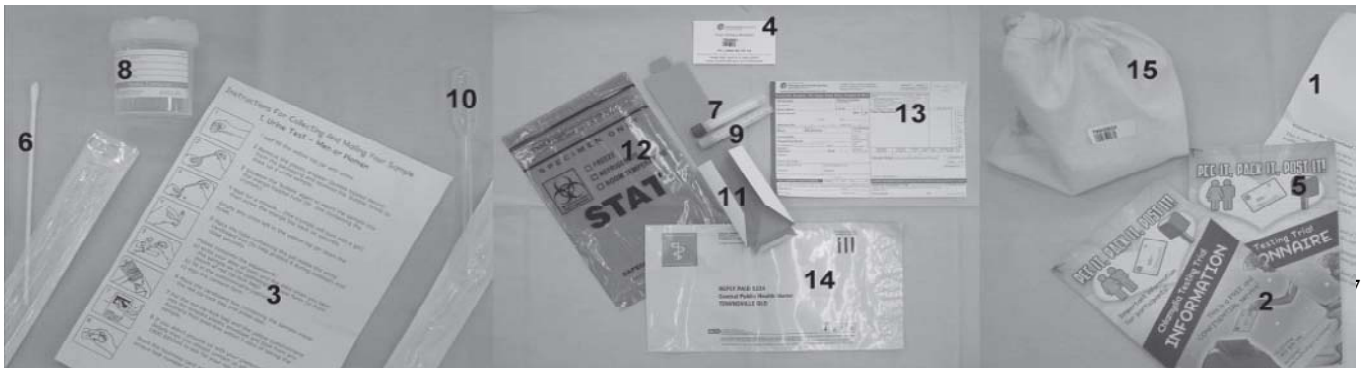
(9) A pre-labelled, colour-coded, sterile container specifically designed for the transport of biological samples filled with 1 g of anhydrous urine transport gel (UTG) to transform the urine into a dry gel suitable for transport.

(10) A single wrapped sterile dropper holding 3mL to transfer urine from the primary container to the transport container.

(11) A cardboard box as secondary packaging of the container (s) (either (7) or (9) or both), which hold the sample(s).

Fig. 1. The content of the chlamydia self-collection kit.

12) A ziploc watertight bag as the tertiary container of the sample, marking it as a biological sample, with a



pocket for the transport of component (13).
(13) A re-labelled pathology request form.
(14) A reply-paid, pre-addressed plastic mailing envelope as the final container of the sample.
(15) A calico bag (15 cm20 cm).

All kit parts are finally enclosed in (15). Consultation with the target population required a non-descriptive packaging that would not reveal the content; also the size was to be kept to fit in a pocket or handbag.

Transport requirements
In order to get approval to transport the samples through regular mail, the packaging of the samples had to comply with postal regulations. In cooperation with the Australian postal service agency a special risk management plan was developed: (1) only a 3-mL urine sample is used to minimise the amount of biological material; (2) liquid urine is transformed into a dry gel; (3) four layers of packaging material protects the sample against pressure and informs about the transport of a 'biological substance' providing a 24-h emergency phone number in case of breakage; (4) use of UTG to inhibit bacterial viability.

Urine transport gel
Each tube contains 1 g of UTG, which is composed of 0.5 g superabsorbent polymer, and 0.5 g of stabilising additive. The granular cross-linked form of poly(acrylic acid), partial sodium salt-graft-poly(ethylene oxide) is an economical and non-toxic member of a family of superabsorbent polymers widely used in spill kits, diapers, agriculture and other liquid absorption and retention applications. This desiccating agent has the capacity to hold multiples of its own weight in water, which it binds within the polymer structure, retaining liquid even under pressure. *Neisseria gonorrhoea* was used as a marker for bacterial viability in the UTG system demonstrating inhibitory qualities at concentrations of a least 1.0 E5 cells mL1. Upon application of isopropanol, the gel partially releases its retained water, in which the cellular particulate matter is resuspended. This reconstituted urine is subsequently drawn off, from which DNA can be extracted using standard nucleic acid extraction methods for the purposes of polymerase chain reaction (PCR) detection of *C. trachomatis*. The gel transport method has been shown to have comparable clinical and analytical sensitivities and specificities to that of neat urine in the context of Chlamydia diagnosis by PCR using the Roche Amplicor test.21

Pilot study
A prototype of the self-collection kit was developed and was piloted in the target group of 16 to 25 year olds attending the sexual health clinic in Townsville. A total of 60 kits in three cycles of 20 kits each were distributed to identify problems and enable the clarification and rewording of five questions of the questionnaire and the instructions for taking a sample. There were no further comments during the third cycle.

Information material
A poster (Fig. 2), a webpage (http://www.health.qld.gov.au/ chlamydia) and a pocket-sized information leaflet were developed to raise awareness about chlamydia and to advertise the kits. A health promotion advisory group designed the health promotion materials in conjunction with an artist. Focus groups with the target population were conducted to refine the materials.

Development of a centralised management system
The centre piece of the centralised management system is a specifically designed database for the project to track kit distribution, return of samples, results, and participants' answers to survey questions, contact details, and perceptions of the kit and testing method.

Results
Implementation
Distributors of the kits were organisations in contact with the target population (16 to 25 year olds, ATSI peoples, and MSM) including youth organisations, pharmacies, student services at tertiary education facilities, community groups, sports clubs, and the trial centre (website, free-call phone number, and email). A wide array of professionals were involved in the promotion of the kits but did not directly distribute them, such as School Based Youth Health Nurses and Flexible Learning Centres that help youth at risk of disengaging from mainstream education. The kits could be picked up from distribution points as advertised on the webpage and on posters. Alternatively kits could be ordered by either ringing the free-call number or emailing. The samples arrived via regular mail at the trial centre where the questionnaire was separated, the pathology request form was checked and amended as necessary, and data entered into the database. The sample was then sent to the laboratory where the urine was reconstituted from gel and analysed. If participants supplied their contact details they were notified of the test result directly. If participants did not want to supply their contact details, they could ring the trial centre 2 weeks after mailing the sample for their result by quoting the unique number.

Field trial
A field trial was conducted between August and November 2007 to investigate whether the kit, systems and procedures carried out as planned using 100 returned kits as the sample. Of these, 86.0% had completely filled out the pathology request form and 99.0% had been packed safely. One participant returned a liquid urine sample in the swab container; however, the packing was sufficient to prevent urine leakage. Overall participants mailed in 63 urine samples and 37 vaginal swab samples. Ninety-two participants provided contact details and indicated a preferred method of contact. They were all contacted and notified of their results. None of the eight people who did not provide contact details contacted the

Fig. 2. Promotion poster

study centre for their results, and are consequently not aware of the test result (Fig. 3).

In addition to the general evaluation of the developed processes for sample handling and result management, a preliminary analysis of the contact preferences and follow-up was undertaken. A total of 96 of the 100 respondents consented to participating in the study (n = 96), 92 (95.8%) participants provided contact details. For the eight participants who indicated no preference, the provided contact detail was assumed as the preference. The contact methods most preferred by participants were mobile phone 47 (51.1%) and SMS 18 (19.6%) followed by mail with 11 (12%) and email and landline telephone with eight (8.7%), respectively.

The chlamydia test result was negative for 87, positive for seven and invalid for two participants. Both people with an invalid test result were contacted and sent materials for the resupply of a specimen, which they subsequently returned (tested negative). Positive cases were referred to their preferred health care provider for treatment with Azithromycin 1 g orally. Treatment was confirmed for all identified chlamydia cases within 6 days of contacting them (Fig. 4). Contact tracing was discussed with all participants who tested positive and

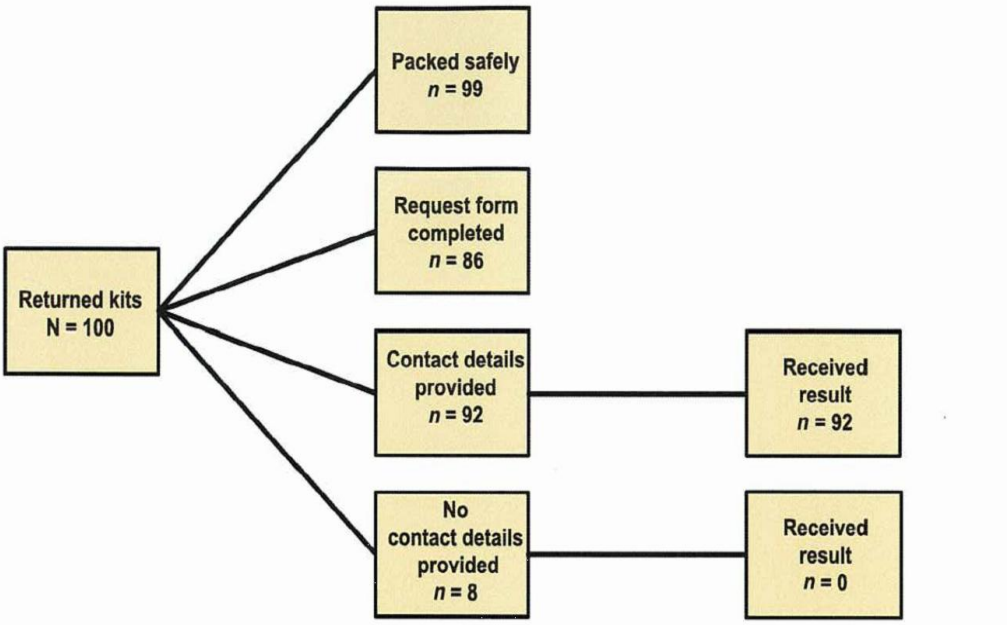


Fig. 3. Returned kits, packaging and communication of results.

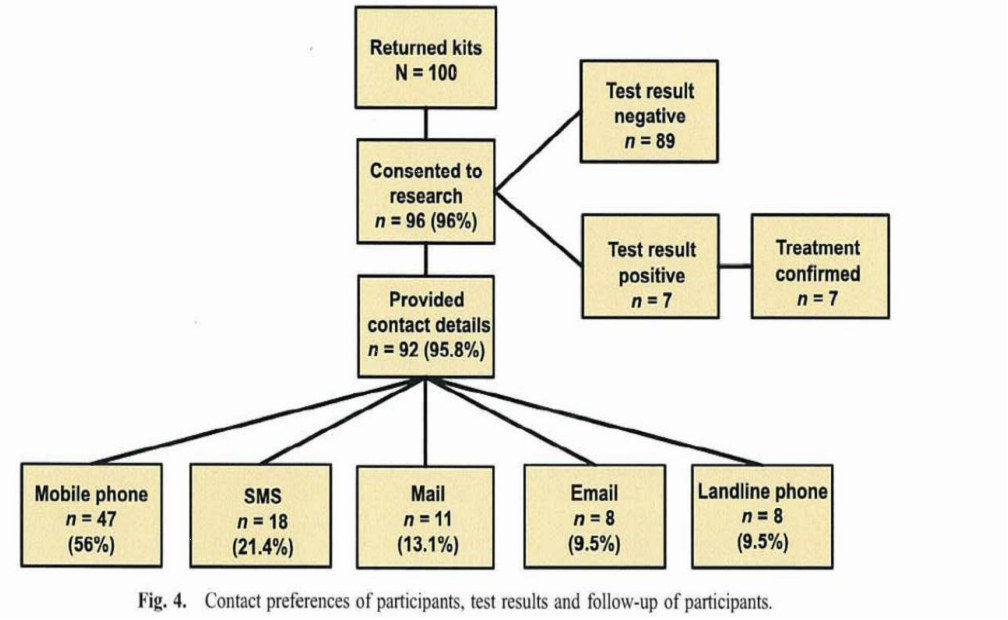


Fig. 4. Contact preferences of participants, test results and follow-up of participants.

either conducted by the participant, project staff or the treating clinician. No data are available on the outcome of contact tracing efforts.

Discussion

This study presents the development, implementation and evaluation of a pilot for a much needed new approach to chlamydia testing. The presented novel approach is based on a self-collection kit with a centralised management system and uses superabsorbent urine transport gel to allow posting of a specimen using standard mail services. The results deliver strong evidence that the developed approach was easy to implement and achieved excellent follow-up and treatment rates even in this small sample from the field trial. The self-collection kit concept minimises important barriers to chlamydia testing as it can overcome geographical and social isolation, as well as the potential

embarrassment of seeking sexually transmissible infection testing in a face to face clinical setting. The presented approach therefore opens important new channels to reach otherwise difficult to access high-risk populations.

Accessibility to chlamydia testing is especially improved as this kit can be used independent of place and time. This feature is of particular interest for Australia where overcoming problems of distance and availability of health services are very important in rural and remote areas.22

The use of a self-collection kit for chlamydia testing and contemporary communication methods to convey results is attractive to young people, the main target group. The promotion material informs potential participants about chlamydia and its risk factors, thereby encouraging people who identify with risk groups to seek testing.

The field trial of the test kit showed that most participants followed the provided instructions and processed the kit correctly. Clients were also willing to provide contact details (mostly as mobile phone numbers). As a consequence most participants received their test results even if they were negative. The management system for results and follow-up is effective.

It should be noted that mailing a self-collected sample for chlamydia testing is not intended to divert patients away from GP practices or sexual health clinics but to engage a previously untapped client base. In this study, test kits could be either personally collected from participating distributors, or ordered through a free-call number or via the internet. As such it can be seen as an extension of the recently tested self-collection kits from Sweden and the USA, but allowing the sending of urine in a dried gel state and thereby avoiding the loss of the specimen due to leakage and the risk of potential exposure of postal workers.17_19.

The self-collection kit can also facilitate the re-testing of previously positive clients. If implemented in a similar way to the current Australian National Bowel Cancer Screening Program the chlamydia self-collection kit could offer the potential for population-wide systematic screening.23

Technical aspects of the new approach

The evaluation of the UTG showed that its use did not alter test results.17 In contrast to standard handling requirements for urine samples, the use of the UTG has no special storage requirements (e.g. cooling) and retains sensitivity for *C. trachomatis* PCR diagnosis for at least 7 days at room temperature. Additionally, the UTG was found to be easily processed by laboratory staff, due to the relatively simple reconstitution procedure and integration with existing DNA extraction protocols. The efficacy of the UTG method is based on the retention of DNA integrity and availability for PCR diagnosis, thus it would not be suitable for *C. trachomatis* culture techniques.

Conclusion

The present study developed and evaluated a novel approach to chlamydia testing, which was proved to be easy to implement. Communication via mobile phone for results was the choice of most participants in the field trial and resulted in excellent follow-up and treatment rates.

The area of chlamydia testing is currently characterised by a lack of progress in known high-risk groups with ever increasing notifications. It is against this backdrop where self-collection of samples for chlamydia testing opens promising new channels to reach otherwise difficult to access high risk populations, such as young people as well as geographically and socially isolated populations.

Conflict of interests

None declared.

Funding

This project was funded by the Australian Commonwealth Government, as part of a National Chlamydia Pilot Program that is currently running to test the effectiveness of several models for chlamydia testing in Australia. This project will assist in developing possible recommendations for a National Chlamydia Program.

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6.3 Summary of results, relevance, and how this project contributes to the overall doctoral studies

This chapter describes the first testing of a self-collection kit for *Chlamydia trachomatis* (chlamydia) testing that allows the transport of a sample by regular mail under field conditions. This self-collection kit, in conjunction with the CMS and a promotional campaign, formed one of the pivotal parts of the Chlamydia Testing Trial (CTT) in Queensland. The field testing of the self-collection kit showed that the vast majority of participants followed the instructions for collecting and packaging the sample.

Of the 100 participants who used the self-collection kits in the field test, 86.0% had completely filled out the pathology request form and 99.0% had packed the sample safely. One participant returned a liquid urine sample in the swab container; however, the packing was sufficient to prevent urine leakage. Instructions were seemingly understood and adhered to and anonymity was much less of an issue than confidentiality. That is, participants were happy to provide contact details under the provision of confidentiality, although the option of anonymous testing existed. These results imply that the self-collection kit is a promising tool for increasing access to chlamydia testing.

Chapter 7 describes the experience gained with respect to the distribution of the kit by partner organisations.

CHAPTER 7 EXPERIENCE WITH THE DISTRIBUTION OF SELF-COLLECTION KITS BY COMMUNITY – BASED PARTNER ORGANISATIONS

7.1 Introduction

As discussed in the literature review (Chapter 2), the highest notification numbers and rates of *Chlamydia trachomatis* (chlamydia) in Australia are found in the 16 to 25 years age group (Australian Government Department of Health and Ageing 2005). Males of this age group are particularly difficult to reach through conventional health services and, of about 80% of young women who saw their general practitioner (GP) in 2004, only 7% were tested for chlamydia (Fairley, Hocking et al. 2005). More recently, a study found that chlamydia testing rates according to Health Insurance Commission data was about 6.3% for females and 1.6% for males in the 16 to 24 years age group, possibly reflecting the differences in healthcare seeking behaviour between males and females (Kong, Guy et al. 2008).

In order to overcome the problem of access to the target population – namely 16 to 24 year olds, people with a history of chlamydia, men who have sex with men (MSM), people who are socially and/or geographically isolated, and Indigenous peoples – various organisations that are in contact with the target population as part of their usual business were approached to distribute the self-collection kits for chlamydia testing. These organisations included youth services, MSM health services, Aboriginal and Torres Strait Islander (ATSI) health services, pharmacies, mobile women's health nurses, special schools and the Australian Defence Force (ADF).

This chapter discusses the feasibility of the distribution of the self-collection kit for chlamydia testing through partner organisations, as well as the feasibility of a central management system (CMS) to administer such an approach to chlamydia testing.

This chapter addresses the overall aims to implement alternative methods of testing for chlamydia and to evaluate alternative methods of testing for chlamydia.

The CMS, that is Ms Rose Gordon and I, organised the distribution of the self-collection kits, promotional materials and educational resources to the community organisations. We were responsible for following up all samples and the management of

test results. The organisations were responsible for displaying the advertising materials and distributing the kit to their clients.

7.2 Experience with community-based partner organisations – accessing various segments of the target population

All partner organisations received promotional materials; including posters and leaflets, as well as the educational resources developed for partner organisations (details are presented in Chapter 5). Education sessions were conducted on request of the partner organisation. Table 7.1 provides details of the organisations involved in this study and the segments of the target population they do business with.

Table 7.1 Partner organisations and population segments accessed through community service collection study

Partner organisation	Population segment
1) Needle Syringe Program (NSP)	Injecting drug users
2) Australian Defence Force (ADF)	Young males
3) Mobile Women's Health Nurse (MWHN) Longreach	Mostly women but also the wider community over a wide rural and remote geographical area
4) Youth- Link Cairns (YLC)	Young males and females
5) Flexible Learning (FL)	Marginalised youth with special education needs, mostly of Indigenous descent
6) Queensland Health Community Health Service Kirwan (QH CHK)	Male and female high school students (across the street from the largest high school in Queensland)
7) Chinese ethnic community in Brisbane (CEC)	Young people of Chinese descent
8) Cunnamulla Health Service (CHS)	Young males, females, Indigenous population, rural and remote/isolated population

Though it would have been preferable if all partner organisations promoted the self-collection kit in a similar way to allow for better comparison, this was not feasible. As the promotion and distribution of self-collection kits had to be integrated into the usual business of each organisation, it was left to the individual service to set up a system according to their individual needs. Records were kept by most providers on promotion activities. The spectrum of promotion varied from just displaying a poster to actively engaging potential participants in a conversation about chlamydia testing and the self-collection kit. Details of the promotional activities are listed in Table 7.2 Most partner organisations who acted as distributors in this study agreed to have their street address and opening hours published on the study website.

Table 7.2 Promotional activities of participating partners in community-based organisation study

Organisation Activity	NSP	ADF	MWHN	YLC	FL	QH CHK	CEC#	CHS#
Poster display in outlet	*	*	*		*	*		
Poster display throughout community identifying outlet	*	*	*		*	*		
Poster display throughout education facility (if available)	*	*			*			
Leaflets on display – self collected	*	*	*		*	*		
Distributed leaflets in product bags intermittently	*							
Staff identified those at risk and recommended kits	*	*	*		*			
Self-access to kits at outlet		*				*		
Kits available on enquiry	*	*	*					
Notice in community newsletter								
Details on CTT website	*			*	*	*		
Information stall at specific event			*					

#Staff was not contactable during normal working hours to provide details.

7.2.1 Results

Of the 608 distributed kits, 46 (7.6%, 95% CI = [6%; 10%]) were returned by participants with samples for chlamydia testing. Details according to distribution site are shown in Table 7.3. As previously discussed, it was not feasible for partner organisations to keep a record of how many people were actually approached or had seen the promotional material. Some people participated repeatedly either because they perceived themselves at risk of chlamydia (*n* = 1) or because they previously tested positive for chlamydia.

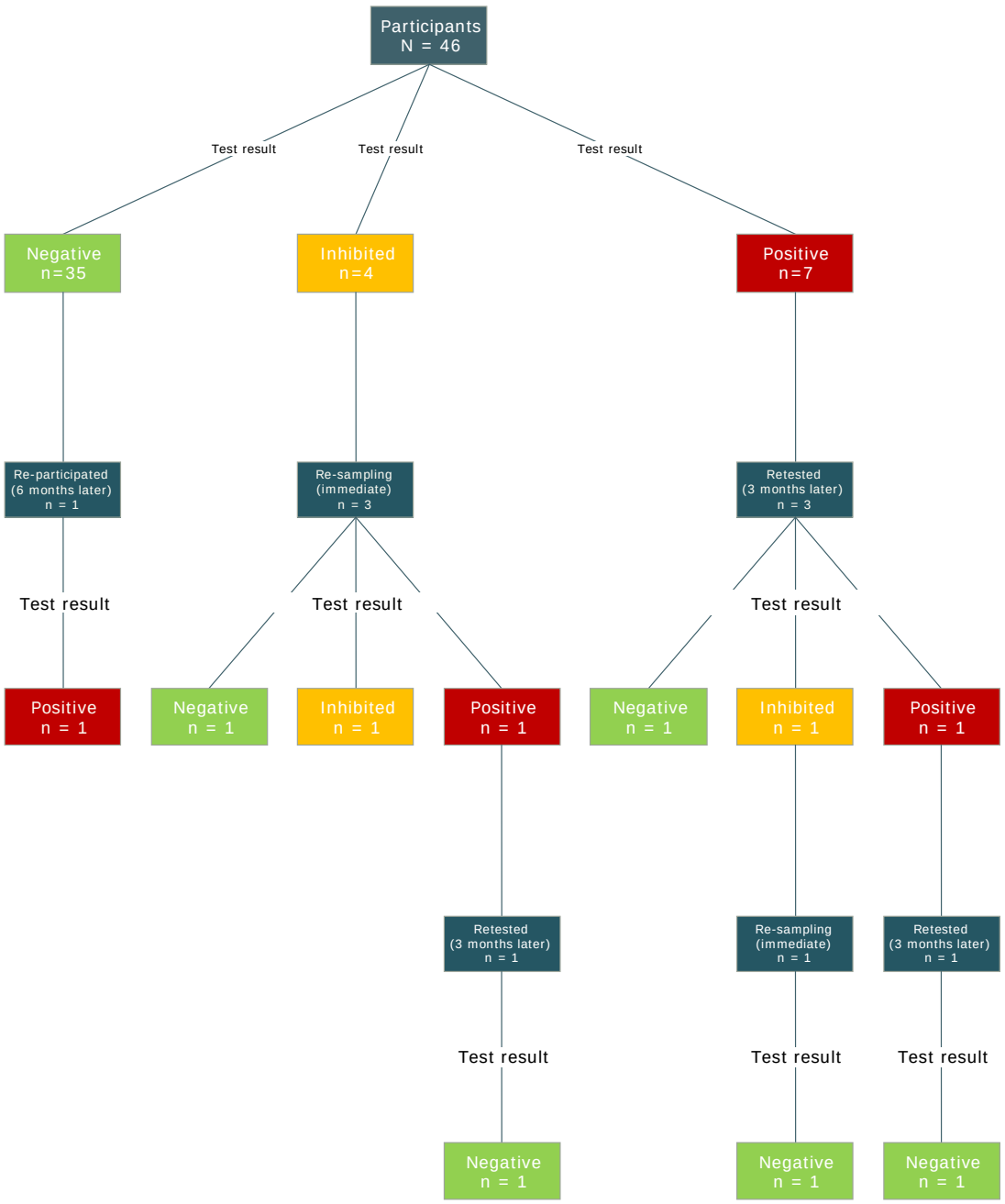
Table 7.3 Kit distribution and return rates by distribution site in community-based organisation study

	Number of kits distributed	Number of kits returned	Number of individuals	Return rate in %*
NSP	20	3	3	15
ADF	28	4	3	10.7
MWHN	210	16	14	6.7
YLC	20	1	1	5
FL	75	13	13	17.3
QH CHK	67	4	4	6
CEC	148	4	4	2.7
CHS	40	4	4	10
Total	608	49	46	7.6 95% CI = [6%; 10%]

*% returned is too small to calculate a meaningful 95% CI for the individual return rates.

Figure 7.1 details the flow of participants in this study. The mean age of participants was 22.5 years (SD = 5.97 years), 39.1% were males and 16.1% identified themselves as being of Indigenous descent. Eight people (17.4%) were positive on initial testing; one initially negative person tested positive when re-participating after several months, while a second person who was initially positive, was positive again when retested after 3 months. All participants with an inhibited (invalid) result were contacted and offered retesting. One person stated that he had had a full screen at the GP in the meantime, while the others agreed to have materials sent to them for a repeat sample; all repeat

Figure 7.1 Participant flow through community-based organisation collection study



samples were sent back. The one person who had had a repeat inhibited result declined to have further materials sent for retesting. Of the three initially positive people, three had a repeat test after 3 to 4 months, with one testing negative, one testing positive and one inhibited test result (Figure 7.1, Table 7.4).

Of the 46 participants, 39 (84.8%) were contactable for results. All positive cases were notified of their result and referred to their preferred healthcare provider for treatment. Treatment was confirmed for all. On average, the time from notification of test result to

treatment was 1.5 days. Retesting was recommended to all participants who tested positive. Table 7.4 provides further details on participants and follow-up.

Table 7.4 Characteristics and follow-up details of the 46 participants in community-based organisation collection study

Demographics		
Mean age (years) (SD*)	22.5 (5.97)	
Male gender, *n* (%)	18/46 (39.1%)	
Indigenous status, *n* (%)	5/31 (16.1%)	
Results and follow-up		
Positive test results, *n* (%)	8/46 (17.4%) Prevelence + 1 incident case 10/49 (20.4%) Positivity	
Contacted with results, *n* (%)	39/46 (84.8%)**	
Treatment completed, *n* (%)	8/46 (100%) of initial cases 2/2 (100%) of other cases	
Median treatment interval (days), [IQR***]	1.5 [0; 3]	
Referral agencies	GP, Community Health Services	
Partner notification		
Total sexual partners	13	
Contactable sexual partners	11	
		Confirmed
Notified by participant, *n* (%)	8/11 (72.7%)	4/8 (50%)
Notified by CMS, *n* (%)		
Notified by referral agency, *n* (%)	n/a	

* Standard deviation **7 people not contacted had negative test results. *** Interquartile range

7.2.2 Discussion

Return rates of the self-collection kits distributed through the Community Service Collection Study were rather low. However, it might be misleading to judge the success of this part of the project on return rates alone. It is obvious that some of the partner organisations involved work with clients who would otherwise be completely

unreachable for chlamydia testing. For example, injecting drug users and disengaged youth are known to be difficult to access but, nevertheless, participated in this project.

It is also noteworthy that the CMS processed all returned kits and all positive cases were treated in a timely fashion. The CMS successfully offered re-sampling to people with initially inhibited test results and contact tracing was organised for all positive cases.

7.3 Pharmacy Collection

Two separate studies were conducted to investigate the acceptability and feasibility of distributing the self-collection kit through community pharmacies.

The first pharmacy collection study (section 7.3.1) was conducted by the University of Queensland as a separate project and focused on determining the usefulness of community pharmacies as a distributor of self-collection kits and the efficacy of questionnaire-based screening for assessing chlamydia risk. The clinical management of all participants was handled by the CMS.

A comprehensive report authored by the investigators from UQ is provided in Appendix 7.

The second pharmacy collection study (section 7.3.2) was conducted by myself under the umbrella of the CMS and investigated the acceptability of the self-collection kit for chlamydia testing to customers of community pharmacies, as well as the feasibility of a CMS to administer such an approach to chlamydia testing.

7.3.1 University of Queensland Pharmacy Collection

A major trial of the distribution of chlamydia specimen collection kits was conducted in Boots pharmacies in London in 2005, the success of the trial suggesting that Australian pharmacies may be suitable screening and distribution centres for such kits (UK Department of Health 2006).

The aims of this study were twofold: to determine the utility of community pharmacies as a distribution site for chlamydia self-collection screening kits, and to determine the efficacy of questionnaire-based screening in pharmacies, accompanying the distribution of self-collection kits, in identifying chlamydia-positive individuals.

Drs Lynne Emmerton and Lisa Nissen, University of Queensland (UQ), School of Pharmacy, developed this part of the study design, as well as a screening questionnaire for chlamydia and organised the study through UQ. Elliroma Gardiner was the project officer for the study and was responsible for the day-to-day conduct of the study. Dr Joseph Debattista, Sexual Health, HIV & Hepatitis Coordinator for the Metro North Health & Sunshine Coast Health Service District, Queensland Health, Brisbane, coordinated the study. I organised the self-collection kits, managed the clinical aspect of participant care and analysed the data.

This study was published as:

Emmerton, L., **Buhrer Skinner, M.,** Gardiner, E., Nissen, L., & Debattista, J. (2011). A trial of the distribution of chlamydia self-collection postal specimen kits from Australian community pharmacies. *Sex Health, 8*(1), 130-132.

7.3.1.1 Publication

A trial of the distribution of chlamydia self-collection postal specimen kits from Australian community pharmacies

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The involvement of pharmacies in offering non-invasive sexually transmissible infection (STI) testing is considered important given their presence in the community, long opening hours, and credibility as health-care providers and promoters. In the UK, pharmacy-based distribution of chlamydia self-collection specimen kits was successfully trialled, in over 200 Boots pharmacies in London in late 2005.[1,2] Clients aged 16 years and over in theUK may now purchase the specimen kits and mail their urine sample to the laboratory for testing.[3]

We report some outcomes of the pharmacy sub-study of a Queensland Chlamydia Testing Program that explored various modes of distribution for specimen self-collection kits. Availability of specimen collection kits from pharmacies may enhance the uptake of testing services. In contrast to other countries, however, Australian postal regulations do not permit mailing of liquid specimens. Development of the regulation compliant kit used in this study has been reported elsewhere.[4,5] Briefly, a transport medium for urine samples, a self-collection postal kit, as well as a clinical management system, including notification of the test result by telephone or text message and referral of positive cases for treatment, were developed and tested for functionality. The community pharmacy arm of this study investigated (1) the feasibility of community pharmacies for distribution of specimen kits and (2) associations between risk-based screening and test results. Four Queensland community pharmacies participated, selected to target sectors of the community lacking opportunity for chlamydia testing. Each pharmacy was issued 75 specimen collection kits (Fig. 1), each with instructions for collection and mailing of the specimen and a code-matched questionnaire exploring published risk factors. In accordance with the ethical approval for this study, pharmacy staff were trained to offer kits to clients 16 years or older, fluent in English and presenting for a sexual health-related product or consultation. The accompanying questionnaires were completed by clients in the pharmacy, submitted in a sealed envelope and retrieved by the researchers. Code-matched chlamydia test results from the testing centre were compared with the nominally-scored questionnaire data. Specimens were tested with the polymerase chain reaction assay, and results reported back to clients in the manner requested when the specimens were mailed in.

As part of the evaluation, pharmacy staff members were interviewed in person (by telephone for a remote pharmacy) at the conclusion of the study regarding their experiences with the processes.

Kits were distributed over a 4-month period in 2008. Of 300 kits, 156 were distributed to clients (1–75 per pharmacy), with 18 persons submitting specimens for testing (12%). This return rate was comparable to the average across the eight arms of the parent study.[5] Four of the 18 specimens received were reactive for *Chlamydia trachomatis*. Forty-four risk-assessment questionnaires were retrieved (28% of the distributed kits), indicating that these clients averaged 25 years (range 16–48 years) and were predominantly females (n = 41). Sixteen respondents (37%) were identified by their questionnaire scores as 'at-risk' of testing positive for chlamydia. Comparing the test results with the questionnaire risk scores, higher risk scores were noted for two of the four positive cases.

Risk behaviours reported in the questionnaires included multiple partners in the past year and symptoms suggestive of an STI. Condom use was sporadic. Twenty-five of the 44 participants reported having been previously tested for chlamydia; of these, six recalled a previous positive test and seven were unsure.

Interviews with all available pharmacy staff identified support for the study, but there were commitment issues relating to workload and, in some cases, no staff member taking responsibility for 'driving' the distribution of the specimen collection kits. Another factor limitation was the restriction of advertising to in-store posters and leaflets. This required pharmacy staff to verbally introduce the concept to potential participants.

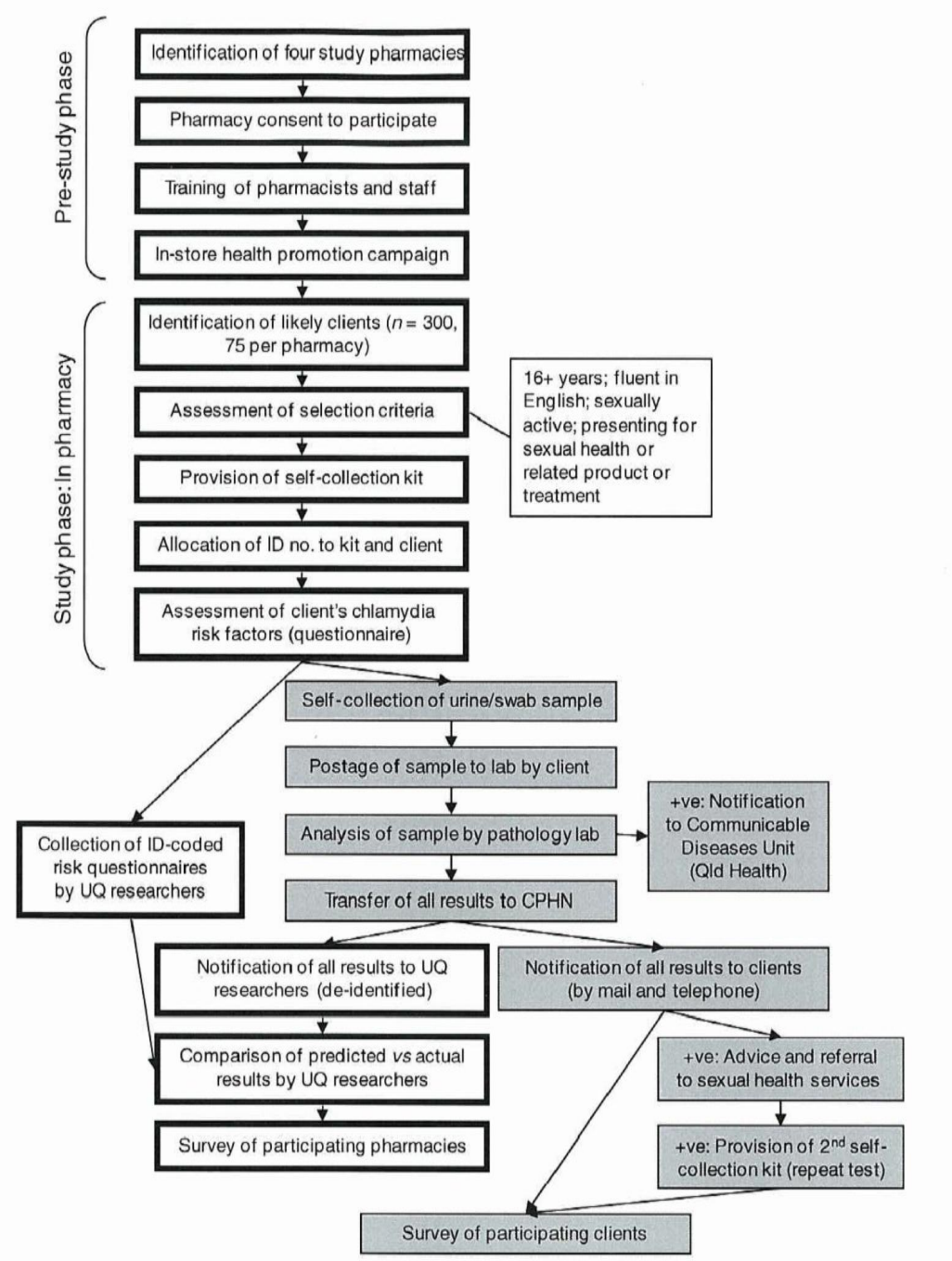

Fig. 1. Study method. CPHN, Central Public Health Nurse; UQ, University of Queensland.

Despite the training and privacy measures incorporated into the study design, some staff members reported a level of discomfort in this process.

The distribution of the postage-compliant specimen kits from our sample of community pharmacies was considered moderately successful in facilitating access to this testing service by an at-risk sector of the population, as determined by the proportion of kits issued and the proportion of specimens submitted. However, pharmacy participation was highly variable, and we recommend staff education to improve motivation to promote kits and approval for public advertising of the service. The association between the risk assessment questionnaires and test results was inconclusive, due to the small sample size. We suggest that the risk criteria may be useful in other ways, such as public awareness campaigns, to encourage self-identification for testing.

Conflicts of interest

None declared.

Acknowledgements

We acknowledge Ms Rose Gordon for technical assistance. This project was funded by the Australian Commonwealth Government, as part of a National Chlamydia Pilot Program testing the effectiveness of several models for chlamydia testing in Australia. This project will assist in developing possible recommendations for a National Chlamydia Program.

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Manuscript received 9 June 2010, accepted 10 June 2010 132

7.3.1.2 Summary of results

The distribution of the self-collection kits through community pharmacies was considered moderately successful in facilitating access to this testing service by an at-risk sector of the population. While over half of the participants who returned questionnaire data had been previously tested for chlamydia and, therefore, had demonstrated access to established testing services, their acceptance of this alternative testing opportunity suggests that they continued to meet risk criteria for infection, and hence were appropriate recipients of this pharmacy-based, anonymous service.

Despite willingness by pharmacy staff to be involved, the provision of a financial incentive, as well as training and contact by the project officer, variable participation was evident between study pharmacies. This variation in participation suggests that future use of pharmacies as distribution sites for chlamydia self-collection kits be an opt-in service, with minimal requirement of pharmacy staff to explain the use of kits or conduct risk screening. A key staff member per pharmacy is recommended to 'champion' the distribution of kits; this might be facilitated by advertising the importance and features of the service.

The efficacy of the risk-screening questionnaire was that 50% of the chlamydia-positive cases were able to be predicted by the questionnaire (sensitivity). However, sample size was minimal (only four positive cases), making the interpretation of the result difficult. The screening questionnaire should be more widely trialled for final recommendations on its use.

7.3.2 CMS Pharmacy Collection Study

The distribution of a mailing kit for the self-collection of a sample for chlamydia testing through community-based pharmacies is well established in the United Kingdom (UK). Since 2005, over 200 Boots (brand name) pharmacies in London have been providing free self-collection kits for 16 to 24 year old men and women on a large scale (Anonymous 2005). No evaluation data is available to date, apart from the initial success of selling about 6,000 kits within the first month (UK Department of Health 2006).

A survey conducted with pharmacists in Australia found that pharmacists would be comfortable with providing self-collection kits for chlamydia and would be supportive of a pharmacy-based screening program and the provision of antibiotic therapy (Taylor, Clifford et al. 2007).

7.3.2.1 Methods

I approached nine community-based pharmacies in the Townsville area about being a distributor of the self-collection kit for chlamydia testing. Pharmacies were chosen based on their location in suburbs with a high proportion of young people or proximity to gathering points for young people, such as high schools and shopping centres. One of the approached pharmacies declined participation (participation rate, 88.9%). One additional pharmacy heard about the study and actively contacted the CMS in order to be included as a distributor for the kits.

All pharmacies received promotional materials, including posters and leaflets, and the educational resources developed for partner organisations. Education sessions were conducted on individual pharmacy-manager request. Though it would have been preferable if all pharmacies had promoted the self-collection kit in a similar fashion, it was, as in the Community Service Collection study, not feasible. Again, the promotion and distribution of self-collection kits was left to the individual service as processes had to be integrated into the usual business of each pharmacy. Records were kept by most providers on promotional activities. Details of the promotional activities are listed in Table 7.5.

Table 7.5 Promotional activities of participating pharmacies in CMS pharmacy collection study

Pharmacy activity	1	2	3	4	5	6	7	8	9
Poster display in outlet	*		*	*	*	*	*	*	*
Poster display throughout community identifying outlet	*		*	*	*	*	*	*	*
Leaflets on display – self-collected	*		*		*				*
Leaflet intermittently distributed in product bags	*			*	*			*	*
Pharmacists recommended kits to those identified at risk: accessing ECP*/COC**/condoms	*		*	*	*	*	*	*	*
Pharmacy staff distributed leaflets to those identified at risk: accessing COC/condoms	*			*	*				*
Staff identified those at risk and recommended kits	*								
Self-access to kits at outlet	*								*
Kits available on enquiry	*		*	*	*	*	*		
Details on CTT website	*	*	*	*	*	*	*	*	*

*Emergency contraceptive pill **combined oral contraceptive pill

7.3.2.2 Results

Of the 479 kits distributed by pharmacies in the Townsville area, 68 (14.2%, 95% CI = [11.2%; 17.7%]) participants returned samples for testing. In this study one person participated three times because she correctly perceived herself at risk of chlamydia as evidenced by her first test being negative, the second test being positive and the third test being negative again. Further information on the individual return rates per pharmacy and the flow of participants is detailed in Table 7.6 and Figure 7.2.

Table 7.6 Kit distribution and return rates by distribution site in CMS pharmacy collection study

	Number of kits distributed	Number of kits returned	Number of individuals	Return Rate in %*
1	26	6	6	23.1
2	10	0	0	0
3	9	2	1	11.1
4	60	14	13	21.7
5	10	5	5	50.0
6	1	0	0	0
7	20	8	8	40.0
8	36	4	4	11.1
9	307	31	31	10.1
Total	**479**	**70**	**68**	**14.2** **95% CI = [11.2%;17.7%]**

*% returned is too small to calculate a meaningful 95% CI for the individual return rates.

The median age of participants in this study was 21.8 years (interquartile range (IQR) = [18.1; 28.0]), 23.5% were males and 5% identified as being of Indigenous descent (Table 7.7). Five people tested positive on the first test, with one incident case on repeat testing. Both participants who had an inhibited initial result were offered retesting, with one person accepting this offer; the other person, being a tourist from overseas, preferred to retest on return home. Of the 68 persons, 66 (97.1%) were contacted and advised of their test result. All positive cases were referred for treatment, which was confirmed for all. The median time to treatment was 2 days. Further details on participant characteristics and follow-up are listed in Table 7.7.

Figure 7.2 Participant flow through CMS pharmacy collection study

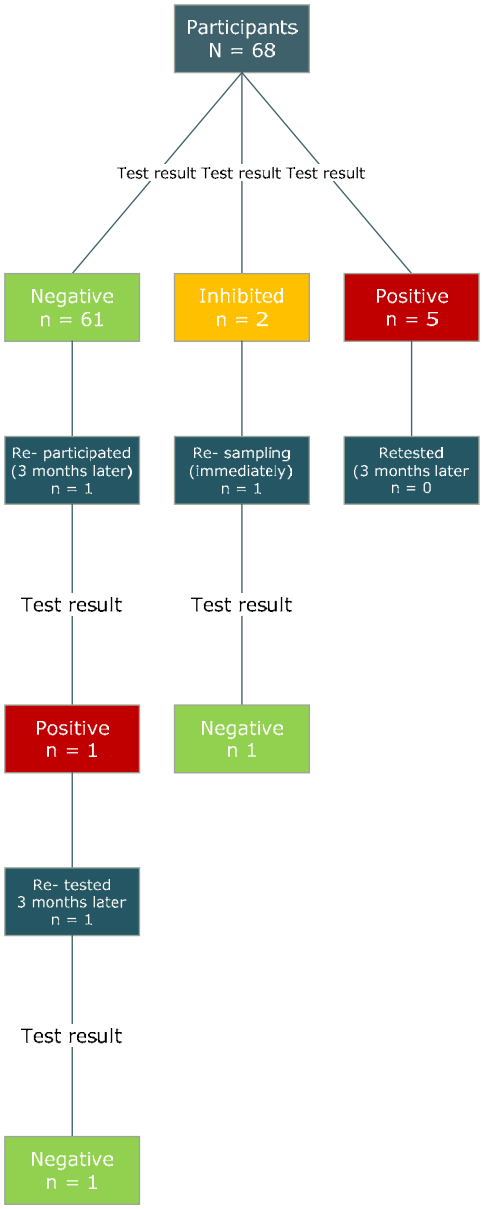


Table 7.7 Characteristics and follow-up details of the 68 participants in the CMS pharmacy collection study

Demographics		
Median age (years) [IQR]	21.8 [18.1,28.0]	
Male gender, *n* (%)	16/68 (23.5%)	
Indigenous status, *n* (%)	3/60 (5.0%)	
Results and follow-up		
Positive test results, *n* (%)	5/68 (7.4%) Prevalence + 1 incident case 6/70 (8.6%) Positivity	
Contacted with results, *n* (%)	66/68 (97.1%)*	
Treatment completed, , *n* (%)	5/5 (100%) of initial cases 1/1 (100%) of other cases	
Median treatment interval days [IQR]**	2[0.5,4.5]	
Referral agencies	Community Health Services	
Partner Notification		
Total sexual partners	11	
Contactable sexual partners	11	
		Confirmed
Notified by participant, *n* (%)	9/11 (81.8%)	0/8 (0%)
Notified by CMS , *n* (%)	2/11 (18.1%)	2/2 (100%)
Notified by referral agency, , *n* (%)	n/a	

*2 people not contacted had negative test results. **interquartile range

7.3.2.3 Discussion

The kit promotional activities between the different pharmacies varied widely, and the return rates from the different pharmacies were mixed and did not necessarily correspond to the varying promotional efforts. One could speculate that some consumers might have been persuaded into taking a free kit home through the promotional material on display in the pharmacies but might then, in hindsight, not have considered themselves at risk of chlamydia. The UQ pharmacy study (section 7.3.1) showed, however, that even after a thorough risk assessment (risk was being young and purchasing reproductive health items) conducted by the pharmacist, only 9.6% (95% CI: 5.5%, 15.4%) of distributed kits were returned. Therefore, other reasons, such as forgetfulness, low priority of chlamydia testing, unease with the testing process and denial of being at risk, must be considered. Further education of the general population and, in particular, of the high-risk groups about chlamydia infection and its consequences seem warranted to boost return rates.

The CMS was again found to be effective and efficient in coordinating the supply of self-collection kits, processing of samples and follow-up of participants.

7.4 Aboriginal and Torres Strait Islander Community Collection Study

The health status of Indigenous peoples in Australia, and in Queensland, is consistently reported as below that of the non-Indigenous population (Harper, Cardona et al. 2004). While the determinants of health are multifaceted, the high prevalence of sexually transmitted infections (STIs) in the Indigenous population is certainly one factor, with infections rates of 20% and above reported (Miller, McDermott et al. 2003; Harper, Cardona et al. 2004; Australian Government Department of Health and Ageing 2005a; Panaretto, Lee et al. 2006). Improving access to STI prevention, education, care and support has, therefore, been identified as a priority area for action by the Australian Government, as outlined in the National Sexually Transmissible Infectious Disease Strategy 2005 – 2008.

Access to testing for STIs is available in many areas through Community Health Services or programs such as the ‘Well Persons’ Health Check’, now the ‘Adult Health

Check' and 'Young Person Health Check'; however, the self-collection approach to testing as used by the Chlamydia Testing Trial (CTT) may be an acceptable addition to testing options. The method of a self-collected, mailed specimen for chlamydia testing has never been trialled in Indigenous communities.

Thus, I conducted a study to investigate the acceptability and feasibility of chlamydia testing using self-collected and mailed samples to Indigenous communities on Thursday Island and Palm Island.

7.4.1 Methods

Community consultation

Comprehensive community consultation was undertaken in both locations with the Council as well as key organisations and members of the communities. During this process, formal approval of Council was gained to conduct the studies in the communities. Organisations in contact with the target population were identified and many agreed to be promoters and distributors of the self-collection kit.

A variety of issues requiring investigation were identified at that stage.

- Self-collection kit

  Self-collection kits were given to local health professionals and community members for comment on appropriateness and useability. The feedback in regards to appropriateness was positive; however, concerns were raised in regards to the amount of written materials in the kit apart from the instructions. As this extra paperwork was due to the ethical requirements for the conduct of research, it was not feasible to remove the materials from the self-collection kits destined for this study. As the instructions were deemed appropriate, it was decided to leave the standard self-collection kit unchanged.

- Perceptions of confidentiality/privacy

  The lack of a mailbox on Palm Island was raised as a potential barrier to participation in this study. Mail has to be handed over at the post office counter. While the self-collection kit's return envelope is quite plain, it is, nevertheless, unique and has the CTT address printed on it. This problem was addressed by

offering a secure alternative drop-off point at the local hospital. The local sexual health nurse took responsibility for taking the samples to the post office for mailing.

Concerns were also raised that the presence of a self-collection kit at a home could lead to speculations about fidelity within relationships and subsequent domestic violence. While this concern was taken seriously and discussed comprehensively, no feasible solution could be found to alleviate it. The problem certainly constitutes a potential barrier to testing in this specific setting.

Distribution and promotion

The Thursday Island Men's and Women's Health Service (TIMWHS) agreed to coordinate the promotion and distribution of self-collection kits in the Torres Strait. Self-collection kits were also promoted by the School Based Youth Health Nurse, based in Bamaga. On Palm Island, the promotion and distribution of self-collection kits was facilitated by the CMS and staff at the Palm Island Sexual Health Service. Partner organisations included the Women's Community Centre, the Justice Group, Community Development and Employment Program, Men's Group, Youth Justice, Ambulance Service, Pharmacy, TAFE College, Community Health Services, and the Department of Corrections Centre. Additionally, an article about the study was published in the community paper and an information stall was conducted at a community event focusing on World Aids Day to raise awareness and increase participation in the project.

Promotional materials, including posters and leaflets and educational resources, were supplied to both study locations. The CMS conducted two education sessions with distributors and promoters of self-collection kits on Palm Island. Further promotion and education sessions were conducted by local organisations at the TAFE College and the public high school. Posters and leaflets were displayed throughout the two communities.

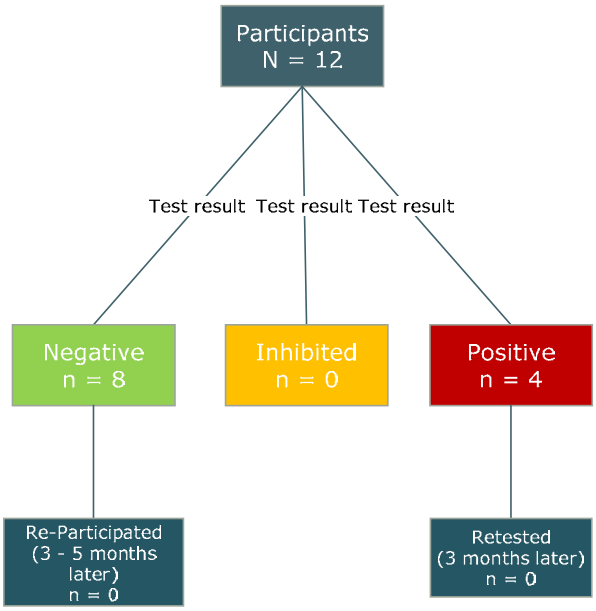
7.4.2 Results

Overall 254 self-collection kits were distributed. Samples were mailed by 12 participants, resulting in a return rate of 4.7% (95% CI = [2.46%; 8.1%]). Details according to location are given in Table 7.8.

Table 7.8 Kit distribution and return rates by distribution site in Aboriginal and Torres Strait Islander community collection study

	Number of Kits Distributed	Number of Kits Returned	Number of Individuals	Return Rate in %
Palm Island	84	3	3	3.5
Thursday Island	170	9	9	5.3
Total	254	12	12	4.7 95% CI = [2.46%;8.1%]

Figure 7.3 Participant flow through Aboriginal and Torres Strait Islander community collection study



Data collection on how many people were approached was not feasible. Figure 7.3 details the flow of participants through this study.

The median age of participants was 17.4 years (IQR = [16.4, 24.1], 41.7% were male and 91.7% identified as being of Indigenous descent (Table 7.9). Four of the 12 participants (33.3%) tested positive for chlamydia. No person participated more than once. Of the 12 positive participants, 9 (75%) were contactable for results; one positive case among the participants could not be contacted. Eventually it was established that the person had left the area. Treatment with azithromycin 1 gram orally was confirmed for three of the four cases (75%) of chlamydia. Retesting was recommended to all participants. Table 7.9 provides further information on participants and follow-up.

Table 7.9 Characteristics and follow-up details of the 12 participants in the Aboriginal and Torres Strait Islander community collection study

Demographics		
Median age (years) [IQR]	17.4 [16.4, 24.1]	
Male gender, *n* (%)	5/12 (41.7%)	
Indigenous status, *n* (%)	11/12 (91.7%)	
Results and follow-up		
Positive test results, *n* (%)	4/12 (33.3%) Prevalence	
Contacted with results, *n* (%)	9/12 (75.0%)*	
Treatment completed, , *n* (%)	3/4 (75%)	
Average treatment interval days	2	
Referral agencies	Community Health Services	
Partner Notification		
Total sexual partners	5	
Contactable sexual partners	5	
		Confirmed
Notified by participant, *n* (%)	1/5 (20%)	1/1 (100%)
Notified by CMS , *n* (%)	1/5 (20%)	1/1 (100%)
Notified by referral agency, , *n* (%)	3/3	3/3 (100%)

*2 people not contacted had negative results, one had a positive result.

7.4.3 Discussion

The low return rates of test kits from the Indigenous communities of Palm Island and Thursday Island suggest that this method of testing for chlamydia is, in general, not acceptable in these settings. Therefore, the approach taken for testing for chlamydia should be reviewed to suit Indigenous communities better.

Kit promotion activities varied widely between as well as within the two locations and data on details is very limited. The ongoing observed low return rates from Thursday

Island prompted an enquiry into the situation and a focus group was conducted to shed light on the issue. The investigation was conducted by staff from the Tropical Public Health Unit (TPHU), who also prepared the respective report (Appendix 8). Results from the focus group suggest that the kit's content should be simplified and that separate kits for men and women should be developed. Investigations conducted on Palm Island revealed that the amount of paperwork involved when using the self-collection kit was prohibitive in the low literacy community. Subsequently, the local sexual health clinic developed an approach that involved no paperwork but still allowed for self-collection of samples. The samples were then dropped off at the sexual health clinic.

In contrast to this, people who chose to return kits were contacted by the CMS and referred for treatment when necessary. This implies that management of test results and follow-up from a centralised position is feasible.

7.5 Tertiary Education Collection Study

The highest chlamydia prevalence is found in young people aged 16 to 25 years, as evidenced by notification rates in this age group (Australian Government Department of Health and Ageing 2005; Vajdic, Middleton et al. 2005; Sturrock, Currie et al. 2007; James, Simpson et al. 2008; Buhrer-Skinner, Muller et al. 2009) (Australian Government Department of Health and Ageing 2005; Vajdic, Middleton et al. 2005; Sturrock, Currie et al. 2007; James, Simpson et al. 2008; Buhrer-Skinner, Muller et al. 2009). As the age bracket of high notification rates coincides with the age profile of students in tertiary education facilities, it was postulated that tertiary education students are part of the target population for chlamydia screening.

7.5.1 Methods

Two universities in regional Queensland were identified as partner organisations for the promotion and distribution of the self-collection kit: the University of Southern Queensland (USQ), which is a regional university with about 5,000 on-campus students and approximately 15,000 external students at campuses in Toowoomba, Springfield and on the Fraser Coast; and James Cook University (JCU), which is similar in size, with 14,500 students enrolled at the Townsville and Cairns campuses.

Student Services at both locations took on the major role of promoters and distributors of self-collection kits, with additional activities conducted by the CMS at JCU on campus during the semester. The idiosyncrasies of both organisations required an individual approach to promotion and distribution. The contact details of both organisations were available on the CTT website. All promotional materials, including posters and leaflets, were provided to both participating organisations and displayed at their discretion (Table 7.10). Additional promotional activities are described below.

Table 7.10 Promotional activities of participating organisations in tertiary education collection study

Organisation Activity	JCU	USQ
Poster display in outlet	*	*
Poster display throughout community identifying outlet	*	*
Poster display throughout education facility (if available)	*	*
Poster display in licensed premises	*	
Leaflets on display-self collected	*	*
Distributed leaflets in product bags intermittently	*	
Self-access to kits at outlet	*	*
Notice in community newsletter	*	
Kits available on enquiry	*	*
Information stall at specific event	*	*
Details on CTT website	*	*

USQ

- An email was sent to all students who were enrolled in at least one subject during the semester every two months (December 2007, February 2008 and April 2008). The email included the following or variations of the following message:

Chlamydia Home Sampling Kit

Chlamydia is a sexually transmitted infection that often shows no symptoms. If you have had any sexual contact, you are at risk. The Qld Health Department has a new initiative to make identification of this disease free, easy, and confidential. You can *Pee It, Pack It, Post It!* by collecting a sample at home using the Home Sampling Kit, mail it back for testing, and you will be contacted with your results.

For further information and/or kits please contact Jannine (Campus Nurse) at Student Services, G Block, Phone: 4631 2386 or online at: http://www.health.qld.gov.au/chlamydia/default.asp

- During orientation week, Student Services had a stall with information material about the project. Condoms and pocket-sized leaflets were directly given to students.

- All three residential colleges on campus were visited by two Student Services officers during teatime in order to give a short education session on chlamydia and to demonstrate the kit.

- Additionally, kits were left outside the Student Services office on a table to allow interested people to pick them up without being seen.

JCU

- During orientation week, the CMS had a stall with information material about chlamydia and the self-collection kit.

- A 10-minute presentation about the self-collection kit was given during a lecture with approximately 200 students in attendance.

7.5.2 Results

Of the total of 390 kits that were distributed through the two universities, 52 kits were returned by 52 individuals (13.3%, 95% CI = [10.1; 17.1]). The return rates from both universities were quite similar (Table 7.11), despite the difference in promotion activities.

Table 7.11 Kit distribution and return rates by distribution site in tertiary education collection study

	Number of Kits Distributed	Number of Kits Returned	Number of Individuals	Return Rate in % [95% CI]*
JCU	170	30	30	17.7 [12.2%; 24.2%]
USQ	220	22	22	10.0 [6.4%; 14.8%]
Total	390	52	52	13.3 [10.1%;17.1%]

*95% CI = 95% Confidence interval

None of the participants re-participated in the project. The mean age of participants was 22.5 years (SD = 4.9), just over a quarter were males and 8.5% identified as being of Indigenous descent. Two people (3.9%), one from each university, tested positive for chlamydia. Of the 52 participants, 50 (96.2%) were contacted with their results. The two positive cases, which were among those contacted, were referred for treatment and

treatment was confirmed for both. The time to treatment was 1 day for one person and 7 days for the other person. Retesting was recommended to both. Overall, three contacts were identified. Two partners were notified by the CMS and one partner was an index case herself and had already been treated. Test results for the partners were not available. Further information on participant characteristics and follow-up is detailed in Table 7.12

Table 7.12 Characteristics and follow-up details of the 52 participants in the tertiary education collection study

Demographics		
Median age (years) (SD)	22.5 (4.9)	
Male gender, *n* (%)	14/52 (26.9%)	
Indigenous status, *n* (%)	4/47 (8.5%)	
Results and follow-up		
Positive test results, *n* (%)	2/52 (3.9%) Prevalence	
Contacted with results, *n* (%)	50/52 (96.2%)*	
Treatment completed, , *n* (%)	2/2 (100%)	
Average treatment interval days	3	
Referral agencies	Community Health Services	
Partner Notification		
Total sexual partners	3	
Contactable sexual partners	3	
		Confirmed
Notified by participant, *n* (%)	1/3 (33.3%)	1/1 (100%)
Notified by CMS , *n* (%)	2/3 (66.6%)	2/2 (100%)
Notified by referral agency, , *n* (%)	n/a	

*2 people not contacted had negative test results.

7.5.3 Discussion

Return rates of kits from the tertiary education facilities were low. Anecdotally, kits were taken by students who gave them to fellow students as a joke at both universities. Although students at tertiary teaching facilities fit the age bracket of the high-risk population, one must concede that university students do not represent all people aged 16 to 25 years. It can be argued that university students might be better informed about health risks than people of a similar age who do not attend university. Admittedly, university students are also a relatively easy group to access.

Again the CMS processed all samples and was successful in contacting and following up participants, including treatment and partner notification, indicating that the systems and procedures in place were effective.

7.6 Regional and Isolated MSM Collection Study

Gay and other homosexually active men (MSM) are at high risk of STIs, including chlamydia infection (Lister, Smith et al. 2003; Holt, Jin et al. 2004; Hull, Prestage et al. 2006). Additionally, the presence of an STI increases the risk of HIV transmission and infection (Australian Government Department of Health and Ageing 2005a). Given that many MSM are reluctant to disclose their sexual preferences to their healthcare provider, in particular in rural and remote settings, self-collected and mailed testing for chlamydia could be attractive for this community as it is confidential and even completely anonymous if required (Meckler, Elliott et al. 2006) (Meckler, Elliott et al. 2006).

7.6.1 Methods

The Queensland Association for Healthy Communities (QAHC), an organisation concerned with health promotion in the MSM community, took responsibility for the promotion and distribution of the self-collection mailing kit to MSM. The standard self-collection kit for chlamydia testing was modified to accommodate for two samples to be mailed: one urine sample and one anal swab sample. Samples and follow-up were managed by me and Ms Rose Gordon.

QAHC promoted the kit through their website and in their newsletter, as well as during special events and at ‘sex on premises’ venues.

7.6.2 Results

Exact details of the distribution sites, methods and number of distributed kits per site are not available. A total of 348 kits were sent to QAHC for distribution to the MSM community. Overall, 25 (7.2%, 95% CI = [4.7%; 10.4%]) kits with 48 samples were returned for testing and none tested positive. None of the participants indicated Indigenous descent, while 96% of participants were male. The median age was 46.6

Table 7.13 Characteristics and follow-up details of the 25 participants in the regional and isolated MSM collection study

Demographics	
Median age (years) (SD)	46.6 [33.3; 57.4]
Male gender, *n* (%)	24/25 (96%)
Indigenous status, *n* (%)	0/25 (0%)
Results and follow-up	
Positive test results, *n* (%)	0/25 (0%) Prevalence 0/48 (0%) Positivity
Contacted with results, *n* (%)	25/25 (100%)*
Treatment completed, , *n* (%)	n/a
Median treatment interval days , [IQR]	n/a
Referral agencies	n/a

years (IQR = [33.3; 57.4]. All 25 negative participants received their results. Twenty-three participants sent an anal swab as well as a urine sample for testing. Further details are listed in Table 7.13.

7.6.3 Discussion

Return rates in this study were low given that the relative risk for HIV/AIDS, gonorrhoea and syphilis in this community is high (Holt, Jin et al. 2004) (Holt, Jin et al. 2004). However, chlamydia was considered only one STI of several to be tested for and participants of the phone survey suggested that testing for all STIs would be preferable. An interesting observation in this study was that all participants supplied contact details,

not necessarily a name but a phone number, indicating that the need for anonymity in participants was low. Participants proposed that combining testing for gonorrhoea and chlamydia would be more acceptable and preferable, as this combination would reduce the need for retaking a sample by their health service provider.

A limitation of the methodology of this study is that the distribution of the kits was managed only through QAHC. Naturally, an organisation such as QAHC reaches mainly 'organised' members of the community. Hence, this approach cannot reach out to MSM who do not disclose their sexual preferences and might be, therefore, under-serviced.

The assessment of the suitability of the gel for gonorrhoea PCR testing is warranted as it would allow for the combined testing of chlamydia and gonorrhoea using the self-collection kit. This would be of benefit not only to MSM populations but to Indigenous communities as well.

7.7 Internet and Phone Request Study

New approaches for chlamydia testing are needed in a situation where conventional testing strategies are failing to contain ever-increasing chlamydia notification rates (Vajdic, Middleton et al. 2005). My studies offered chlamydia testing by means of a self-collection kit. Infrastructure for the conduct of the study in Queensland included an 1800-freecall number and a website. A 'web request' facility was added to the website by simply attaching an extra webpage directly linked to the CMS email address. Information about the availability of the self-collection kit by 'phone request' was included in all promotional materials. A similar approach had been trialled in the US with good return rates (Gaydos, Dwyer et al. 2006). This study evaluated the acceptability of using the internet or a free-call number in Queensland for free chlamydia testing, based on a mailed self-collection kit and the feasibility to administer such an approach to testing.

7.7.1 Methods

The availability of the self-collection kit for chlamydia testing over the internet and a free-call number was promoted through the study website, all partner organisations, including pharmacies, tertiary education providers and community-based organisations,

as well as on posters and pocket-sized leaflets. Ms Rose Gordon and myself, as well as cooperating partner organisations, placed the promotional resources at locations frequented by the target population of 16 to 25 year olds, and the socially and/or geographically isolated. After receiving a request by email or phone, a self-collection kit was mailed through the regular mail service to the address nominated by the participant.

7.7.2 Results

During the 1-year study period from August 2007 to July 2008, a total of 252 kits were actively requested by responders through the website and the 1800-freecall number, of which 84 (33.6%, 95% CI = [27.5; 39.5]) participated by returning a sample for chlamydia testing. Of those 84 participants, 12 participated twice. Further information on return rates and the flow of participants through this part of the study is provided in Table 7.14 and Figure 7.4.

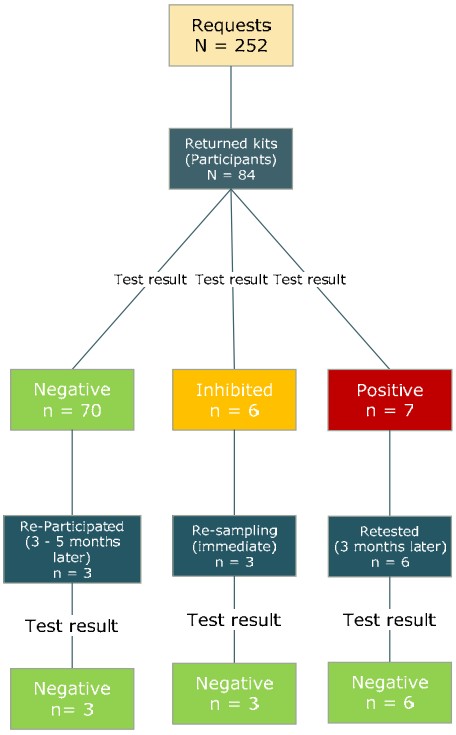
Table 7.14 Kit distribution and return rates of internet and phone request study by request mode site

	Number of Kits Distributed	Number of Kits Returned	Number of Individuals	Return Rate in % [95% CI]*
Internet-Requests**	223	66	66	29.7 [23.7; 36.1]
Phone Requests	29	18	18	64.3 [42.3; 79.3]
Total	252	84	84	33.3 [27.5%,39.5%]

*95% CI = 95% Confidence interval

** includes 32 suspected hoax requests, return rate excluding the hoax requests is 34.6%

Figure 7.4 Participant flow through internet and phone request study



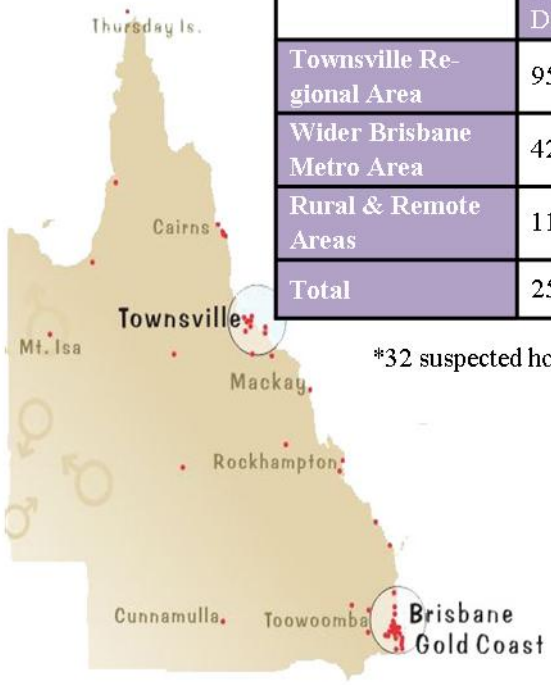
The mean age of participants was just less than 25 years, with 28.6% being male and 3.7% identifying as being of Indigenous descent (Table 7.15). The requests came from people residing in a wide geographical area, with the details of locations outlined in Figure 7.5.

Table 7.15 Characteristics and follow-up details of the 84 participants in the internet and phone request study

Demographics		
Median age (years) (SD)	24.9 (6.7)	
Male gender, *n* (%)	24/84 (28.6%)	
Indigenous status, *n* (%)	3/81 (3.7%)	
Results and follow-up		
Positive test results, *n* (%)	7/84 (8.3%) Prevalence 7/96 (7.3%)	
Contacted with results, *n* (%)	78/78 (100%)	
Treatment completed, , *n* (%)	7/7 (100%)	
Average treatment interval days	3 [3,8]	
Referral agencies	GP, Community Health Services	
Partner Notification		
Total sexual partners	12	
Contactable sexual partners	12	
		Confirmed
Notified by participant, *n* (%)	1/12 (41.6%)	4/5 (80%)
Notified by CMS , *n* (%)	7/12 (58.3%)	7/7 (100%)
Notified by referral agency, , *n* (%)	n/a	

There was a suspicion that 32 of the requests from Townsville were hoax requests, as they were all launched within seconds of each other and all stated addresses of a college accommodation block at JCU.

Figure 7.5 Kit distributions and return rates in internet and phone request study by geographic area



	Kits Distributed	Kits Returned	Return Rate
Townsville Regional Area	95*	28	29.7%
Wider Brisbane Metro Area	42	20	47.6%
Rural & Remote Areas	115	36	31.3%
Total	252	84	33.3%

*32 suspected hoax requests

** Dots represent locations-not number of kits

Of all participants, 7 tested positive, resulting in a prevalence of 8.3%. Re-sampling was offered to all participants with an inhibited test result (n = 6), with only three returning a sample (all negative). Retesting was offered to all positive cases and taken up by 6 of the original 7 (85.7%), who all tested negative.

All 78 respondents who provided contact details were notified about their results; the median treatment interval was 3 days. Further participants and follow-up details are outlined in Table 7.15.

7.7.3 Discussion

This study indicated a high acceptability of using the internet or a free-call number in Queensland for ordering a free chlamydia self-collection kit for testing. The use of mobile phones, email and SMS allowed access to the young target population, but also the geographically more isolated. This approach, therefore, offers new options for chlamydia control, especially in rural and remote areas where conventional strategies are limited.

7.8 Summary of results

It seems that working with partner organisations was a good strategy to access the target population. However, return rates were varied. In particular, the return rate for ATSI Community Services was very low at only 4.7%. One possible explanation for this low response rate could be that the methods used during the study were unacceptable for ATSI people. Further investigations are required to address this issue.

However, the success of the distribution method should not be solely based on return rates. Further analysis of the questionnaire data showed that a majority (72%) of participants would not have been tested for chlamydia without the self-collection kit offer (see Chapter 9). A more detailed discussion of these problems is given in Chapter 9, which provides the results of the aggregate analysis based on all participants from all studies combined.

The studies faced no logistical issues. Participants did not seem concerned with anonymity as most participants were willing to provide their contact details. Follow-up of participants, who were previously unknown to the service, was straightforward. However, control over the distribution of the self-collection kits was limited and partner organisations were more or less active in promoting and handing out kits. Hence, the question remains whether all people who would have liked a self-collection kit did actually receive one.

The above-described studies all refer to opportunistic samples of the target population who accessed partner organisations for the services that they provide. I also investigated the feasibility of the self-collection kit testing method in a different part of the target population: people who previously tested positive for chlamydia. The results of this study are described in Chapter 8.

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CHAPTER 8 POST-TREATMENT RETESTING STUDY

8.1 Introduction

Chlamydia trachomatis (chlamydia) is the most commonly notified sexually transmitted infection (STI) in most countries, including Australia (World Health Organization 2001; Australian Government Department of Health and Ageing 2005). People who have previously been diagnosed with genital chlamydia infection have a 10% to 15% risk of recurrent infection within months after treatment (Veldhuijzen, Van Bergen et al. 2005; Peterman, Tian et al. 2006; Niccolai, Hochberg et al. 2007). This recurrent infection is either due to persistent infection caused by treatment failure or due to re-infection by an untreated sexual partner (Whittington, Kent et al. 2001; Wang, Papp et al. 2005). No national guidelines for retesting exist within Australia; however, in Queensland retesting is recommended 3 months after treatment of the initial chlamydia infection (Queensland Health 2006). Similarly, the US Centers for Disease Control (CDC) recommends retesting 3 to 4 months after initial treatment (Workowski and Berman 2006).

Current evidence suggests that the adverse sequelae, such as pelvic inflammatory disease and tubal factor infertility, are more likely in people with repeated chlamydia infections (Hillis, Owens et al. 1997; Egger, Low et al. 1998). Nevertheless, data on retesting rates are sparse. A randomised controlled trial conducted in the United States (US) reported retesting rates of 11.4% for the group that was advised to return for retesting after 3 months, 13.2% for the group that also received a US$20 incentive payment on return for testing, and 23.9% for the group that received motivational counselling in addition to a reminder for retesting (Malotte, Ledsky et al. 2004). A second US study sent 321 self-collection kits for retesting and 22.4% were returned (Bloomfield, Steiner et al. 2003).

I conducted **two separate studies** to investigate the effectiveness of the self-collection kit for post-treatment retesting in Queensland.

The first study is described in detail in section 8.2 and focused on assessing the viability of a self-collection kit for retesting. It evaluated the acceptability of the self-collection kit in people diagnosed at three different locations and health services as, well as through the Chlamydia Testing Trial (CTT). It also evaluated the feasibility to

administer such an approach to retesting by the central management system (CMS), that is, by myself and Ms Rose Gordon.

For this study, participants were recruited through the collaborating clinic staff from the Gold Coast Sexual Health Clinic (GCSHC), the Rockhampton Family Planning Clinic (FPQ RH), and the Townsville Sexual Health Clinic (TNSH). In addition, participants were also recruited from the CTT pool of participants with a positive diagnosis. Contact details of consenting participants were sent to the CMS, allowing us to mail out the self-collection kits. For the second study, I, together with Ms Rose Gordon, conducted the chart review to create an historic control group. The kit distribution and management of returned kits, including results and follow-up, was managed through the CMS for both studies.

Results from the first study have been published together with the results from the second study and are included in section 8.3.1. Additional information from this study is detailed below.

The second study assessed the self-collection kit as an intervention to increase post-treatment retesting rates in a sexual health clinic using two types of controls: (1) previous clients; and (2) concurrent clients from this clinic who were only verbally advised to return for retesting (standard practice). This study was published in *Sexual Health* in 2011 and a reprint of the article is included as section 8.3.1 of this chapter.

8.2 Feasibility of using the self-collection kit for retesting

8.2.1 Methods

Three clinics interested in participating in this study were identified during the preparation phase of the CTT; these were the Gold Coast Sexual Health Clinic, the Rockhampton Family Planning Clinic and the Townsville Sexual Health Clinic. Additionally, participants were recruited through the CTT parent study. The use of a mailed self-collection kit for retesting was an original feature of the CTT study design and participants indicated their consent on the questionnaire of their original kit.

Recruitment procedure

Clinical staff at the three clinical sites were informed about the project and advised to recruit clients with a positive chlamydia test or clients receiving presumptive treatment for chlamydia into the study. At that time participants received an information sheet about the study, and signed a consent form for their contact details to be forwarded to the CMS for the purpose of mailing a self-collection kit approximately 3 to 4 months after treatment if the test was positive.

Mailing of self-collection kits

The self-collection kit was mailed to all recruited participants to the address they nominated. If a kit was returned as undeliverable, then the participant was contacted via any phone contact provided and asked about an alternative postal address, to which the same kit was mailed.

Recruitment periods

- Gold Coast: January 2007 to March 2008
- Townsville: April 2007 to March 2008
- Rockhampton: July 2007 to March 2008
- CTT: August 2007 to March 2008

8.2.2 Results

During the study period, 491 people were diagnosed with chlamydia through the four participating services. Approximately 50% of those were asked to participate in the study. Details on how many potential participants were approached, how many accepted to have a kit mailed and how many actually returned a sample for testing are given in Table 8.1. The most common reason for staff not to approach a potential participant was forgetting about the study. Data on reasons for declining is limited but clinicians stated that potential participants most commonly declined the offer of a mailed self-collection kit for retesting because they were either from overseas or they did not know where they would reside in 3 to 4 months.

Table 8.1 Acceptance of mailed self-collection kit by participating services in retesting study

	TNSH	GCSHC	FPQRH	CTT	total
Positive cases diagnosed in service during study period	194	223	32	42	491
Asked to participate	68/194 (65/194	108/223 (48.4%)	31/32 (96.9%)	39/39 (100%)	246/491 (50.1%)
Declined*	17/65 (26.15%)	54/108 (50%)	1/31 (3.2%)	7[+5*]/39 (30.7)	84/246 (34.2%)
Consented to kit	48	54	30	17	149
Potentially received kit	46	47	27	17	137
Returned kit	16/46 (34.8%)	12/47 (50%)	6/27 (22.2)	8/17 (47.1)	42/137 (30.7%)

* Non-answering was regarded as declining.

It seems noteworthy that of the 39 persons diagnosed by the CTT, 30 (75%) consented to a reminder by the CTT, although only 17 wanted that reminder in the form of a mailed self-collection kit. Return rates between the services varied between 22.2% and 47.1%, but the differences were not statistically significant (P = 0.145) (Table 8.1), possibly due to the relatively small sample size.

Male participation in the study varied between services from 13.3% to 55.8%, the mean age of responders was 23.1 years of age, with a standard deviation of 5.4 years. Demographic information by participating service is detailed in Table 8.2.

Only one person tested positive on retesting, resulting in a prevalence of 2.4% in this study population (95% CI =[0.1%;12.6%]). The participant was referred to the nearest sexual health clinic and treatment with azithromycin 1 gram orally was confirmed. The treatment interval was 1 day. Partner notification was conducted by the participant and it was confirmed that the partner was also tested and treated.

Table 8.2 Demographic details of participants and notification of results in retesting study

	TNSH	GCSHC	FPQ RH	CTT	TOTAL
Positive test result,	Jan-16	0/47	0/6	0/8	1/42 (2.4%)
***n* (%)**	-6.25%	0%	0%	0%	95% CI* = [0.1%; 12.6%]
Male gender all recruited, *n* (%)	14/48 -29.20%	29/47 -55.80%	Apr-30 -13.30%	Mar-17 -17.60%	50/149 (34%) 95% CI* = [26.0%; 41.7%]
Male gender responders, *n* (%)	2 (12.5%)	7 (58.3%)	0 (0%)	3 (37.5%)	12/42 (28.6%) 95% CI* = [15.7%; 44.6%]
Mean age of responders (years) (SD)	22.9 (6.6)	26.1 (3.7)	22.4 (3.8)	21.9 (2.9)	23.1 (5.4)
Indigenous status of responders, *n* (%)	1/16 (6.25%)	0/47 (0%)	0/6 (0%)	0/8 (0%)	1/42 (2.4%) 95% CI* = [0.1%; 12.6%]
Contacted with result	16/16	12-Dec	6-Jun	8-Aug	42/42

*95% confidence interval

We contacted all participants and notified them of their results.

8.2.3 Discussion

Eligibility to participate in the study was defined by a positive result for a chlamydia test at the facility during the study period. In reality, not everyone who tested positive for chlamydia returned for treatment at the diagnosing facility; thus, the total of people eligible to participate in the study is probably an overestimation.

The offer of a mailed self-collection kit as a means for retesting for chlamydia infection was acceptable to the majority of people asked, with two-thirds agreeing to receive a kit. A major problem in the research setting of this study was that staff members at some clinics were too busy and/or forgot to ask eligible people to participate in the study, resulting in only about half of the eligible population being asked to participate. The most common reason stated for not wanting to participate was uncertainty about place of residence.

Male participation was in line with the overall male participation in the project and reflects attendance of males at the different services.

Communication between the different recruitment sites and the CMS was unproblematic, with recruitment details being faxed through a secure fax line. A self-collection kit was mailed to all participants. The provision of the participant's phone

number on the recruitment form facilitated mailing the kit to a current address when the kit was ‘returned to sender’.

All responders were contacted and given their test result; the one positive person was referred to a sexual health clinic with an appointment made by the CMS and treatment confirmed by the clinic with the permission of the participant, indicating a robust system of managing the mailing of kits, processing samples and conveying results, including referral for follow-up. The CMS, again, proved to be able to handle the organisation and management of the clients effectively.

Overall, the results indicate high acceptability of the self-collection kit for retesting. The achieved return rates of between 20% and 50% (dependent on location) have to be regarded as high. They are especially well above return rates for clinical retesting achieved in the US, where, even with an incentive of US$20 for retesting at the clinic, only a 13% return rate was achieved.

The use of the developed self-collection kit is a very effective approach in increasing rates for retesting for chlamydia.

8.3 The self-collection kit as an intervention to increase post-treatment retesting rates in a sexual health clinic

This second study was conducted at the Townsville Sexual Health Service. The study aimed to assess whether the self-collection kit was able to improve return retesting rates in the clinical setting by comparing current retesting rates based on the self-collection kit with: (1) concurrent retesting rates from clients who did not use the kit; and (2) historic retesting rates.

This study was published as:

Buhrer-Skinner, M., Muller, R., Buettner, P. G., Gordon, R., & Debattista, J. (2011). Improving Chlamydia trachomatis retesting rates by mailed self-collection kit. *Sex Health, **8***(2), 248-250.

8.3.1 Publication

Improving *Chlamydia trachomatis* retesting rates by mailed self-collection kit

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Abstract. ***Background*:** To assess a mailed self-collection kit for chlamydia testing as an intervention to increase posttreatment retesting rates. ***Methods*:** This prospective intervention study took place at a sexual health clinic in Townsville, North Queensland (Australia) between 2006 and 2008. The intervention consisted of offering to mail a self-collection kit for retesting 3 months after treatment. The achieved retesting rates were compared to those from the previous year and to concurrent controls who did not participate in the intervention. Both control groups received standard advice on retesting. ***Results*:** Of the 46 participants in the intervention group, 34.8% returned the sample for retesting 3 to 4 months after initial treatment, in comparison to 6.8% of the historic control groups (n = 206) and 1.4% of the concurrent control group (n = 142) (P < 0.001, respectively). ***Conclusions*:** Retesting rates for *Chlamydia trachomatis* were substantially and significantly improved using the mailed self-collection kit evidencing that the kit could deliver a much needed intervention to improve notoriously low retesting rates.

Additional keywords: Australia, non-clinic based testing, postal kit.

Introduction

Persons previously diagnosed with genital Chlamydia infection have a high risk of re-infection within months after treatment.[1,2] Current evidence suggests that adverse sequelae are more likely in people with repeated Chlamydia infections.[3]

Nevertheless, data on retesting rates in clinical settings are sparse. A randomised controlled trial conducted in the USA reported retesting proportions of 11.4% for the group that was advised to return for retesting after 3 months, 13.2% for the group that also received a US$20 incentive payment and 23.9% for the group that received motivational counselling in addition to a reminder for retesting.[4]

Methods

This prospective intervention study was conducted in a sexual health clinic in North Queensland, Australia, from April 2007 to March 2008 using a mailed self-collection kit for Chlamydia testing (the kit) developed by the same research team.[5,6] Clients diagnosed with chlamydia were offered the kit 3 months after treatment (intervention group).

A retrospective chart audit was conducted for all Chlamydia positive clients diagnosed by the same clinic between April 2006 and March 2007 (controls 1). According to standard clinical practice at the time, controls 1 were advised to return to the clinic for retesting after 3 months.

Recruitment of intervention participants occurred during routine practice, and although clinic staff was instructed to approach all positive clients for retesting, many clients were missed. Recruitment of intervention participants occurred during routine practice. Although clinic staff was instructed to approach all positive clients for retesting, many were missed. These missed positive cases plus the clients who did not want the kit (n = 17) form the second control group of concurrent clients.

All chlamydia-positive clients were treated orally with 1 g of azithromycin.

Results

Description and comparison of intervention and control groups

A total of 206 people (controls 1) were diagnosed with chlamydia in the 12 months before the intervention. During the 12 months' intervention period, 188 persons tested positive, of which 46 were recruited into the study (intervention group), while 142 formed the concurrent controls (controls 2) (Table 1).

Table 1. Demographics, symptoms and retesting rates after 3–4 months post treatment of initial chlamydia infection (percentages and counts)
*First *P*-value refers to comparison between controls 1 and intervention group; second *P*-value refers to comparison between controls 2 and intervention group

	Controls 1 ($n = 206$)	Controls 2 ($n = 142$)	Intervention group ($n = 46$)	*P*-value*
	Demographics and initial clinical presentation			
Median age, years (inter-quartile range)	22 (19–24)	20 (17–23)	21 (19–24)	0.638 0.229
Female	53.9% (111)	61.3% (87)	71.7% (33)	0.027 0.199
Non-indigenous	76.6% (157)	78.2% (111)	92.9% (13)	0.158 0.003
Symptoms at initial diagnosis	29.1% (60)	Not available	23.1% (3)	0.640
	Retesting			
Retesting	6.8% (14)^	1.4% (2)^	34.8% (16)^	<0.001 <0.001
Positive at retest	7.1% (1/14)^	0% (0/2)^	6.3% (1/16)^	1.000 1.000
Asymptomatic at retesting	77.8% (7/9)^	50.0% (1/2)^	76.9% (10/13)^	1.000 0.476

^Sample size reduced to participants who were retested and answered questions about symptoms.

Retesting rates and retest results

Of the initial 46 participants in the intervention group, 16 (34.80%, 95% confidence interval (CI) = 21.35–50.25) returned the sample for retesting 3 to 4 months after initial treatment, compared with 6.80% (95% CI = 3.80–11.10) of the historic controls group (controls 1) and 1.40% (95% CI = 0.17–5.00) of the concurrent control group (controls 2) ($P < 0.001$). Retest results and percentages of clients presenting as asymptomatic were similar for all three groups (Table 1).

Discussion

The intervention markedly improved post-treatment retesting rates, despite the fact that some persons might have chosen to retest at a different clinic. Our study confirms earlier results published by Bloomfield *et al.*,[7] who also used a self-collection kit at a sexual health clinic based in San Francisco and exceeded the rates achieved within the motivational intervention group that involved 20 min of individual counselling.[4]

Our study also confirmed that retesting rates following standard practice are low, thus further corroborating the importance of an effective intervention to prevent adverse sequelae, which are more likely with repeated Chlamydia infections.[3]

While not a prospective randomised controlled trial, this operational study is a true reflection of a real-life clinical situation. Clients who received the kit were reminded to retest and were able to initiate retesting immediately. This potential to retest was independent of place and time. The kit was therefore expected to – and did – perform better than a reminder-only system where clients would still have to attend a clinic for retesting.

The current study showed no differences between groups with respect to positivity and presence of symptoms at retesting; that is, the improved retesting in the intervention group was not symptom driven. This observation provides further circumstantial evidence that the groups were comparable. The low recruitment rates, in conjunction with the low retesting rates in the controls, suggest that staff might not be consistent in advising positive persons to retest. Despite the small size of the study, it provides evidence that a reminder system based on a mailed self-collection kit can improve retesting rates for chlamydia.

Conflicts of interest

None declared.

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8.3.2 Summary of results

The intervention of the assessed self-collection mailing kit markedly improved post-treatment retesting rates to the highest overall level reported so far. This study also confirmed that retesting rates following standard practice (i.e. advising clients to return for retesting after 3 months) were very low, thus further corroborating the need for an effective intervention to prevent adverse sequelae, which are more likely in people with repeated chlamydia infections (Egger, Donovan et al. 1993; Hillis, Owens et al. 1997).

Unfortunately, project constraints did not allow for a prospective randomised controlled trial, but the presented operational study is a true reflection of a real-life clinical situation. Clients who received a self-collection kit were reminded to retest and were able to initiate retesting immediately by using the kit. The kit enabled a retest completely independent of place and time and, therefore, an entirely new quality of access to sexual health services. The self-collection kit system was, therefore, expected to – and did – perform substantially better than a reminder-only system where clients still would have to attend a clinic for retesting.

The above-described two studies (sections 8.2 and 8.3) showed that retesting with the self-collection kit is feasible and was able to improve retesting rates substantially. These two studies conclude the series of investigations conducted into the feasibility and usefulness of the self-collection kit for chlamydia testing.

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CHAPTER 9 AGGREGATE ANALYSIS OF CHLAMYDIA SELF-COLLECTION KIT STUDIES

This chapter provides a summary of Chapters 4 to 8 and enables an overview and evaluation of the benefit of the self-collection kit as a novel approach to Chlamydia trachomatis (chlamydia) testing.

The aim of the Chlamydia Testing Trial (CTT) was to develop, implement and evaluate a system for the self-collection, transportation and processing of specimens for chlamydia testing, as well as a system for the clinical management of test results in a non-clinical setting. Both a self-collection kit and a central management system (CMS) were developed, implemented and evaluated, as outlined in Chapters 4 to 6. The self-collection kit complies with standards set by Australia Post for the transport of biological specimens, which allows the transport of urine specimen in a urine transport gel (UTG) by ordinary mail. The UTG allows storage of a specimen at room temperature for extended time periods and, consequently, in combination with the self-collection kit, allows for the self-collection of a specimen for chlamydia testing completely independent of place and time.

A series of studies were conducted to evaluate the utility of the self-collection kit in different target populations at risk of chlamydia (see Chapters 7 to 8).

The repeated participation of 22 people resulted in some inconsistencies between the individual studies and the summary data. As the unit of investigation is the individual, only the data from the first participation were used for analyses presented in the following. The significance level for all statistical tests was set to an alpha of 0.05 (two-sided). Where appropriate, exact test statistics were calculated. Exact 95% confidence intervals (CI) were calculated or estimated where applicable.

9.1 Kit distribution from each partner organisation

Overall, 2,918 self-collection kits were distributed through the different partner organisations and studies. Every attempt was made to retrieve any remaining self-collection kits from distribution sites at the end of the clinical phase of the project. Since all the studies were conducted under 'field' conditions, it is unknown how many self-collection kits are still out in the community. Arrangements have been made with Townsville Sexual Health Service (TNSH) to process and manage those 'late arrivals' according to the CTT procedures. The number of self-collection kits distributed by each project is listed in Table 9.1 and shown in Figure 9.1. The participant area of residence is depicted in Figure 9.2.

Figure 9.1 Distribution of self-collection kits by geographical area

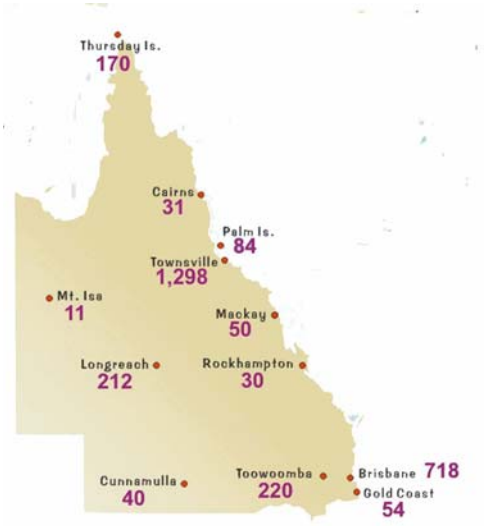
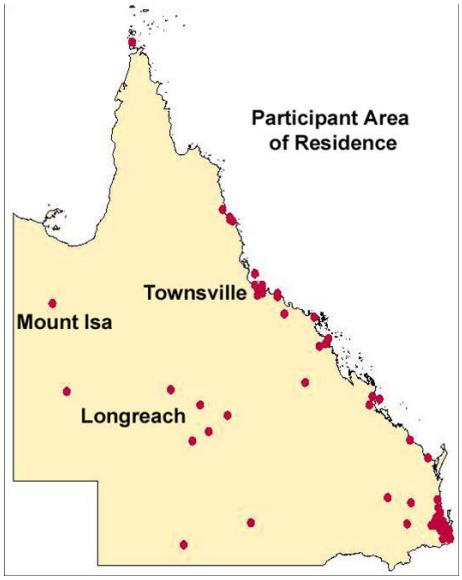


Figure 9.2 Participant area of residence*



*dots just represent locations not number of kits returned.

Table 9.1 Distribution of self-collection kits by study

	Kits distributed
Retesting Study	**137**
Community Service Collection Study	**608**
Pharmacy Collection Study	**479**
ATSI Community Study	**254**
Tertiary Education Collection Study	**390**
Regional and Isolated MSM Study	**348**
Field Test*	**131**
Internet and Phone Request Study	**252**
Contact Tracing**	**9**
UQ Pharmacy Project	**156**

*The 131 'field test' were kits which were sent out during the original kit development phase (see Chapter 6).
**The 9 kits distributed because of contact tracing were part of the routine clinical management of the CTT. Because of the small sample size, no separate chapter was dedicated to contact tracing.

In this context, it is especially noteworthy that three-quarters of the participants lived outside the Brisbane metropolitan area (Figure 9.2).

9.2 Overall return rates by project

Overall, 397 people used the self-collection kit and participated in any of the studies at least once during the 12-month clinical period of the project. Of those 397, 375 participated once only, 18 participated twice and 4 individuals participated three times. Examination of the information provided by the repeat participants revealed that they were at risk of chlamydia each time they decided to test. The repeat participants accessed the self-collection kits through a variety of distribution modes. Only two people returned a specimen that was not packaged to the specifications in the self-collection kit; however, no leakage occurred.

The return rates by study project are listed in Table 9.2. A statistically significant difference was found between the return rates. Overall, 14.6% of self-collection kits were used for mailing a sample, while the overall return rate for the CTT project was 13.8% (after excluding repeat participants).

Table 9:2 Returned self-collection kit by study

	KITS DISTRIBUTED	PARTICIPANTS	RETURN RATE*	95% CI
Re-testing Study	137	42	30.70%	[23.1%; 39.1%]
Community Service Collection Study	608	46	7.60%	[6%; 10%]
Pharmacy Collection Study	479	68	14.20%	[11.2%; 17.7%]
ATSI Community Study	254	12	4.70%	[2.46% ;8.1%]
Tertiary Education Collection Study	390	52	13.30%	[10.1%; 17.1%]
Regional and Isolated MSM Study	348	25	7.20%	[4.7%; 10.4%]
Field Trials	131	38	29.00%	[21.4%; 37.5%]
Internet and Phone Request Study	252	84	33.60%	[27.5%; 39.5%]
Contact Tracing	9	6	66.60%	[29.9%; 92.5%]
UQ Pharmacy Project	156	16	10.25%	[6.0%; 16.1%]
			***P* <0.001**	

In the following sections, further analyses of the factors possibly associated with participation rates are presented.

9.3 Association of return rates with gender, age and ethnicity of participants

Demographic information on age, gender and Indigenous status of participants was recorded across all studies (Table 9.3). A subset of 2,587 self-collection kits could be classified into ‘by request’ and ‘opportunistic’ as a distribution mode. Those distributed by pharmacies, community organisations and tertiary educational facilities are combined (n = 2,084) and will be referred to as ‘opportunistic’ distribution; while those distributed through the internet and phone study, the retesting study and contact tracing (n = 503) are combined to constitute the ‘request’ group. Data relating to remoteness and socio-economic indices were additionally investigated and are described separately in Chapter 10. Not all participants provided information on all items; hence, the differences in denominators.

Male participation in the CTT was 31.6% and differed significantly across the studies. The proportion of males was similar to that of sexual health clinic attendees but well below the population average and influenced by the inclusion of the MSM population in the sample. Removal of the MSM study from analysis showed no significant difference in the proportions of males between the different studies.

Indigenous status was indicated by 330 participants, of which 29 identified as being of Indigenous descent (8.8%), which is not surprising given that Aboriginal and Torres Strait Islander communities were included as study sites.

The median age of all participants was 22.6 years. The different studies attracted participants from different age groups (*P* <0.001). The removal of the older MSM study population from analysis still showed significant differences between studies. The data showed that the general aim of reaching the population in the 16 to 25 years age bracket was achieved.

Table 9.3 Participants demographics by study and distribution mode

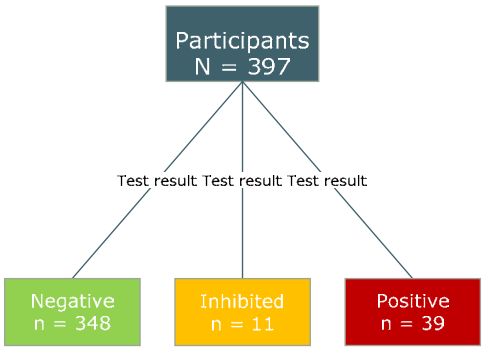
	MALE GENDER	INDIGENOUS	MEDIAN AGE
	N(%)	**N(%)**	**[IQR]***
Retesting Study	50/149 (34%)	1/42 (2.4%)	23.6 [20.0; 26.3]
Community Service Collection Study	18/46 (39.1%)	5/31 (16.1%)	21.7 [18.8; 24.5]
Pharmacy Collection Study	16/68 (23.5%)	3/60 (5.0%)	21.8 [18.1;28.0]
ATSI Community Study	5/12 (41.7%)	11/12 (90.9%)	17.4 [16.3;24.1]
lTertiary Education Collection Study	14/52 (26.9%)	4/47 (8.5%)	21.2 [19.5;22.8]
Regional and Isolated MSM Study	24/25 (96%)	0/22 (0%)	46.6 [33.3;57.4]
Field Trials	8/38 (21.1%)	2/27 (7.4%)	23.7 [21.0; 34.6]
Internet and Phone Request Study	29/84 (34.5)	3/83 (3.6%)	23.7 [19.8; 27.3]
Contact Tracing	0/5 (0%)	0/5 (0%)	20.2 [20.0;25.8]
UQ Pharmacy Study	2/16 (12.5%)	1/16 (6.25%)	21.7 [20.4;25.6]
CTT Project	125/396 (31.6%)	29/330 (8.8%)	22.6 [19.8; 28.3]
***P* value**	<0.001	sample size too small	<0.001
By request distribution	38/137 (27.7%)	4/115 (3.5%)	23.3 [20.0;26.6]
Opportunistic distribution	77/203 (37.9%)	22/171 (12.9%)	22.1 [19.3;28.5]
***P* value**	0.061	0.006	0.55

*IQR = interquartile range.

9.4 Chlamydia prevalence

On their first participation in the CTT, 39 (9.8%) of the 397 participants tested positive for chlamydia. Repeated testing of participants resulted in the detection of three further infections in two individuals. Initially, 23 samples contained inhibitors, which prevented a PCR test being conducted. Participants were contacted where possible, offered repeat testing and supplied with the necessary materials. The offer was accepted by 14 of those 23 (60.1%) participants and resulted in the detection of 1 infection, 11 negatives and two second-time inhibited results. Figure 9.3 depicts the results of the first test of participants.

Figure 9.3 First test results of CTT participants



The prevalence of chlamydia in participants accessing the various studies varied widely, as described in Table 9.4. Participants who tested positive for chlamydia on their first test were not different with respect to age, gender and Indigenous status from those who tested negative.

Table 9:4 Positive chlamydia tests by study and distribution mode

	POSITIVE RESULTS	95% CI
	N (%)	
Retesting Study	1/42 (2.4%)	[0.1%; 12.6%]
Community Service Collection Study	8/46 (17.4%)	[7.8%; 31.4%]
Pharmacy Collection Study	5/68 (7.4%)	[2.4%; 16.3%]
ATSI Community Study	4/12 (33.3%)	[9.9%; 65.1%]
Tertiary Education Collection Study	2/52 (3.9%)	[0.4%; 13.2%]
Regional and Isolated MSM Study	0/25 (0%)	[0%; 13.7%]
Field Trials	5/38 (13.2%)	[4.4%; 28.1%]
Internet and Phone Request Study	7/84 (8.3)	[3.4%; 16.4%]
Contact Tracing	4/5 (80%)	[28.4%; 99.5%]
UQ Pharmacy Study	4/16 (25.0%)	[7.3%; 52.4%]
CTT Project	39/397 (9.8%)	[7.1%; 13.2%]

9.5 Referrals of participants

Prior to the clinical phase of the CTT, a network of collaborating healthcare providers was established to facilitate management and follow-up of participants. Those healthcare providers were informed about the CTT project and agreed to provide priority access to participants of the studies should the need arise.

As all positive results were given out by the CMS, the referral provider options could be discussed with the participant. No referral to an external provider took place without the consent of the participant. Participants were given the option of contacting their own healthcare provider or were given the contact details of one of the collaborating providers in their local area. Support with arranging an appointment was offered to all participants. The location of the CMS in the same building as the TNSH afforded a direct connection to the clinic appointment system. Appointment times could be made in an efficient way while talking to the participant. If appointments were made by the CMS, permission was obtained from the participant to forward a referral letter to the referral agency. Referral letters were also mailed or emailed to participants directly to take to their provider. Each positive chlamydia case was unique in the circumstances and managed so as to achieve the outcome of timely treatment and follow-up. This was achieved for 38 (97.4%) of the 39 positive participants on their first test and the other three participants who tested positive on their second participation. Being able to talk to the participant was very helpful for establishing a rapport. Giving the results provided an opportunity to assess participant knowledge about chlamydia and sexually transmitted infections (STIs) in general, fill some of the knowledge gaps, address concerns, discuss partner notification and retesting options and provide practical support with all these functions. The option of having an appointment organised by the CMS was readily accepted by many participants and the data indicates that those appointments were actually kept. The high rate of confirmed treatment and the short treatment time intervals for the participants in this project demonstrates that a ‘virtual’ health service is quite feasible, acceptable and effective.

9.6 Follow-up of participants

Communication with participants in the CTT was a key factor for the feasibility of such a testing program. The CTT was a 'virtual' healthcare provider as it had no clinical space or front office, and contact with participants was restricted to phone, mail, email or SMS.

Usual clinical practice in regards to results is that the onus is on the consumer to initiate contact. Clinicians typically initiate contact with the client only if a result is abnormal and then have to hope that contact details are current. A review of records at TNSH showed that only about one-third of clients ever contact the service again for their results. Receiving the test result is an important part of the testing process and is also an opportunity to engage the participant with the healthcare system and provide professional advice. Hence, it was decided that results will be actively given to participants by CMS staff. We investigated the communication preferences of participants and how these preferences translated into actually reaching participants for results and follow-up (i.e. referral for treatment, partner notification and retesting).

9.6.1 Methods

Participants could indicate their contact preferences on the questionnaire contained in the self-collection kit. They could choose between mobile phone, SMS, email, phone, letter or not being contacted at all. Information on whether participants were contacted, and when and how they were contacted was extracted from the clinical management database, together with the information on referral, treatment and partner notification.

9.6.2 Results

Over 50% of participants preferred the use of the mobile phone in one form or another for receiving their result. Many participants did not indicate a preference but did provide contact details (Table 9.5). Only 22 (6%) participants did not provide any contact details at all, whereas over 70% of participants provided two or three options (Table 9.6).

Table 9.5 Contact preferences indicated by participants

	n = 397	%
Mobile phone	**147**	**37%**
SMS	65	16%
No preference stated	73	18%
Email	63	16%
Letter	35	9%
Home phone	14	4%

Table 9.6 Contact details provided by participants

	n = 397	%
Mailing address	323	81%
Mobile phone number	290	73%
Email address	176	44%
Home phone number	60	15%
No contact details	22	6%

Of the 375 participants who provided contact details, 357 (95.2%) were contacted and given their test result. Of the 22 participants who did not provide contact details, only 5 (22.7%) rang for their test result.

9.6.3 Discussion

Communication with participants was unproblematic and a high result notification rate was achieved. Participants resided mostly outside the Brisbane metropolitan area. The provision of contact details was acceptable for the vast majority of participants despite the fact that they had the option of not providing contact details. This allows the conclusion that anonymity is not necessarily required by people who seek testing for chlamydia. However, confidentiality seems to be a problem, especially in smaller communities, as is outlined in Chapter 11.

Test results were primarily conveyed by the CMS contacting participants, with the outcome that over 95% of participants who provided contact details actually received their results, which compares favourably to 22.7% of participants who chose to contact the service themselves. Fortunately, all positive cases had decided to provide contact details, allowing the CMS to contact all but one person by the end of the study period. While the sample was self-selected and possibly not representative of the target population, the results of the contact preferences clearly show that modern

communication technology is the medium of choice and that most people prefer to be contacted by the healthcare provider.

As the CMS was staffed by experienced sexual health professionals, all participants, including those diagnosed with chlamydia, could discuss a variety of sexual health issues (not just the chlamydia diagnosis), including other tests they might need, how to tell a partner about the infection, where to get treatment, recommendation for retesting after 3 months and other issues as they arose. The methodology of actively giving results to participants combined with asking participants to indicate their preferred contact method proved to achieve high notification rates.

9.7 Treatment of positive cases

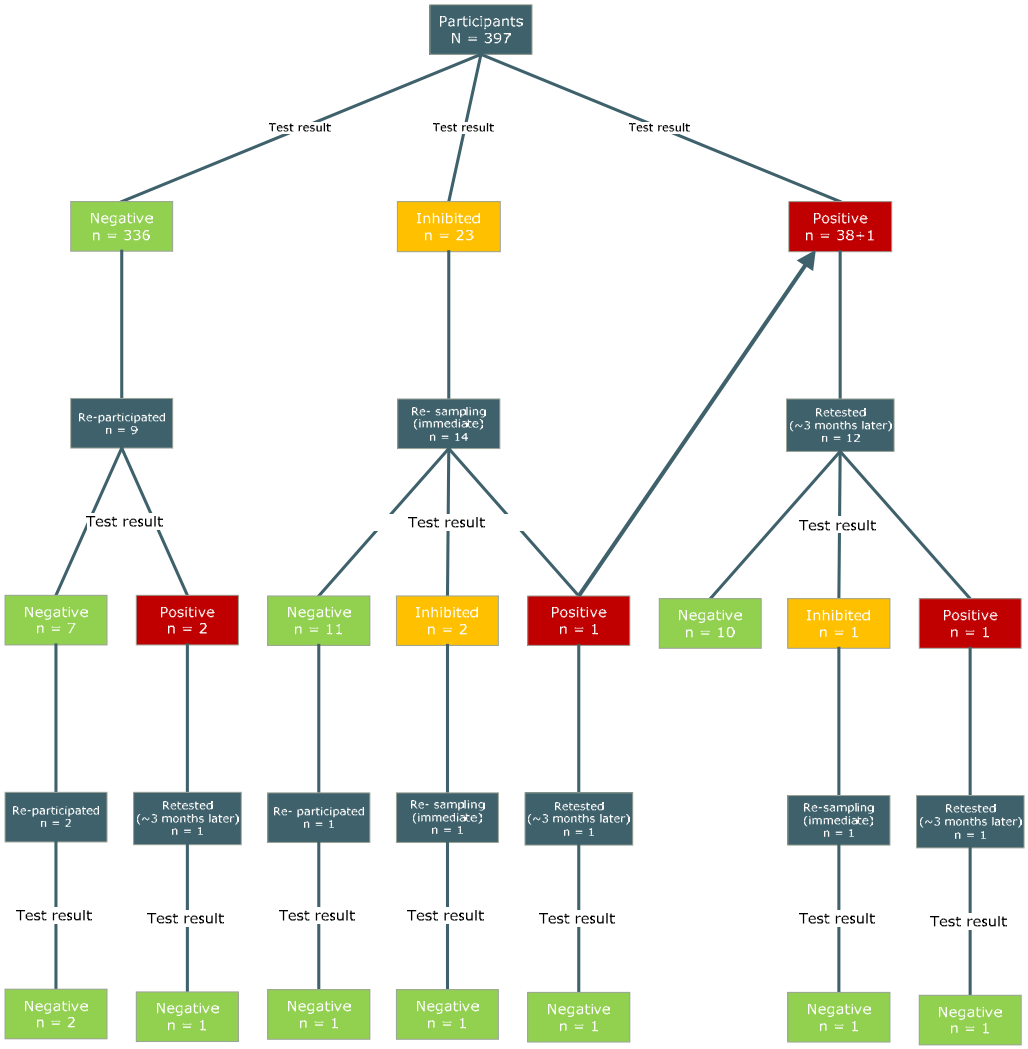
Overall, 39 (9.8%) of the 397 participants tested positive for chlamydia in the first valid sample they mailed in. A further two participants tested positive for chlamydia when they re-participated after several months, whereas one person tested positive for chlamydia again 3 months after treatment (Figure 9.3). Demographic details of the participants are listed in Table 9.7.

Table 9.7 Characteristics and follow-up details of the 39 CTT participants with a positive test on first testing

Demographics	
Mean age (years) (SD)	21.9 (4.1)
Male gender, *n* (%)	10/39 (25.6%)
Indigenous status, *n* (%)	6/34 (15.4%)
Results and follow-up	
Positive test results, *n* (%)	39 on first test 3 on second test
Contacted with results, *n* (%)	38/39 (97.4%) 3/3 (100%) incident cases
Treatment completed, *n* (%)	38/39 (97.4%) of initial cases 3/3 (100%) of other cases
Median treatment interval days, [IQR*]	2 [0; 3]
Referral agencies	Community Health Services, GP

*IQR = interquartile range.

Figure 9.4 Participant flow through CTT



9.8 Contact tracing

Contact tracing is an important aspect of chlamydia management and contributes to the interruption of the infection cycle. As previously outlined, a discussion about partner notification was an integral part of every notification of a positive test result. Participants were provided with information about partner notification (either mailed or emailed) and given the following choices:

- self-notification of partner
- notification of partner by CMS
- notification of partner by treatment/referral agency.

The options were available for every identified partner; thus, in some cases the partner notification was shared between the participant, CMS and/or the treatment agency.

Overall, 81 sexual partners were identified by 35 people with a positive chlamydia result (2.3 partners per case). Four people did not provide information on the number of sexual partners over the past 3 months; one person could not be contacted. Participants chose to contact 44 (54.3%) partners themselves, 18 (22.2%) partners were contacted by the CMS and 14 (17.3%) were managed by the treatment agency. For 5 contacts, no information was available. No definite statements can be made about the participants' own partner notification and outcomes or treatment agency partner notifications and outcomes. However, 17 of the 18 people (94.4%) to be contacted by the CMS were contacted (Table 9.8). For 9 people, an appointment at the chosen referral agency was arranged, 4 people chose to have a self-collection kit mailed and the remaining 4 chose to make their own arrangements with their local GP.

Partner notification was facilitated by the CMS. Participants received education and support from the CMS or could give partner details to the CMS to notify the partner. Support with notification was well received by participants, especially for those partners with whom they were no longer on 'speaking terms'.

The results confirm that the CTT methodology is feasible and that a testing program can be managed from a centralised position.

Table 9.8 Partner notification details

Partner notification*		
Total sexual partners	81	
Contactable sexual partners	76	
		Confirmed
Notified by participant, *n* (%)	44/76 (57.9%)	12/44 (27.3%)
Notified by CMS, *n* (%)	18/76 (23.7%)	17/18 (94.4%)
Notified by referral agency, *n* (%)	14/76 (18.4%)	?/14 (?%)

*Combined for all positive participants.

9.9 Publications

The following publications resulted from the studies summarised in this chapter (see Appendix 9).

Journal articles:

Buhrer-Skinner, M., et al., The check is in the mail: piloting a novel approach to Chlamydia trachomatis testing using self-collected, mailed specimen. *Sex Health*, 2009. 6(2): p. 163-9.

Emmerton, L., Buhrer Skinner, M., Gardiner, E., Nissen, L., & Debattista, J. A trial of the distribution of chlamydia self-collection postal specimen kits from Australian community pharmacies. Sex Health, 2011;8(1), 130-132.

Buhrer-Skinner M, Muller R, Buettner PG, Gordon R, Debattista J. Improving Chlamydia trachomatis retesting rates by mailed self-collection kit. Sex Health, 2011;8(2): 248-50.

Buhrer-Skinner M, Muller R, Buettner PG, Gordon R, Debattista J. Reducing barriers to testing for Chlamydia trachomatis by mailed self-collected samples. Sex Health, 2011 in review.

Bialasiewicz S, Whiley DM, Buhrer-Skinner M et al. A novel gel based method for self collection and ambient temperature postal transport of urine for PCR detection of chlamydia trachomatis. *Sex Transm Infect.* 2009;85:102-105

Conference contributions:

Buhrer Skinner M and Muller R. *Plans for a trial to evaluate home-sampling kits for chlamydia.* Presented at 2nd Australian Chlamydia Conference, Institute of Health and Biomedical Innovation, Queensland University of Technology, Brisbane 16-17 July 2007.

Buhrer Skinner M, Muller R, Bialasiewicz S, Debattista J. *The check is in the mail: A novel approach to Chlamydia trachomatis testing using self collected, mailed specimen.* Presented at the Australasian Sexual Health Conference 2007, Conrad Jupiter, Gold Coast ,8-10 October 2007.

Bialasiewicz S, Whiley DM, Buhrer Skinner M, et al. *Development and validation of a novel gel-based urine transport system for use in chlamydia trachomatis PCR based diagnosis.* Presented at the Australasian Sexual Health Conference 2007, Conrad Jupiter, Gold Coast ,8-10 October 2007.

Buhrer Skinner M, Buettner PG, Muller R, Gordon R, Debattista J. *The check was in the mail: Contact preferences of participants.* (Sexual Health 2008;4:381-404.) Presented at the Australasian Sexual Health Conference 2008, Perth Convention Centre, Perth, 15-17 September 2008.

Buhrer Skinner M, Muller R, Buettner PG, Debattista J, Gordon R. *Participant perceptions of the use of a self collection kit for chlamydia testing.* Presented at the Australasian Sexual Health Conference 2008, Perth Convention Centre, Perth, 15-17 September 2008.

Buhrer Skinner M, Muller R, Bialasiewicz S and Debattista J. *The check is in the mail: An interim mail check.* Presented at 2008 Meeting of Sexual Health Clinicians, Novotel, Brisbane 22-23 May 2008.

Gordon R, Buhrer Skinner M, Muller R, Buettner PG, Debattista J. *An innovative approach to testing for chlamydia reinfection.* Presented at the Australasian Sexual Health Conference 2008, Perth Convention Centre, Perth, 15-17 September 2008.

Gordon R, Buhrer Skinner M, Muller R, Buettner PG, Debattista J. *Acceptability of using the internet or phone to request a self- collection kit for chlamydia testing.* Presented at the Australasian Sexual Health Conference 2008, Perth Convention Centre, Perth, 15-17 September 2008.

Bialasiewicz S, Whiley DM, Buhrer-Skinner M. et al. A Novel Approach to Collecting and Mailing Urine for use in Chlamydia trachomatis PCR Detection Australian Society of Microbiology 2008. Presented at the 2008 Australian Society of Microbiology Conference, 6th to 10th July 2008, Melbourne, Australia

Emmerton L, Buhrer-Skinner M, Nissen L, Gardiner E, Debattista J. *Can community pharmacies play a role in Chlamydia testing?* Presented at the 2009 Pharmacy Australia Congress, 16th to 18th October 2009, Sydney, Australia.

9.10 Conclusion

These studies proved that it was feasible to manage test samples and results, including follow-up, treatment, contact tracing and retesting by using a centralised management system. Modern communication technologies allowed effective and timely contact with participants regardless of place and time.

Chapters 4 to 9 provide a summary of the study results using measureable indicators, such as return rates, positivity and retesting rates, which are generally available to service providers. I further analysed return rates and participant characteristics in an attempt to identify barriers to testing. The results of this analysis are provided in Chapter 10.

CHAPTER 10 BARRIERS TO CHLAMYDIA TESTING

10.1 Introduction

Chapter 9 provided a detailed summary of the experiences with the self-collection kit for *Chlamydia trachomatis* (chlamydia) testing for each individual distribution mode tested within the Chlamydia Testing Trial (CTT). The analysis showed that return rates varied between 4.7% and 66.6%, and that the overall return rate was 13.2%. Compared with other published return rates between 16.5% and 38.5% from the United States (US) and Sweden (Bloomfield, Steiner et al. 2003; Novak, Edman et al. 2003; Gaydos, Dwyer et al. 2006), the achieved return rate of 13.2% is mediocre. However, when comparing these return rates one has to bear in mind that my studies constituted 'real life', operational research, while other authors were able to exert more control over the distribution of their testing kits. In contrast, in my studies I only knew distribution details for a small percentage of the testing kits that were dispensed.

This chapter describes an analysis of my return rates with a focus on differences between urban, regional and rural/remote areas and between socio-economic indicators and participants' characteristics. For this analysis I distinguished between 'opportunistic' and 'by request' distribution modes. As already stated in Chapter 9, those kits distributed by pharmacies, community organisations and tertiary educational facilities were combined (n = 2,084) and are referred to as 'opportunistic' distribution; while those distributed through the internet and phone study, the retesting study and contact tracing (n = 503) were combined to constitute the 'request' group.

This manuscript is submitted for publication to *Sexual Health* and in the review process as:

Buhrer-Skinner, M., Muller, R., Buettner, P. G., Gordon, R., & Debattista, J. Reducing barriers to testing of *Chlamydia trachomatis* by mailed self-collection samples.

10.2 Publication

Reducing barriers to testing for *Chlamydia trachomatis* by mailed self-collected Samples

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Abstract

Background: *Chlamydia trachomatis* (chlamydia) infection is the most commonly notified sexually transmissible bacterial infection in Australia where distance to health services can be a major barrier to testing. This study investigated the acceptability of a self-collection kit for chlamydia testing (be sent by regular mail) and assessed the risk profiles of the participants with respect to their geographical locality.

Methods: 2,587 self-collection kits were distributed opportunistically through several partner organisations or sent directly to participants upon request. A structured selfadministered questionnaire accompanied the kit allowing risk profiling.

Results: Overall return rate was 13.2% (n=341). Return rate did not differ with geographic location (p=0.522), but with mode of distribution (opportunistic: 9.7%; by request: 27.4%; p<0.001). Nearly four out of five (77.5%) participants said that they

would not have sought Chlamydia testing otherwise. Median age of participants was 22.6 years, 33.8% were male and 9.1% of Indigenous descent. Overall 9.0% of participants were chlamydia positive. Prevalence of Chlamydia increased with remoteness (p<0.001), as did percentage of Indigenous participation (p<0.001), while self-reported condom use was significantly reduced for remote and very remote locations (p=0.008). Within remote and very remote locations, 30.8% (4 of 13) of Indigenous and 38.9% (7 of 18) of non-Indigenous participants were chlamydia positive(p=0.718).

Discussion:

Testing for chlamydia using a mailed self-collection kit proved acceptable to the targetpopulation and opened access to a pre-dominantly test naïve population. Actively requested kits were more likely to be returned. Remoteness rather than Indigenous status was identified as a risk marker for chlamydial infection.

Key words: Australia; Geographic location; sexually transmitted infection; Indigenous; Remote; Queensland.

Introduction

Chlamydia trachomatis (chlamydia) infection is the most commonly notified sexually transmissible bacterial infection in the developed world. [1-3] Total notifications of chlamydia infections as well as notification rates in Australia have been increasing by up to 20% per annum over recent years, with 62,653 cases (a rate of 280.5 per 100,000) notified in 2009. [4] Risk groups consistently identified comprise those less than 26 years of age, the socio-economically disadvantaged, minority groups such as Indigenous people, men who have sex with men (MSM), migrants, and military personnel. [5-12]

Previous research has also shown that the general population and, in particular the higher risk younger age group, know little about chlamydia and do not perceive themselves at risk. [13-15] Additionally, many infected or at-risk people do not actively seek health care due to the predominantly asymptomatic nature of chlamydial infections and may therefore be at risk of pathological sequelae and its severe long term effects on the sexual and reproductive health of males and females.[16, 17]

In Australia most testing for chlamydia is conducted in General Practice [18] and sexual health services; either as opportunistic screening, on-demand screening, or testing people with symptoms. Opportunistic screening for chlamydia in General Practice may be hampered by an already heavy workload especially in rural and remote parts of Australia [19, 20], while the over 80 specialist sexual health clinics in Australia are mostly located in the larger population centres along the coast.[21] These specialist clinics may be inaccessible for many potential patients, particularly those at higher risk within Aboriginal and Torres Strait Islander (ATSI) populations living in rural or remote areas.[22]

To overcome these barriers our research team recently developed and evaluated a selfcollection kit for chlamydia testing and a system for the central management of specimen, test results and follow-up of participants [23, 24]. The kit and chlamydia testing were free of charge and transport of specimen was by regular mail; hence barriers to testing should have been reduced. This study investigated the acceptability of the self-collection kit and the risk profile of the participants with respect to their geographical locality.

Methods

The study was conducted in Queensland, Australia, between August 2007 and July 2008, as part of a National Chlamydia Pilot Program that is testing the effectiveness of several

models for Chlamydia testing in Australia. All kits were processed centrally by the study centre located in Townsville. [23] Ethics approval for all parts of the study was granted by all relevant Health Districts ethics committees and by the James Cook University Human Ethics Committee.

The self-collection kit

The kit contained all materials and instructions necessary for obtaining a specimen and mailing it by regular mail [23]. Testing was confidential and free of charge. A structured self-administered questionnaire covering demographics (age, gender, ethnicity, place of residence), sexual behaviour including number and gender of sexual partners, use of condoms, history of chlamydia testing and diagnosis, as well as hypothetical questions with respect to chlamydia testing was part of the kit.

The central management system (CMS) processed specimens, notified test results and facilitated follow-up including treatment, partner notification and re-testing of participants. [23]

Distribution of self-collection kits:

Opportunistic distribution: A network of partner organisations with access to the target population (including, young people between the age of 16 and 25, Aboriginal and Torres Strait Islander peoples, men who have sex with men, those previously infected with chlamydia and those living in regional, rural and remote areas) was established for the promotion and distribution of the self-collection kit.

Participation by request: Participants were able to request a kit by using the project website with an email link or by calling a 1800 free call number. Previously diagnosed cases of chlamydia at participating sexual health clinics could request to have a kit mailed for retesting three months after treatment.

Within the 12 month study period a total of 2,587 self-collection kits were distributed throughout Queensland to a range of partner organisations, including pharmacies (n=479), community organisations (n=1,215), tertiary educational facilities (n=390), combined referred to as opportunistic distribution; as well as directly by active request (n=503). At the beginning of the project each distributor was contacted regularly by phone to inquire about kit distribution and kit stock levels. Phone support was provided to all distributors. In addition, partner organisations received promotional materials including pocket sized

leaflets and posters. A webpage (http://www.health.qld.gov.au/chlamydia) was developed to raise awareness about Chlamydia and to advertise the kits [23].

Statistics

Information about place of residence formed the basis to determine whether participants lived in either "highly accessible", "accessible", "moderately accessible", "remote" or "very remote" environments. Classification was conducted using the ARIA+ coding system [25, 26]. In addition, information about place of residence was also the basis to determine a broad classification of economic resources available to participants. This classification is in accordance with the Socio-Economic Indexes for Areas- Index for Economic Resources (SEIFA-IER) which is based on ranks [27]. The lower the rank the more deprived a person is assumed to be of economic resources. Ranks were categorised into four groups using the quartiles of the distribution.

Age and the SEIFA-IER ranks were summarised using median values and inter-quartile ranges (IQR). Comparisons between return rates and ARIA+ categories respective SEIFA-IER categories were conducted using Chi-square tests for trend. Comparisons between return rates from participants who opportunistically received a kit and those who actively requested one were carried out using Chi-square tests. Prevalence of *Chlamydia trachomatis* was presented together with 95%-confidence interval (95%-CI). Positive predictive value of "reporting symptoms of chlamydia infection" were presented with 95%-CI. Comparisons of participants' characteristics, history of chlamydia infection, and sexual behaviour between ARIA+ and SEIFA-IER classifications were conducted using Kruskal-Wallis tests and Chi-square tests for trend. The strengths of the correlation between age and the SEIFA-IER were assessed using Spearman rank correlation. Statistical analysis utilised SPSS for Windows, version 17 (SPSS Inc, Chicago, Illinois).

Results

Return rate

Of the 2,587 self-collection kits distributed, a total of 341 (13.2%) were returned (Table 1). Five hundred and thirty seven kits where distributed in remote or very remote locations, such as Longreach or Barcaldine. The nearest sexual health clinic for people living in Longreach or Barcaldine is either in Townsville (about 660 km) or Mt Isa (675 km). The overall return rate for remote and very remote locations was 7.8%.

Irrespective of mode of distribution (opportunistic or by request), return rates showed no significant trend with increasing remoteness (Table 1). Participants who requested kits were significantly more likely to return a sample (27.4%) than participants who received a kit opportunistically (9.7%; p<0.001). Participants who received a kit opportunistically, were more likely to return a sample when they were in the highest quartile of the SEIFAIER category (p=0.019)(Table 2). These findings were similar in all three ARIA+ and in all four SEIFA-IER categories (Tables 1 and 2).

Characteristics of participants

Median age of the 341 participants who returned a sample was 22.6 years (IQR = 19.628.0), 33.8% were male, and 9.1% were of Indigenous descent (Table 3). Of all male participants, 77 provided information on their sexual preference; of whom 31.2% reported having had sex with men.

Of all participants, 22.5% (62/276) reported that they would have had a chlamydia test anyhow. This percentage was reduced to 15.2% (32/211) when participants who previously tested positive for Chlamydia were excluded. Overall 9.0% of participants (95%-CI = 6.1, 12.5) tested positive for *Chlamydia trachomatis*; 9.5% of the participants who opportunistically acquired the kit and 8.1% who actively requested the kit (p=0.702).
A total of 98.2% of participants provided their contact details, 93.3% of those were giventheir results. All chlamydia positive cases were notified and 96.7% were treated. The medium time between notification of result and treatment was 2 days IQR [0, 4].

Overall 27% of participants reported symptoms such as dysuria or discharge. Eight point five per cent of participants who reported no symptoms tested positive for Chlamydia compared to 10.7% of participants who reported symptoms (p=0.639). The positive predictive value of self-reported symptoms was 10.7% (95%-CI = 4.7, 19.9).

Relationships between mode of distribution and characteristics of participants

Participants who received the self-collection kit in an opportunistic way were more likely to be of Indigenous descent (12.9% versus 3.5%; p=0.007), were more likely to live remote and very remote (15.3% versus 8.0%; p=0.018), and were more likely, although not significantly, to be male (37.9% versus 27.7%; p=0.051). Participants with a previous history of Chlamydia infection were significantly more likely to obtain a self-collection kit via request than opportunistically (46.1% versus 18.8%; p<0.001).

Relationships between ARIA+ classification and characteristics of participants

The percentage of chlamydia positive results increased with increasing remoteness from 5.3% (highly accessible) to 31.6% (very remote)($p<0.001$)(Table 3). Indigenous participation increased with remoteness ($p<0.001$). Within the remote and very remote living group, 30.8% (4 of 13) of Indigenous and 38.9% (7 of 18) of non-Indigenous participants were chlamydia positive ($p=0.718$; ten missing Indigenous status). Condom use was significantly reduced in participants from remote and very remote communities ($p=0.008$). Participants who lived remote or very remote had less economic resources compared to participants who lived more accessible ($p<0.001$).

Relationships between SEIFA-IER and characteristics of participants

In the sample SEIFA-IER ranged from 3 to 423. SEIFA-IER increased slightly with increasing age ($r=0.14$, $p=0.013$), while men (median rank 242; IQR = [162, 325]) had a higher median SEIFA-IER compared to women (median rank 178; IQR = [130, 246]; $p=0.002$).

Participants with a chlamydia positive test result had lower economic resources (median rank 131; IQR = [82.5, 202.25]) compared to participants with a negative test result (median rank 189; IQR = [162, 299]; $p=0.001$). This result remained true for the highly accessible and accessible category of ARIA+ ($p=0.006$), but not for the moderately accessible ($p=0.727$), and the remote and very remote areas ($p=0.850$). In the highly accessible and accessible strata were 100 participants with negative test results and a median SEIFA-IER rank of 230 (IQR = [162, 336]) compared to five Chlamydia positive participants with a median SEIFA-IER of 112 (IOR = [67, 156]). In comparison, the 28 participants with a negative test result in the remote and very remote strata had a median SEIFA-IER of 84 compared to the 12 participants with a positive test result who had a median SEIFA-IER of 87.

Self-reported history of chlamydia testing ($p=0.625$), self-reported history of Chlamydia infection ($p=0.607$), and a positive response to the question whether or not they would have done a Chlamydia test anyhow ($p=0.410$) were not related to the SEIFA-IER. Similarly, self-reported use of condoms was not related to the economic index ($p=0.386$).

Discussion

The present study showed that the recently developed self-collection kit reached the intended target populations of the young (16 to 25 years), Indigenous, MSM, previously positive, and the geographically isolated. The overall return rate was 13.2%, showing neither a distinct difference between the three ARIA+ nor between the four SEIFA-IER categories. Return rates were markedly higher for participants who actively requested the kit. These results are in accordance with those reported by Gaydos et al (2006) [28] who used a similar methodology to increase access to chlamydia testing for young American women. As with Gaydos' study, return rates in the present study were markedly higher for people who had actively requested kits. Return rates in a study conducted by Bloomfield et al (2002) [29] in San Francisco were higher (38%) however most of returned samples came from MSM. Two Swedish studies [30, 31] used the population registry of the country and university registry to directly access young men. Novak et al (2003) sent a Chlamydia self-collecting kit to all 22 year old males in one town, while Domeika et al (2007) invited 2000 men 19 to 24 years of age to order a self-collection kit. Novak achieved the highest ever reported return rate (38.5%) targeting the notoriously difficult to access young male population. High levels of education and the use of modern communication technology were seen as main reasons for attracting young men. In the present study, websites, emails, and mobile phones were also successfully used for communication.

Only 22.5% of participants in our study claimed that they intended to have a Chlamydia test independently of the availability of the self-collection kit. This implies that more than 250 persons were tested who were at risk of chlamydia and would not have sought testing otherwise. The kit accessed a pre-dominantly test naïve population. Reasons may be multi-fold: (1) The kit and subsequent testing were free of charge. (2) Testing was independent of place and time and did not require face to face contact with a health professional. (3) The management of testing was centralised and removed from the participants' immediate vicinity, increasing the perception of confidentiality. The latter reason could be particularly important for clients living in remote areas who might feel uneasy if local health professionals knew their STI status. In contrast, anonymity was of no concern to most participants, as 98.2% were willing to provide contact details (including names and phone numbers). A similar emphasis on confidentiality rather than anonymity was observed by Ryder et al. (2009) who surveyed sexual health clinic clients' reasons for accessing a specialist clinic. The ready provision of contact details allowed an unusually high notification rate in the present study.

In the current study chlamydia prevalence was found to be 9.0% amongst participants. Prevalence increased with increasing remoteness from about 5% to 30% as did the proportion of Indigenous participants. Apart from access to health services, behavioural differences, such as less frequent use of condoms, might be an explanation for the observed differences between urban and remote populations. While there are no published reports for remote non-indigenous populations, studies on Chlamydia prevalence in Australian Indigenous populations found high rates ranging between 14.4% in regional pregnant women [33], 15% in regional high-school students [34], and 23% in remote communities. [35] These studies indirectly suggested that the prevalence of chlamydia is higher in Indigenous than in non-Indigenous populations. In contrast our study found similarly high rates for Indigenous (30.8%) and non-Indigenous (38.9%) participants living remote and very remote. This finding indicates that remoteness rather than Indigenous status might be a main risk marker for Chlamydia infection.

Similar to previous results from British studies [36, 37] prevalence of chlamydia was higher for participants with low socio-economic index. However, in the present study this association was only statistically observed for the highly accessible areas where SEIFAIER for participants with a positive test result were much lower. In contrast, SEIFA-IER for participants living in remote locations was almost identical. These results further support the hypothesis that remoteness might be a central risk marker for Chlamydia infection while socio-economic status may only be relevant in certain sub-groups. However, these results have to be confirmed by a specifically designed and adequately powered study, as sample sizes in sub-population analyses were small.

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Conflict of interests

None declared.

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several models for chlamydia testing in Australia. This project will assist in developing possible recommendations for a National Chlamydia Program.

Table 1: Return rates by ARIA+ classification[#] of accessibility and mode of distribution.

Return rate	Total	ARIA+ classification			p-value*
		Highly accessible and accessible	Moderately accessible	Remote and very remote	
Overall return rate	13.2% (341/2587)	11.0% (105/953)	17.7% (194/1097)	7.8% (42/537)	P=0.522
Opportunistic distribution	9.7% (203/2084)	7.1% (55/770)	14.5% (117/813)	6.1% (31/509)	P=0.862
Requested kits	27.4% (138/503)	27.3% (50/183)	26.7% (77/288)	34.4% (11/32)	P=0.676
p-value**	P<0.001	P<0.001	P<0.001	P<0.001	

[#]ARIA+ classification of accessibility according to Australian Bureau of Statistics[25]; *Results of Chi-square tests for trend comparing return rates between ARIA categories of accessibility; **Results of Chi-square tests comparing return rates between opportunistic and requested distribution format.

Table 2: Return rates by SEIFA classification[#] of economic resources and mode of distribution.

Return rate	Total	SEIFA-IER classification				p-value*
		Lowest quartile	Second	Third	Highest quartile	
Overall return rate	13.2% (341/2587)	17.6% 85/482	9.5% 22/231	5.3% 51/959	20.0% 183/915	P=0.135
Opportunistic distribution	9.7% (203/2084)	11.9% 40/337	9.2% 20/218	4.1% 37/906	17.0% 106/623	P=0.019
Requested kits	27.4% (138/503)	31.0% 45/145	15.4% 2/13	26.4% 14/53	26.4% 77/292	P=0.367
p-value**	P<0.001	P<0.001	p=0.619	P<0.001	p=0.001	

[#]SEIFA-IER classification of economic resources according to Australian Bureau of Statistics [27] categorised by quartiles of distribution; *Results of Chi-square tests for trend comparing return rates between SEIFA-IER categories; **Results of Chi-square tests comparing return rates between opportunistic and requested distribution format.

Table 3: Characteristics of 341* participants returning self-collection kit for Chlamydia testing stratified by ARIA+ classification (based on place of residence).

		ARIA+ classification			
	Total	Highly accessible & accessible	Moderately accessible	Remote or very remote	p-value[$$]
Median Age [IQR]* (years)	22.6 [19.6, 28.0] n=341	24.4 [20.8, 30.5] n=105	21.7 [19.3, 27.1] n=194	22.0 [18.2, 25.0] n=42	p<0.001
Median Index of Economic Resources [IQR]**	189 [156,281] n=341	215 [162,336] n=105	201 [167,246] n=194	87 [3,87] n=42	p<0.001
% Male	33.8%; (115/340)	41%; (43/105)	29.5%; (57/193)	35.7%; (15/42)	p= 0.225
% Aboriginal and Torres Strait Islander	9.1%; (26/286)	3.4% ; (3/89)	6.1%; (10/165)	40.6%; (13/32)	p<0.001
% Chlamydia positive test results	9.0%; (30/335)***	4.8%; (5/105)	6.8%; (13/190)	30%; (12/40)	p<0.001
% History of Chlamydia testing	37.0% (105/284)	39.8% (35/88)	35.4% (58/164)	37.5% (12/32)	p=0.378
% Previously diagnosed with Chlamydia	22.1% (62/280)	21.8% (19/87)	21.1% (34/161)	28.1% (9/32)	p=0.419
% Self assessed risk of Chlamydia	84.2% (235/279)	84.1% (74/88)	83.1% (133/160)	90.3% (28/31)	p=0.595
% Experienced pain or discharge	27.0% (75/278)	25.6% (22/86)	29.2% (47/161)	19.4% (6/31)	p=0.800
% Respondents who reported that they would have done a Chlamydia test anyhow	22.5% (62/276)	22.1% (19/86)	18.8% (30/160)	43.3% (13/30)	p=0.124
Median self reported number of partners during past 3 months, [IQR]	1 [1, 2] n=281	1 [1, 3] n=87	1 [1, 2] n=162	1 [1, 2] n=32	p=0.595
% Reported condom use for more than 50% of the time	45.2%; (122/270)	41.0% (34/83)	51.6% (82/159)	21.4%; (6/28)	p=0.527; p=0.008[$$]

*Sample size varies as not all participants provided all information; **SEIFA index of economic resources [27]; the lower the rank the more deprived of resources; ***There were 6 inhibited test results; [$]p-values are results of Kruskal-Wallis tests and Chi-square for trend; [$$]First p-value is result of Chi-square for trend, second p-value result of Chi-square test.

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10.3 Summary of results and relevance

The analyses showed that the self-collection kit reached the intended target populations: the young (16 to 25 years), Indigenous, men who have sex with men (MSM), previously positive, and geographically isolated groups. Neither remoteness nor socio-economic indicators showed a strong effect on return rate. However, return rates were markedly higher for participants who actively requested the kit.

One interesting finding from this analysis was that similarly high positivity rates were detected for Indigenous (30.8%) and non-Indigenous (38.9%) participants who were living in remote and very remote areas. This finding is in contrast to other studies, which indirectly suggested that the prevalence of chlamydia is higher in Indigenous than in non-Indigenous populations (Miller, McDermott et al. 2003; Panaretto, Lee et al. 2006), in contrast my study suggests that remoteness rather than Indigenous status might be a main risk marker for chlamydia infection.

This chapter concludes the description of the analysis of findings from the distribution of the self-collection kits. The last aspect that remains to be discussed in Chapter 11 is the satisfaction with the self-collection kit as reported by the participants.

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CHAPTER 11 SATISFACTION OF PARTICIPANTS

Consumer input into health service program evaluation is generally considered a crucial component of the overall evaluation of the program; however, the overall role of consumer satisfaction is often small (Larsen, Attkisson et al. 1979; Nguyen, Attkisson et al. 1983; Pascoe 1983). Nonetheless, satisfaction with service processes can potentially influence treatment outcomes as people who are dissatisfied with a service might not return to the service or might use alternative services. Assessment of consumer satisfaction is distinct from the assessment of clinical outcome or effectiveness of clinical care; nevertheless, the concepts are inter-related (Pascoe 1983; World Health Organization (WHO) 2000).

As satisfaction data can be enhanced by triangulation of measurements and methodology (Larsen, Attkisson et al. 1979), the following approaches to participant satisfaction assessment were undertaken:

- Participant phone survey after the completion of the episode of care using a fully structured and validated instrument (CSQ-8; see Appendix 10) plus additional questions.
- Participant survey at the time of participation using a self-administered questionnaire.
- Analysis of participant behaviour of repeated participation in the project.
- In addition, partner organisations were surveyed in an informal way on an ongoing basis during the conduct of the Chlamydia Testing Trial (CTT).

11.1 Participant Satisfaction Survey

Participant satisfaction with services was assessed by directly asking participants to evaluate the services provided to them. The Client Satisfaction Questionnaire-8 (CSQ-8) is a validated, efficient, sensitive and relatively comprehensive instrument for measuring experiences with a specific service rather than healthcare in general (Larsen, Attkisson et al. 1979; Nguyen, Attkisson et al. 1983; Attkisson and Greenfield 2004). It has been evaluated in a wide range of healthcare settings, including primary care

settings, and is also validated for use as a phone survey (LeVois, Nguyen et al. 1981; Nguyen, Attkisson et al. 1983).

11.1.1 Methodology

Instrument

The CSQ-8 has good psychometric properties (Cronbach's alpha unweighted mean = 0.88) (Attkisson and Zwick 1982; Attkisson and Greenfield 2004). The fully structured, standardised CSQ-8 questionnaire was complemented by five additional questions:

(1) Have you visited a healthcare provider in the past 12 months?

(2) How much time did you spend using the chlamydia kit?

(3) If you had a chlamydia test elsewhere, which method of chlamydia testing would you prefer for a future test?

(4) Has the use of the kit increased you knowledge about chlamydia?

(5) Any comments: (open ended)

Recruitment

Primary participant recruitment was through a question in the questionnaire included in the self-collection kit. Question B9: 'May we contact you in the future about your experiences with home testing for chlamydia?' offered the options of ticking either 'yes' or 'no'. Not answering the question was classified as 'no'. The answers to this question were recorded in the central management system (CMS) database and subsequently a list of 'potential satisfaction survey participants' was produced.

As the survey was administered by phone, those 'potential' satisfaction survey participants who did not provide contact details were excluded. Those few participants who provided email addresses only were sent an email and were asked to contact the CMS for participation in the survey or, alternatively, provide phone contact details. None of the participants had provided a mailing address only.

Secondary participant recruitment was at the point of contact for the survey. Verbal informed consent was obtained from all participants.

Conduct

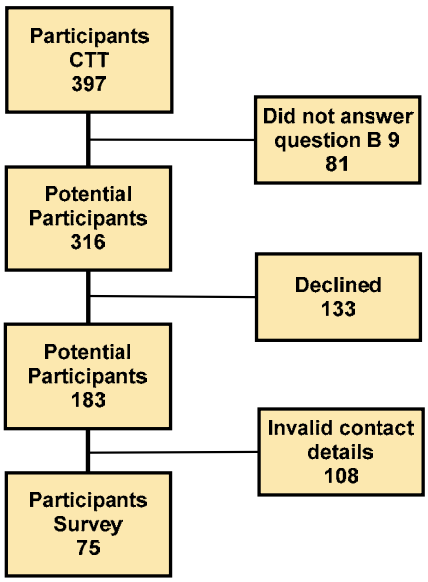
A protocol for the administration of the survey was established outlining the standard procedure for the conduct of the survey, including the sequence of questions and provision of answers. The additional questions were asked after the CSQ-8 questions. Three interviewers were trained in the use of the questionnaire. The satisfaction survey was administered by phone.

All data was directly entered into the survey database by the interviewer during the conduct of the survey.

11.1.2 Results

Overall, 75 participants in the CTT also participated in the satisfaction survey. Figure 11.1 outlines participant recruitment.

Figure 11.1 Participant recruitment for satisfaction survey



The reasons for unsuccessful contact with 'potential satisfaction survey participants' were invalid contact details, including disconnection of phone, no answer to phone call after multiple attempts or not having responded to the email. None of the 'potential satisfaction survey participants' contacted declined to participate in the survey.

Demographics

The median age of participants was 25.0 years (interquartile range (IQR) = [20.0; 30.3]); 20 (26.7%) were males and 55 (73.3%) were females. Age and gender as well as the chlamydia test result of the participants in the satisfaction survey are not significantly different from the age, gender and test result of 'potential satisfaction survey participants', or the overall CTT sample population.

CSQ-8

On a scale from 1 to 4 (1 = 'totally dissatisfied' to 4 = 'extremely satisfied'), the mean total satisfaction score is 3.76, with a standard deviation of 0.18. The distribution is skewed to the right. It is suggested by Le Vois to reduce the mean score of the CSQ-8 by 10% when the questionnaire is administered orally (LeVois, Nguyen et al. 1981). Following this recommendation, the resulting mean total satisfaction score would be 3.38. The itemised satisfaction scores and the percentage of maximum scores are listed in Table 11.1.

Table 11.1 Itemised CSQ-8 Satisfaction Survey results

	ITEM	*N*	MEAN SCORE	STANDARD DEVIATION	% OF MAXIMUM SCORE
1	How would you rate the quality of service you have received?	75	3.68	0.55	72
2	Did you get the kind of service you wanted?	75	3.8	0.49	82.7
3	To what extent has our program met your needs?	75	3.77	0.58	81.3
4	If a friend were in need of similar help, would you recommend our program to him or her?	75	3.93	0.251	93.3
5	How satisfied are you with the amount of help you have received?	75	3.81	0.425	82.7
6	Have the services you received helped you to deal more effectively with your problems?	75	3.36	0.63	40
7	In an overall, general sense, how satisfied are you with the service you have received?	75	3.89	0.31	89.3
8	If you were to seek help again, would you come back to our program?	75	3.8	0.49	82.7
	Overall mean score		3.76	0.18	

The total satisfaction score of males when compared to females was not significantly different (P = 0.539). There was no association between age and the total satisfaction score (r = 0.038, P = 0.747), and the total satisfaction score of those diagnosed with chlamydia was not significantly different from those who tested negative (P = 0.084).

Additional questions

Of the 75 participants, 63 (84%) had visited a healthcare provider such as a general practitioner (GP) in the past 12 months. The 75 participants spent a median time of 15 minutes (IQR = [10; 20]), ranging from 2 minutes to 60 minutes, on using the self-collection kit. Overall, 95% of participants stated that it took them less than 30 minutes to use the kit.

The question: 'If you had a chlamydia test elsewhere, which method of chlamydia testing would you prefer for a future test?' was only asked if participants had undergone chlamydia testing in the past. Of the 68 participants who had a previous chlamydia test, 54/68 (72%) stated that they would prefer the self-collection kit method for future testing, 4/68 (5.3%) stated that they would prefer testing at a GP's office and 10/68 (13.3%) stated that they would prefer testing at a sexual health clinic.

Of all 75 participants, 60 (80%) answered yes to the question: 'Has the use of the kit increased you knowledge about chlamydia?', whereas 15/75 (20%) answered no to this question.

Comments to the open-ended question were thematically analysed. The following main themes emerged:

(1) The self-collection mailing kit concept is acceptable.

(2) The time from testing to receiving of results was surprisingly short.

(3) The active management of results by the CMS is welcomed.

(4) The self-collection mailing kit concept is preferable to other options of chlamydia testing.

(5) A perception of increased confidentiality and privacy for participants from smaller rural and remote communities.

(6) The self-collection kit concept is not sufficient for the needs of the men who have sex with men (MSM) community.

(7) Testing with the self-collection kit is less embarrassing.

11.1.3 Discussion

The satisfaction of participants with the self-collection mailing kit testing method was evaluated by using a validated questionnaire. Results indicate a high to very high level of participant satisfaction with the service in all items of assessment. A comparison of participant satisfaction over time was not possible as only one measurement was taken; however, comparison with the standard baseline of 3.38 for a similar population in a primary care setting indicates identical levels of overall satisfaction. Within-CTT project comparison did not indicate differences in satisfaction according to gender, age or chlamydia diagnosis.

The participation rate of 41% of eligible persons is less than optimal and, while no statements can be made about the satisfaction of non-participants, they were not demographically different from the participants. The discrepancy between the ability to contact participants for their results and contacting them for participation in the survey could be explained by the time lag, as the survey was conducted towards the end of the CTT study period.

The findings in this survey on attendance at other healthcare services support findings from another study (Fairley, Hocking et al. 2005). Although 84% of respondents reported a visit to their GP during the past 12 months, only 27% had been tested for chlamydia in that time period. Of those, 53% tested positive, suggesting that possibly symptoms were the reason for testing rather than opportunity.

Participants needed relatively little time for the preparation of a sample and paperwork involved, with 95% of them completing the task in less than 30 minutes. The time aspect was later mentioned in the open-ended questionnaire part. The convenience and privacy afforded by the self-collection kit testing method was seen as positive by most, which is in contrast to the findings from the pilot study in Aboriginal and Torres Strait Islander communities (see Chapter 7.4), where concerns were raised about confidentiality because of the lack of mail boxes.

The majority of participants in the survey had undergone chlamydia testing previously and were in a position to realistically compare testing options. The finding that nearly three-quarters of respondents would prefer the CTT methodology for a future test is a

further indication of the acceptability of the self-collection mailing kit concept for chlamydia testing.

The question about the educational aspects of the project indicated that there was some increase in knowledge about chlamydia in the sample population through the promotional materials and information included in the self-collection kit. This finding supports the evidence-based approach to the development of the resources.

Many participants appreciated the opportunity to comment about the project in the open-ended question. The general opinion was positive, with some much differentiated contributions. A cluster of participants from rural and remote areas without specialist sexual health services was quite adamant that the confidentiality of any testing in their community would not be guaranteed and that they would not have had a chlamydia test if it were not for the option of mailing the sample.

Several members of the MSM community were concerned that the self-collection kit was only for chlamydia testing. It was mentioned that this sends the message that a chlamydia test is now all that is needed for a sexual health check and that a visit to a healthcare provider was still necessary to test for other infections. The first issue raised should not be of great concern to participants in the CTT as the vast majority received their results and additional advice on further testing requirements. The second issue could be addressed by offering gonorrhoea testing simultaneously with chlamydia testing. While the system is not yet validated for gonorrhoea testing, it has the potential. Cross-examination of the survey data and the data from other parts of the study indicated that some MSM would not have attended a healthcare service for any testing at all; thus, at least a contact with a service was established and at least one test was conducted.

The findings from this study provide valuable insight into participant perceptions about the service, even though the sample was self-selected.

11.2 Participants' Recommendations

While the assessment of participant satisfaction after the completion of the episode of care gives an indication of the satisfaction with the total health service experience, it is limited by the necessity to contact the participant again. As expected and described in the previous section, the ability of the service to recruit participants for a specific satisfaction survey was limited.

Three proxy questions for satisfaction were added to the self-collection kit questionnaire as it was not feasible to include all CSQ-8 questions. This analysis was undertaken to provide additional information about participant satisfaction, as assessed at the time of mailing the sample.

Methods

A fully structured, self-administered questionnaire was included in the self-collection kit for chlamydia testing (Chapter 6). Two of the three items included in the questionnaire were also items of the CSQ-8. Returning the questionnaire with the sample was optional. The three items were:

(8) Would you recommend this way of testing for chlamydia to a friend?

(9) Would you use this testing kit again if the need arose?

(10) Would you like us to contact you for retesting in the future if you test positive for chlamydia?

All data was entered directly into the CMS database on receipt of the questionnaire.

Results

The questionnaire was at least partly completed by 332 of the 397 participants in the CTT. The median age of participants was 23 years (IQR [20; 29]); 91 (27.4%) were males and 28 (8.7%) identified as being of Indigenous descent.

All respondents stated that they would use the kit again and 99.4% would recommend the kit to a friend, while over 75% of participants gave consent to be reminded of the need for retesting if they were positive for chlamydia. Details are listed in Table 11.2. For all questions, there was no statistically significant difference detected in regards to age, gender and ethnicity.

Table 11.2 Participant responses to satisfaction questionnaire in self-collection kit

Questions	*N**	responses
Would you recommend this way of testing for chlamydia to a friend?	323	Yes = 321 (99.4%)
Would you use this testing kit again if the need arose?	320	Yes = 320 (100%)
Consent for reminder	301	Yes = 228 (75.7%)
Questions	N*	Top responses only

*Participants did not answer all questions.

Discussion

The data for this analysis was collected at the time of the mailing of the sample for testing, using three items for the assessment of satisfaction. The responses indicated a high to very high level of satisfaction, with nearly all participants stating that they would use the self-collection kit again or recommend it to a friend. The answers were consistent with those given in the phone survey conducted after the episode of care was completed. This concordance is not surprising as the sample of the phone survey was a subset of the participants in this survey. It is interesting that the high level of satisfaction was expressed at a time when the test result was as yet unknown and no contact with the health service had been established.

The finding that three-quarters of participants would like to have a reminder for retesting was higher than expected, but consistent with participant behaviour in regards to receiving results rather than having to obtain them. Given the low retesting rates for clinic attendees reported in Chapter 8, this finding provided evidence that a reminder system for retesting might be acceptable.

11.3 Repeated participation

Satisfaction and acceptability influence behaviours such as reuse of a service or following professional advice, and consequently influence health outcomes (World Health Organization (WHO) 2000). As a further measure of participant satisfaction with the CTT methodology and in addition to asking participants directly about their satisfaction with the CTT, an analysis of participant behaviour was undertaken.

Methods

The CMS data for the 12-month study period was examined and those who participated repeatedly were identified. Most participants had provided either names, dates of birth, mobile phone numbers, addresses, email addresses or a combination of those identifiers. A participant was considered a repeat participant if a match for either three of those identifiers could be established. Resubmission of a sample due to an inhibited test result was not considered a repeat participation.

Results

Overall, 425 self-collection kits were returned with at least one sample for chlamydia testing during the study period, and 397 discrete participants were identified. Of those 397 participants, 22 (5.5%) participated more than once. There were no differences between repeaters and non-repeaters in regards to age, gender and Indigenous status; however, there was a statistically significant difference between those who were positive and those who were not. Details are listed in Table 11.3.

Table 11.3 Comparison of persons who participated more than once in the CTT with those who participated once only

RE-PARTICIPATION			
	YES	**NO**	***P* value**
	(*n* = 22)	**(*n* = 375)**	
Median age (IQR)*	24.0 (21.3; 26.0)	22.5 (19.6; 28.6)	0.46
Male gender	22.7% (5)	32.1% (120)	0.48
Indigenous descent	0% (0)	9.3% (29)	0.385
Positive test result of first test	30.8% (12)	2.9% (10)	**<0.001**

*IQR = interquartile range.

Of the 23 participants who initially had an inhibited test result, 14 (60.8%) resubmitted an alternative sample for chlamydia testing.

Discussion

The overall return rate of participants in the CTT was 5.5%. This is high given that the project only had a clinical lifespan of 12 months. The even higher return rate of 30.8% for those who tested positive can be regarded as an indicator of satisfaction and acceptability of the CTT testing methodology.

11.4 Satisfaction of partner organisations

The assessment of partner organisation satisfaction with the CTT methodology was conducted informally throughout the life of the project.

Potential partner organisations had been identified during the preparation stage of the CTT. The identification process of partner organisations was guided by their access to the target populations of the CTT. No data is available on how many organisations were formally approached about participation in the project, so no statements can be made about the acceptability of the methodology to potential partner organisations.

Those organisations that did become partner organisations of the CTT and did either promote or distribute kits were in regular contact with the CMS. Problems and concerns were addressed on an ongoing basis, with all partner organisations continuing to distribute self-collection kits until the end of the project. This leads to the conclusion that the CTT methodology was acceptable to the partner organisations involved.

11.5 Conclusions

Methodological triangulation of participant satisfaction was achieved by combining participant survey data with observational data on participant behaviour. A consistently high level of satisfaction was detected by all three components of the satisfaction assessment, leading to the conclusion that participant satisfaction was high. The problems encountered with contacting potential participants for the satisfaction survey can be avoided in the future by conducting a survey closer to the end of the episode of care.

Satisfaction of the MSM population with the self-collection kit methodology could be increased by adding gonorrhoea testing as a further test. Validation of the urine transport gel (UTG) for gonorrhoea testing would be required. A chlamydia/gonorrhoea self-collection kit would also be useful for testing in the Aboriginal and Torres Strait Islander population.

11.6 References

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CHAPTER 12 OVERALL DISCUSSION

This chapter discusses the overall achievements of my doctoral studies and also updates the original literature review (Chapter 2) conducted in early 2005 with information available until mid 2010.

This thesis combines a series of studies that investigated the feasibility of novel, non-clinic-based approaches to *Chlamydia trachomatis* (chlamydia) testing. I started by studying the occurrence of genital chlamydia in suspected high-risk groups in Queensland to create an evidence base for the optimal target populations for the active outreach clinics approach.

Further, I developed an intervention to increase access to chlamydia testing. The intervention consisted of a self-collection kit that allowed sending a specimen for testing through the regular Australia Post mail service. I implemented and evaluated this novel approach for chlamydia testing in Queensland.

The first project, a needs assessment, investigated the prevalence of chlamydia and was set up as a series of outreach chlamydia screening clinics targeting specific groups. These outreach clinics were successfully organised and conducted by a primary healthcare service as an alternative to regular clinic-based testing and without the need for additional funding. My study showed that outreach clinics could be an effective part of an inclusive chlamydia management program as they allow targeting high-risk groups that would not usually access mainstream health services. This seems particularly important in the absence of an organised screening program. Sturrock and co-workers (2007) described similar positive experience with outreach clinics for four different risk groups in the ACT, and other studies concluded that targeting high-risk groups is a promising screening approach for chlamydia (Fairley, Hocking et al. 2005; Gotz, van Bergen et al. 2005; Hocking and Fairley 2005; Sturrock, Currie et al. 2007). The outreach clinics were set up in a sustainable way and, indeed, most of them are still regularly conducted, 6 years after their commencement.

Chlamydia prevalences in these outreach clinic populations varied depending on the context between 0% in high school graduates and 15% in Indigenous high school students. The prevalences were similar to those reported in the Australian literature and

abroad (Table 12.1) (Bowden, O'Keefe et al. 2005; Vajdic, Middleton et al. 2005). My literature review (Chapter 2) and an additional review of more recent prevalence studies published between 2004 and 2010 (see below) included reports from Canada, the United States (US), Australia, Luxembourg, Norway and the United Kingdom (UK), which targeted school students and disengaged youth, as well as incarcerated people and people accessing health services (Shields, Wong et al. 2004; Schillinger, Dunne et al. 2005; Auerswald, Sugano et al. 2006; Bakken, Skjeldestad et al. 2007; Lamontagne, Baster et al. 2007; Scholes, Heidrich et al. 2007; Joffe, Rietmeijer et al. 2008; Mossong, Muller et al. 2009; Oakeshott, Kerry et al. 2010) (Table 12.1). In addition, two population-based studies were identified from Norway and the US (Bakken, Nordbo et al. 2006; Satterwhite, Joesoef et al. 2008). Only two of these studies were from Australia, targeting high-risk youth and pregnant women in antenatal care (Kong, Guy et al. 2008; Chen, Fairley et al. 2009). These studies found varying prevalences ranging from below 1% to above 20%, depending on the context, comparable to my own data as well as to the earlier literature (see Chapter 2, Table 2.1).

Some of the more recent articles also identified risk factors (Bakken, Skjeldestad et al. 2007; Joffe, Rietmeijer et al. 2008; Chen, Fairley et al. 2009; Mossong, Muller et al. 2009). The results of these analyses were supporting previous findings; young, sexually active people engaging in unprotected sex with changing partners are classified as high risk (Table 12.1). No new risk factors were identified.

Table 12.1 Literature review of occurrence and risk factors for *Chlamydia trachomatis* conducted between 2005 and 2010 (green are Australian studies)

Author, year, country	Design; time frame; location	Population and sample size	Testing methods used	Prevalence/ incidence/ relative risk overall	Men	Women	Risk factors
Shields, S. A. et al., 2004, Canada	Cross-sectional study, 2/1999 to 10/1999, large urban centres in Canada	Street youth, *n* = 1,355, 867 males, 488 females, mean age 18.8 years	PCR[1]	*P*[2]: 8.6%; 95% CI [7.1%; 10.1%]	*P*: 7.3%	*P*: 10.9%	/
Schillinger, J. A. et al., 2005, US	Cross-sectional study, 10/1999 to 4/2003, 4 cities US	Mostly asymptomatic men, *n* = 23,507, detention centres, school clinics, street outreach, median age 21 years	PCR	*P*: 7%; 95% CI [6.7; 7.3]	*P*: 7%; 95% CI [6.7; 7.3]	-	/
Kang, M. et al., 2006, Australia	Cross-sectional study, 11/2000 to 11/2003, NSW, Australia	High-risk youth 14 to 25 years old accessing youth centres, *n* = 274	Not stated	5.7% 95% CI[3] [3.0%; 8.4%]	-	-	/
Auerswald, C. L. et al., 2006, US	Cross-sectional study, 2/2004 to 3/2003, San Francisco, US	Homeless youth, *n* = 218, 144 males, 74 females, mean age 20.5 years	PCR	*P*: 6.9%	-	-	/
Bakken, I. J. et al., 2006, Norway	Population-based registry study	Population of 15 to 24 year olds' testing data between 11/1990 and 12/2003, *n* = 28,599, 4,717 males, 23,882 females	to 1992 EIA[4], then NAAT[5], PCR		*P*: 15–19 year olds 15.5% to 22.7%, 20–24 year olds 15.4% to 23.4%	*P*: 15–19 year olds 7.1% to 11.2%, 20–24 year olds 5.7% to 8.7%	/
Bakken, I. J. et al., 2007, Norway	Cross-sectional study, 4/2005 to 10/2005, Oslo and Trondheim, Norway	Young men, mostly students, *n* = 1,032, mean age 23.6 (SD[6] 2.5) years	PCR	*P*: 7.8%	*P*: under 21 years 5.3%, 21–25 year olds 9.0%, over 25 years 5.1%		Being single, symptoms, high number of sexual partners, lack of condom use
Scholes, D. et al., 2007, US	RCT, population-based, 11/2001 to 10/2002, Washington State,	Managed Care Plan members, males aged 21–25, *n* = 8,820, I[7]-1: 2,940, I-2: 2,940	LCR[9], ELISA[10]	*P*: I-1 1.0%, 95% CI [0.1%; 5.1%] I-2 2.6%, 95% CI [1.0%; 5.2%], for mailed samples, overall:	*P*: I-1 1.0%, 95% CI [0.1%; 5.1%] I-2 2.6%, 95% CI [1.0%; 5.2%], for mailed samples, overall:	-	

Author, year, country	Design; time frame; location	Population and sample size	Testing methods used	Prevalence/ incidence/ relative risk overall	Men	Women	Risk factors
	US	C[8]: 2,940, mean age 22.5 years		I-1 0.07% , I-2 3.6%, 16.7%	I-1 0.07% , I-2 3.6%, 16.7%		
Lamontagne, D. S. et al. 2007, UK	Cohort study, 18 months observation, 3/2002 to 8/2003, UK	Women aged 16 to 24 years, GP practices, family planning clinics, GUM[11] units, *n* = 1,424	NAAT			I: GP 4.9% per 100 PY[12], 95% CI [2.7%; 8.8%] FP[13] 6.4% 95% CI [4.2%; 9.8%], GUM 10.6% 95% CI [7.4%; 15.2%]	
Joffe, A. et al., 2008, US	Cross-sectional study, 10/1999 to 1/2003, Baltimore and Denver, US	Male middle and high school students	NAAT	*P*: 6.8%	*P*: Baltimore 7.5% Denver: 4.7%		Young age, more than 1 sex partner in past 12 months, history of STI, race, any sex in past 2 months
Satterwhite, C. L., et al. 2008, US	Population-based surveillance systems, secondary analysis of several datasets from 1999 to 2005, US	Males, mostly young, correctional facilities, National Job Training Program, MSM[14] Prevalence Monitoring Project, Notifiable Diseases System, National Health and Nutrition Examination Survey, Longitudinal Study of Adolescent Health	NAAT, LCR	Notifiable Diseases System: 2005 323,781 notifications = 161.1/100,000 population, NHANES: 1999–2002 0.7%—3.2%, highest in 20 to 29 year olds, AddHealth: 2001 to 2002 3.7% 18 to 26 year olds, Juvenile Corrections: 2005 2.4% to 8.7%, highest in 18 to 20 year olds, Adult corrections: 2005 2.9% to 8.8% , highest in 18 to 20 age group, National Job Training Program: 2003 to 2004 8.0% to 8.8%, highest in 20 to 24 age group	MSM Project: 2005 15 to 80 age group 6.0%		

Author, year, country	Design; time frame; location	Population and sample size	Testing methods used	Prevalence/ incidence/ relative risk overall	Men	Women	Risk factors
Chen, M., et al. 2009, Australia	Cross-sectional study, 10 2006 to 7/2007, Victoria, Australia	Pregnant women, antenatal clinics, 16 to 25 years, median age 23, *n* = 987,	PCR		-	*P*: 3.2% 95% CI [1.8% to 5.9%]	More than 1 partner in last year, antibiotic use in past 3 months protective
Mossong, J., et al. 2009, Luxembourg	Cross-sectional study,	Mostly women, Family Planning Clinics, Secondary schools, Occupational Health Centres, *n* = 4,141 FP: *n* =1,355 High Schools: *n* =1,328 OHC[15]: *n* =1,458	PCR		*P*: Secondary Schools 0.9% 95% CI [0.3%; 2.2%] *P*: OHC 3.0% 95% CI [1.9%; 4.6%]	*P*: FPC 7.7% 95% CI [6.3%; 9.2% *P*: High Schools 1.9%, 95% CI [1.2%; 2.8%] *P*: OHC 5.8%, 95% CI 4.2%; 7.8%]	Young age, number of partners, lack of condom use
Oakeshott, P. et al., 2010, UK	RCT, 2004 to 2007, UK	Young women, mean age 21 years, *n* = 2529 I: 1259 C: 1270	NAAT		-	I: 5.4% C: 5.9%	/

Abbreviations: [1]PCR, polymerase chain reaction; [2]P, prevalence; [3]CI, confidence interval; [4]EIA, enzyme immunoassay; [5]NAAT, nucleic acid amplification test; [6]SD, standard deviation; [7]C, control group; [8]I, intervention group; [9]LCR, ligase chain reaction; [10]ELISA, enzyme-linked immunoassay [11]GUM, genitor-urinary medicine; [12]PY, person-year; [13]FP, family planning; [14]MSM, men who have sex with men; [15]OHC, Occupational health centre.

Although the results of the needs assessment were important, useful and encouraging for conducting outreach clinics instead of clinic-based testing, the general limitations inherent to outreach clinics need to be recognised. Only people who are part of specific, defined groups are targeted for testing; the outreach clinics are only conducted at specific times; and trained staff is required for conducting outreach clinics at the location. Thus, access to testing by using outreach clinics is still restricted. People who live in locations without outreach clinics, such as rural and remote areas of Australia, are still missing out. In order to address this major barrier to testing, in collaboration with the University of Queensland and Queensland Health, I developed a self-collection kit for chlamydia screening. This approach was supported by my literature review, which had shown that mailing kits increased the screening coverage in different populations from Denmark and the US (see Chapter 2, Table 2.4).

My intervention showed that using mailed self-collection kits for chlamydia testing is feasible and acceptable. This finding is supported by a recently published study from the US, which offered a sample of 403 women (who were part of a large cohort study investigating contraceptive choice) three options for chlamydia testing: 1.) send a mailing kit to the participant; or 2.) free chlamydia testing without appointment at the nearest family planning clinic; or 3.) chlamydia testing with their general practitioner and reimbursement of costs (Graseck, Secura et al. 2010). The majority (75.7%) of women opted for the mailing kit, of which 65% (197 of 305) returned a sample for testing.

As noted before, barriers to testing include young age, the asymptomatic nature of chlamydia, access to services, cost, lack of knowledge, perceived low risk, as well as perception of confidentiality and privacy. My data showed that participants were concerned about privacy and confidentiality, in particular in smaller communities, although to my knowledge there is no evidence supporting these concerns. My results show that the availability of a mailed self-collection kit can overcome some of the barriers. My study focused on the high-risk group of young sexually active people and proved that young people can be persuaded to be screened for chlamydia given the right circumstances.

Table 12.2 gives an overview about recent studies on interventions to increase screening for chlamydia testing. Similarly to my findings, Cook and co-workers (2007) demonstrated increased screening coverage by mailing out self-collection kits

(intervention) to young high-risk women (Cook, Ostergaard et al. 2007). The study was controlled by a group of women who received a reminder card that invited them to chlamydia testing at a clinic. Another randomised controlled trial (RCT) carried out in the US by Scholes et al. (2007) aimed to increase screening coverage by comparing two interventions: 1.) sending out an invitation card to request a home sampling kit; or 2.) sending out a home sampling kit, with usual care at a clinic. Scholes' study used almost 3,000 young men in each comparison group (Scholes, Heidrich et al. 2007). Although uptake of screening was disappointingly low, with less than 8.4% in the most successful 'intervention group 2', comparisons with the control group showed that both intervention groups successfully increased screening coverage. The studies by Cook and Scholes were the only published RCTs identified between 2005 – which was the year my study commenced – and 2010 that tried to increase screening coverage in non-clinical settings.

One could argue that inconvenience might be a driving factor for not attending screening opportunities at a clinic. However, issues such as timely access to services, confidentiality and privacy concerns, as well as other more non-tangible issues may be underlying reasons. The use of modern communication technologies certainly helped in engaging the younger age group and avoided the perceived issues of confidentiality and privacy. In addition, my results showed that the mailing kit reached individuals who would not have been tested otherwise. Follow-up of participants was close to 100% and all positive cases, apart from one person who moved away to an unknown location, were treated. When contact tracing was conducted by the clinical management team, it was also close to 100% and even included contacts from overseas. All this was achieved with one full-time position operating out of one location.

Table 12.2 Literature review of occurrence and risk factors for *Chlamydia trachomatis* conducted between 2005 and 2010 (green are Australian studies)

Author, year, country	Design, time, location	Sample size control and intervention	Intervention	Patient population	Outcome measures	Comment
Cook, R. et al., 2007, US	RCT, 11/2000 to 4/2003, Pennsylvania, US	*n* = 388, I[1]: 197 C[2]: 191 mean age 18.9 years	I: mailing of home testing kit after 6, 12 and 18 months C: reminder card to see clinic for testing	All female, high-risk women, previous infection, high prevalence neighbourhood	Primary outcome: number and % of tests completed I: 1.94 tests per woman year C: 1.41 tests per woman year; *P* <0.001 Secondary outcome: number of STI detected I: 28.7 per 100 woman year C: 24.1 per 100 woman years; *P* = 0.280	Only more tests done, no increased prevalence
Scholes, D. et al., 2007, US	RCT, 11/2001 to 10/2002, Washington State, US	*n* = 8,820 I-1: 2,940, I-2: 2,940 C: 2,940	I-1: letter plus request card for home sampling kit plus reminder, I-2: letter plus home sampling kit plus reminder C: usual care (access to clinic)	Managed Care Plan members, all males aged 21–25, mean age, 22.5 years	Primary outcome: participation rates: I-1: 3.6% (+0.9% who returned to clinic), I-2: 7.8% (+0.6 who returned to clinic) C: 0.8% Secondary outcome 1: relative risk of testing: I-1 vs C: RR[4]; 5.6; 95% CI: [3.6; 8.7] I-2 vs C: RR: 11.1; 95% CI: [7.3; 16.9]; I-1 vs I-2: RR: 2.3 95% CI[5]: [1.8; 2.9] Secondary outcome 2: chlamydia prevalence: I-1: 1.0%; 95% CI: [0.1; 5.1] I-2: 2.6%; 95% CI: [1.0; 5.2]; C: 16.7%; 95% CI: [4.8; 37.3]	
Graseck, A. S. et al., 2010, US	Trial, self-allocation, 8/2008 to 12/2008, St Louis, Missouri, US	*n* = 403 I: *n* = 305 C-1: *n* = 65 C-2: *n* = 33 C: *n* = 98	Offer of no-cost chlamydia screening, either home collection or regular provider or family planning clinic (clinic-based analysed together)	Participants in cohort study about contraceptive choice, all female, mean age: I: 25.1years; C: 24.7 years	Primary outcome: Completed tests: I: *n* = 197 (65%) C: *n* = 31 (32%) RR of testing: 2.04 95% CI: [1.51; 2.76] Secondary outcome: Choice of testing: I: *n* = 305 (75.7%) C: 98 (24.3%); *P* <0.001	Substudy of a cohort study not RCT, patients could self-select into groups, positivity was not major outcome: I 4/197 positives, 2.0% 95% CI [0.6; 5.1] C: 2 /31, 6.5% 95% CI [0.7; 21.2]

Abbreviations: [1]I, intervention group; [2]C, control group; [3]P, prevalence; [4]RR, relative risk; [5]CI, confidence interval.

Outcome/Significance

The desired outcome was the development of the discussed novel approaches to chlamydia testing that take account of the specific situation in Australia, and especially Queensland, and provide new avenues to make a cheap and accurate test – together with an effective and inexpensive treatment –available to asymptomatic people, especially in non-metropolitan areas.

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

The developed and evaluated novel approach – the self-collection kit and accompanying management system – especially fulfil all requirements outlined in the 'aims' by being:

1.) Based on an 'active' approach, that is, actively educating and informing the target population and promoting chlamydia testing;

2.) Available independent from 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 knowledgeable about follow-up (i.e. 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' (not requiring complicated procedures, instructions, accommodating low literacy skills); and

8.) Connected to existing infrastructure, including communication systems.

More specifically:

1.) The methodology presented is accompanied by education and information campaigns to ‘actively’ promote chlamydia testing in the relevant segments of the target population.

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

3.) 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.

4.) The operation of the centralised management system by a qualified health professional provides – also for people living in remote areas – access to a high level of quality of care with respect to information, follow-up, treatment, partner notification, retesting and further testing.

5.) A further advantage of the centralised management system is the provision of testing opportunities under assured confidentiality by enabling access to testing outside the local social sphere, thus avoiding potentially perceived issues with confidentiality, which are especially prevalent in the smaller communities of rural or remote areas.

6.) The developed system is independent of the general primary healthcare sector, thus 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.

7.) 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.

8.) By using 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 – evidenced by six publications in peer-reviewed journals and 11 conference presentations (see Appendix 9) – not only demonstrated feasible and inexpensive ways of how chlamydia testing can be improved in Australia but has already been implemented into the routine service provisions of Queensland Health.

The studies also contribute to the evidence base on the utility of self-collection mailing kits internationally. Findings by my studies are consistent with findings in the US, the UK, Scandinavia and the Netherlands. Indeed the Netherlands are moving towards a national screening program for chlamydia using the mailing kit approach rather than going down the path of the UK where the national screening program is based in the primary care sector and dependent on the target population having access to a GP.

As already mentioned, the Townsville Sexual Health Service now routinely conducts outreach clinics in segments of the target population identified using the methodology developed and the segment 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 relocated to the Queensland Sexual Health website) or by phone request.

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

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

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Appendix 1. Pee it Pack it Post it - HP resource development report

"Pee it, Pack it, Post it"

The Development of Educational Resources to Promote Home Sampling Kits for Chlamydia Testing

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July 6, 2007

Table of Contents

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List of Abbreviations

ADF	Australian Defence Force
AUD . . .	Australian dollar
GP . . .	General practitioner
JCU . . .	James Cook University
PID . .	Pelvic inflammatory disease
SBYHN . .	School Based Youth Health Nurse
SPHTMRS . .	School of Public Health, Tropical Medicine, and Rehabilitation Science
STI . . .	Sexually transmitted infection
THSD . . .	Townsville Health Service District
TSHS . . .	Townsville Sexual Health Service
USD . . .	United States dollar

Abstract

Objectives: Home testing for Chlamydia is a new service about to be introduced across a number of areas in Queensland. The objectives of this study were to define what resources are most suitable to promote the Chlamydia Home Sampling Kit, to identify what key messages need to be in the resources, and to identify design aspects most appealing to the target audience.

Methods: Qualitative data was collected from the target audience through focus groups to inform the resource development process. This information was presented to a steering committee composed of specialists from Sexual Health, Health Promotion, and Aboriginal Health for further comment and input. A graphic designer was then commissioned to develop the resources. Piloting and further refinement of these resources was undertaken using another focus group.

Results: Focus group participants were able to provide valuable insight and advice to inform both the type of resources to be developed and the overall content and design. Together with expert input from the steering committee members a poster and pocket sized pamphlet have been developed and are ready for distribution.

Conclusions: Reducing barriers to Sexually Transmitted Infection and specifically chlamydia testing is important and home testing has the opportunity to increase testing rates. The development of health education resources such as posters and pamphlets can be effective tools to raise awareness of the new home sampling kit and increase the uptake of Chlamydia testing.

Preface

The Chlamydia Testing Trial (CTT) is a Queensland based initiative which came about in response to the Australian government's recent investment into chlamydia research. This state-wide, multicentre collaborative project aims to address barriers around chlamydia testing by offering an alternative to clinic-based testing with home-sampling kits. The development of the home-sampling kit allows for specimens to be posted through the mail and test results sent to participants by a variety of media.

In order for the home-sampling kit to be accepted and known to the target population, it was decided that some form of limited reach media promotion should be developed for the release of the home-sampling kits. This project was borne of this decision, and educational resources were developed to address the issue of raising awareness around this new testing option. This paper addresses the process of developing the educational resources, by providing the background information, methods used, results found, a discussion and conclusion.

Introduction

Genital Chlamydia is a sexually transmitted infection (STI), caused by the bacteria *Chlamydia trachomatis* (Heymann, 2004), and ranks as Australia's most common notifiable disease (Yohannes, Roche, Roberts, Liu, Firestone, Bartlett, East, Hull, Kirk, Lawrence, McDonald, McIntyre, Menzies, Quinn & Vadjic, 2006).

Chlamydia infection has serious implications for personal and public health if left untreated, as it can lead to pelvic inflammatory disease (PID), ectopic pregnancies, chronic pelvic pain, tubal factor infertility, prostitis, and epididymitis (Ford, Viadro & Miller, 2004; McKay, 2006; Scholes, Stergachis, Heidrich, Andrilla, Holmes & Stamm, 1996; Vadjic, Middleton, Bowden, Fairley & Kaldor, 2005). The World Health Organization (WHO) (2007) estimates that the United States may pay as much as $10 billion (USD) annually for the treatment and caring of patients with PID. A recent cost analysis study has been undertaken in Australia by Walleser, Salkeld & Donovan (2006), citing the estimated average cost per person with PID as an outpatient to be $348.41 (range $296.30-$400.54) AUD, and up to $4741.00 (range $1372.00-$8110.00) AUD as an inpatient.

Infected persons are often unaware of their infection status as genital Chlamydia presentation is mostly asymptomatic or subclinical (Dixon-Woods, Stokes, Young, Phelps, Windridge & Shukla, 2001; Schachter, 1999; WHO, 2007). Data shows that up to 40-50% of males and 70-85% of females present without symptoms (Institute of Medicine, 1997 in Vajdic *et al*, 2005; Stamm, 1999 in Vajdic *et al*, 2005). This contributes not only to the propagation of the infection, but also to an avoidance of testing. Also, many people at risk of infection do not seek testing, or do not get tested during routine care (Ford *et al*, 2004). Based on this, it is clear that sexually active individuals in the high risk age group need further educational and promotional support to seek testing options based on behaviour, rather than symptoms.

In 2004, the reported cases of Chlamydia infections in the Townsville Health Service District (THSD) exceeded the national average in citing 456.3 cases per 100 000 compared to 180.1 cases per 100 000 in Australia (National Notifiable Disease System, 2006). Reasons for the seemingly high infection rates in the district are unknown; however the demographic characteristics of the population such as age and Indigenous status may be factors. The average age of the general population of the city is markedly lower than that of the state, at 32.7 years of age (ABS, 2003), whereas Queensland cites 35.5 years (ABS, 2003). Increased testing in the district compared to other districts may also have led to the higher prevalence rates.

Up until recently, testing options for Chlamydia in the THSD required patients to seek out a qualified clinician to obtain a sample for testing. This could be done at a general practitioner's (GPs) office, by visiting the Townsville Sexual Health Service (TSHS), or at a local hospital's Emergency Department. Within the past two years however, upon receiving funding from the Australian Commonwealth Government a group of researchers from Townsville and Brisbane have worked together to assemble a Home Sampling Kit for to test for Chlamydia infection.

As this type of testing has never been available before in Australia, it was important to ensure that the target demographic was made aware of this new testing option. One option for promoting a new resource is through written print materials, as they are the most common instructional tool used by health professionals to educate their clients and target audiences (Bernier, 1993, in Grriffen, McKenna & Tooth, 2003). It is important to note that resources can vary in quality however, and therefore it is necessary to utilise rigorous approaches in their development phase. Formative research should dictate and guide the development of resources (Egger, Spark, Lawson & Donovan, 1999), to ensure that both the topic and target audience are identified and needs are met. This project actively involved members of the target audience in a series of focus groups to inform on the development of the visual appearance, content, slogan, and key messages of the educational resources. A Steering Committee comprised of local authorities, including the Health Promotion Team Leader for THSD, a Health Promotion lecturer from the School of Public Health, Tropical

Medicine and Rehabilitation Science (SPHTMRS) at James Cook University (JCU), two Central Public Health Nurses who specialise in Sexual Health, and an Aboriginal Health Worker from the THSD. The role of this group was to guide best practice principles in resource design and development and provide expert advice on content and clinical data.

TSHS have identified key risk factors for Chlamydia infection to include: age, specifically being in the 16 to 25 years old bracket; new sexual partner in the last 2 to 3 months; multiple partners, and inconsistent condom use or non-condom use. Thus, the target group for the educational campaign was 16 to 25 year olds.

Preliminary trial kits were made available from April 2006 to June 2007 at local pharmacies, some local post-secondary education institutions, and at the TSHS (Bührer-Skinner, pers. comm., 2006, November 10). These kits were similar to the final Home Sampling Kits however the samples collected were not able to be mailed, but rather dropped off at pathology labs. These kits were distributed to aid in the collection of baseline data prior to the launch of the finalised kits.

At this time, the finalised Chlamydia Home Sampling Kits contain:

- instructions
- a sterile swab (recommended for women in collecting their sample)
- a urine collection cup (for male or female samples)
- a transport tube containing a liquid absorbent non-silicon based polymer substance, to absorb urine
- a dropper to transfer urine from collection cup into transport tube
- a small box to protect the transport tube during handling and mailing
- a sealable plastic bag to wrap the sample box
- a pathology request form
- a reply paid opaque plastic bag to mail entire package to pathology
- an information card to call for de-identified test results (with a personal reference number in relation to the sample)
- an information pamphlet on Chlamydia

- a condom
- paperwork (questionnaire to aid in research of Chlamydia, user perceptions of test, and corresponding consent forms)

The entire kit fits in an inconspicuous cotton bag measuring approximately 14cm by 20cm, and is free of charge. Distribution points for the finalised kit will most likely include pharmacies, JCU Student's Association, local youth services, TAFE's, through School Based Youth Health Nurses, Sexual Health clinics and medical facilities around town. Kit samples can be sent in the mail to the nearest pathology lab, and test results returned to the client by email, SMS, regular telephone, or mail.

This report describes the process of developing and piloting the print resources to raise target group awareness around the availability of the Chlamydia Home Sampling Kit in the Townsville Health Service District (THSD).

Methodology

This project is part of the formative assessment process of a broader health promotion campaign around the Chlamydia Home Sampling Kits. Media materials and campaigns are shaped by formative measures, as described by Egger *et al* (1993), through quantitative research approaches. Focus groups are considered to be the most valuable form of data collection in the formative process, supplemented by surveys, literature reviews and epidemiological analysis. Uncovering the needs and wants of the target audience is essential in the formative resource process to ensure target audience resonance with the final product.

The key research questions for this study were:

- to define what resources are most suitable to promote the Chlamydia Home Sampling Kit
- to recognize what key messages need to be in the resources
- to identify the design (including graphics, colour, layout, etc.) most appealing to the target audience

Through a series of focus groups data was collected and assimilated according to the reality-oriented perspective. As explained by Patton (2002), the reality-oriented approach assumes you can talk to people and get legitimate responses that apply directly in the real world. It seeks out lived experience and validates their role in data by emphasising the lessons learned through practice and practical life. The experiences and opinions offered by the focus groups were applicable in the development of resource design.

Focus Group Participants and Design

Ethics approval was sought and granted from the James Cook University (JCU) Ethics Committee preceding focus group research. Three focus groups were held, Groups A and B prior to resource design for input suggestions and analysis, and Group C after resource design to pilot and offer final recommendations. This was done congruent with the suggestions of Paul, Redman & Sanson-Fisher (1997), in that the target group become active participants in the resource development process in order to improve their efficacy.

Groups A (n=6) and B (n=5) were comprised of JCU students and were divided by gender. This was done to enhance ease of discussions, for while resource creation was the goal of the focus groups, chlamydia and STIs would be discussed and can be considerably sensitive topics. Participants were recruited from the JCU campus through posters and word of mouth. Participation was completely voluntary and all participants signed “Informed Consent” forms upon being further briefed on the purpose of the study. Upon presentation of the findings of Focus Groups A and B to the Steering Committee, new ideas were generated in terms of style, design, and slogans. These ideas were then discussed one on one with a couple of members of Focus Groups A (n=2) and B (n=2) in follow up face to face interviews over the course of a few days to affirm that the ideas were grounded, relevant, and worth including in the brief for the resource designer (GR).

Table 1: Demographic Data of Focus Groups				
Group	**No. of Participants (n)**	**Gender**	**Mean Age**	**Age Range**
A	6	Female (F1-F6)	20.67	18 – 25
B	5	Male (M1-M5)	20.4	18 – 24
C	5	Female & Male (F7, F8, F9, M6, M7)	21	18 – 24

Group C (n=5) was comprised specifically of non-university students. This was done to remove any biases from the print materials associated with education. A snowballing technique was attempted, whereby participants of Groups A and B were asked to encourage a friend to participate in the follow up group; disappointingly this approach was not effective. The Project Officer (BE) contacted acquaintances and former colleagues that matched the required demographics, who were able to recommend willing and interested participants. Again, all participants signed "Informed Consent" forms upon being further briefed on the purpose of the study. Refer to *Table 1* for demographic data of the focus groups.

Focus Group Process

The author (BE) facilitated all three focus group. The Health Promotion expert from JCU (SD) was present at the first two focus groups to help supervise and take notes. For the third group, a Sexual Health Nurse (KB) with Health Promotion training sat in to take notes in her place. Each group also had a Central Public Health Nurse (RG or MBS) present to ensure all data pertaining to the Chlamydia Home Sampling Kit was accurate and up to date. The Central Public Health Nurses also took notes.

All participants agreed to be called by their first names and consented to the focus group being recorded. Their names have been coded to maintain

confidentiality in this report. Food and drink were provided at the focus groups to thank the participants for their time, opinions, and input.

Prior to the focus group meetings, the focus group composition and questions were approved by the Steering Committee as appropriate and suitable for the participants. A series of semi-structured questions were posed to Groups A, B, and C, modelled after the framework presented by Krueger and Casey (2000) which consisted of: opening questions, introductory questions, transition questions, key questions, and ending questions. This framework created a focused interview technique, guided by approximately 10-11 questions designed to stimulate discussion and explore a range of participants' ideas and perceptions.

To Groups A and B, the key questions centred on types of resources, location of both resources and Home Sampling Kits distribution points, slogan preference, graphics and style of resources, and key messages (refer to *Appendix 1* and *Appendix 2* for PowerPoint presentations used with Focus Groups A and B, respectively). The key questions used for Group C enquired about the poster and pamphlet designed, eliciting feedback in terms of overall likeability, slogans, graphics, colours, readability, language, and key messages (refer to *Appendix 3* for PowerPoint presentation used with Group C). These questions, while following the guidelines of Krueger and Casey, are also congruent with the "kinds of measures taken after exposing people to campaign materials", as outlined by Egger *et al* (1993) (refer to *Table 2*).

Table 2: Copy Testing: what to measure

1. the thoughts and feelings generated spontaneously by the material
2. the extent to which the message is correctly understood
3. the extent to which the message is credible
4. the extent to which the message is seen to be personally relevant, important, and useful
5. the extent to which the message motivates the recommended action
6. the extent to which the audience see the recommended action as effective and themselves as capable of performing the action
7. the likes, dislikes and specific confusions associated with the material(s)
8. the extent to which the presenter or models in the materials are credible and relevant as role models to the target audience (where appropriate)

Source: Egger *et al* (1993), p. 154.

After each topic was covered during the focus groups, the facilitator summed up key ideas that emerged during the discussion and identified where consensus was reached by the group or dissention was present. All three presentations also incorporated some elements of education, as it was necessary to explain the relevance of the Home Sampling Kits to young people and how they work, as well as some basic facts about Chlamydia infection (statistics, epidemiology, risks, etc).

After all key questions had been answered and all topics exhausted by participants, an anonymous feedback survey was administered requesting basic information (age, name, discipline if a university student, or type of employment if working exclusively), as well as a rating on individual experience, highlights of the focus group, areas for improvement, and the option of including an email address for any participant was interested in an electronic copy of the final resources once completed.

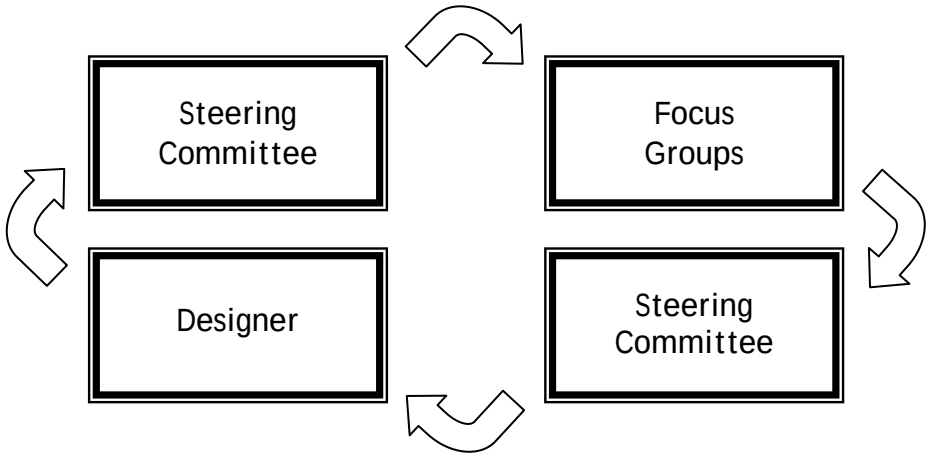
Data Analysis

The recordings of the focus groups were transcribed verbatim (refer to *Appendix 4, Appendix 5, and Appendix 6* for transcriptions of Groups A, B, and C, respectively) and reviewed by the author along with the notes provided by the group facilitators and nurses. Manual analysis was undertaken. This data was collated, recurrent themes were identified, and ideas highlighted to provide observations and suggestions to the Steering Committee and the designer hired to create the educational resources for the project.

Steering Committee

After the first focus group was held and the designer selected, the Steering Committee played an important role in filtering, mediating, and defining the information that went through to the designer from the target group (see *Diagram 1* for stakeholder's flow of information).

Diagram 1: Steering Committee, Stakeholders, and Flow of Information



The Steering Committee met nearly weekly (refer to *Table 3* for a timeline of Steering Committee meeting and focus group meeting dates) to ensure best practice principles were adhered to in the development phase of the education resources, all voices were equally heard in the process, and all clinical data remained correct. Refer to *Appendix 7* for Steering Committee Meeting Minutes.

Table 3: Timeline of Steering Committee and Focus Group Meeting Dates

Group	Date
Steering Committee	April 4, 2007
Steering Committee	April 12, 2007
Steering Committee	April 19, 2007
Focus Group A	April 20, 2007
Focus Group B	April 20, 2007
Steering Committee	April 26, 2007
Focus Group A & B Individual Follow Up	April 28, 29, 30, 2007
Steering Committee	May 10, 2007
Focus Group C	May 21, 2007
Steering Committee	May 23, 2007
Steering Committee	May 24, 2007
Steering Committee	May 30, 2007
Steering Committee	To be called.

Steering Committee and Resources Development

The Steering Committee responded to feedback from Focus Groups A and B. According to Griffin, McKenna and Tooth (2003), it is important that messages are written in a way that promotes their readability, and content is presented simply and clearly. Thus the input from the focus groups was taken into consideration, and their perceptions were matched with that which is defined by experts.

In regards to graphics and design, the focus groups relayed different ideas back to the facilitator which were filtered through the Steering Committee. The Steering Committee ruled in favour of hand drawn or cartoon style graphics rather than photograph style graphics based on majority consensus of the participants, which was then communicated to the graphic designer.

Graphic Artist

Following analysis of focus groups and recommendations from the Steering Committee, the Project Officer (BE) worked with the graphic artist (GR) to design and develop the first draft of resources to be piloted. The designer remained involved in the feedback process until the final resources were complete.

Results

As a result of the questions asked during the focus groups, a number of themes emerged. Results are summarised under the main questions asked.

Themes from Focus Group A & B Discussions

"What type of education resources would you find useful to gain awareness about this product?"

Participants were asked what resources were most suitable for promoting awareness about the home testing kit. Posters and pamphlets were

recommended. This is in line with the preferences of the Steering Committee who felt that posters and pamphlets would be the limited reach media of choice for the Chlamydia Home Sampling Kit. The Focus Groups were asked to suggest other resources which they felt may be of use. Other resources such as bookmarks, pens, and coasters were discussed as potential resources that could be developed in the future. Mass media campaigns such as print (magazine and newspaper), radio, and television advertisements were also recommended. As one male participant (M5) said:

But why would you want to look at that when you're at the pub having a good time?

One resource idea brought up by the male focus group was to create small advertisements in the aisles of grocery stores and pharmacies particularly in the areas were male toiletries and displayed. This may appeal to men seeking health advice, as explained by a male participant, (M4):

If I think I've got something, the first thing I'm going to do is I'm going to try and cure it myself without going to the doctor.

Smaller, more discrete pamphlets were preferred by the females interviewed, and the males liked a variety of smaller sizes, up to a postcard size. It was emphasised that graphics of some sort needed to be included in the design of the resources. Both the females and the males expressed discomfort about being seen reading a poster or picking up a pamphlet with "chlamydia" written on it. The female group agreed that if the message was clear on the poster then you wouldn't have to stare too long to understand what it was about. One female (F1) summarized with:

I think how you'd like to get the message across, um in relation to posters, is just to make people aware of it: big, loud, where you'd see them all the time. And then more specific information, that people can then once they're aware of, think, 'oh, maybe I should go and get tested'. And then you can have these little, kind of discrete things with more concise information. Like still quite simple, but then they can go and read about it.

This idea was reiterated by both female and male focus groups in the discussions on the location of resources as well.

“Where do you think the resources should be located?”

To resonate with the theme of discreteness, both females and males felt that toilet doors and above urinals (or in urinals, if urinal pucks were to be used) were ideal places for chlamydia advertisements, as they were, according to participant F5, “*inconspicuous*”. Some locations where the target population was definitely present were offered, such as on-campus toilets or toilets in movie theatres. There was some dissention between the female and the male groups in deciding whether toilets in bars and pubs were a good location. The female group thought they would be effective, while the male group, as described, were not interested in thinking about serious matters like STIs when out for a good time.

Places where people naturally seek advice on health, such as pharmacies, post-secondary institution health centres, army health centres, sexual health clinics, private clinics, and pathology labs were suggested as resource distribution points. Gyms, sporting venues and locker rooms were considered as locations to specifically target men, and convenience locations such as ferry and bus terminals, backpackers or hostels and service stations were also discussed by both the female and male focus groups as potential locations for resources.

Opportunistic awareness raising was considered, as reaching out to high risk groups outside of education settings and traditional medical settings was deemed important. Therefore, places such as Centrelink, Reconnect and Queensland Youth Services were suggested. Also, shopping centres on “late night” shopping nights when many youth are around, or fast-food restaurants such as McDonalds or Eagle Boys Pizza where young adults tend to congregate were also highlighted as potential locations where chlamydia and STI awareness may be raised.

Many of the resource locations cited by the focus groups had already been identified by the Steering Committee, but the consistency of the suggestions is worth noting.

“Where do you think the home sampling kits should be distributed from?”

Many of the same locations mentioned for resource distribution points were repeated as kit distribution points. This includes pharmacies and other health-related service locations such as clinics, high school based and post-secondary based nurses and health campuses, and outreach locations such as Centrelink, Reconnect and Queensland Youth Services. Discreteness was still a big issue, and distribution points were discussed with this in mind. For example, the Sexual Health Nurse (RG) asked the male focus group if asking a pharmacist or counter-person for a kit would be a barrier to using the product, to which M4 replied:

Oh hell yeah.

Another suggestion promoting anonymity was to advertise in pharmacies under a banner which read, “Grab a kit for your mate”.

Both the male and the female groups asked about ordering kits, either by telephone or over the internet, which the facilitators assured would be another option for distribution points.

Some other ideas for distribution points included: sporting venues, gyms, service stations, student services at post-secondary institutions. Again, many of the suggestions were in line with those already considered by the Steering Committee.

Slogans: “Pee it, pack it, post it”, “Do your own thing”, or “Peace of mind is a piece of p…”?

Of all of the slogans suggested, “Do your own thing” was the least well received by both the female and the male focus group. One of the females in the group suggested, “DIY” (F1), which the females liked, but it did not resonate with the males. “Pee it, pack it, post it”, “Peace of mind is a piece of p…”, or a combination of the two slogans, were favoured for the campaign.

What style of graphics do you feel would be most effective?

In terms of graphics, the female group decidedly preferred cartoon imagery, over real life photographs. There was an association between cartoons and humour, which the female group felt would be most effective. The male group was split. The first theme to emerge was “sex sells”, then humour, then serious. When asked about a brand colour for the campaign, the female group’s preference was purple, while the male group’s preference was yellow.

What theme of design do you feel would be most effective?

Both focus groups were shown images from other chlamydia and STI campaigns to generate ideas (refer to *Appendix 1*, *slide 21 to 23* and *Appendix 2, slide 21 to 23* for images shown). The female group wanted something that was:

> *simple, but clever and cheeky* (F1)

The male group came to no consensus. Similar themes as mentioned above were reiterated.

What are the key messages that would encourage you to undertake a home sampling kit for chlamydia?

The key messages elicited by Group A and Group B were:

- anonymous, discrete, confidential test
- asymptomatic nature of chlamydia
- simple statistics (i.e.: 1 in 10 people have it)
- consequences if untreated
- easy treatment
- risk groups
- location of kit distribution points
- duration of time for test results
- methods of result delivery
- free, painless, simple (self-explanatory, easy to use) test

Summary Process of Focus Groups A & B

The results and ideas from the first two focus groups were analysed by the author (BE) and then presented to the Steering Committee. The designer (GR) was selected and two participants each from Focus Groups A and B were shown some of the artist's pervious work in brief follow-up meetings for further input and consensus. A brief was generated for the resource designer (GR) based on the findings of the groups and the guidance of the Steering Committee. (Refer to *Appendix 8* for Artist's Brief).

The artist provided some sketches to the Steering Committee which were in need of refinement. It was discussed that the poster could be designed to reflect "sexual landscape" and highlight the different landscapes where the target group live throughout Queensland. This was relayed back to the artist who commenced developing drafts for comment.

Themes from Focus Group C Discussions

The slogan, "Pee it, pack it, post it" became part of the Home Sampling Kit logo. The slogan "Peace of mind is a piece of p…" was not well received by all parties involved, as it was deemed a bit too risqué. Another slogan "The check's in the mail" was generated by the graphic artist (GR), and therefore also piloted with Focus Group C.

General Poster, No Slogan Feedback

The poster was first presented to Group C without any slogan in an effort to elicit feelings on the art work without the influence of the words used. There were mixed reactions to the slogan-free poster presented (*Appendix 9)*. "Cluttered" was the preliminary response. The participants had a difficult time conceptualising the poster without colour, as well as grasping meaning of the poster without something clearly grabbing their attention. The post box insinuated it was an advertisement for Australia Post. It was felt that the longer

you looked at the poster the more interesting it got, but it required a good slogan to make one want to look for a "*second glance*" (F7).

One participant suggested that the cartoon nature of the poster put forth the idea that the poster was not racy enough, as the group agreed, "sex sells". The group was asked if they noticed the sexual imagery in the poster, but beyond the two copulating toads in the foreground, no one realised there were hidden sexual graphics.

All of the key messages outlined on the poster were easily identified by the focus group. It was felt that the asymptomatic nature of chlamydia and the potential seriousness of the infection could be further highlighted, as "*the fear of God*" (F8) should be instilled in people reading the poster to encourage the use of Home Sampling Kits or general Sexual Health check-ups.

Poster with Slogan 1: "Peace of mind is a piece of p…" Feedback

The participants were then shown the same poster again with "Peace of mind is a piece of p…" as the heading. The group was not offended by "P…" and were surprised to hear that one of the background partners to the project had reservations about using it as a slogan. The focus group did not find it inappropriate in the context it was presented. While there was a general agreement that the slogan was amusing, it was raised that the word "peace" could be misleading. As one participant (M7) said:

> *I don't know, eh… You can look at that in many different ways. Like, if you don't read the bottom of it I still don't think you'd understand what exactly what it meant… 'Cause I'd be thinking "peace" maybe, "peace" between bands or something…. Send them a letter, say hello or something like that…*

The font was generally liked, but it was agreed that it did not help the slogan to stand out well (refer to *Appendix 10*). It was also expressed that the word "chlamydia" needed to stand out more. This raised the issue that the meaning of the poster may get overlooked if "chlamydia" was not larger. When asked individually, there was not a consensus as to whether the participants would be inclined to access the service or not if they saw the advertisement.

Poster with Slogan 2: "The check's in the mail" Feedback

There were a couple of participants who did not understand the slogan at first glance. It was agreed that the font used for the heading was bolder and more appropriate (refer to *Appendix 11*). There was a consensus that the heading was also much easier to read. Of those who understood the slogan, it was deemed effective in grabbing attention. The reference to money was soon established and the group discussed the misconceptions which may be raised.

When asked what their preferred slogan was, "Peace of mind is a piece of p…" seemed to be more popular, but two participants responded that they didn't particularly care for either. The participants all liked the heart logo with "Pee it, pack it, post it", and it was suggested that perhaps it be the main header instead of the other slogans discussed.

Pamphlet Feedback:

The pamphlet was very well received by the focus group (*Appendix 12*). Some even suggested using the cover of the pamphlet as a supplementary poster to the original. The focus group was not convinced the pamphlet and the poster matched as a brand due to the different fonts and colours used, and seeing one would probably not make you think of the other. The size was approved (wallet-sized), and the group felt the text was suitable and easy to read.

Summary Process of Focus Group C

A summary of the findings from Focus Group C were presented to the Steering Committee (refer to *Appendix 13)*. A decision was then made to use the heart-shaped logo with "Pee it, pack it, post it" as the main slogan for the campaign, and move it from the bottom of the poster to the top. The Steering Committee felt the poster was still quite good, and even though it did not receive resounding approval at the pilot session, the Steering Committee had faith that with colour and a few minor changes it would be an excellent product.

It was also agreed that the pamphlet and the poster needed to match. This idea was relayed to the designer (GR) to edit and make more uniform. The Steering

Committee made an executive decision to make the pamphlet look like the poster, rather than the other way around, as it was felt the poster had more potential to be attention grabbing and artistically appealing.

The designer added colour to the poster and detailed a few minor changes. The pamphlet was made to match to coloured poster and the resources were complete. Refer to *Appendix 13* to *Appendix 16* for examples of colour poster development. *Appendix 17* is the final pamphlet from GR.

Discussion

This study reinforces the value of undertaking formative evaluation processes when developing health education resources. Mailed home sampling kits for chlamydia testing have been piloted elsewhere in the world such as in Europe and the United States with varying success (Andersen, Østergaard, Møller & Olesen, 2001; Ford *et al*, 2004; Götz, Veldhuijzen, Van Bergen, Hoebe, De Zwart & Richardus for the Pilot CT Study Group, Van Bergen, Broer, Coenen, Götz, De Groot, Hoebe, Richardus, Van Schaik, Veldhuijzen & Verhooren, 2005), but the Chlamydia Testing Trial is the first project in Australia to test for an STI with a mailed in home sample. The development of resources using a formative process will be integral to the uptake of these kits in the future.

Research in health promotion has shown the effectiveness of using limited reach media such as leaflets and pamphlets to help promote informed choice around screening decisions (Fox, 2006). It is important however that health care and health promotion professionals adhere to best practice approaches when developing educational (Griffin *et al*, 2003, Paul *et al*, 1997). In this study we applied a number of approaches when developing the educational resources, to ensure the content is evidence-based. The reality-oriented approach to the data collected from the focus groups, combined with the empirical evidence and data provided by the experts on the Steering Committee, as well as direction from both national and state health departments, made the adherence to any single development process impossible. The final product reflects the opinions and requests of all parties and stakeholders involved.

Some interesting themes emerged in this study, which mirror many themes currently being used or exemplary of traditional STI campaigns. As STIs can represent a sensitive topic to many, people tend to find them more palatable if they are presented under the guise of humour. This idea runs concurrent with a recent Australian-based study conducted with Melbourne street-youth (Henning, Ryan, Sanci & Dunning, 2007). “Sex sells” was another prominent theme which was raised. This presents a slight dichotomy, as it can be difficult

to promote STI testing with “sexy”, as iterated by one study participant, that people could accuse you of promoting risky sexual behaviour. Current chlamydia and gonorrhoea campaigns in West Australia (the “Could I Have It?” campaign) and the UK (the “Condom Essential Wear” campaign) have managed to incorporate this approach. The poster developed from our study included both overt and subtle sexual imagery to identify with this theme.

Using best practice participatory approaches throughout this project were useful in understanding the perceptions of the target audience. This has resulted in the development of a product that is likely to resonate with and appeal to the target audience.

Limitations

All of the focus groups were small which may be considered a limitation to this study. Overall, the difference in gender was not that great, in having 56.25% of the participants female (9/16) and 43.75% male (7/16). Recruiting participants was difficult, possibly due to misconceptions around the actual subject matter of the focus groups (i.e.: chlamydia vs. chlamydia resource design). Two high-risk sub-populations, Australian Defence Force (ADF) personnel and Indigenous Australians, were identified in preliminary research. Unfortunately neither sub populations were represented in the focus groups. Having the first round of focus groups comprised exclusively of university students may be considered a limitation, and perhaps the final product would be different if the first focus groups were non-university youth.

While the aim of the final product for this project was to produce a resource appealing to 16 to 25 year old, the age range for the focus groups excluded those under 18 years. This was due to ethics specifications, and therefore unavoidable, however hopefully the higher age mean does not prevent under 18 year olds from resonating with the resources developed.

Comments on improvement elicited from the feedback surveys included:

- greater diversity of participants
- to have a finalised kit (not just the pilot sampling kit) present at the focus group
- offer comparisons of foreign company products and resources to facilitate ideas and comparisons, and analyse success rates
- provide more information to participants on the effects of the STI

The participants were asked to rate their focus group experience out of 5, to which the overall score for the three focus groups was 88.75% (mean 4.4/5).

The funding bodies behind this project exercised influence and had a definitive effect on the final product, ruling out suggestions of the focus groups such as “Peace of mind is a piece of p…”.

Literacy was identified as a limitation to the actual resources developed. According to standard promotion principles and practices, copy and text should be written at a grade 5 or 6 general literacy level (Griffen *et al*, 2003). This concept was adhered to; however the imagery of the posters does not explicitly describe what they are all about. Thus, they will not be effective to anyone in our target audience who does not have at least a grade 5 or 6 literacy level.

Conclusions

Reducing barriers to STI and specifically chlamydia testing is a multifaceted social issue. The development of health education resources such as posters and pamphlets can be effective tools to raise awareness of the new home sampling kit and increase the uptake of Chlamydia testing for high-risk groups. The quality of the resources is likely to be enhanced by the active participation of the target group in the development process. Addressing the increasing rates of chlamydia nation-wide is an important priority in preventing future, more permanent sequelae of the infection and the costly public health burden. By raising awareness of the new home sampling kit it is anticipated that there will be an increase in the uptake of Chlamydia testing.

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Appendix 2. Ethics Approval

Administrative documentation has been removed

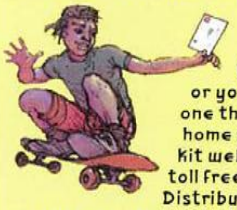
Appendix 3. Pee it, Pack it, Post it Poster

Appendix 4. Pee it, Pack it, Post it, Leaflet

You can go to your GP or local Sexual Health Clinic to get a test done.

Or you can
PEE IT, PACK IT, POST IT.
Collect a sample at home using the home sampling kit, mail it back for testing and you will be contacted with your result.

How Do I Get A Home Sampling Kit?



You can pick up a kit from various locations, or you can order one through the home sampling kit website or the toll free number. Distribution points are listed on the website. The kit and testing is free and confidential.

TELEPHONE
1 800 895 544

INTERNET
www.health.qld.gov.au/chlamydia

Where Can I Get More Information on chlamydia and STIs?

QUEENSLAND SEXUAL HEALTH CLINICS:

Brisbane	(07) 3837 5611
Bundaberg	(07) 4150 2754
PA Hospital/Brisbane Sth	(07) 3240 5881
Cairns	(07) 4050 6205
Gold Coast	(07) 5576 9033
Ipswich/West Morton	(07) 3817 2428
Mackay	(07) 4968 3919
Mt Isa	(07) 4744 4805
Nambour	(07) 5470 5244
Palm Island	(07) 4752 5165
Redcliffe/Caboolture	(07) 3897 6300
Rockhampton	(07) 4920 5555
Thursday Island	(07) 4069 0413
Toowoomba	(07) 4616 6446
Townsville	(07) 4778 9600

Queensland Sexual Health Website:
www.health.qld.gov.au/sexhealth

THE CHLAMYDIA TESTING TRIAL WAS FUNDED BY THE AUSTRALIAN GOVERNMENT

What is Chlamydia?

Chlamydia is a sexually transmissible infection (STI) that can affect both men and women. It is the most common bacterial STI and is spread through vaginal, anal or oral sex.

Most infections are found in young people between the ages of 15 and 29. People can have chlamydia without being aware as often there are no signs or symptoms.

If left untreated, chlamydia infections can cause serious health problems. Once diagnosed, chlamydia can easily be treated and cured.

Am I at Risk of Chlamydia?

You are at risk if you have sex and:

- don't use condoms consistently
- have sex with a new partner

How Do I Know if I Have Chlamydia?

Often people are not aware they have chlamydia because there are NO SIGNS OR SYMPTOMS. More than half of all men and three-quarters of all women who have chlamydia have no symptoms. If symptoms do occur, they usually develop about five to 14 days after becoming infected and could be:

- Pain when you pee
- Unusual discharge
- Lower belly pain or painful sex
- Bleeding after sex or between periods
- Pain in the testicles or anus

If you experience any of these symptoms please seek advice.

The only way to know if you've got Chlamydia is to get tested.

How Can I Prevent Infection?

The best way to avoid getting chlamydia is to always practice safer sex; for example always use a condom when you have vaginal, anal or oral sex.

What Happens if I Have Chlamydia?

Chlamydia is easily treated with a single dose of antibiotics, although in some cases a longer course of treatment may be given. It is also recommended that people talk to their partner(s) about getting tested.

What Happens if Chlamydia is Not Treated?

In women, untreated infection can spread into the womb and cause pelvic inflammatory disease (PID). PID can cause permanent damage to the womb and surrounding tissues. The damage can lead to chronic pelvic pain, infertility and potentially fatal ectopic pregnancy (pregnancy outside the uterus). Complications in men include infection of the testicles and possible sterility.

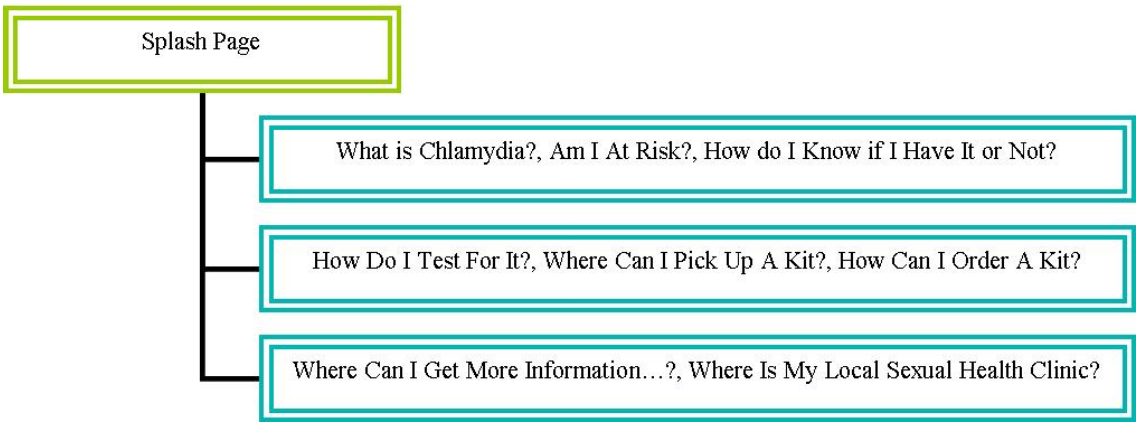
How Do I Test For It?

There is a safe and simple test for chlamydia.

Appendix 5. Web Site Content

Web Site Content

Layout Tree



Content

What is Chlamydia?

Chlamydia is a sexually transmitted infection (STI) that can affect both men and women. It is caused by bacteria that are passed during unprotected vaginal, anal or oral sex. Chlamydia is now one of the most common STIs in Australia for people aged between 15-25 years of age. The trouble is that you can have Chlamydia without even knowing it. Often people with Chlamydia don't see or feel anything wrong so they can unknowingly pass on Chlamydia to their partners.

If untreated, Chlamydia infections can progress to serious reproductive and other health problems with both short-term and long-term consequences. Once diagnosed, Chlamydia can be easily treated and cured.

For more detailed information on Chlamydia, visit the Teen Sexual Health HIV and Hepatitis C Web Site or the Adult Sexual Health HIV and Hepatitis C Web Site, or click here for a Fact Sheet on Chlamydia.

Am I At Risk?

You are at risk if you are sexually active and…

- You have never been tested
- You have changed your sexual partner in the last 2 to 3 months
- You are under 25 years old

How Do I Know If I Have It Or Not?

You may not! Up to 80% of people with a Chlamydia infection have NO SYMPTOMS. If symptoms do occur, they usually develop 5 to 14 days after becoming infected. These symptoms could be:

- Tingling or burning when you pee, even once
- Unusual discharge, itch or irritation
- Lower belly pain or painful sex
- Bleeding after sex or bleeding between periods
- Pain in the testicles or bum

The only true way to know if you've got Chlamydia is to get tested.

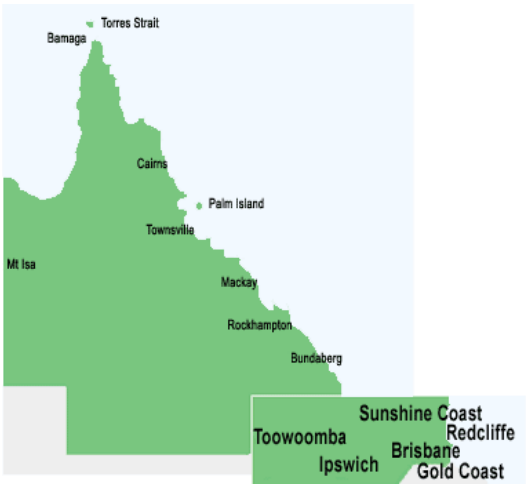
How Do I Test For It?

There is a safe and simple test for Chlamydia. You can go to your GP or local Sexual Health Clinic to get a test done, or you can *pee it, pack it, post it*. Do it at home with a Chlamydia Home Sampling Kit. The Home Sampling Kits can be picked up at various distribution points, or ordered over the phone or internet.

Where Can I Pick Up A Kit?

** *Roll over map*

Cairns:
Cunnamulla:
Ingham:
Longreach:
Magnetic Island:
Palm Island:
Townsville:
Toowoomba:



How Can I Order A Kit?

If you live in Queensland you can order a Home Sampling Kit by calling the number below or by emailing the address below to request one. Or, fill out the online form and submit it for a kit to be mailed to you.

Telephone: 1 800 895 544 (Queensland residents only)

Email: chlamydia@health.qld.gov.au

Order Online:

** *Insert order form*

Where Can I Get More Information on Chlamydia, STIs and Sexual Health?

I Stay Safe: Queensland Health Teen Sexual Health HIV and Hepatitis C Web Site:
http://www.health.qld.gov.au/istaysafe/

Queensland Health Adult Sexual Health HIV and Hepatitis C Web Site:
www.health.qld.gov.au/sexhealth/

Family Planning Queensland:
www.fpq.com.au

QHAC (Queensland Association for Healthy Communities):
http://www.qahc.org.au/

Where is My Local Sexual Health Clinic?

Find your nearest sexual health clinic by following the links below to each State's Sexual Health and related services websites.

Queensland

Queensland Health Sexual Health Services
http://www.health.qld.gov.au/sexhealth/Where_Can_I_Go_For_Help.shtml

Outside Queensland

(*please note, these lists may not be complete as some sexual health services are covered in community health programs)*

New South Wales
http://www.health.nsw.gov.au/sexualhealth/getting_tested.html#clinics

Clinic 34, Northern Territory
http://www.nt.gov.au/health/contact/contactc.shtml#clinic34

South Australia
http://www.stdservices.on.net/

Tasmania
http://www.dhhs.tas.gov.au/services/view.php?id=384

Victoria
http://www.health.vic.gov.au/ideas/diseases/gr_sti/sti_furtherinfo

West Australia
http://www.health.wa.gov.au/services/category.cfm?Topic_ID=8

Appendix 6. Self-Collection kit contents

Appendix 6.1. Information Brochure- Page 1

Where Can I Get More Information on chlamydia and STIs?

QUEENSLAND SEXUAL HEALTH CLINICS:

Brisbane	(07) 3837 5611
PA Hospital/Brisbane Sth	(07) 3240 5881
Cairns	(07) 4050 6205
Gold Coast	(07) 5576 9033
Ipswich/West Moreton	(07) 3817 2428
Mackay	(07) 4968 3919
Maroochydore	(07) 5479 2670
Mt. Isa	(07) 4744 4805
Palm Island	(07) 4752 5165
Redcliffe/Caboolture	(07) 3897 6300
Rockhampton	(07) 4920 5555
Thursday Island	(07) 4069 0413
Toowoomba	(07) 4616 6446
Townsville	(07) 4778 9600

Queensland Sexual Health Website: www.health.qld.gov.au/sexhealth

THE CHLAMYDIA TESTING TRIAL WAS FUNDED BY THE AUSTRALIAN GOVERNMENT

Easy Guide

- Read the white information leaflet
- Collect sample following diagrams found in red ziplock bag
- Pack sample as directed
- Put your date of birth & today's date in shaded areas on pathology request form
- Complete the yellow questionnaire
- Place zip-lock bag containing sample & completed yellow questionnaire in reply paid plastic envelope
- Put envelope in the mail
- Please keep your unique number if you need to contact us for results

Queensland Government
Queensland Health

Appendix 6.2. Information Brochure- Page 2

Chlamydia Information Sheet

What is chlamydia?

Chlamydia is a sexually transmissible infection (STI) that can affect both men and women. It is the most commonly notified bacterial STI and is spread through vaginal, anal or oral sex. Most infections are found in young people between the ages of 15 and 29.

People can have chamydia without even knowing it as often there are no signs or symptoms. If left untreated, chlamydia infections can cause serious health problems. Once diagnosed, chlamydia can easily be treated and cured.

Who is at risk of chlamydia?

The risk of contracting chlamydia increases when:

- condoms are not used consistently (all the time, every time)
- having sex with a new partner
- having sex with someone under the age of 25 (young people are more likely to be infected)

How do I know if I have chlamydia?

Often people do not know they have the infection because there are no signs or symptoms. More than half of all men and three-quarters of all women who have chlamydia have no symptoms and do not know that they are infected. If symptoms do occur, they usually develop about five to 14 days after becoming infected.

Women with chlamydia may notice that they have:

- crampy pain in the lower abdomen (just above the pubic bone)
- menstrual changes including longer, heavier periods which may be more painful
- pain when passing urine
- bleeding or spotting between periods or after having sex
- pain during or after sex
- a change in their vaginal discharge (more discharge or a change in colour and smell).

Men with chlamydia may notice:

- a discharge from the penis
- pain when passing urine
- swollen and sore testicles

If you experience any of these symptoms please seek advice. The only way to find out whether you have chlamydia is to have a test. Men can have a urine test. Women can have either a urine or a swab test.

What happens if I have chlamydia?

Chlamydia is easily treated with a single dose of antibiotics, although in some cases a longer course of treatment may be given. It is also recommend that people talk to their partner(s) about getting tested.

What happens if chlamydia is left untreated?

In women, untreated infection can spread into the womb and cause pelvic inflammatory disease (PID). This happens in up to 40 percent of women with untreated chlamydia. PID can cause permanent damage to the womb and surrounding tissues. The damage can lead to chronic pelvic pain, infertility and potentially fatal ectopic pregnancy (pregnancy outside the uterus). Women infected with chlamydia are more likely to become infected with HIV, if exposed. Complications in men are less common and include inflammation of the testicles and possibly sterility.

How can I prevent chlamydia infection?

The best way to avoid getting chlamydia is to always practice safer sex; for example always use a condom when you have vaginal, anal or oral sex.

Can I become reinfected?

Yes - you risk becoming reinfected with chlamydia each time you have unprotected sex.

Should I get tested again after treatment?

Yes, you should. It is recommended to test again for chlamydia three months after treatment. If any symptoms become noticeable in the meantime you need to seek advice.

More information about chlamydia can be found on the Queensland Health website at https://www.health.qld.gov.au/sexhealth/factsheets.shtml

Information for Study participants

Evaluation of home sampling for Chlamydia trachomatis infection

What is the Queensland Health Chlamydia Testing Trial?

The Queensland Chlamydia Testing Trial is a joint project between Queensland Health, the Australian government and James Cook University. The project aims to evaluate the acceptability and effectiveness of the mailing of self collected samples for a Chlamydia test.

How do I participate in the trial?

A kit has been developed to provide information about how to participate in the trial. It is important that you read the information in the kit carefully.

You may also want to talk to a friend or family member before deciding to participate.

If you do decide to participate in the trial after reading this information, simply follow the test instructions contained in this kit, complete the questionnaire (optional) and post the completed prepaid package at any Australia Post mailbox.

Alternatively you can choose to go to your GP or to a Sexual Health Clinic and request a test.

Participation in the study is entirely voluntary. If you wish, you can use an alias. No identification is required to receive this service.

Whether you participate in the study or not will in no way affect the health care you receive!!

Do I need to give consent to participate?

Signing the consent section of the questionnaire means you agree to participate in the trial and for Queensland Health to use your information to evaluate this project. This information will help us to find out whether home testing for chlamydia is an effective way for people who don't have easy access to a GP or sexual health service to be tested for chamydia. It will also help determine whether the program should be introduced throughout Queensland and other states.

Signing the consent form gives us permission to use the following data: (date of test, type of specimen, suburb of residence, age, gender, ethnicity, symptomatic status, test result, gender of partner, use of condoms, number of partners in past three months, previous diagnosis of chlamydia plus all your answers to Part B of the questionnaire).

If you do decide to complete all or some of the questionnaire, all information provided will be treated as strictly confidential, and not linked to any other medical record held by Queensland Health. No names or personal details will be included in any reports or evaluations, and all data will be held securely by Queensland Health for ten years after which it will be destroyed.

A summary report of the project will be placed onto the Queensland Health Sexual Health website at the end of the project.

How can I find out more about the Queensland Health Chlamydia Testing Trial?

If you have any questions regarding your participation in this trial, or about completing this questionnaire you can contact the Trial Centre on 1800 895544.

Information about the trial can also be found on the Queensland Health website at www.health.qld.gov.au/chlamydia

NB: This project has been approved by the Institutional Ethics Committee of the Townsville Health Service District and the Human Ethics Committee at James Cook University. If you have any questions please contact Monika Bühner Skinner (1800 895544). If you have any ethical concerns about the way the project is conducted then please contact either the THSD Institutional Ethics Committee through Dr Andrew Johnson (07 4796 0623) or the JCU Ethics Committee through Ms Tina Langford (07 4781 4342).

Appendix 6.3. Questionnaire Page 1

PEE IT, PACK IT, POST IT!

Chlamydia testing trial

QUESTIONNAIRE

TELEPHONE
1800 895 514

INTERNET
www.health.qld.gov.au/chlamydia

Kit Contents

1. Paperwork

a. Welcome letter
b. Information (white)
c. Questionnaire (yellow)
d. Your unique number on business card

2. Red ziplock bag containing:

a. Instructions
b. Yellow topped jar, orange capped tube, blue capped tube
c. Plastic dropper
d. Cotton bud
e. Card board box
f. Pathology request form

Queensland Government
Queensland Health

Questionnaire Part A -
Your details for our records

A1. Date ____/____/____

A2. Gender? ❑ Male ❑ Female

A3. Date of Birth ____/____/____
dd mm yyyy

A4. Town or suburb you live in?

A5. Are you: of Aboriginal/Torres Strait Islander or South Sea Islander heritage? ❑ No ❑ Yes

A6. Do you think that you are at risk of having chlamydia?
❑ Yes, why? ❑ New partner in past 3 months
❑ Don't use condoms all the time
❑ Other:

❑ No - why not:

A7. Have you ever been tested for chlamydia?
❑ No ❑ Don't know ❑ Yes (approximately when)
Month____ Year____

A8. Have you ever had Chlamydia?
❑ No ❑ Don't know ❑ Yes (approximately when)
Month____ Year____

A9. Have you experienced any pain when you urinate or any unusual discharge from your penis or vagina in the past months?
❑ No ❑ Yes

A10. How often do you use condoms properly (meaning no genital contact before condom is on)?
❑ Hardly ever or no: at all ❑ Less than half of the time
❑ More than half of the time ❑ All the time

A11. How many persons have you had sex with in the past 3 months?
____Male ____Female

A12. Would you like us to contact you for retesting in the future if you test positive for chlamydia? ❑ Yes ❑ No

Please turn over >>>

Questionnaire Part B - What do you think of the kit?

B1. How did you find out about the chlamydia home testing kit?
❑ From the staff where the kit was given to me
❑ Poster where I picked up the testing kit
❑ Poster in other location ❑ Newspaper ❑ Radio
❑ Someone else told me ❑ Other – please specify

_____

B2. What made you decide to use this test kit for chlamydia?

_____

B3. Is the information sheet in the testing kit clear and understandable?
❑ Yes ❑ No - please specify:

_____

B4. Are the instructions for taking a sample clear and understandable?
❑ Yes ❑ No - please specify:

_____

B5. Would you recommend this way of testing for chlamydia to a friend? ❑ Yes ❑ No, why not?

_____

B6. Would you use this testing kit again if the need arose?
❑ Yes ❑ No, why not?

_____

B7. Would you have done a chlamydia test anyhow?
❑ Don't know ❑ Definitely not ❑ Maybe ❑ Definitely yes

B8. If you answered yes/maybe to Question B7, where would you have gone to be tested? ❑ Don't know ❑ GP
❑ Sexual Health Service ❑ Hospital
❑ Family Planning Clinic ❑ Other - please specify:

B9. Can we contact you in the future about your experiences with home testing for chlamydia? ❑ Yes ❑ No

How Can We Contact You?

Once your results are available we will need to contact you.
These details will not be stored as part of your clinical record and are optional.

❑ Home phone ❑ Mobile phone ❑ SMS text
❑ Email ❑ Mail

Please print the necessary information below:

Name: _____

Phone or Mobile: _____

Address: _____

_____

Email: _____

Alternatively:

If you don't want to provide us with contact details, 10 days after you post the sample please ring **1800 895544** for your results.

You will need to quote the unique test number included in your kit.

Please ensure you store this number safely as results will not be provided over the phone without it.

Have you put the date and your date of birth on the Pathology request form? Thank you for participating.

Consent to use this Data

I have read the instructions included in this kit and acknowledge that:

Declining to participate in the study or withdrawing at any stage from the study will not affect in any way the provision of health services to me now or in the future.

My participation in the study is voluntary and that I am free not to participate.

I have received an information sheet that explains the nature and purpose of this study, and how the data I provide will be utilised and stored.

I have had the opportunity to discuss taking part in the study with a family member/ friend.

I understand and agree to the use of the data for research as outlined in the information sheet.

I also understand that such information will be held conficentially, that it will not be possible to identify me from any of the information collated, and that only summary data will be published.

Data held on me will not be linked to any other Queensland Health record on me that may exist, and all records of this study will be destroyed after 10 years.

I understand that I can contact the stucy centre on 1800 895544 if I have any questions prior to participation in this study, or when completing this questionnaire.

Name_____
Please Print

Signature_____

Date _____/ _____/_____

Appendix 6.5. Welcome Letter

Welcome to the Queensland Health Chlamydia Testing Trial

This is your opportunity to have a private and confidential test for chlamydia and to receive the results in the way that you choose.

This project is a joint initiative between Queensland Health and the Australian Government. It aims to trial new Queensland technology that allows self collected samples for a chlamydia test to be mailed to a laboratory. If successful, the project may be introduced across Queensland and other states and lead to changes in sexual health testing practices.

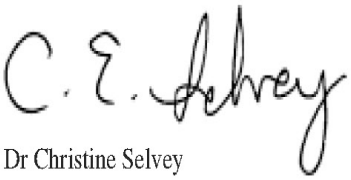
Chlamydia is the most common bacterial sexually transmissible infection (STI) in Queensland with more than 11,700 cases notified during 2006. Most infections are found in young people between the ages of 15 and 29.

Chlamydia often has no signs or symptoms and if left untreated can cause serious health problems including infertility. Once diagnosed, chlamydia can easily be treated and cured.

This kit provides you with all the necessary components to take part in the trial. Please read the information contained in the kit carefully before participating.

For more information about the trial visit the Queensland Health website at www.health.qld.gov.au/chlamydia or call the Trial Centre on 1800 895 544.

Yours sincerely



Dr Christine Selvey
Senior Director
Communicable Diseases Branch
08/05/2007

Office	Postal	Phone	Fax
Queensland Health 147-163 Charlotte Street BRISBANE QLD 4000	GPO Box 48 BRISBANE QLD 4001	(07) 3234 1152	(07) 3234 0057

Appendix 6.6. Pathology Request Form

Queensland Health Pathology & Scientific Services (APA) Request Form

CHLAMYDIA TESTING TRIAL

33854-3036

Clinical Trial & Commercial

UR Number CTT2100

Surname

Given Name

D of B __/__/__

Sex F M

Patient Address

P/code

Ph:

HCF TNSHS

From Ward CTT

Results to Ward/Clinic

Consultant MENA~TNSHS

Requesting Practitioner SKIM~TNSHS

Surname Initials

Signature

Date / /

Extra Copies To: Dr

Address

Extra Copies To: Dr

Address

LABORATORY USE ONLY

Rec'd Time

Sig

ALL collectors must complete

Fasting Y☐ N☐ Time hrs

Date __/__/__

Collector Code

Signature

Tests Requested (State Specimen Type and Site)

Urine / Swab

Chlamydia PCR

LAB USE ONLY

CHLPCR

EDTA

HEPA

SST

CITRA

ESR

7ml ED (Blood

FL O

Blood Cultu

GAS

Tissu Swa

Community Screen

Lab + UR = 2 forms of ID

BILLING CATEGORY COM

Appendix 6.7. Unique Number Card

Your Unique Number

Ph: 1800 89 55 44

Please phone after 2 weeks if you have not received your results

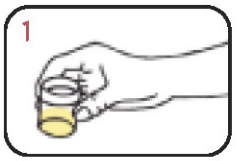
Keep this card in a safe place

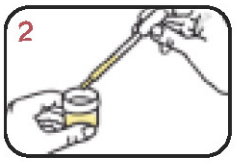
www.health.qld.gov.au/chlamydia

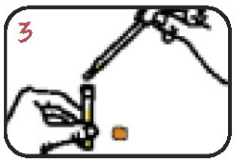
Appendix 6.8. Instructions for testing a sample-Urine

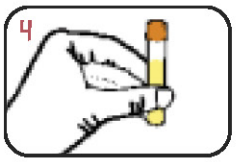
Instructions For Collecting And Mailing Your Sample

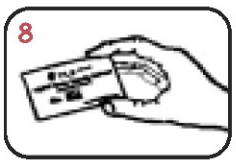
1. Urine Test – Men or Women











1 Half fill the yellow top jar with urine.

2 Remove the plastic dropper (bubble topped device) from the packaging and squeeze the 'bubble' firmly to draw up a urine sample.

3 Squeeze the 'bubble' again to squirt the sample into the orange topped tube (the one containing the crystals).

4 Wait for a minute... (the crystals will turn into a gel) then screw the orange top back on securely.

Empty any urine left in the yellow top jar down the toilet.

5 Place the tube containing the gel inside the white cardboard box (to help protect it during postage) and close securely.

Please complete the paperwork:

a) write your date of birth and the date when you take the sample on the pathology request form (in front pouch of red zip-lock bag),

b) fill in the questionnaire (optional),

c) sign the consent form.

6 Place the cardboard box containing the sample inside the red zip-lock bag and press seal.

7 Put the red zip-lock bag and the yellow questionnaire into the prepaid plastic envelope and post from any Australia Post post-box within 5 days of taking the sample.

8 If you didn't provide us with your preferred contact details then you should contact the clinic after 2 weeks on 1800 895544 to ask for your results.

Store the business card with the phone number and your unique test number in a safe place until that time.

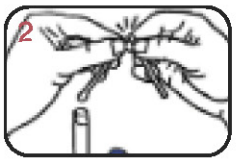
Appendix 6.9. Instructions for testing a sample-Vaginal

Instructions For Collecting And Mailing Your Sample

2. Vaginal Swab Test

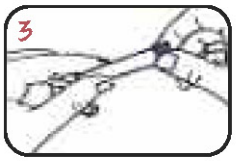
For women who prefer not to provide a urine sample, a swab of the vagina is an acceptable alternative.

1 Remove the plastic cotton bud from its packaging and gently insert the cotton tipped end into your vagina (about as far, and in the same way as you would insert a tampon.) Leave it there for ten seconds.



Remove and place the cotton bud into the empty blue topped tube (not the one with the crystals).

2 The cotton bud will be too long, so just break off the handle to make it fit into the tube.



3 Screw the blue cap back on securely.

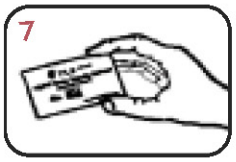
4 Place the tube containing the cotton bud inside the white cardboard box (to help protect it during postage) and close securely.

Please complete the paperwork:
a) write your date of birth and the date when you take the sample on the pathology request form (in front pouch of red zip-lock bag),
b) fill in the questionnaire (optional),
c) sign the consent form.

5 Place the cardboard box containing the sample inside the red zip-lock bag and press seal.

6 Put the red zip-lock bag and the yellow questionnaire into the prepaid plastic envelope and post from any Australia Post post-box within 5 days of taking the sample.

7 If you didn't provide us with your preferred contact details then you should contact the clinic after 2 weeks on 1800895544 to ask for your results.



Store the business card with the phone number and your unique test number in a safe place until that time.

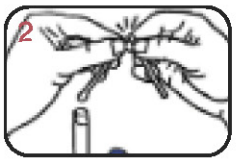
Appendix 6.10. Instructions for testing a sample-Anal Swab

Instructions For Collecting And Mailing Your Sample

2. Anal Swab Test

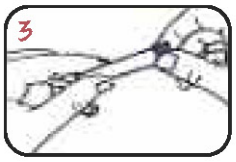
Chlamydia can also be found in the anus. If you have been the receptive partner of unprotected anal intercourse you may wish to also provide an anal swab for testing

1 Remove the plastic cotton bud from its packaging and gently insert the cotton tipped end into your vagina (about as far, and in the same way as you would insert a tampon.) Leave it there for ten seconds.



Remove and place the cotton bud into the empty blue topped tube (not the one with the crystals).

2 The cotton bud will be too long, so just break off the handle to make it fit into the tube.



3 Screw the blue cap back on securely.

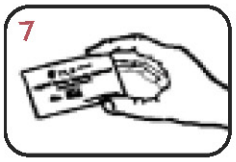
4 Place the tube containing the cotton bud inside the white cardboard box (to help protect it during postage) and close securely.

Please complete the paperwork:
a) write your date of birth and the date when you take the sample on the pathology request form (in front pouch of red zip-lock bag),
b) fill in the questionnaire (optional),
c) sign the consent form.

5 Place the cardboard box containing the sample inside the red zip-lock bag and press seal.

6 Put the red zip-lock bag and the yellow questionnaire into the prepaid plastic envelope and post from any Australia Post post-box within 5 days of taking the sample.

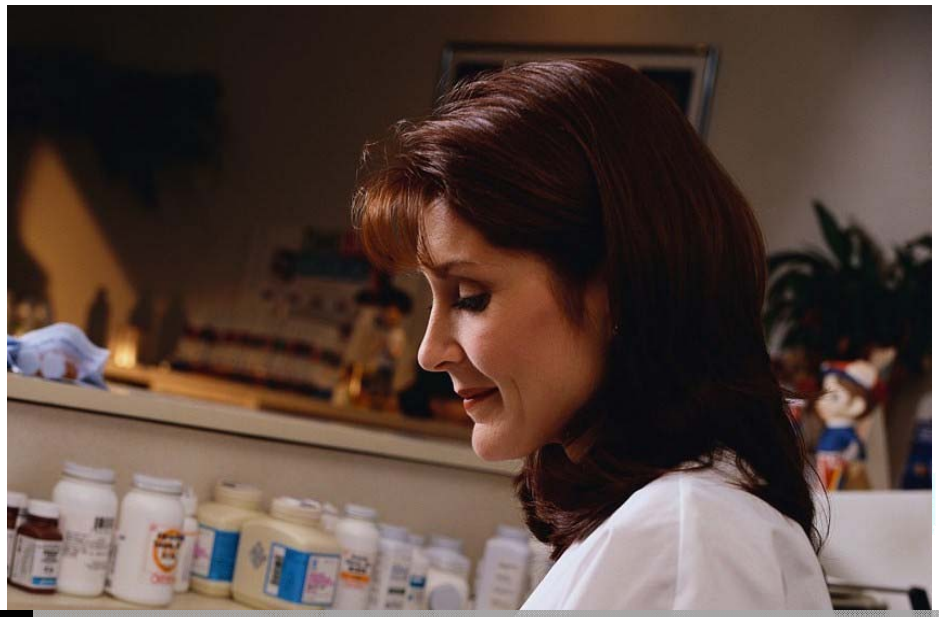
7 If you didn't provide us with your preferred contact details then you should contact the clinic after 2 weeks on 1800895544 to ask for your results.



Store the business card with the phone number and your unique test number in a safe place until that time.

Appendix 7. University of Queensland Report

2008



FINAL REPORT

CHLAMYDIA SCREENING PILOT PROJECT

The School of Pharmacy
THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Executive Summary

Introduction: This study represents the third arm of Phase 2 of the Chlamydia Pilot Program, funded by the Commonwealth Department of Health and Ageing. A major trial of the distribution of Chlamydia specimen collection kits was conducted in Boots pharmacies in London in 2005, the success of the trial suggesting that Australian pharmacies may be suitable screening and distribution centres for such kits.

Aims: The aims of this sub-study were twofold: to determine the utility of community pharmacies as a distribution site for Chlamydia specimen collection screening kits, and to determine the efficacy of questionnaire-based screening in pharmacies, accompanying the distribution of specimen collection kits, in identifying Chlamydia-positive individuals. The latter had not been tested in the London trial.

Method: Four Queensland pharmacies, three located in metropolitan areas (Brisbane City, Fortitude Valley, Redbank Plains) and one in a regional centre (Yeppoon) participated in the pilot project. Each pharmacy was issued 75 Chlamydia specimen collection kits, developed in Phase 1 of this study, for distribution over an eight-month period. A screening questionnaire was customised with reference to risk factors reported in the literature, for self completion in the pharmacy by each client receiving a specimen collection kit. Distribution and return data were monitored, and positive test results were matched with retrieved screening questionnaire data. Pharmacies were paid $500 each for their participation. Pharmacy staff provided qualitative feedback at the conclusion of the study.

Results: The total number of kits distributed was 156 (of 330), ranging from 1 to 75 per pharmacy, with 18 specimens received for testing (11.5%). The number of screening questionnaires retrieved from the pharmacies was 44 (28.1% of the number of kits distributed). Analysis based on scoring of the risk-screening questionnaire indicated that 16 of the participants (36.6%) were predicted as 'at-risk' of testing positive for Chlamydia. Pathology data indicated that 4 of the specimens (22.2%) tested positive. The risk-screening questionnaire predicted the Chlamydia-positive individuals in 50% of cases.

Discussion: Despite willingness by pharmacy staff to be involved, the provision of a financial incentive, and training and contact by the project officer, variable participation between study pharmacies was evident, suggesting that future use of pharmacies as distribution sites for Chlamydia specimen kits be an opt-in service with minimal requirement of pharmacy staff to explain the use of kits or conduct risk screening. A key staff member per pharmacy is recommended to 'drive' the distribution of kits; this might be facilitated by advertising of the importance and features of the service. The efficacy of the risk-screening questionnaire was satisfactory, in that 50% of the Chlamydia-positive cases were able to be predicted by the questionnaire; however, with a more heterogeneous sample, the efficiency of screening via questionnaire is expected to increase. The questionnaire may be trialled in other specimen kit distribution sites; if equally favourable, it could offer a cost-effective method for targeted distribution of the kits to individuals at greatest risk of positive diagnosis.

Introduction

Chlamydia was the most frequently reported sexually transmitted condition in Australia in 2004, with 35,189 diagnoses. Recent studies have suggested that the number of people infected each year is on the increase.[1]

Every sexually active person is at risk of contracting Chlamydia. However, the risk is higher among sexually active young people with multiple partners. Up to 90% of women and 50% of men have no symptoms, so most people infected are not aware of their infection and may not seek health care. The true prevalence of the disease today is likely to be much greater than the figures above.

Once diagnosed, Chlamydia can easily be treated and cured. If left untreated, Chlamydia can cause serious health problems. Some studies suggest that 10-40% of untreated Chlamydial infections may progress to pelvic inflammatory disease (PID), which can lead to chronic pelvic pain, salpingitis (inflammation of the fallopian tubes), ectopic pregnancy, and infertility.

Community-based screening is a method of identifying diseases in people who do not have any signs of symptoms of the disease and would not routinely have sought diagnosis. High volume testing, with treatment and follow-up of Chlamydia-positive individuals and their sexual contacts, is essential to reduce prevalence rates among young sexually-active populations.

Pharmacy-based distribution of Chlamydia specimen kits has been trialled in over 200 Boots pharmacies in London in late 2005,[2] and is now an ongoing service at a cost of £25 per kit (approximately AUD$54). The Boots model involves urine specimen kits, which are then returned to the pharmacy for sending to the pathology lab where clients receive their results within 7 days from when they sent the specimen. It was reported that over 6000 kits were distributed in the first month of the trial.[3] In Australia, Taylor and colleagues (2007) administered surveys to 25 pharmacists and 50 females to ascertain the acceptability of a Chlamydia screening program in community pharmacies. Data indicated that 84% (21 pharmacists) supported a pharmacy-based Chlamydia screening program and indicated that they would be comfortable providing the kit (92%), counselling results (88%) and providing antibiotics (80%). The responses from the female respondents indicated that a large portion (76%) would accept and return a sample. Together, these responses strongly indicate that a Chlamydia screening program in community pharmacies would be well received.

Combined, these studies suggested that there is potential for further development and trial of pharmacy involvement in Chlamydia testing services for the Australian community.

This study aims to report how well pharmacies serve as distribution sites for specimen collection kits for Chlamydia and how accurately a self-completed risk-screening questionnaire (issued by the pharmacy staff upon handing out the kit) can predict the laboratory test results for Chlamydia. The study was conducted by two School of Pharmacy researchers, Drs Lynne Emmerton and Lisa Nissen, and a part-time Project Officer, Elliroma Gardiner, as the third arm of Phase 2 of the Chlamydia Pilot Program, funded by the Commonwealth Department of Health and Ageing. Study materials were supplied in part via the parent project, with the remainder (questionnaires, training materials) custom designed for this arm of the study. An itemised account of all expenditure incurred is provided as part of the study final financial report in Appendix A (Expenditure).

Method

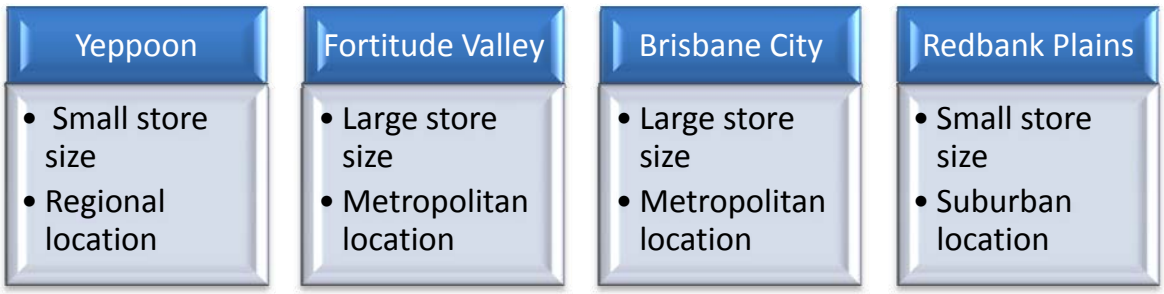
Ethical Approval:

The conduct of this sub-study was approved by The University of Queensland Human Research Ethics Committee (approval number 2006000396).

Participants:

Four pharmacies were selected to represent a range of locations and socio-demographic descriptors of their clientele. Common in the selection of the pharmacies was the attempt to offer this service to sectors of the community who may otherwise not have the opportunity to be tested for Chlamydia. The managers of the four pharmacies were formally approached by the researchers to request their participation in the pilot project (Appendix B); each gave signed informed consent for their pharmacy's participation. Each pharmacy received 75 kits to distribute to eligible customers over an eight-month period. The pharmacy size, number of staff as well as store location varied from site to site (Figure 1).

Figure 1: Study Sites



Materials:

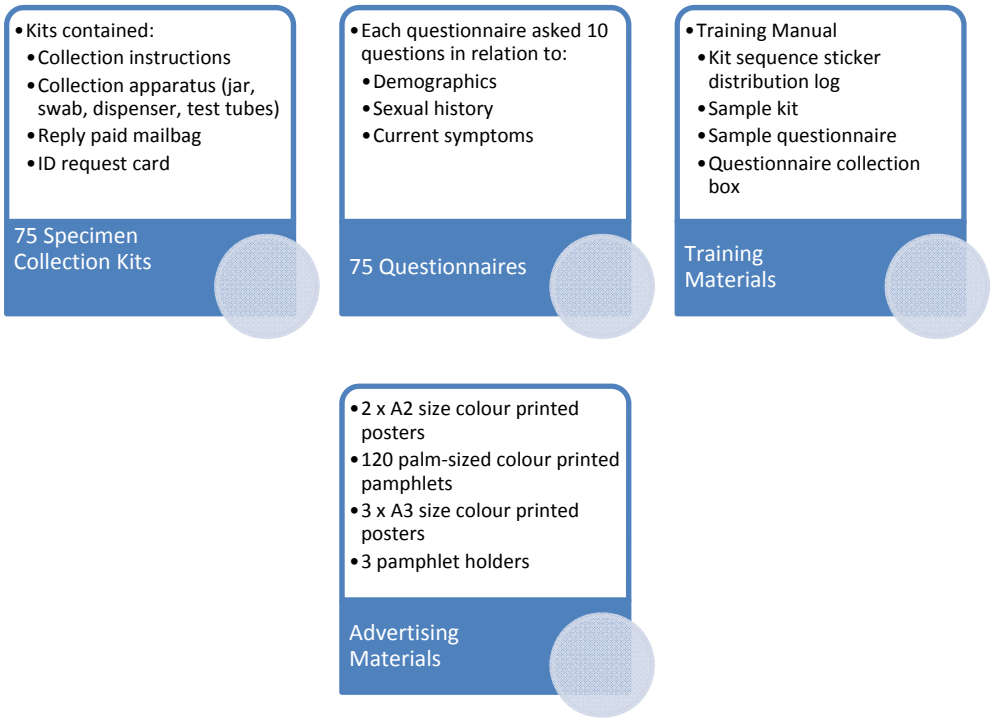
A screening questionnaire (Appendix C) was customised with reference to risk factors reported in the literature[4-7] for self completion in the pharmacy by each client receiving a specimen collection kit. The questionnaire was reviewed by the chief investigator of the parent project. Respondents were identified by code number matching the code number on the specimen collection kit.

Training materials were prepared for the pharmacies, and consisted of information about the project and summaries of relevant literature reporting prevalence and risks associated with Chlamydia. The materials were intended as support for the pharmacy staff to confidently discuss aspects of the project and disease with clients. Study materials (demonstration kit, and kits and questionnaires for distribution) were also supplied.

Advertising materials were supplied via the parent project, and consisted of posters and pamphlets for in-store display (Figure 2). External advertising was not part of this study protocol, to restrict kit distribution to eligible clients identified by pharmacy staff rather than requested by clients.

The specimen kit is described in more detail in the report from Phase 1 of the parent study.

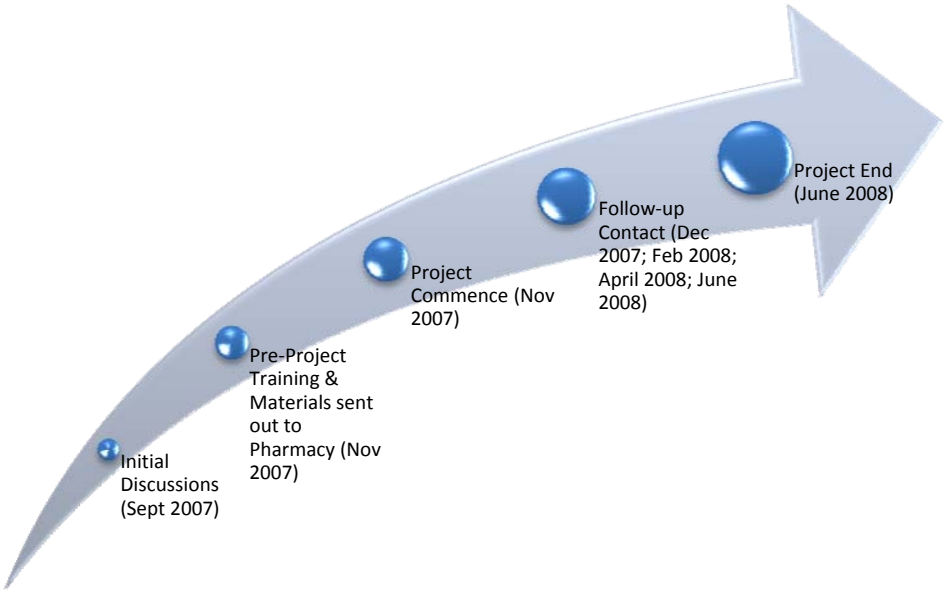
Figure 2: Study Materials



Timeline:

Each pharmacy was phased in to the study to facilitate training. Collectively, the study was conducted over a period of 9 months (Figure 3). Ethical approval for this arm of the project was granted by the Medical Research Ethics Committee and Behavioural and Social Ethical Review Committee of The University of the Queensland in June 2008.

Figure 3: Study Timeline



Pre-Project Training:

Shortly after confirming pharmacy involvement in the pilot project, each pharmacy manager was contacted by the Project Officer and preliminary training materials were delivered for perusal. Follow-up face-to-face training was then carried out in each pharmacy (except the Yeppoon store) with the store manager and pharmacy dispensing staff. Training for the Yeppoon store consisted of face-to-face training by the Project Officer to the Yeppoon pharmacy owner who then relayed the information to the store manager. Additional training for the manager was carried out by the Project Officer via telephone and email correspondence.

Preliminary training was carried out as per the Training Manual. The training session was a 35-minute training program that was designed to provide trainees with all the information required to complete this arm of the pilot project. Teaching methods and activities employed the techniques of advanced organisers, part- and whole-task training and guided feedback.

Additional training was required for the Fortitude Valley and Redbank Plains locations to accommodate for new employees taking part in the project. Training in both cases was provided in a face-to-face format.

Recruitment Procedure:

Pharmacy staff were advised to approach eligible clients to take part in the pilot (Figure 4).

Figure 4: Inclusion Criteria

No signed consent was required of clients, due to the anonymity of the study. Approached clients who expressed interest in receiving a specimen collection kit were given a questionnaire and kit with a matching serial number. The pharmacy staff retained a copy of the serial number for the sequence log and recorded the date of distribution. The client was then taken to a quiet area of the pharmacy to self complete the questionnaire. The completed questionnaire was then placed in the sealed questionnaire collection box kept at the pharmacy by either the client or staff member. The client then took away the kit to collect his/her specimen. Instructions and packaging in the kit facilitated postage of the specimens to the pathology lab for testing. Since the samples were only identifiable via a unique code number, it was the responsibility of the client to follow-up his/her test result. Results were available from the public health nurse after a period of 2 weeks from sending the sample. Participants who tested positive for Chlamydia were provided with treatment information by the nurse.

Results and Discussion

Quantitative Data:

Table 1: Distribution and Return Data

	Yeppoon	Redbank Plains	Fortitude Valley	Brisbane City	Total
Kits distributed to sites	75	75	75	75	330
Kits distributed to customers	1	15	65	75	156
Kits recorded on log as distributed to customers	1	9	41	9	60
Questionnaires returned to Pharmacy	1	3	31	9	44
Specimens received by lab	1	3	9	5	18
Inhibited results	0	0	3	0	3*
Positive results	0	0	1	3	4
Negative results	1	3	5	2	11

*New samples were collected from all 3 participants, and for each participant their retest was negative.

Questionnaire Data

Further data analysis will focus on questionnaire data. As can be seen from the table above, there is some variability in terms of the number of kits distributed, questionnaires collected and samples received. This discrepancy suggests that future ventures should work on improving procedural compliance by pharmacy store staff when distributing kits and enlisting techniques to increase the motivation of participants to ensure that they send the specimen kits to pathology.

Demographics

Of the 60 kits distributed to participants, 44 participants returned partially or fully complete questionnaires. Of these 44 participants, 41 were female and 3 were male. The ages of participants ranged from 16 to 48 (mean 25 years; SD=6.0). A majority of participants (63.6%) had attained either TAFE or Tertiary qualifications, with the remaining participants having either completed only Year 12 (29.5%) or Year 10 (4.5%). Only a very small portion of the sample (2.3%) had less than a Year 10 education. Given these age and education statistics, it is unsurprising that a large number of the participants were either studying at TAFE/Uni (part-time 2.3%; full-time 22.7%) or working (full-time 61.4%; part-time 11.4%).

It should also be noted that no participant in this study reported identifying as Aboriginal or Torres Strait Islander.

Sexual History

Males

Of the 3 males who participated in the study and returned questionnaires, 2 reported sexual relations with 2-4 female partners, and 1 reported having sex with more than 4 female partners in the past 12 months. One of these males, along with another male, also reported to sexual relations with ≥1 males in the last 12 months. Only 1 of these participants had not been previously tested for Chlamydia and all 3 had reported not having Chlamydia before. Condom use amongst this sample was reported as either less than half the time (2 participants) or more than half the time but less than all the time (1 participant).
Two participants reported suffering from either discharge from the penis (1 participant) or painless lumps around their genitals (1 participant). One of the male participants tested positive for Chlamydia – these results are further examined below.

Females

Of the females who participated in the study and returned questionnaires, 18 (43.9%) reported sexual relations with 1 male within the last 12 months, 9 (22%) with 2-4 male partners, and 10 (24.4%) with more than 4 males. Only 2 females (4.9%) reported having sex with female partners within the past 12 months (frequency in both cases was 2-4). A majority of female participants (23 participants, 56.1%) had been tested for Chlamydia before, and whilst a majority (28 participants, 68.3%) had not previously had Chlamydia, the remaining female participants were either unsure (7 participants/17.1%) or knew that they had previously contracted this STI (6 participants, 14.6%).
23 participants (56.1%) reported having at least 1 of the listed symptoms in the past 12 months, and 11 of these 23 females reported having 2 or more symptoms. The most frequently reported symptom was unusual vaginal discharge (14 participants, 60.8% of those females experiencing symptoms) and the second most commonly reported problem (11 participants, 47.8% of those females experiencing symptoms) was burning while urinating.

Use of questionnaire data for calculating those at risk

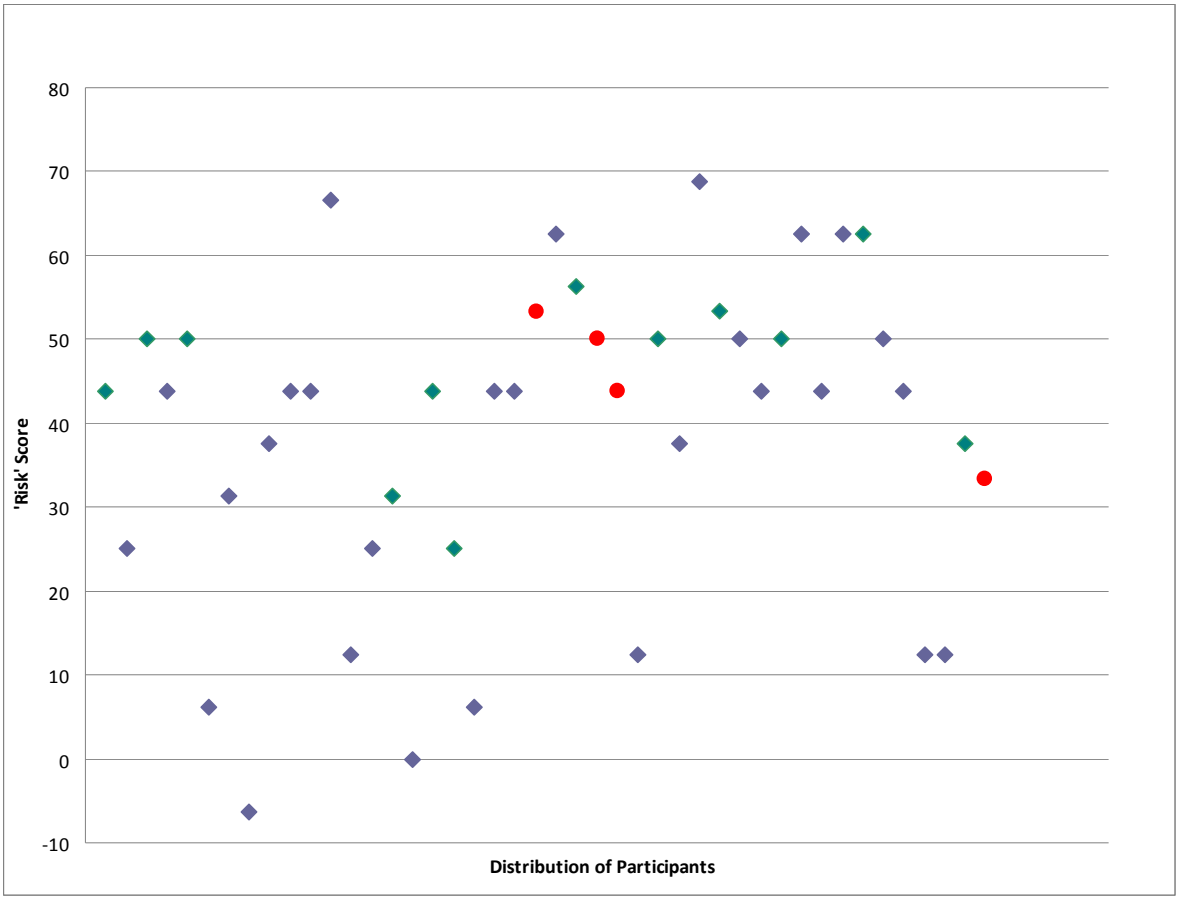
Relevant variables in the questionnaire were used to calculate a 'risk' score for each participant. This score is thought to be a crude estimate of the likelihood that a participant will have Chlamydia, that is, the higher the score, the more they are at-risk. Table 2 below shows the scores attributed to each risk factor as well as protective factors. Variables relating to male and female symptoms differed in number, so scores for these groups were presented as percentages. We decided that a score greater than 40 (ie 40% of the maximum possible score for that gender) indicated significant risk. Demographic variables (education, occupation and age) were not included in the risk score calculation due to the homogeneity of the sample.

Table 2: Risk Score calculation

Question	Score	Bonus Point	Total
How many different people have you had sex with in the past 12 months?	None = 0 points One partner = 1 point Two to four = 2 points More than four = 4 points	An extra point was added for bisexual activity, due to risk-related behaviour	For females – Out of 5 For males – Out of 5
Have you ever been tested for Chlamydia before?	Yes = 1 point No = 0 points Don't know = 0 points		For females – Out of 1 For males – Out of 1
Have you ever had Chlamydia before?	Yes = 1 point No = 0 points Don't know = 0 points		For females – Out of 1 For males – Out of 1
How often would you use a condom properly?	Hardly ever, or not at all = 4 points Less than half the time = 3 points More than half of the time = 2 points All the time = -1 point (considered a protective factor)		For females – Out of 4 For males – Out of 4
Have you had any of the following problems in the past 12 months?	For Females: An unusual discharge from the vagina; Burning when you urinate; Painful sores or blisters around your genitals; Painless lumps around your genitals; Pain in your lower regions (not period pain); Pain during sex = 1 point awarded per symptom. For Males: Discharge from your penis; Burning when you urinate; Painful sores or blisters around your genitals; Painless lumps around your genitals; Swollen and/or painful testicles = 1 point awarded per symptom.		For females – Out of 6 For males – Out of 5
		Total score x 100%	Out of 16 for Females Out of 15 for Males

Figure 5 displays the scatter plot of all the questionnaire data. The data points in red indicate those participants who returned positive samples to pathology. The green data points indicate those who returned negative samples and the blue points are for those participants who did not return samples to pathology. Analysis of the risk-screening questionnaire indicates that 16 of the participants (36.6%) were predicted as being 'at-risk' of testing positive for Chlamydia. It is interesting to note that 2 of the 4 participants (50%) who returned positive samples had 'risk' scores of 50 or greater. It is expected that this questionnaire may prove to be more effective in screening participants if administered to a larger and more diverse sample, as other scores based on education, occupation and age may add to its efficacy. It is also interesting to note that pathology samples were not received from 5 of the 6 participants (83.3%) who had very high risk scores (≥63). Future research should be aimed at examining factors that may increase study compliance by those who are at higher risk of testing positive for Chlamydia.

Figure 5: Distribution of Risk Scores



- Indicates positive pathology results
- Indicates negative pathology results
- Indicates no pathology results received

Questionnaire data for those tested positive

Table 3 displays the questionnaire data for the 4 participants who tested positive. Some interesting observations are made. Firstly, each participant had been previously tested for Chlamydia. Secondly, each participant had been with multiple (2 or more) partners within the past 12 months; finally, only 1 of the 4 positive participants reported using condoms with every sexual encounter. It is also interesting to note that all 4 of these females were aged under 23 years.

Although the generalisability of these data is limited by the small sample size of positive cases, trends were noted in line with previous studies regarding age, unsafe sexual practices and multiple partners.[4-7]

Table 3. Questionnaire responses for positive participants

Question	Participant 1	Participant 2	Participant 3	Participant 4
Location	Brisbane City	Brisbane City	Brisbane City	Fortitude Valley
Sex	M	F	F	F
Age	27.8	21.8	22.8	20.6
Education	TAFE/Uni	TAFE/Uni	TAFE/Uni	Year 12
Occupation	FT Work	FT TAFE/Uni	FT TAFE/Uni	PT TAFE/Uni
Number of M Partners in the past 12 months	Not reported	More than 4	2 - 4	2 - 4
Number of F Partners in the last 12 months	More than 4	Not reported	Not reported	Not reported
Previously tested for Chlamydia?	Yes	Yes	Yes	Yes
Have you ever had Chlamydia?	No	No	Yes	Don't know
Condom use	Less than half the time	Less than half the time	More than half the time (but not all the time)	All the time
What symptoms have you experienced in the last 12 months?	None	None	Burning when urinating	Burning when urinating An unusual discharge from vagina Pain in lower regions (not period pain)
Risk Score	53	50	44	33

Qualitative Data:

From discussions with pharmacy staff involved in the pilot during and following the project, a number of issues were identified as potential barriers to increasing kit distribution numbers. The issues have been arbitrarily classified as follows:

Pharmacy store restrictions: These largely refer to the general busyness of the store, and the opportunity to clearly advertise the study. For example, pharmacy staff at one location revealed that due to the lack of prominent advertising material, they were concerned that their customers were unaware that the pilot study was taking place. Furthermore, staff at all locations explained that they were unable to dedicate as much time to the project as required due to the pharmacy being busy over the Christmas/New Year period. Further, staff of one pharmacy noted lack of opportunity to approach clients who matched the study participant requirements.

Pharmacy staff characteristics:Staff characteristics include the confidence, ability and willingness of pharmacy staff to dedicate their efforts to approaching their customers to participate in this project. For example, a staff member at one location commented on her extreme unease at approaching customers due to the sensitive nature of the target STI. Interestingly, this staff member appeared to be the only staff member at that pharmacy involved in the project, so this may have contributed to her lack of confidence. In contrast, at a different pilot site, two staff members were allocated the project by the store manager to act as 'drivers', and unsurprisingly, they were more willing and confident in approaching customers to partake in the project. It is believed that the enthusiasm of the respective staff member(s) and their approach to clients may have also affected the level of acceptance. No measure of the acceptance rates for the kits was incorporated, and given the variable pharmacy participation in this trial, it is expected to vary from store to store. Anecdotally, however, the acceptance rate in the highest-performing pharmacy was very high, although it should be kept in mind that relatively few specimens were subsequently received for pathology testing. In future studies involving a larger number of distribution sites, data regarding uptake or refusal rates would help guide staff training about the initiative, and consequently, the efficient distribution of the kits.

Customer characteristics*:* Participation in this pilot project was affected by the individual characteristics of the customer, specifically, the awareness of the customer about Chlamydia, their ability to understand the study instructions and compliance with the selection criteria. From comments by the pharmacy staff at all sites, there was some difficulty by a few customers in understanding why the project was being conducted, why they needed to complete the questionnaire and how to collect their specimen. These characteristics did not seem to be unique to any one location. It should also be noted that the selection criteria, approved in the study protocol, required participants to be aged between 16 and 25, fluent in English, sexually active and presenting for a condition or medication relating to sexual health; this predominantly included oral contraceptive pill prescriptions, vaginal thrush medication or emergency hormonal contraception purchases. As the majority of participants were female, it cannot be determined whether the majority of clients meeting the inclusion criteria were indeed female (suggesting a bias in the selection criteria) or whether female clients were deemed more approachable for a topic of a sensitive nature by predominantly female pharmacy staff. As mentioned above, no records of kit refusals were incorporated into the study; it could also be possible that male and female clients were approached in similar numbers, but females were associated with a greater acceptance rate. Research indicates that pharmacy clients are predominantly female (around 60-70%).

Table 4 provides some possible solutions to correct for the aforementioned issues. In summary, the feedback from all participating locations seems to suggest that although the project is worthwhile, the issues mentioned above present some difficulties in providing this screening service as part of a community pharmacy's usual functions. However, most of these issues can be remedied with more comprehensive training and perhaps the use of individual incentives to increase pharmacy staff motivation and involvement.

Table 4: Suggestions to Increase Kit Distribution

Issue	*Possible Solutions*
Pharmacy Store Restrictions	
Store Busyness	*Provision of a self-service facility for distributing screening kits during busy times, dedication of non-busy times for approaching customers/distributing kits*
Clientele type	*Not relevant – the screening project is only applicable to those within a particular demographic*
Advertising	*More posters for in-store display, bag inserts/flyers accompanying purchases of sexual health products, newspaper article, advertising at sexual health clinics*
Pharmacy Staff Characteristics	
Confidence	*Additional training and practice, project 'drivers' assigned at each site, more feedback*
Ability	*Additional training, feedback on technique, 'expert' allocated to a 'novice' to increase learning*
Willingness	*Incentives to individual staff members for participation, further emphasis on the significance of this project*
Customer Characteristics	
Chlamydia awareness	*More information for approached clients, option of reading materials and later collection of kits*

References

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Appendix A – Expenditure

Financial Transaction Report of 424.2236.01 Chlamydia Screening Project Account
CI'S: Dr Lynne Emmerton, Dr Lisa Nissen

Year	Month	Transaction Description	Amount	
2007	October	Research Grant Income	(23,400.00)	
			Total Income	**(23,400.00)**
	ACTUALS			
2007	April	Campus Travel: LNissen Car Rental - Visit to regional site	181.85	
2007	April	Campus Travel: LNissen Accommodation - Visit to regional site	100.00	
2007	April	Campus Travel: LNissen Subsistance Allowance - Visit to regional site	144.40	
2007	April	Printing	82.52	
2007	November	Postage	6.91	
2007	November	Pharmacy Site Participation Fees (Valley, City and Redbank Plains)	1,500.00	
2007	February	Parking Fees	43.64	
2007/2008	April 07- July 07	Salaries - Elliroma Gardiner	6,934.83	
	COMMITMENTS			
2008	June	Pharmacy Site Participation Fee (Yeppoon) Commitment	500.00	
2008	September	Parking Fees and Mileage	80.00	
2008	September	Printing	80.00	
2008	September	Postage	60.00	
2008	September	Salaries - Elliroma Gardiner	2,000.00	
2008	September	Project Management Fees - Lisa Nissen	5,800.00	
2008	September	Project Management Fees - Lynne Emmerton	5,800.00	
			Total Expenses	**23,314.15**
			FINAL BALANCE	**(85.85)**

Appendix B – Letter to Pharmacist

<<Date>>

<<Pharmacy Name>>
<<Address line 1>>
<<Address line 2>>
<<Address line 3>>

Dear <<insert name>>

Re: Chlamydia Screening Program

Many thanks for expressing interest in involving your pharmacy in the Chlamydia Screening Program. As previously mentioned, this is an initiative of Queensland Health, and is funded by the Australian Government Department of Health and Ageing. This program involves the distribution of Chlamydia specimen collection kits to various target groups. The arm of the study targeting pharmacy clients through community pharmacies is being managed by Dr Lynne Emmerton, Dr Lisa Nissen and Ms Elliroma Gardiner (Project Officer) of the University of Queensland's School of Pharmacy.

This is a project that is of particular importance to community pharmacists. We believe that community pharmacists are ideally placed to assist in the detection, education and referral of individuals at elevated risk of Chlamydia and have the potential to make a very major contribution to health promotion and health education. We see this project as a catalyst for further research and development of products and services carried out by community pharmacists in treating a wide variety of conditions.

Please find enclosed a resource cd containing information about the project aims and some background material. The background material presented is an overview of the literature available, and is not required reading to participate in the project.

Within the next few weeks, Ms Elliroma Gardiner (Project Officer) will contact you to arrange a time for a brief visit to speak with you and your staff about the operational aspects of the project.

Should you have any questions regarding the cd content or the project, please do not hesitate to contact any of the team listed below. We look forward to working with you on this project over the coming months.

Kind regards

Dr Lisa Nissen
Lecturer
Tel: 07-3365 2868
Email: l.nissen@pharmacy.uq.edu.au

Dr Lynne Emmerton
Senior Lecturer
Tel: 07-3365 8280
Email: l.emmerton@pharmacy.uq.edu.au

Ms Elliroma Gardiner
Project Officer
Tel: 0414 388 135
Email: elli@pharmacy.uq.edu.au

Are you at risk?

We're helping young adults find out if they carry Chlamydia.

What's the problem?

Chlamydia is a very common infection that's passed on when people have sex. Most people who have it don't know that they do, so it was probably given to them and could have been passed on further without knowing.

The good news is it can be easily tested for, and then easily treated using a course of antibiotics. If you have it and don't know about it, it could cause you problems later on when you're trying for a baby. It's best to know about it as early as possible and get rid of it, then safe sex should stop you catching it again.

Queensland Government

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

#

Pharmacy Stamp

What are you doing here?

This pharmacy is involved in University research that asks them to hand out Chlamydia test kits to people aged 16-25 who've ever had sex.

All you have to do is:

1. Take your kit home
2. Follow the instructions to either take a urine (pee) sample or swab from your vagina (girls only, of course)
3. Fill out the form, and
4. Simply send it all off to the lab for testing.

You'll then be contacted by a Public Health Nurse and told whether you do or don't have Chlamydia. If you do have it, the Nurse will tell you what to do next.

Before you get your kit, please answer this checklist of questions here in the pharmacy. You don't have to give any information that you don't want to give. However, **it's all done without giving your name or contact details**, so there's no need to worry about having a 'record' in the pharmacy. The pharmacy is giving out 75 of these, so you're one of many who'll be answering these questions. The questions are simply for the researchers to work out how easy it is to guess on paper whether someone does or doesn't have Chlamydia.

Ready? Please continue …

1. Are you .... Male ○ Female ○

2. What is your age?

years | months

3. What is your highest level of education?

Less than Year 10 ○ Year 12 ○
Year 10 ○ TAFE/Tertiary ○

4. What is your current occupation?

High school student ○
Full-time tertiary (Uni, TAFE) ○
Part-time tertiary (Uni, TAFE) ○
Unemployed ○
Full-time employed ○
Part-time employed ○
On a pension or benefit ○

5. Do you identify as Aboriginal or Torres Strait Islander?

Yes ○
No ○

6. How many different people have you had sex with in the past 12 months?

	Male Partners	Female Partners
None	○	○
One	○	○
Two to four	○	○
More than four	○	○

7. Have you ever *been tested for* Chlamydia?

Yes ○
No ○
Don't know ○

8. Have you ever *had* Chlamydia?

Yes ○
No ○
Don't know ○

9. How often would you use condoms properly?
By this, we mean no genital contact before the condom is on.

Hardly ever, or not at all ○
Less than half of the time ○
More than half of the time ○
All the time ○

10. Have you had any of the following problems in the *past 12 months*?

For females:

An unusual discharge from your vagina ○
Burning when you urinate (pee) ○
Painful sores or blisters around your genitals ○
Painless lump(s) around your genitals ○
Pain in your lower regions (not period pain) ○
Pain during or after sex ○

For males:

Discharge from your penis ○
Burning when you urinate (pee) ○
Painful sores or blisters around your genitals ○
Painless lump(s) around your genitals ○
Swollen and/or painful testicles (balls) ○

That's it!
Thank you very much for your answers.
Now, please seal this in the envelope, pop it in the box, and take the test kit home and follow the instructions inside.

Appendix 8. Thursday Island-Focus group report

Report on Chlamydia Test Kit Focus Group

Thursday Island: 22 April 2008

Introduction

The Queensland Health Chlamydia Testing Trial was designed to offer young people a private and confidential test for chlamydia. Test kits were piloted in a number of sites in Far North Queensland, including on Thursday Island. Initial uptake of the test kits from participating locations on Thursday Island was high. However, very few specimens were forwarded to the laboratory for testing. A focus group was organised for young men and women aged between 15 and 19 years to seek to understand the reasons for the very poor response rate.

Recruitment

Initial plans were for the Men's and Women's Health Program on Thursday Island to recruit young men and women to participate in the focus group. A modified 'snowball' approach was used for recruitment. Care was taken to ensure that none of the young people who had participated in a sexual health knowledge, attitudes and practices survey and focus group in late 2007 were invited to participate in the chlamydia test kit focus group. An information sheet (Annex 1) was used to inform young people invited to participate in the focus group session of its purpose. Participants were paid for their time.

The Test Kit

The chlamydia test kits handed out contained fifteen separate elements:

- Calico carry sac (bar-coded)
- Welcome letter
- Instructions for collecting and mailing various kinds of samples (2-sided print)
- Chlamydia testing trial information
- Chlamydia testing trial questionnaire (bar-coded)
- Chlamydia testing trial pathology request form (bar-coded)
- Unique number card (bar-coded)
- Specimen envelope
- Reply paid envelope
- Urine collection jar
- Dropper-pipette

- Sterile swab
- Orange-capped gel-containing tube (bar-coded x 2)
- Blue-capped tube (bar-coded x 2)
- White cardboard box

Focus Group Activities and Discussion

The focus group sessions were divided into four separate activities.

1. A brief introduction to the issues around infection with chlamydia
2. Using the kit
3. Single sex group discussion of the experience of using the kit
4. Joint sharing of issues and discussion

On the day, eight young women and three young men presented at the venue ready to participate in the focus group discussion. Local male and female facilitators led the discussions. Following an introductory session by the local female facilitator, chlamydia test kits were handed out to each participant. Participants were requested to follow the kit instructions, substituting tap water for a urine sample to reduce embarrassment if desired. Several participants indicated their desire to submit a *bona fide* specimen. Only two of the eleven participants had seen or heard of the kits previously.

Although participants were requested by both male and female local facilitators to individually attempt to use the kit, young people spent several minutes in single sex groups discussing the kit and its contents. Participants then moved to the privacy of toilet facilities adjacent to the meeting rooms to use the kit.

The young people and their facilitators then separated into same sex groups to begin a discussion of the experience of using the kit. The discussion occurred predominantly in *kriol* in both girls and boys groups.

Boy's sub-group
Comments made by the boys on their experiences included:

- Test was a bit easy
- Better to do it privately than in front of people – on your own and not with friends
- There needs to be two different kits (one for boys and one for girls)
- Would recommend to friends and partners

From a participant observation perspective, there were initial high levels of shyness and embarrassment displayed by the boys on entering into the venue. All boys sat at the same table as the male facilitator. All boys were actively listening in the introduction process and readily accepted a test kit when one was offered. Most (2 of 3) of the boys had some difficulty with the instructions. They initially skimmed over the material in the instruction brochure, not paying close attention to the detail. One of the boys then read the whole page of urine sample collection information to the other two boys. During this (spontaneous) pre-kit-use discussion, boys sought clarification from the facilitator.

There seemed to be some confusion regarding the contents of the kit package. The instructions for the use of swabs (women only in the kits provided) were included on the rear of the sheet containing the instructions for producing a urine sample. It seemed that the purpose of the swabs in kit was not immediately apparent to the boys and, once it became apparent, was a cause of significant distraction. This is reflected in the later comment that there ought to be two different kits, one for boys and one for girls

There was no indication from their comments that the boys encountered difficulty with the mechanical aspects of the sample collection and preparation (urine test instructions 1-4).

None of the boys read the Welcome letter carefully. All boys had some difficulty completing the (yellow) questionnaire. The significance of the unique number provided on the calling card did not appear to be immediately evident, and some boys had initially discarded the card with the other kit remnants. Once the anonymous nature of the testing process was understood by the boys, two of three boys retrieved the card and submitted an actual specimen. The pathology request slip was also the cause of some confusion, with meaningless (to the participants) acronyms and no effective simple language explanation of the slip's purpose. Facilitator support was needed to complete the details required for the pathology report.

Girl's sub-group
Comments made by the girls on their experiences included:

- Using the test is embarrassing
- Girls using it for the first time should do the urine test because it is easier
- I felt unsure of how to use the swab. I wasn't confident of using it
- I was confident in using the test
- Using the urine test simpler (for girls) than the swab
- First time user will find it difficult
- It was easy to follow the instructions given
- Girls who were not aware of the kit before found it difficult to understand the questions (on the yellow slip)
- It is a good idea to use the kit in our own privacy
- Would recommend to a friend

From a participant observation perspective, lower levels of shyness were displayed by the girls on entering the venue than by the boys. All girls sat at one of two girls-only (at their own choice) tables in the meeting room and appeared to be actively listening during the introduction session presented by the female facilitator. As with the boys, none of the girls read the introduction letter carefully and the girls also appeared to only skim the instruction sheet before opening the kit and examining its contents. There was significant spontaneous group discussion among the girls before any moved to the privacy of the toilets to use the kits. Two of the eight girls submitted an actual specimen.

During the same sex discussion, several girls indicated embarrassment over using the swabs and recommended among themselves that first-time users only take the urine test. As with the boys, there did not appear to be any difficulty with the mechanical

aspects of the urine sample collection and preparation, except that there was some confusion among the girls about the volume of urine to be transferred to the gel tube.

Most girls appeared to have some difficulty completing the (yellow) questionnaire, reflected in the comments on not understanding the questions asked. As with the boys, the significance of the unique number provided on the calling card did not appear to be immediately evident and cards were initially discarded with the kit remnants. The pathology request slip also appeared to be the cause of considerable confusion with the girls. Facilitator assistance was sought in completing the details.

Combined group session

A representative from each group gave a brief presentation of the discussion and detailed key issues in the experience of using the kits. All boys and girls indicated a willingness to recommend the kit to friends and all excess stock of kits available at the focus group session was taken by participants. There was almost no discussion of these presentations.

The issue of the location of the sites where kits could be obtained was discussed, as only two of the participants had previously seen or heard of them. Initial distribution sites chosen included the ITEC employment Agency, the toilets at the TAFE college and the Torres 'Bottlo' (liquor store). None of these locations was routinely accessed by adolescent-aged residents of Thursday Island.

On checking, those kits available through the ITEC agency were stored on a high shelf attached to a wall behind the reception counter, and people wishing to obtain a kit were obliged to ask the receptionist. Those kits located in the toilets of the TAFE college had been removed by a cleaner over concerns about littering from kit remnants. The focus group participants suggested a different set of locations more likely to be frequented by young people including:

- In the public toilets at the Thursday Island hospital
- Through the School-based Youth Health Nurse
- In the public toilets at the Ken Brown Oval
- At the Hammond Island ramp shed at Rose Hill

The combined session was also used by some participants to clarify the requirements and complete the details needed to actually submit a specimen. Four kits (2 from boys and 2 from girls) were presented to the female facilitator to expedite postage arrangements.

Analysis and Conclusions

The goals of the project of which the kit is a key element appear to include both the trial of a mail-in sample self-collection methodology for chlamydia testing and the conduct of a social survey on chlamydia testing, STI symptoms, condom use and safe sex practices 9designated *optional* in the Information brochure. The project designers have attempted to achieve efficiency, service-provider convenience and enhanced testing outcomes by including provision for both urine (men and women) and swab sampling

(for women only in the kits distributed) in each kit. However, this service-provider convenience may have been achieved at the expense of kit simplicity and functional usability.

The reaction of the boys to the universal-use composition of the kit, including both the swabs and the detailed instructions for their use, indicated both confusion and clear distraction in the process of using the kit. Based on the boy's comments, there may be value in gender-specific tailoring of the kit composition and instruction sheet where the target population is of adolescent age. Alternatively, a urine-only collection strategy could be adopted for a universal kit.

The inclusion of four separate documents, with no immediately apparent index document, appeared to contribute to the initial confusion for both groups. As presented in the kit at the time of the focus group, the Information brochure was among an abundance of unpacked kit components and the Easy Guide, printed as an internally folded element of the Information brochure, became lost to the view immediately the brochure was fully opened.

Facilitator reflection on this matter after the focus group process was completed concluded that the kit could be significantly improved with a more prominent index or roadmap document. This could be achieved in the existing kit by folding the Information brochure such that the 'Easy Guide' page became the title page and by packing the kit in such a manner that this Easy Guide page was the first kit element to be seen on unpacking.

Although both girls and boys reported that the Instructions document was easy to use, some additional tightening of the text in Urine Test Instruction 3 to convey that the whole volume of the dropper bubble was to be squirted into the orange-topped tube seems appropriate, given the confusion expressed by some of the girls.

The Welcome to the Queensland Health Chlamydia Testing Trial letter was quickly judged by the participants to be extraneous material not helpful in completing the test. It is probably an unnecessary element of the kit from a youth user perspective.

The yellow Questionnaire sheet was a source of major difficulty for both boys and girls. There are three elements to the form:

1. Parts A and B of the actual questionnaire;
2. Participant contact details recording (optional) and;
3. A data use consent sheet.

The content and presentation of this brochure resulted in a number of issues:

- Significant facilitator interaction was required to explain the Part A questions;
- The operation of the option of anonymity (How can we contact you?) and the purpose of the unique number card was not sufficiently explicit in the Information brochure to enable unsupported use of this option

- Although described as *optional* in the Instructions, completion of some elements of the yellow Questionnaire form appeared to the participants to be a requirement for submitting a sample;

Based on some of the clarifications made by facilitators regarding the unique number card, it appeared that the option of anonymity was a pull factor in the use of the kit among the Thursday Island participants, as evidenced by those who submitted samples for testing after understanding the purpose of the card. Yet, the consent form for use of the Questionnaire data, an integral element of the Questionnaire brochure, required a name and signature. This tear-off sheet was part of the bar-coded Questionnaire brochure, presumably to be detached on receipt at the testing laboratory. It appears that the option of true anonymity for participants may have been effectively lost to the needs of the trial organisers for ethical publication of research data.

The pathology request form also caused considerable confusion, with no clear indication on or attached to the form of what information was required. Although this information was referenced in the Questionnaire document, focus group participants were not able to complete the task unsupported by the facilitators.

In conclusion, the design of the pilot study appears to have assumed a high degree of health literacy among potential users of the kit. This is evident in the language used in the Information and Questionnaire brochures, and the welcome letter. It is also evident in the simple inclusion of an unannotated and essentially incomprehensible medical document (the pathology slip) in the kit. This assumption of high levels of health literacy may have contributed to the poor response by adolescent-aged residents of Thursday Island.

Recommendations

1. That the goal of the trial among adolescent-aged targets in remote communities in Far North Queensland be limited to the piloting of the self-sampling mail-in test kit methodology

2. That the kit be provided in gender-specific form, or as a urine-only universal kit

3. That the kit documentation be simplified and that unnecessary documents– eg the Welcome letter – be removed

4. That, for use in remote communities, the language in the Information and Questionnaire brochures be modified to target an adolescent audience for whom English is a second language

5. That the Information brochure be folded to display the Easy Guide page as the title page and that this document be prominent in the kit packaging

6. That the text in Urine Test Instruction 3 be amended to convey that the whole volume of the dropper bubble is to be squirted into the orange-topped tube

7. That the pathology form be augmented with plain language stick-on guides indicating the place and nature for information to be recorded (***D of B*** is not

necessarily intuitively discerned as ***date of birth*** by people for whom English is effectively a second language)

8. That a separate envelope be provided for a separate Consent form if one is required, to preserve the option of true anonymity

9. That, for routine (post-trial) use, a urine-only kit be developed containing:

    a. Combined ‘Easy Guide’ and sample collection Instruction sheet, with the ‘Easy Guide’ folio displayed

    b. Unique identifier card, perhaps renamed as a ‘PIN NUMBER’ with STORE SAFELY in bold red and simple explanatory material on the unprinted side (eg this number is used instead of your name to protect your privacy)

    c. Pathology request slip with stick-on guidance for filling in details

    d. Urine collection jar

    e. Dropper

    f. Gel-containing specimen tube

    g. Reply paid envelope (with specimen tube box included if this is an Australia Post biohazard requirement)

Appendix 9. All Publications (papers & conferences)

Publications

Articles in peer reviewed journals

Buhrer-Skinner M, Muller R, Menon A, Gordon R. Novel approach to an effective community-based chlamydia screening program within the routine operation of a primary healthcare service. Sex Health 2009; 6: 51–56.

Bialasiewicz S, Whiley DM, Buhrer-Skinner M et al. A novel gel based method for self collection and ambient temperature postal transport of urine for PCR detection of chlamydia trachomatis. Sex Transm Infect. 2009;85:102-105

Buhrer-Skinner, M., et al., The check is in the mail: piloting a novel approach to Chlamydia trachomatis testing using self-collected, mailed specimen. Sex Health, 2009. 6(2): p. 163-9.

Emmerton, L., Buhrer Skinner, M., Gardiner, E., Nissen, L., & Debattista, J. A trial of the distribution of chlamydia self-collection postal specimen kits from Australian community pharmacies. Sex Health, 2011;8(1), 130-132.

Buhrer-Skinner M, Muller R, Buettner PG, Gordon R, Debattista J. Improving Chlamydia trachomatis retesting rates by mailed self-collection kit. Sex Health, 2011 8(2), 248-250.

Buhrer-Skinner M, Muller R, Buettner PG, Gordon R, Debattista J. Reducing barriers to testing for Chlamydia trachomatis by mailed self-collected samples. Sex Health, 2011 in review.

Conference presentations

Buhrer-Skinner, M. and Muller R., Novel approach to genital chlamydia testing and management in budget travellers in Queensland, Australia.

Presented at the 16th Annual Scientific Meeting of the Australasian College of Tropical Medicine & Annual Conference of the North Queensland Centre for Cancer Research 19.-21 July 2007.

Buhrer Skinner M, Muller R, Bialasiewicz S, Debattista J. The check is in the mail: A novel approach to Chlamydia trachomatis testing using self collected, mailed specimen.

Presented at the Australasian Sexual Health Conference 2007, Conrad Jupiter, Gold Coast ,8-10 October 2007.

Bialasiewicz S, Whiley DM, Buhrer Skinner M, et al. Development and validation of a novel gel-based urine transport system for use in chlamydia trachomatis PCR based diagnosis.

Presented at the Australasian Sexual Health Conference 2007, Conrad Jupiter, Gold Coast ,8-10 October 2007.

Bialasiewicz S, Whiley DM, Buhrer-Skinner M. et al. A Novel Approach to Collecting and Mailing Urine for use in Chlamydia trachomatis PCR Detection Australian Society of Microbiology 2008

Presented at the 2008 Australian Society of Microbiology Conference, 6th to 10th July 2008, Melbourne, Australia

Buhrer Skinner M and Muller R. Plans for a trial to evaluate home-sampling kits for chlamydia.

Presented at 2nd Australian Chlamydia Conference, Institute of Health and Biomedical Innovation, Queensland University of Technology, Brisbane 16-17 July 2007.

Buhrer Skinner M, Muller R, Bialasiewicz S and Debattista J. The check is in the mail: An interim mail check.

Presented at 2008 Meeting of Sexual Health Clinicians, Novotel, Brisbane 22-23 May 2008.

Buhrer Skinner M, Buettner PG, Muller R, Gordon R, Debattista J. The check was in the mail: Contact preferences of participants.

Presented at the Australasian Sexual Health Conference 2008, Perth Convention Centre, Perth, 15-17 September 2008.

Gordon R, Buhrer Skinner M, Muller R, Buettner PG, Debattista J. An innovative approach to testing for chlamydia reinfection.

Presented at the Australasian Sexual Health Conference 2008, Perth Convention Centre, Perth, 15-17 September 2008.

Gordon R, Buhrer Skinner M, Muller R, Buettner PG, Debattista J. Acceptability of using the internet or phone to request a self- collection kit for chlamydia testing.

Presented at the Australasian Sexual Health Conference 2008, Perth Convention Centre, Perth, 15-17 September 2008.

Buhrer Skinner M, Muller R, Buettner PG, Debattista J, Gordon R. Participant perceptions of the use of a self collection kit for chlamydia testing.

Presented at the Australasian Sexual Health Conference 2008, Perth Convention Centre, Perth, 15-17 September 2008.

Emmerton L, Buhrer-Skinner M, Nissen L, Gardiner E, Debattista J. Can community pharmacies play a role in Chlamydia testing?

Presented at the 2009 Pharmacy Australia Congress, 16th to 18th October 2009, Sydney, Australia.

Appendix 10. Client Satisfaction Questionnaire-8

CLIENT SATISFACTION QUESTIONNAIRE (CSQ-8)

1. How would you rate the quality of service you have received?

4	3	2	1
Excellent	Good	Fair	Poor

2. Did you get the kind of service you wanted?

1	2	3	4
No, definitely	No, not really	Yes, generally	Yes, definitely

3. To what extent has our program met your needs?

4	3	2	1
Almost all of my needs have been met	Most of my needs have been met	Only a few of my needs have been met	None of my needs have been met

4. If a friend were in need of similar help, would you recommend our program to him or her?

1	2	3	4
No, definitely not	No, I don't think so	Yes, I think so	Yes, definitely

5. How satisfied are you with the amount of help you have received?

1	2	3	4
Quite dissatisfied	Indifferent or mildly dissatisfied	Mostly satisfied	Very satisfied

6. Have the services you received helped you to deal more effectively with your problems?

4	3	2	1
Yes, they helped a great deal	Yes, they helped	No, they really didn't help	No, they seemed to make things worse

7. In an overall, general sense, how satisfied are you with the service you have received?

4	3	2	1
Very satisfied	Mostly satisfied	Indifferent or mildly dissatisfied	Quite dissatisfied

8. If you were to seek help again, would you come back to our program?

1	2	3	4
No, definitely not	No, I don't think so	Yes, I think so	Yes, definitely

Publications

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