



Australian Government
Department of Health and Ageing



The Pharmacy
Guild of Australia

To develop and pilot a best practice community pharmacy chlamydia screening model

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FINAL REPORT

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Miss JM – Stakeholder – female consumer

Miss XLY – Stakeholder – female consumer

Mrs Kim Watkins – Stakeholder – community pharmacist

Mrs Geraldine Ormonde – Stakeholder – Western Diagnostic Pathology Centres

Acronyms

Acronym	Explanation
CATI	Computer Assisted Telephone Interview
EC	Emergency Contraception
ECOMPACT	Emergency Contraception Mediated Pharmacy Access of Chlamydia Testing
ESR	Effective Screening Rate
FPWA	Family Planning Western Australia
FVU	First Void Urine
GP	General Practitioner
LVS	Low Vaginal Swab
NAAT	Nucleic Acid Amplification Technique
NCSP	National Chlamydia Screening Program
PID	Pelvic Inflammatory Disease
PSA	Pharmaceutical Society of Australia
STI	Sexually Transmitted Infection
UK	United Kingdom (of Great Britain)
US	United States (of America)
UWA	University of Western Australia

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1 INTRODUCTION

Chlamydia trachomatis is the most frequently notified bacterial Sexually Transmitted Infection (STI) in Australia.¹ The notification rates for chlamydia have risen almost six-fold, from 9096 cases in 1997 to 58,507 cases in 2008.¹

Up to 75% of infected women and about 50% of infected men do not exhibit any symptoms, so are unaware of their infection and do not seek appropriate health care.² If left untreated, chlamydial infections can lead to serious reproductive health problems with both short-term and long-term consequences. Some studies suggest that about 10-40% of untreated chlamydial infections may progress to pelvic inflammatory disease (PID).^{3, 4} This can cause permanent damage to the fallopian tubes, uterus, and surrounding tissues and can increase the chances of an ectopic pregnancy and even infertility. Therefore, like the chlamydia infection itself, the long-term complications are often "silent."

Traditionally testing for chlamydia required a physician to collect a pathology sample from the cervix in women or the urethra in men. However with recent advances in Nucleic Acid Amplification Techniques (NAAT) easy and non-invasive methods such as first-void urine (FVU) or a self-collected low-vaginal swab (LVS) have made diagnosis easy, accurate and cost-effective.^{5, 6} Once diagnosed it is easily treated with a single dose of antibiotic (azithromycin).

Internationally, chlamydia screening programs have reduced the number of people infected and the cases of complications arising from infection.^{7, 8} In the United States (US), a 56% rate in reduction in PID was seen in a group of women screened for chlamydia when compared to a control group.⁷ In Sweden, two observational studies showed a decline in the incidence of PID and ectopic pregnancy after the introduction of population based testing for chlamydia.⁸

Based on the evidence of these studies, and the increasing rate of long-term PID due to undetected chlamydia in age-bearing women, the Department of Health in England initiated a National Chlamydia Screening Program (NCSP) in 2003.⁹ The aim of the NCSP was to provide free chlamydia screening to all sexually active men and women under the age of 25 years from a range of healthcare and non-healthcare venues such as general practice, sexual health clinics, youth clubs, schools, prisons and community pharmacies. Annual evaluations by the NCSP suggested that community pharmacies compared favourably to other venues in providing access to the service for consumers, and suggested that the consumers found the service to be highly convenient, confidential and anonymous.⁹

In 2005, the Department of Health in England funded a National Pharmacy Chlamydia Screening Pilot from 200 "Boots" pharmacies in London.¹⁰ Consumers were provided with a chlamydia urine specimen kit, which they returned to the pharmacy. The pharmacy then sent the test for pathology and the consumer got their result 7 days later. The study concluded that pharmacy-based chlamydia screening provided an opportunistic, anonymous, and easily accessible service to a range of people.¹⁰

Several other interventions in the UK have demonstrated practical and innovative models of community pharmacy-based chlamydia screening services which involved pharmacists providing screening kits to both males and females consumers.¹¹

Encouraged by the findings of the NCSP and the "Boots" study, the National Health Service (NHS) in the UK commissioned the sale of chlamydia testing kits from all community pharmacies in August 2008.¹² The price for the kit ranges from £20-45 (AUD\$48-\$108). Furthermore, in 2009, the antibiotic treatment for chlamydia (azithromycin), became available for sale to chlamydia positive patients and their sexual partners without the need of a prescription from a community pharmacy.¹²

In Australia, chlamydia screening has not yet been made widely available, and currently consumers have to visit their GP or a family planning services to be tested. In 2005, the Commonwealth Government of Australia released the first National Sexually Transmissible Infections Strategy, which stated that chlamydia screening programs should be specifically designed to target those who would not otherwise have been tested and that the screening sites should be easy to access, confidential, affordable, youth-friendly and have late evening and weekend opening hours.¹³ They subsequently committed \$3.5 million to conduct a chlamydia screening pilot in general practice, on the basis that nearly 90% of women and 70% of men aged between 15 and 24 see a GP at least once a year.¹⁴ A retrospective evaluation of Medicare data for the period of October 2007 to March 2008 however, indicated that only 6.3% of women and 1.6% of men in that age group were recorded by the Health Insurance Commission as having been tested for chlamydia.¹⁵

In general terms, community pharmacies fulfil the criteria for screening sites outlined in the National Sexually Transmissible Infections Strategy. We therefore believe pharmacies to be in an ideal position to offer a screening program and propose this study to develop, pilot and evaluate a program that can be implemented in the Australian health care setting. While international studies offer valuable guidance on how to set up a screening program, they

cannot be directly transferred to the Australian setting. In Australia, as in any other country, new services must be in line with national and state priorities and conform to the national health system that it relies on for support and funding.

Initial studies have already been carried out in Australia to pave the path for pharmacy-based chlamydia screening. In 2007, Taylor and colleagues surveyed 25 pharmacists and 50 women to determine the acceptability of a chlamydia screening program in community pharmacies.¹⁶ Data indicated that 84% (21) of the pharmacists would support a pharmacy-based chlamydia screening program and indicated that they would be comfortable with providing the kit (92%), counselling results (88%) and providing antibiotics (80%). The responses from the women respondents indicated that a large portion (76%) would accept the kit and return the sample.

Apart from determining the site and general scope of a chlamydia screening program, the National Sexually Transmissible Infections Strategy of Australia also identified groups of individuals displaying certain risk factors that must be screened for chlamydia. These are:

- Sexually active young men and women aged 15 to 29 years;
- Those with new or multiple sex partners;
- When no/inconsistent barrier contraception methods are used; and
- Those with a prior history of diagnosed STIs.

In another recent study by Gudka et al. women asking the pharmacist for emergency contraception (EC), were identified as carrying at least two of the above risk factors: being sexually active women aged of 15-29 years and having had unprotected sexual intercourse (either did not use condoms or had inconsistent use of condoms).¹⁷

Prior to the deregulation of EC from “*Schedule 4*” (prescription only medicine) to “*Schedule 3*” (pharmacist only medicine) in 2004, this group of women would have visited a GP, family planning service or sexual health service to obtain EC, and an intervention for STI screening would have been offered to them. While the sale of EC from a community pharmacy has allowed timely and convenient access for many consumers, it has prevented them from having the opportunity of getting a chlamydia test (Figure 1).

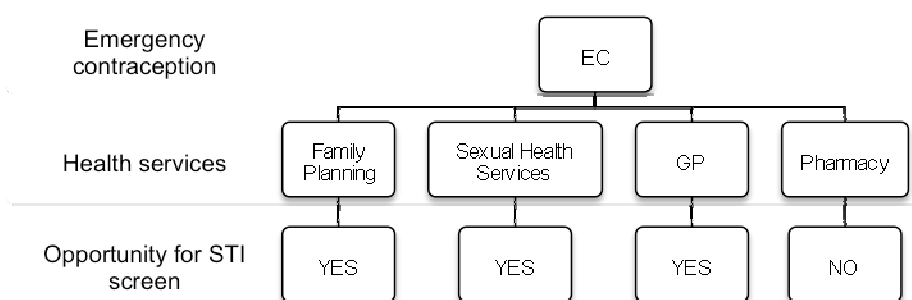


Figure 1: Current EC and STI screening services

The aim this study was to develop pharmacy-based chlamydia screening for EC consumers. The objectives of the study were to:

1. Develop a pharmacy-based chlamydia screening model.
2. Conduct a feasibility study of this model in 20 pharmacies in Perth over 6 months.
3. Construct an evaluation framework to monitor the uptake of the study.
4. Evaluate the acceptability of this model via qualitative and quantitative research.
5. Utilise the experience gained during the study to develop recommendations for a national pharmacy-based chlamydia program.

2 DEVELOPING A PHARMACY-BASED CHLAMYDIA SCREENING MODEL

The first objective of the study was to develop a pharmacy-based chlamydia screening model for the Australian setting. Five key groups of stakeholders were engaged in the process of developing the study protocol:

- 2 x Women aged 18-30 years (to represent the average pharmacy EC consumer)
- 1 x Community Pharmacist
- 1 x Pathology Representative
- 1 x Sexual Health Physician
- 1 x Sexual Health/Medical Educator
- 1 x Pharmacist with experience in sexual health and health promotion
- 1 x Pharmacist with expertise in research

2.1 Stakeholder meetings

Date: 7th February 2008, 17th March 2008 and 13th May 2008.

Based on the five core requirements identified by Gudka et al, the following questions were discussed.¹⁸

- How should consumers be recruited?
- What is the best test and specimen for pharmacy-based chlamydia screening?
- Should the consumer return the specimen to the pharmacy or a pathology drop-off site?
- Who should disseminate positive and negative results to the consumer?
- How should sexual partner of positive consumers be notified?

The discussions at the stakeholder meetings continued until there was consensus on all answers to these questions amongst all participants. Minutes of the three meetings are summarised in Appendix 1.

2.1.1 Summary from the stakeholder meetings

A pharmacy-based chlamydia screening protocol was developed over the three meetings.

Key decisions from the three meetings are summarised below.

- The screening protocol was labelled the Emergency Contraception Mediated Pharmacy Access of Chlamydia Testing (ECOMPACT).
- To integrate the ECOMPACT study protocol with the existing workload of the pharmacist, the pharmacists should discuss the risk of STIs as per the Pharmaceutical Society of Australia (PSA) supply protocol for EC. (Appendix 2).
- Both FVU and LVS have been shown to be highly accurate, therefore a decision to use LVS was made on the basis that Australia Post does not permit the postage of urine samples.
- It was decided to mimic the requirements of the current healthcare system - whereby a clinician orders a pathology test, and it is the responsibility of the consumer to deliver their sample directly to a pathology drop-off site.
- The consumer would have to call a designated phone number to obtain their results. A trained sexual health nurse at Fremantle Hospital would attend to this phone-line.
- All positive patients would immediately be examined by a physician and treated accordingly. The physician would also initiate the partner notification process.

Figure 2 illustrates the complete ECOMPACT model that was developed and agreed by all the stakeholders.

Recruitment Strategy	<ul style="list-style-type: none"> • Pharmacist Initiated • As part of the EC consultation • Opportunistic screening for STIs of all EC consumers
Patient Eligibility Criteria	<ul style="list-style-type: none"> • Consumers that request EC from a pharmacy • Over 18 years of age
Screening and Assessment	<ul style="list-style-type: none"> • Screening for STI symptoms • Ensure consumers with symptoms are immediately referred for appropriate investigations. • Offer ECOMPACT Testing Kit to all other eligible and asymptomatic consumers
Type of Specimen	<ul style="list-style-type: none"> • Consumer collects their pathology sample • Low Vaginal Swab
Return of Specimen	<ul style="list-style-type: none"> • Designated pathology drop-off sites • Selected ECOMPACT pharmacies - decision left on each pharmacy
Dissemination of Results	<ul style="list-style-type: none"> • Designated free phone number • Results handled by a sexual health nurse based at Sexual Health Services, Fremantle Hospital
Partner Notification Method	<ul style="list-style-type: none"> • Sexual health physician based at Sexual Health Services, Fremantle Hospital

Definitions used

Screening: Members of a defined population, who may not know they are at risk of a disease or its complications, are asked questions, in order to identify individuals who may have the disease and who therefore require further, more specific investigations.

Opportunistic screening: A health professional screens patients attending health care or other defined setting for any reason. Individuals who do not use relevant health services will not have an opportunity to be offered screening.

Symptomatic: Women that exhibit symptoms suggestive of undiagnosed STIs.

Asymptomatic: Women that do not have any obvious signs or symptoms of STIs and chlamydia.

Partner notification (or 'contact tracing'): The process of identifying relevant contacts of a person with an infectious disease and ensuring they are aware of their exposure. For STIs, relevant contacts include those with whom the index case (the original person identified with an infection) has had sex during the infectious period.

Figure 2: The ECOMPACT model (stakeholder consensus)

3 FEASIBILITY STUDY OF THE ECOMPACT MODEL

3.1 Ethics Approval

The Human Research Ethics Committee at the University of Western Australia (UWA) granted ethics approval for the study. All consumers and pharmacists were required to read a Participation Information Sheet and sign the Participation Consent Form prior to enrolment in the study.

3.2 Sample size

The lack of Australian research and literature field meant that we could not calculate the power to assess the success of the feasibility study. To test the feasibility and study protocol, we aimed to recruit 20 pharmacies, each supplying approximately 8 EC a month. This would result in a sample size of approximately 960 consultations in the 6-month study period.

3.3 Recruitment of pilot pharmacies

A brief overview of the ECOMPACT study and an Expression of Interest to Participate form (Appendix 3) was sent to all registered pharmacies in the Perth metropolitan region.

The inclusion criteria were:

- The pharmacy must be within the boundaries of the Perth metropolitan region as defined by the Department of Planning Western Australia Metropolitan Regional Scheme (Appendix 4);
- The pharmacy should have a consultation room, screened or otherwise private area;
- The pharmacy should have approximately eight or more EC consultations per month, to ensure an adequate consumer recruitment sample size; and
- At least one pharmacist from every participating pharmacy must attend an ECOMPACT training course.

The first 20 pharmacies that responded and met these criteria were selected, and sent further information about the study and the ECOMPACT training course (Appendix 5).

3.4 Materials

The research team developed the following materials, consciously keeping in mind the need to reduce the amount of paperwork and duplication for the pharmacists.

- Form F1: The Consumer Eligibility and Consent Form (Appendix 6) was designed as a pad of single-page, no carbon required (NCR) duplicates. Each individual form was pre-assigned a unique 4-digit patient ID code, the first 2 digits (01-20) of which identifying the pharmacy, the last 2 the consumer. The back of each form contained patient information and consent forms.
- Form F2: The Health Review Request Form (Appendix 7) was designed in consultation with the pathology centres and Fremantle Hospital. It served as a pathology request form, and recorded the patients' full name, residential address, date of birth, contact phone number and the date when the ECOMPACT kit was given out. The pharmacist also had to fill in the unique patient ID code from the Consumer Eligibility and Consent Form to track the progress of the patient.
- The ECOMPACT leaflet entitled "What You Need to Know" (Appendix 8) was deigned to be a quick reference guide for the participating consumer to inform them about the study, and their involvement. Diagrammatic instructions on how to collect the swab where also included in the leaflet.
- An ECOMPACT reminder card (Appendix 9), with details on how to obtain the test results and a space for patients to record the date on which they returned their test to the pathology centre.

ECOMPACT testing kits were assembled and packaged in discrete white envelopes. They contained:

- The ECOMPACT "What You Need to Know" leaflet;
- 1 x GEN-PROBE APTIMA unisex collection swab;
- 1 x GEN-PROBE APTIMA swab transport medium tube;
- 1 x biohazard bag; and



- The ECOMPACT reminder card.

3.5 The ECOMPACT Study Protocol

Using the data collected from the literature reviews and the stakeholder meetings, the research team developed a protocol for chlamydia screening. The ECOMPACT Study Protocol is shown in Figure 3, and accompanied by Explanatory Notes in Appendix 10.

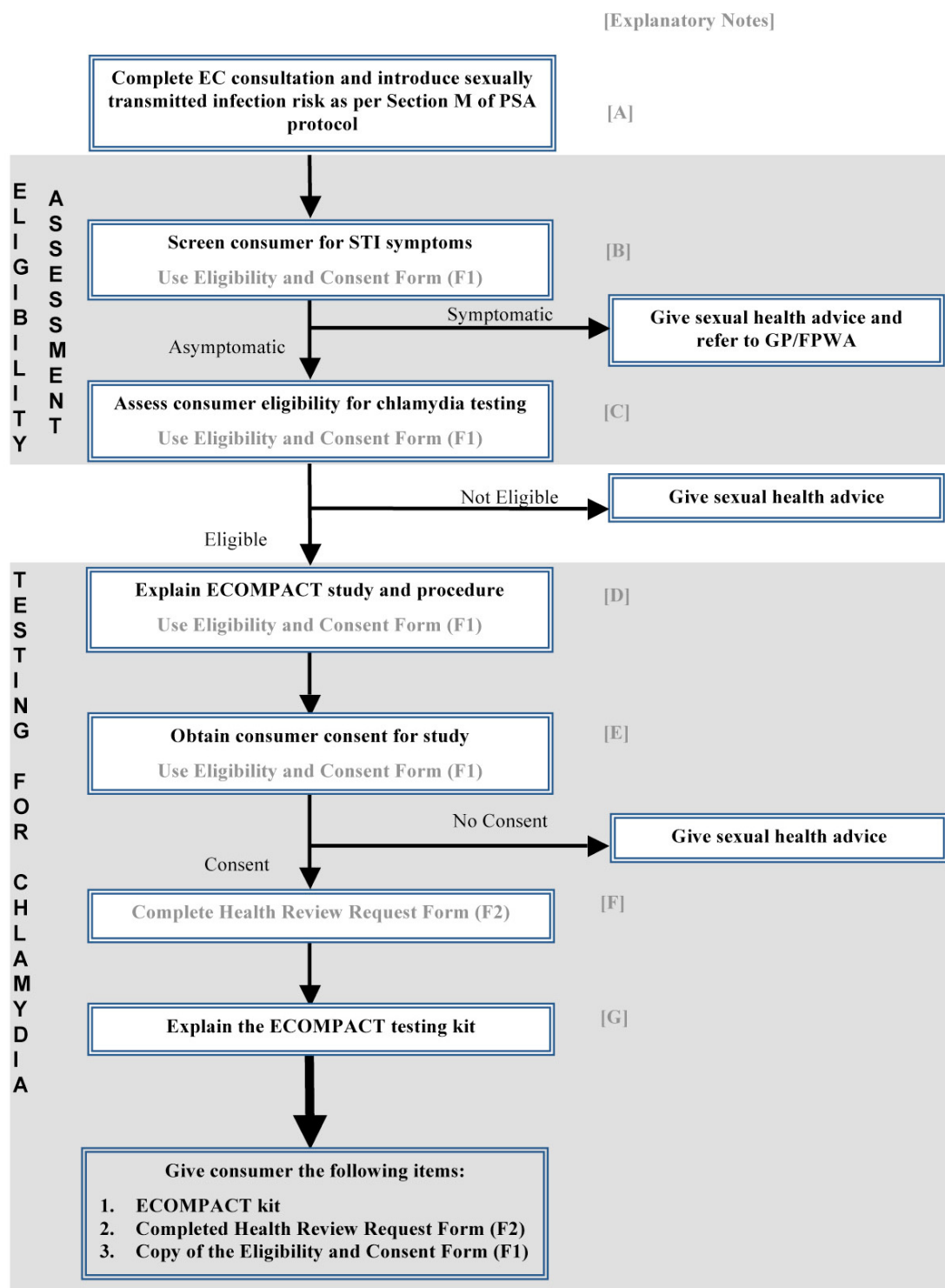


Figure 3: The ECOMPACT protocol

The ECOMPACT screening protocol is divided into two stages:

Stage 1 - the Eligibility Assessment:

- The first step was to identify all consumers with symptoms suggestive of any STI using the Eligibility Assessment Checklist (Appendix 6) and in accordance with the national screening guidelines refer them to a physician for a full sexual health check.¹⁹ These consumers were not be eligible for the chlamydia test. For ethical reasons we could not follow the outcome of their referral.
- All consumers under the age of 18 years are also ineligible. This is because the Human Research Ethics Committee at University of Western Australia in accordance with the National Health and Medical Research Council Act 1992 and the National Statement on Ethical Conduct in Human Research identifies a “dependent adult” as a person being under the age of 18 years.²⁰ Accordingly, parental consent would have been required for consumer under the age of 18 years to participate in ECOMPACT. Due to the practical and ethical complications associated with this, we excluded those consumers.
- Any consumer that had a positive chlamydia tests in the previous four weeks are regarded as ineligible they must have already seen a physician.

Stage 2 – Testing for Chlamydia

- The second stage of the screening protocol was to offer all asymptomatic and eligible consumers a free ECOMPACT Testing Kit with instruction on how to test themselves for chlamydia using a self-collected sample, where to take the sample for pathology testing and how to get the results by the pharmacists.

3.6 Training Course

The research team identified learning objectives that were deemed necessary for the successful implementation of ECOMPACT.

These objectives included knowledge of:

- Key issues in sexual health and STIs;
- Overview and prevalence of *Chlamydia trachomatis* in Australia;
- Types of chlamydia screening tests;
- Evidence for pharmacy-based chlamydia screening;
- ECOMPACT Study Protocol;
- Patient journey through ECOMPACT;
- Pharmacist and the pharmacy staffs' role and process for ECOMPACT;
- Communication strategies for discussing sexual health issues with consumers;
- Ethics, confidentiality and privacy issues, with particular reference to ECOMPACT; and
- Recruitment processes.

A two-hour specialised training course was designed to deliver these objectives (Appendix 11a). The course material is attached to Appendix 11b. A total of 5 identical sessions, each with up to 8 participants, were conducted over a two-week period.

The course had two themed sessions. Session 1 introduced the participating pharmacists to the theory behind STIs and chlamydia screening. Session 2 focused on the implications of pharmacy based chlamydia screening and ECOMPACT and strategies to discuss STIs and chlamydia screening with the EC consumer. A variety of techniques, including lectures, discussions of scenarios and role-play (skill rehearsal), were used.

3.7 Role of the research team

The structure of the research team reflects the requirements of the study.

The core members of the team and their immediate responsibilities were:

- A principal investigator based at UWA provided supervision and expert knowledge at every step.

- A Project Co-ordinator, also based at UWA was responsible for leading the project team and coordinating all matters related to project such as implementing the feasibility study, ensuring the effective preparation and delivery of all project events, production of all necessary documentation and controlling the effective flow of information between pharmacists, the pathology centres and Fremantle Hospital. Other responsibilities included evaluation of the study and report writing.
- A Medical Educator at Family Planning Western Australia, provided project supervision and clinical expertise.
- A sexual health physician at Fremantle Hospital was responsible for downloading patient results from the pathology centre database on a daily basis, updating the ECOMPACT database, and treating any positive patients and their partners.
- A sexual health nurse at Fremantle hospital was engaged to answer the free-phone number that the consumers called to obtain their results. She also updated the database with dates of when the consumer rang for their results and sent monthly updates to the researchers at UWA.

In collaboration with the pathology centre, the research team from UWA and Fremantle Hospital created the Health Review Request Form and created a user profile in their computer system to enable Fremantle Hospital to access the pathology results for all ECOMPACT consumers. The pathology centre sent monthly invoices to the research team at UWA for the pathology tests and testing kits.

After the training course the Project Co-ordinator from UWA visited each pharmacy in person and provided them with their ECOMPACT file and testing kits. The research team were not directly involved in consumer recruitment but provided ongoing support, training and resources to participating pharmacists in the form of:

- Fortnightly emails;
- Monthly telephone calls; and
- Personal visits if further information or training was requested.

During the pilot period of ECOMPACT the research's team role became predominantly a coordination role between participating pharmacies, pathology centres and Fremantle Hospital.

At the end of the 6-month pilot period, the Project Co-ordinator from UWA collected all the ECOMPACT files and remaining kits from every pharmacy in person.

3.8 Pharmacy Incentives and Payments

Each participating pharmacy received a \$1000 readiness payment to enable for their involvement with ECOMPACT. A further incentive of \$15 per chlamydia screening test returned was paid to each pharmacy.

3.9 The 6-month pilot period

The 6-month pilot was conducted from July 2008 to Dec 2008 from the 20 participating pharmacies in Perth.

4 EVALUATION FRAMEWORK

The third objective of the study was to develop an evaluation framework to evaluate the feasibility of the ECOMPACT study protocol in the 6-month pilot period.

Key barriers and facilitators for pharmacy-based chlamydia screening were identified from similar studies, and consultations with the stakeholders. Themes were assessed within the context of the ECOMPACT model and the evaluation framework consisting of quantitative and qualitative data was developed:

1. To assess the uptake of ECOMPACT;
2. To understand the consumer perspective; and
3. To understand the pharmacist perspective.

The evaluation framework timeline (Figure 4) comprised a continuous tracking element through the 6-month study period and four months of post study evaluations to understand the consumer and pharmacist's perspectives.

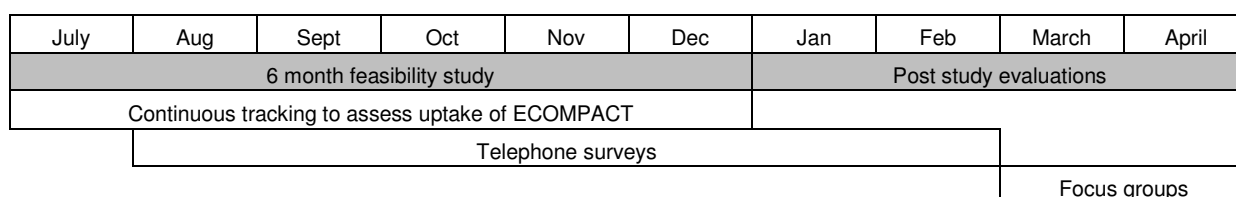


Figure 4: Evaluation Framework Timeline

Table 1 illustrates the evaluation framework and the research techniques used to obtain the relevant information.

Table 1: Evaluation Framework Table

	Summary form S1	Summary form S2	Telephone interview	Focus group
To assess the uptake of chlamydia screening				
Number of EC consultations	✓			
Number of consumers offered ECOMPACT	✓			
Proportion outside the eligibility criteria	✓			
Number of kits being accepted	✓			
Number of tests being returned		✓		
Consumer demographics			✓	✓
To understand the consumer perspective				
Overall perception of ECOMPACT			✓	✓
Ease of use of chlamydia kit			✓	✓
Ease of returning test			✓	✓
Ease of obtaining test results			✓	✓
Reasons for refusing			✓	
Reasons for non-return			✓	✓
Perception of confidentiality in pharmacy			✓	✓
Reaction to being offered ECOMPACT			✓	✓
Perceived benefits and drawbacks			✓	✓
Improvements to ECOMPACT			✓	✓
To understand the pharmacist perspective				
Ease of implementing ECOMPACT				✓
Interaction with consumer				✓
Perception of confidentiality in pharmacy				✓
Perceived benefits and drawbacks				✓
Improvements to ECOMPACT				✓

4.1 Summary Form S1

Summary Form S1 (Appendix 12a) was used by the pharmacists to record the number of EC consultations, consumers that were offered ECOMPACT, patients outside the eligibility criteria and ECOMPACT testing kits that were accepted. The pharmacists were asked to fax or email the form to the research team on a monthly basis.

4.2 Summary Form S2

Summary Form S2 (Appendix 12b) was designed to monitor the number of tests returned and when the consumer called for their results. It was filled in by the sexual health nurse at Fremantle Hospital.

4.3 Telephone Interviews

The primary aim was to understand and quantify the consumer's experience with and perspectives on ECOMPACT. The final interview questionnaire was piloted on five female pharmacy graduate students and revised accordingly.

The Computer Assisted Telephone Interview (CATI) style questionnaire, incorporated 34 questions that addressed demographics, contraceptive practices, and 5-point Likert scale questions to assess consumer's satisfaction at various stages of their journey through ECOMPACT (Appendix 13). It also contained open-ended questions where the consumer could further explain any barriers and/or facilitators they experienced. The final section of the survey assessed the consumers willingness-to-pay for future pharmacy-based chlamydia screening services.

For consistency and validity of the questioning style and data entry, a research assistant, experienced with the process of CATI surveys, was employed to conduct all the surveys. An interactive Microsoft Access Database was customized to aid the flow of the survey, and the sequence and number of questions asked depended on the answers provided to certain questions.

4.3.1 *Participants*

All consumers who had given consent for further contact, and supplied their phone number on the ECOMPACT Eligibility Checklist and Consent Form (Appendix 6), were asked to participate in the telephone survey.

4.3.2 *Survey process*

If the consumer was willing to become a respondent, but could not complete the survey when contacted, then an appropriate time/date was arranged for re-contact. In cases of no contact, a voice message was left briefly explaining the purpose of the call, and a number to contact the researcher. At least three attempts (on different days and time periods) were made to contact each consumer.

4.4 Focus Groups

4.4.1 *Participants and setting*

All participating pharmacists and consumers that had given consent to be involved in focus groups were invited to the focus group sessions (Appendix 14,15). Pharmacists and consumer focus groups were held separately.

A courtesy follow up telephone call was made to all confirmed participants the day before the focus group to confirm attendance and resolve any logistical issues such as parking and dietary requirements. The focus group sessions were held at UWA in the Pharmacy Building Seminar Room. Refreshments were provided and each participant in the consumer focus group received an \$80 incentive for their participation.

4.4.2 *Focus group protocol and demographic survey*

The focus group themes were designed to be broad, open-ended questions exploring attitudes and experiences in being involved in ECOMPACT. Sub-sets of probes were created to enable the facilitator to promote discussion and obtain specific information (Appendix 16,17). All participants read an Information Sheet and signed a Consent Form (Appendix 18,19). A basic demographic survey was created for the consumer group, and was self-administered by the participants at the end of the session (Appendix 20).

4.4.3 *Group facilitator*

To create an environment where all participants could have an open discussion, an experienced external facilitator was appointed to conduct the focus groups. The facilitator was sensitive to the nature of sexual health research and the ECOMPACT process. In addition, two independent moderators observed the groups discretely.

4.5 Statistical Analysis

The data from Forms S1, S2 (Appendix 12a, b) and the CATI telephone surveys (Appendix 13) were collated and entered into an interactive Microsoft Access Database.

4.5.1 *Quantitative data*

Statistical analysis was carried out using SPSS Version 17.0. Data were reported as mean \pm sd for normally distributed data and median (IQR) for non-normally distributed data. Frequency tabulation was conducted to examine categorical variables. The Likert scale response are illustrated diagrammatically and reported as mean for normally distributed and median (IQR) for non-normal distributed data. The proportion of respondents who were willing to pay, and the overall mean of their monetary figure was calculated.

4.5.2 *Qualitative data*

Qualitative data from the telephone interviews were transcribed verbatim, coded, thematically analysed and interpreted. Digital audio recordings were made and transcribed verbatim of all focus group sessions. Manual coding was subsequently undertaken using a data index. Issues were categorised into themes and sub-themes by two independent analysts. The independent analysts and an investigator then discussed their thematic analysis and reached consensus on the main and recurrent themes. Discrepancies found between the two independent analysts led to further discussion till a mutual decision was reached to reduce information bias.

4.6 Final Stakeholder Meeting

The final objective of the study was to utilise the experience gained during the study to develop recommendations for a national pharmacy-based chlamydia program. To achieve this, the information from the quantitative and qualitative analysis will be presented to the stakeholders after the completion of the pilot period.

5 RESULTS

This chapter is divided into three sections:

1. Pharmacy recruitment and ECOMPACT uptake data;
2. Consumer demographics and evaluation from the CATI telephone interview; and
3. Analysis of the consumer and pharmacist focus group sessions.

5.1 Pharmacy Recruitment and ECOMPACT Uptake Data

5.1.1 Pharmacy Recruitment

To participate in the study, pharmacists were required to have a private area for consultations. Ten (50%) pharmacies had a consultation room, 8 (40%) a screened area, and 2 (10%) said they had a designated quiet part of the counter where EC consultations take place.

From the 20 participating pharmacies, 36 pharmacists, 9 pharmacy students and 2 pharmacy assistants attended one of the three training session (Appendix 21).

Four weeks into the pilot period, one pharmacy withdrew from the study. An exit interview was conducted to elicit the reasons for their withdrawal. The pharmacists said *“it is a good study, and we can see the benefits of it, but we feel uncomfortable and out of our depths discussing sexual health with young girls. We do not have any female pharmacists or studentsits just very difficult.”*

5.1.2 Uptake of ECOMPACT

Figure 6 shows the numbers of consumers progressing through the study. The key results are:

- In the 6-month period, a total of 769 EC consultations were recorded by the 20 pharmacies.
- A total of 596 (78%) of the EC consumers were invited and 247 consumers agreed to participate in the study, giving a recruitment rate of 41%.
- The main reasons for not wanting to participate was that the consumer was married or in a stable relationship (24%) or had been screened for STI in the last 4 weeks (14%).
- 33 (13%) consumers were indentified as showing symptoms of undiagnosed STIs and referred for a full sexual health check (Figure 5).
- 48 (19%) were ineligible because they were under 18 years of age.
- 166 consumers were eligible for the ECOMPACT Testing Kit.
- 46 consumers completed the full study protocol, giving a return rate of 28% for the study.
- All 46 consumers tested negative for *chlamydia trachomatis*.
- The effective screening rate (ESR) for the study is 6% (46 out of 769).
- The mean age of the consumer at every step of the journey was 24±5 years.

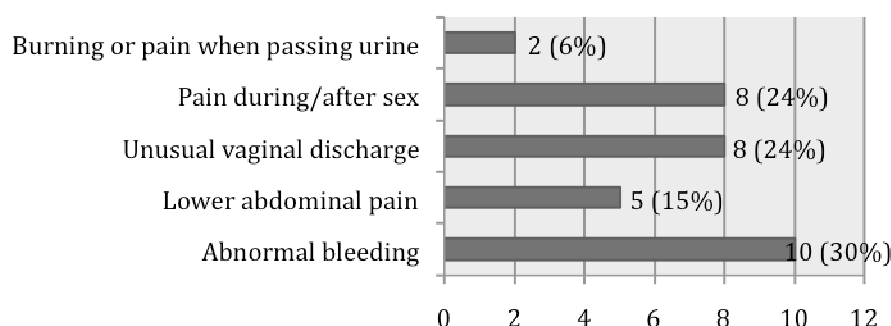
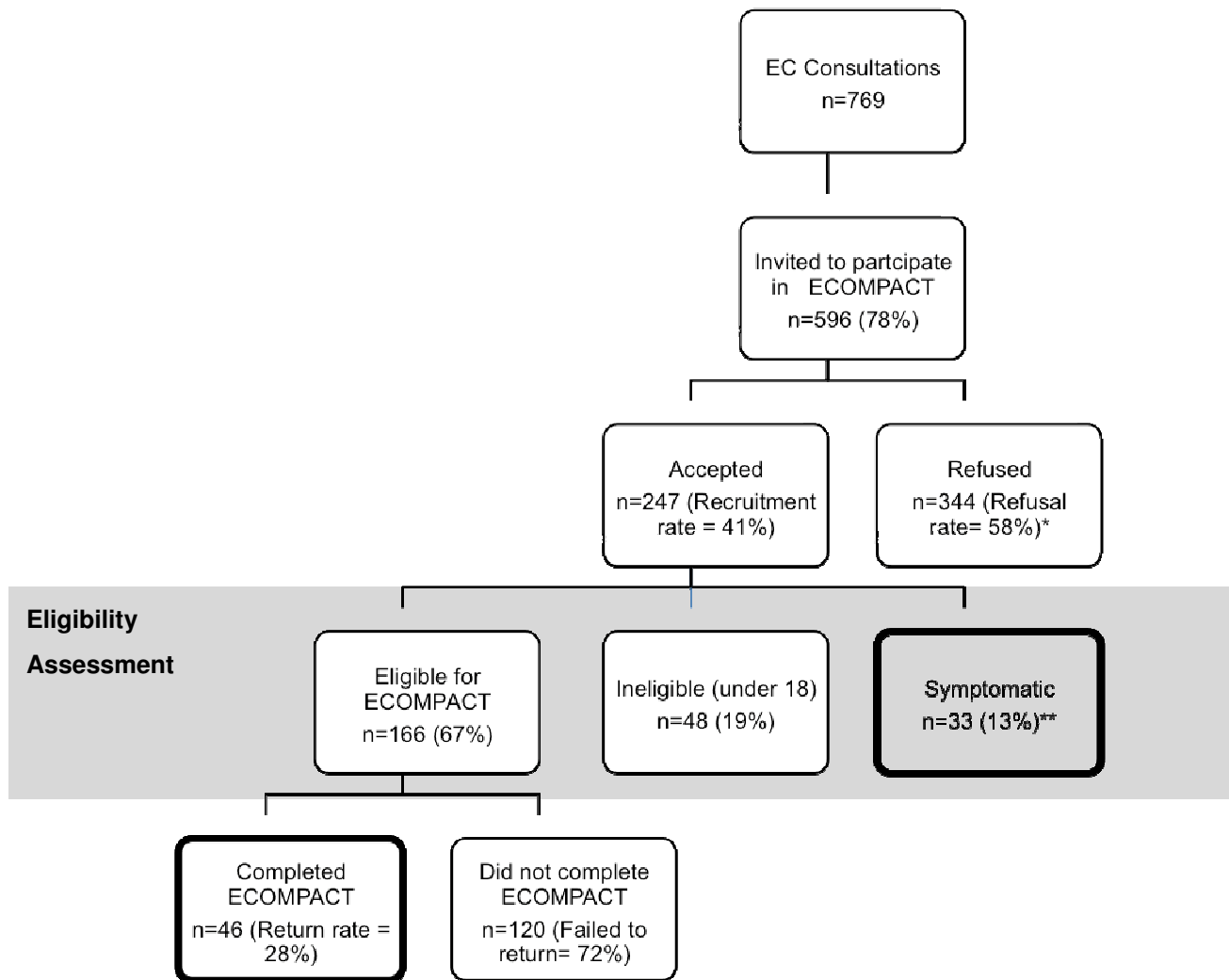


Figure 5: Symptoms of STIs in EC consumers (n=33)



*5 consumers (1%) data is unclear

**33 consumers were symptomatic and referred to a physician for a full sexual health check.

Recruitment Rate = accepted to participate / invited to participate

Refusal Rate = refused to participate / invited to participate

Return Rate = completed ECOMPACT / eligible for ECOMPACT

Effective Screening Rate = completed ECOMPACT / total number of EC consultations

Figure 6: ECOMPACT uptake data

5.2 CATI Telephone Interview

Out of the 166 eligible consumers, 150 (90%) consented to be contacted for the telephone survey and 91 (61%) were conducted. 17 consumers (29%) had incorrectly entered their phone number, 9 (15%) refused the survey when contacted, and 33 (56%) consumers were called on 3 different occasions with no answer. The categorised uptake data for telephone interview is shown in Appendix 22a.

Appendix 22b illustrates the demographics of the 91 consumers that were contacted. The consumers' age, occupation status, qualifications and usual methods of contraception were very similar and no statistical difference was observed in demographics of those that completed ECOMPACT when compared to those that did not complete ECOMPACT. The data suggest that the typical consumer is a 24-year-old female, with minimum year

12/equivalent qualification, working fulltime and uses either condoms or the contraceptive pill as regular contraception.

5.2.1 Generic questions for all consumers

Figure 7 contains the results on questions regarding convenience and comfort.

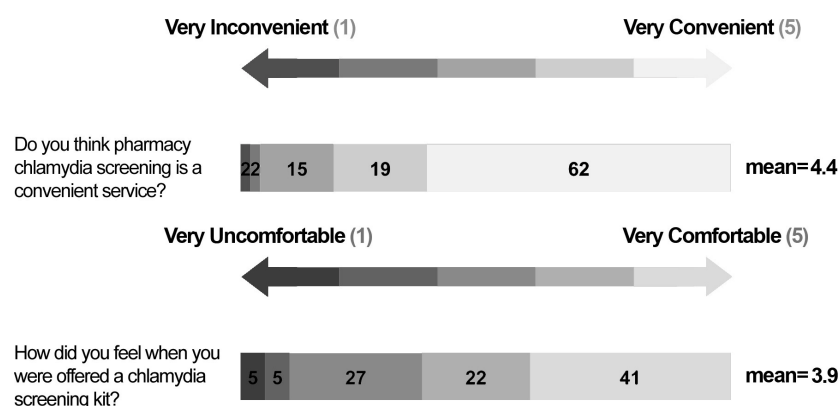


Figure 7: Question regarding convenience and comfort

In yes/no polar questions, 84 (91%) answered that the pharmacist provided enough information, and 79 (87%) stated that they did not have any concerns about confidentiality in the pharmacy.

5.2.2 Questions for consumers that did not complete ECOMPACT

To ascertain if the overall process, or the written instructions for the screening test were barriers for completing ECOMPACT, the 71 consumers that did not complete the test were asked two further Likert scale questions (Figure 8).

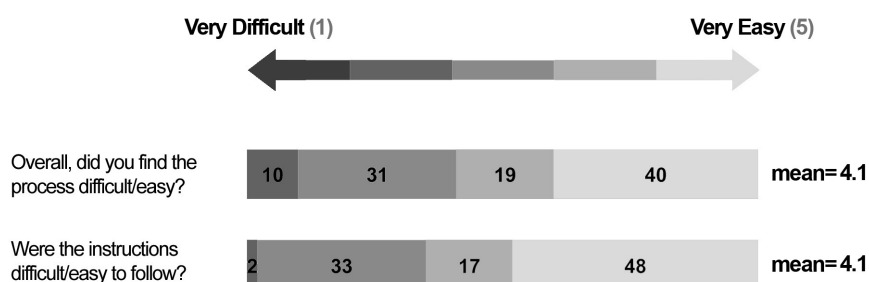


Figure 8: Questions regarding difficulty of overall process and understanding written instructions

65 consumers replied to the open ended questions asking for their reasons for not completing the ECOMPACT procedure (Figure 9). 12 consumers said that they wanted to complete the screening process, but the chlamydia test expired before they had a chance to either collect their sample or deliver the sample to a pathology drop-off site. This response is not entirely clear, as the kit itself had no expiry date. However the instructions did advise that once a sample had been taken, it should be returned to a pathology drop-off site within 72 hours. When asked to explain further, 8 out of the 12 consumers said that they did take a sample, but could not get to a pathology drop-off site within 72 hours and therefore threw it away.

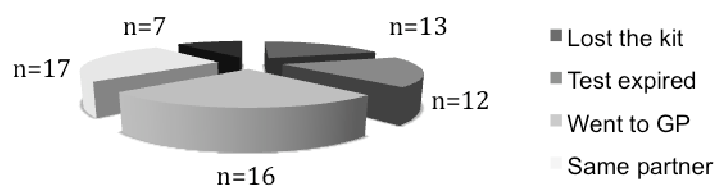


Figure 9: Reasons for not completing ECOMPACT

7 other consumers also stated dropping tests at a pathology drop-off site as a barrier for them, because they either did not have a driver's license or were from rural regions or other states and visiting Perth only for a weekend.

5.2.3 Questions for consumers that completed ECOMPACT

The 20 consumers that completed ECOMPACT were asked to rate each step of the process (Figure 10).

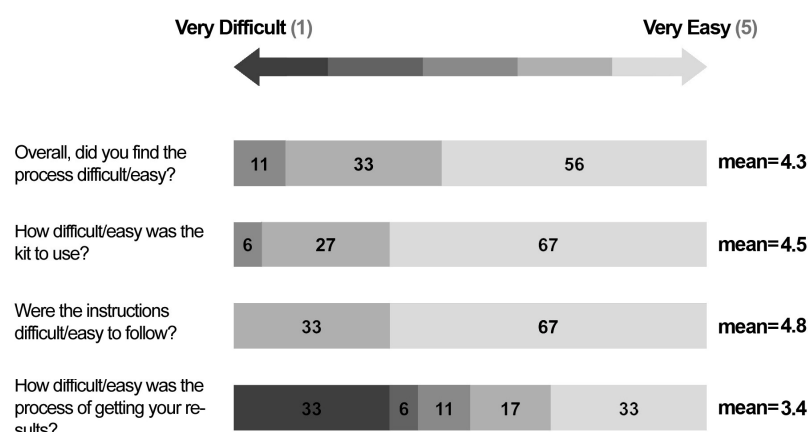


Figure 10: Questions rating difficulty of process

17 (85%) completed the screening test at home, 2 (11%) used the toilet facilities in the pharmacy, and 1 (5%) at a pathology centre. Equal number of consumers 10 (50%) returned the test to a pathology centre and the pharmacy. 6 (30%) of the consumers said that they would prefer to send the sample back by post.

5.2.4 Willingness to pay

The consumers were asked about their willingness to pay for a pharmacy-based chlamydia screening service. Out of the 91 consumers, 34 (37%) answered the question; 28 (76%) willing to pay and 6 (24%) were not. Of the 28 who were willing to pay, 25 gave an amount. The mean was A\$ 26±9 and the overall median was A\$20.

5.2.5 Themes from the open-ended questions

The results from the open-ended questions in the CATI survey were considered as indicators of how people feel about the service, rather than robust quantitative data. The key strengths and suggestions for improvements of ECOMPACT are shown in Table 2.

Table 2: Key strengths and suggestions for improving ECOMPACT

Key strengths of ECOMPACT	Suggestion for improving ECOMPACT
Highly convenient	Ensure all pharmacies have and use private consultation areas
Raising awareness of STIs	Improve pharmacists knowledge, skills and communication style
Providing anonymity	Increase the number of sites where the test can be returned
Not requiring appointments	Create marketing activities to increase awareness

5.3 Focus group results

One consumer (n=5), and one pharmacist (n=6) focus group was conducted. The results of focus groups are not intended to be statistically generalisable, but are used to reveal the range of opinions and attitudes of the participating consumers and pharmacists.

All participants in both the focus groups interacted easily and most of the discussion was participant-led and unprompted, providing rich data for analysis.

5.3.1 Consumer focus group

A total of five consumers attended the focus group (Appendix 23a). Six themes emerged around the consumers experience with the various steps of ECOMPACT.

Theme C1: Approach by pharmacist

As part of the study protocol, pharmacists introduced chlamydia screening after the EC consultation. As there was no prior advertisement of the study, all consumers were unaware of it; they all spoke about being “surprised” when the pharmacist introduced ECOMPACT. They all agreed that the initial “surprise” subsided fairly quickly because

the pharmacists handled the consultation professionally. They were given clear and concise information about the study in lay-terms, thereby making them feel comfortable.

Theme C2: Confidentiality/environment of pharmacy

The nature of the typical pharmacy model, where pharmacy assistants/staff are the first point-of-call, was raised as a discussion point. Consumers thought it *“unusual”* to initially approach a pharmacy assistant for the EC, it made them feel uneasy, and was described as *“sort of problem, they know what’s going on.”*

All five consumers had different experiences about privacy and confidentiality during their consultation with the pharmacist. Two consumers had their consultation at the front counter in the pharmacy with very little or no privacy. One consumer said she was really uncomfortable about the whole process, and the other consumer said that the consultation could have been handled better.

Theme C3: Written instructions and the chlamydia kit

They found the written material and instructions in the ECOMPACT kit well set out, self-explanatory and easy to read and understand. The information was *“thorough and clear.”* One consumer stated that while there was a lot of information to take in, particular in regards to EC, the written material in the ECOMPACT Testing Kit was self-explanatory and encouraged her to do the test.

There was general consensus that the self-collection of LVS was easy to use; and was not a barrier to them. It was noted that the instructions and diagrams provided were easy to read and follow.

Theme C4: Returning the sample for pathology screening

Some of the participating pharmacies, and participating pathology drop-off sites across Perth were listed as places where consumers could drop off their completed pathology sample for testing. One of consumers returned it to the pathology centre on her way home while the other returned it to the pharmacy. Their experiences were pleasant, and the process was simple, easy and non-judgmental.

Two consumers said that returning the pathology sample to the designated places was their biggest deterrent for completing the test. Had this process been simpler, or more convenient, they both would have completed the process.

Theme C5: Obtaining results from Fremantle Hospital

The consumers that completed the screening process said that while calling Fremantle Hospital for their results was not a barrier to them, they suggested that since they could only obtain their results during working hours, alternate methods of obtaining their results should be made available. Postal mail and email were suggested.

Theme C6: Future direction and strategies for improving for ECOMPACT

They all said that women should have more access to sexual health services, and that a *“community pharmacist is the appropriate professional”* to start providing chlamydia screening services. They acknowledged that offering chlamydia screening with EC is an ideal opportunity to screen women *“that it was not personal, but because they had unprotected sex, it was a responsible approach and entirely the right timing.”* The overall experience in the study had been *“it’s been really positive”* and that they would *“definitely, definitely I’d do it again.”*

Throughout the focus group session, consumers were encouraged to identify barriers and suggest strategies for improvement to ECOMPACT. Table 3 shows the identified barriers, strategies and relevant consumer quotes.

5.3.2 Pharmacist focus group

A total of 6 pharmacists participated in the focus group (Appendix 23b). Five themes emerged from the discussion around the consumers experience with the various steps of the study.

Theme P1: Overall experience with ECOMPACT

Pharmacists stated that their overall experience in participating in the ECOMPACT study was very positive. They all recognized the importance of the study and said it aided them in developing their professional role as a primary health care provider. It gave them an opportunity to participate in public health initiatives in sexual health.

Theme P2: Pharmacists experience in engaging with the EC consumer

All pharmacists agreed that they felt confident and comfortable talking about EC and chlamydia screening but their experiences in engaging with the consumer varied. They suggested that having the more time, more skills and private consultation areas in the pharmacy might be a useful strategy to enhance interactions with the consumers.

A common barrier most pharmacists found when recruiting consumers to participate in ECOMPACT was that the women did not want to spend time in the pharmacy or were not interested in chlamydia screening. The most

common reasons stated were “don’t have time to find out about the study” followed by “long-term relationship or married.”

Theme P3: Infrastructure (time, paperwork, money and staff resources)

Infrastructure issues were common discussion points in the focus group. They all agreed that the paperwork and documentation added took extra time.

EC was usually requested on the weekends and evenings. This allowed some of the quieter pharmacies to spend time with the consumer, while those that ran on locum pharmacists on the weekend found ECOMPACT very time-consuming and difficult to implement.

On the topic of money and financial re-imbursement, most pharmacists indicated that the altruistic value of participating in new research to improve their health professional status outweighed financial incentives. However, one pharmacist stated that support staff and pharmacy assistants do not share that passion for the profession.

Theme P4: Approach to participating in ECOMPACT

Those present at the focus group felt that while they knew the study was an important step into the development of the pharmacists’ role in sexual health, other pharmacists in their staff/team might not necessarily share this notion.

Theme P5: Future direction and strategies for improving for ECOMPACT

The pharmacists believe that offering patient a chlamydia screening kit should become part of a long-term service that is provided across the country. They recommended that it should be available to everyone, not just EC consumers. They all agreed that to be able to provide chlamydia screening, pharmacists have to feel confident and comfortable. Training, education and communication skills need to be provided and assessed.

During the focus group session pharmacists suggested various strategies to address barriers they had identified. They have been summarized in Table 3 along with some illustrative quotes.

Table 3: Barriers and strategies to improve ECOMPACT as suggested by consumers and pharmacists

Barrier	Suggested strategies	Consumer Quotations
Privacy/ Confidentiality	All pharmacies should have separate consultation rooms	<i>“In general pharmacies need that facility anyway, because there’s often times in there you want to approach a pharmacist or a pharmacy and you want to ask more questions but you end up, walking away with something to read about it, ‘cause you maybe weren’t talking to someone who could give you the right sort of advice or you know simply it wasn’t appropriate environment, pharmacy outlets or pharmacist.”</i> [Consumer]
Improving screening acceptance rate	<ol style="list-style-type: none"> 1. Available at all times from all pharmacies 2. Advertise the service 3. Education on STI to pharmacist and consumers 4. Package EC and chlamydia kit together 	<i>“I think it should be in every pharmacy so, and then you can return to any pharmacy. I’d just make it easier.”</i> [Consumer] <i>“Advertised that we do STD testing here or something like that.”</i> [Pharmacist] <i>“All included as one package, you’ll pay money for it and I think just generally people would be more likely to do it.”</i> [Consumer]
Improving screening return rate	<ol style="list-style-type: none"> 1. Increase venues for returning sample and postal returns 2. Give options for obtaining results – mail/ email/ phone 	<i>“I think it should be in every pharmacy so, and then you can return to any pharmacy. I’d just make it easier.”</i> [Consumer] <i>“Have the bin the pharmacy for them to drop it and then.”</i> [Pharmacist] <i>“Yeah just that bit easier when it comes back in the mail.”</i> [Consumer]
Pharmacist specific barriers and strategies		
Paperwork, Time and Money	<ol style="list-style-type: none"> 1. Simplify the paperwork or corporate into PSA EC checklist 2. Utilize a web-based system for recording 3. Provide adequate compensation for time 	<i>“Everything’s got to be on one sheet. Maybe that should get incorporated with the sheet that we currently use (referring to the PSA EC checklist)”</i> <i>“A web based system to make the implementation more successful and much easier to gather data.”</i> <i>“You’ve got to remember that we’re in a retail environment and we’re paying a retail rent and we’re paying for a retail space so we understand that and we understand it’s a mix between professionalism and retail.”</i>

6 DISCUSSION

ECOMPACT was developed to offer chlamydia testing to EC consumers from pharmacies, because they are considered to be at risk of STIs. It gave pharmacists an opportunity to approach women from the general population and to offer them access back into the sexual health care system.

ECOMPACT provided the following paths to an intervention in sexual health care and achieved positive outcomes for participating consumers:

1. All women with symptoms suggestive of STIs (13% of participating consumers) were referred to a physician for a sexual health check. Their referral for a sexual health check by the pharmacist was potentially a timely intervention, which may have prevented future complications of PID and subsequent costs on the health system. This finding in itself clearly demonstrates that pharmacists should be actively screening EC consumers.
2. All asymptomatic and eligible women (67%) were given information (health promotion) on chlamydia screening and an opportunity to test themselves (diagnostic and long-term prevention).
3. 28% (n=46) of 166 consumers tested themselves for chlamydia, with negative results. To obtain their results, consumers contacted sexual health services at Fremantle Hospital. This enhanced the STI and sexual health messages they received in the pharmacy.

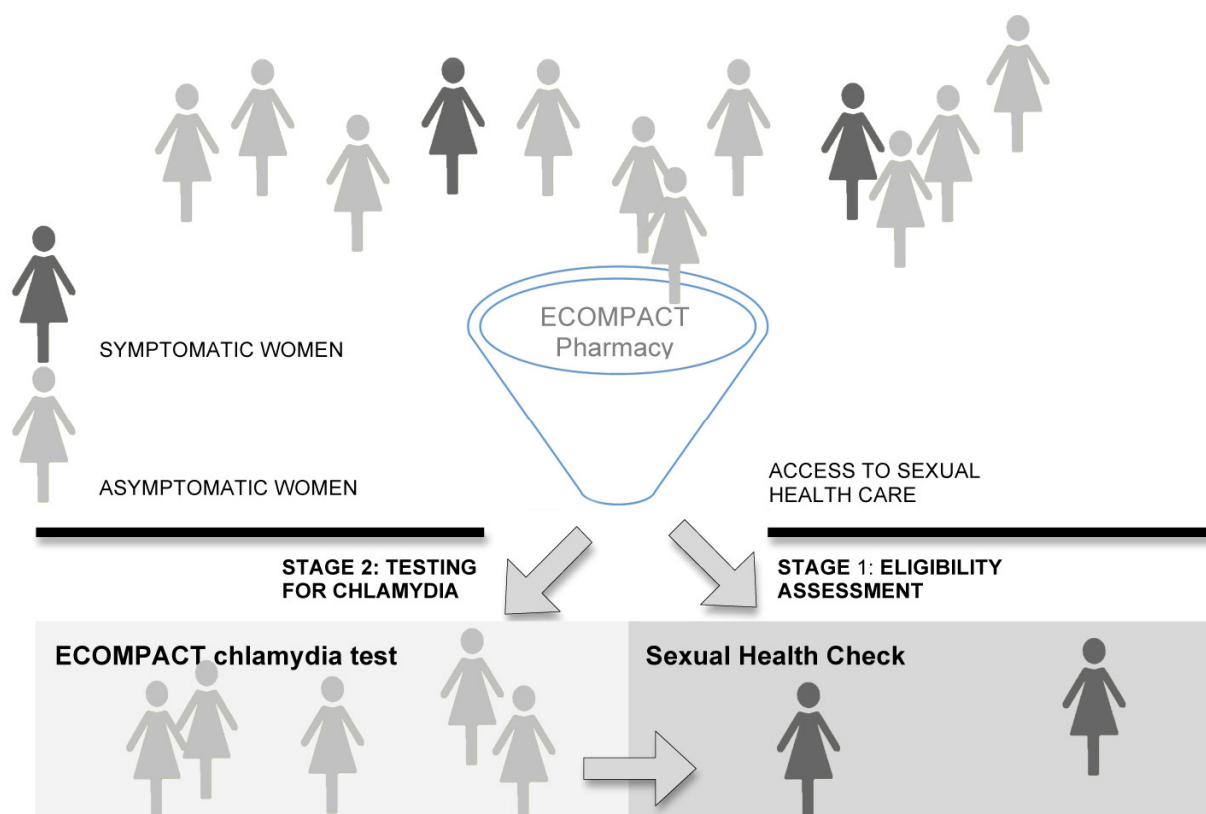


Figure 11: Pharmacists providing EC consumers access to sexual health care

The ECOMPACT protocol was highly successful due to the effective collaboration between participating health care professionals. The study demonstrated that the infrastructure developed by the research team at the beginning proved effective and easily implemented. Consumers and pharmacists both considered the service to be highly convenient, and the timing of offering a chlamydia test with an EC consultation as highly appropriate.

Within the participating pharmacies themselves, the service was embraced and integrated with minimal changes to their existing practice, because it was an extension to EC consultations that were already part of the pharmacies' service schedule. Delivering the ECOMPACT model allowed the pharmacist to utilise the concepts of primary health care and prevention, making referrals to other health professional and provide a professionally rewarding new sexual health service (Figure 11).

6.1 Uptake of ECOMPACT

6.1.1 Recruitment of consumers

The pharmacists invited almost 80% of EC consumers to participate in the study, indicating that the combination of discussing STIs and chlamydia with EC is highly realistic.

6.1.2 Consumer acceptance rate and return rates

Almost half the consumers accepted to participate in the study and from that 28% did the test and returned it to a pathology centre. This represents an ESR of 6%.

To put the participation rate of ECOMPACT into perspective, we have benchmarked our findings against equivalent figures from large-scale population based screening programs to smaller scale chlamydia pilots.

- BreastScreen Australia was established by the Commonwealth and the states and territories in 1991 and is one of the most recognised and comprehensive population-based screening programs in the world. Screening has increased significantly since commencement of BreastScreen Australia, with a total of 1,622,481 women screened across Australia in 2005-2006. Even so, at present, the program has an ESR of just over 50% of women in the target age group.²¹
- The Bowel Cancer Screening Pilot Program tested the feasibility, acceptability and cost effectiveness of bowel cancer screening in Australia between 2002 and 2004. While they do not quantify their total population and ESR, their overall participation rate was 45.5%.²² (ECOMPACT participation rate =28%).
- In the UK, a study of postal chlamydia testing kits given out by pharmacists to those requesting EC found that only 25% of eligible clients were offered a postal kit but only 17% returned a sample.²³ This gave the study an ESR of 9%.
- The Australian Federal Government conducted a chlamydia screening pilot in general practice, on the basis that nearly 90% of women and 70% of men aged between 15 and 24 see a general practitioner (GP) at least once a year, making general practice an excellent opportunity to reach a vast majority of that population.¹⁴ A retrospective evaluation of Medicare data for the period of October 2007 to March 2008 indicated that their ESR was 6.3% for women and 1.6% for men in that age group were recorded by the Health Insurance Commission as having been tested for chlamydia.²⁴

ECOMPACT was a feasibility study of a much smaller scale than any of the studies described above. However these comparisons indicate that while the findings of ECOMPACT fall short of high benchmarks set by well-funded and marketed programs like BreastScreen Australia and the Bowel Cancer Screening Pilot, they are comparable to other successful pharmacy-based and GP chlamydia screening studies.

6.1.3 Stage 1: Eligibility Assessment Checklist

Using the Eligibility Assessment Checklist on the 247 consumers that accepted to participate in the study, the pharmacists identified almost 15% of them to have symptoms suggesting an undiagnosed STI. This demonstrated that by just asking a few simple questions, pharmacists can play a significant role in the detecting and referring women that need further investigations. The importance of such a simple intervention to public health and health care costs has been shown in research.^{7, 8}

A study in Melbourne found that 70% of those tested positive for chlamydia had the same symptoms we identified in this study.²⁵ This suggests that a large majority of our 33 symptomatic consumers may be positive for chlamydia. Other population based studies suggest that almost 40% of women with undiagnosed chlamydia could be susceptible to PID and hence infertility.^{3, 4} Based on these findings, it is probable that just using the Eligibility Assessment Checklist, pharmacists may have identified and prevented cases of PID. This study presents no evidence for this assumption, as although these consumers were referred for a full sexual health check, due to ethical reasons we could not follow the outcomes of the referral.

6.1.4 Stage 2: Testing for chlamydia

46 asymptomatic consumers completed ECOMPACT and tested negative for chlamydia. An Australian prevalence survey of 657 asymptomatic (n=657) found that women of similar age (women aged 18-29 years) and demographics as ECOMPACT had an overall chlamydia prevalence of 0.9%.²⁵ Other Australian prediction models for the prevalence of chlamydia suggest that it ranges from 0.5% to 3.5% and is dependent on the demographics of those tested and their associated sexual risk factors.^{19, 26} Accordingly, the findings of this feasibility study were as expected.

6.1.5 CATI telephone interviews

150 (90%) out of the 166 of the consumers recruited by the pharmacists agreed to leave their full name and mobile phone number for the in-depth telephone surveys. This is a successful outcome as anecdotal evidence from many similar studies state that women do not want to be identified and followed-up when it comes to sexual health. The finding suggests that consumers asking for EC in a pharmacy gained a level of trust and confidence in the pharmacists.

Approximately 60% of consumers eventually participated in the telephone survey. We can conclude that while there are reasons for a high percentage of consumers not completing the study, age and demographics are not barriers to implementing ECOMPACT and in this respect the targeting strategies applied are valid. Demographic information of consumers that refused to participate in the study could not be collected and we are therefore unable to draw comparisons between these consumers and the participating groups.

6.1.6 Reasons for consumer not participating in ECOMPACT

The main reasons for almost 25% of the consumers for not wanting to participate was that they were married or in a stable relationship and therefore may not consider themselves to be at risk from chlamydia. This percentage of women is considered about normal for the EC population according to the two sexual health physician involved in this study. Another common reason was that they had been tested in the last 4 weeks because they had unprotected sexual intercourse. This displays a high-risk behaviour, i.e. they had unprotected intercourse again within this period.

6.1.7 Reasons for consumer not completing ECOMPACT

The most common barriers that prevented consumers from completing ECOMPACT were that they had to drop the test at a designated pathology drop-off site, and that the test expired before they had a chance to use it.

The LVS requires certain precautions and timeframes that need to be observed. For optimal stability, once a LVS has been taken, it has to be stored between 2°C to 30°C, and if stored appropriately remains stable at room temperature for 20 days.²⁷ To prevent the risk of consumers storing the pathology sample incorrectly and compromising the result, by for example keeping it in a car (temperatures in Perth can easily rise above 30°C in cars), consumers were advised to return the specimen to a pathology centre within 72-hours of collection. Some other consumers were deterred by the co-ordination required to return their sample to a pathology drop-off site in time, or simply found it inconvenient to visit a pathology site. In retrospect, educating consumers about the sample and its stability, and giving them specific instructions on how to store the specimen and the actual timeframes might have improved the return rate. A revised ECOMPACT model should explore alternative solutions.

6.2 Pharmacy Setting

6.2.1 Confidentiality and Privacy in the pharmacy

In general, consumers were comfortable to discuss sexual health with the pharmacist. The study did however yield some conflicting results regarding privacy. When consumers were asked a polar (yes/no) question to indicate whether they were concerned about privacy, 87% answered that they were not concerned. By contrast, when the same consumers were asked open-ended questions, almost 50% said they experienced a lack of privacy. The divergence of findings was confirmed in the consumer focus group sessions where every participant had a different experience on where their consultation took place and how they felt about it. While participants expressed that the need for privacy during sexual health consultations varies for each individual, they were clear that a dedicated private consultation area was preferable and that they would not feel comfortable discussing sexual health 'over the counter'.

Sexual health has always been associated with social stigma.²⁸ During the focus group discussions the point was raised that the approach by the pharmacist to talk about sexual health could be perceived as 'singling out' an individual. The concerns of being 'caught' having a discussion about STI with a health professional, are similar to those identified by Pavlin *et al.* in relation to general practice not being confidential or private enough for chlamydia testing.²⁸ However community pharmacies can provide a neutral and anonymous setting if the consultation is handled discreetly and in private, thereby alleviating these concerns.

6.2.2 Communication with EC consumers

Talking to young women about STIs and chlamydia, regardless whether it is in a clinical setting or a community pharmacy is not easy. Many pharmacists are uncomfortable talking about sexual health, and as such may not be in an ideal position to consult a consumer about STIs let alone make them feel comfortable. Themes emerging from the open-ended questions in the CATI telephone interviews confirm this. It is plausible to assume that pharmacists

acquire confidence and develop their communication style in this new field of sexual health the more it becomes part of their regular practice. The ECOMPACT training course was developed to help pharmacists become confident and comfortable with talking about sexual health, but training alone cannot substitute this progressive learning.

Most participating pharmacists thoroughly enjoyed participating in the study. Several found it satisfying that they could extend the EC consultation to completion as per the PSA protocol, by including sexual health advice. Their motivations for participating in ECOMPACT were highly altruistic. They recognised the importance of the study, and participating in ECOMPACT gave them a chance to exercise their professional reputation as a primary health care provider in the field of sexual health services.

6.2.3 Effectiveness of the ECOMPACT Training Course

Participation in sexual health services such as ECOMPACT requires pharmacists to exercise clinical decision-making. The Eligibility Assessment Checklist was designed to form the basis of the pharmacists' clinical decisions, but did not substitute clinical knowledge.

The training course was designed to ensure participating pharmacists had the required knowledge to talk about STIs and chlamydia screening and to ensure that they understood the ECOMPACT protocol. It was not intended to set performance benchmarks and therefore an assessment of the effectiveness of the training course was not within the scope of the study. The success of the training session is exhibited incidentally by the fact that 19 out of 20 pilot pharmacies successfully administered the ECOMPACT study protocol in their pharmacy.

The pharmacists actively engaged with almost all of their EC consumers in consultations about STIs, chlamydia, and the ECOMPACT study. Furthermore, every pharmacy issued ECOMPACT Testing Kits to their consumers and had at least one chlamydia test returned to a pathology centre. We believe that the training course positively contributed to this outcome.

6.2.4 Barriers identified by pharmacists when delivering ECOMPACT

Infrastructure issues within the pharmacy, such as time spent on consultations, appropriate re-imbursement, and staffing issues were raised as the most common concerns during the study, however they had little impact on the participation of pharmacists. These infrastructure issues are synonymous with the findings of Armour et al. that investigated the attitudes of community pharmacists toward pharmacy practice research in Australia.²⁹

6.3 Infrastructure within the ECOMPACT protocol

A unique feature of ECOMPACT model was that community pharmacists could order what is typically called a "medicare" pathology test without a Medicare Provider Number. This feasibility study showed that pharmacists successfully requested a pathology test for 166 consumers, 46 of which returned it to a pathology drop-off site. There were no queries from the pathology centres over any of the pathology requests made by the pharmacists. Disseminating results from pathology centres to the nominated sexual health physician at Fremantle Hospital was also seamless. This demonstrates that the infrastructure and channels developed by the research team were strong and that pharmacists are capable of requesting direct-to-consumer chlamydia tests from pathology centres.

6.4 Limitations

A pre and post training evaluation for the pharmacists that participated in the ECOMPACT study was not conducted. Therefore, it is not possible to quantify the effectiveness of the training session we developed and delivered. Future studies should consider this during the development stages of the study protocol.

Ethical restrictions on the study did not permit us to follow the outcomes of the 33 symptomatic consumers that were referred to a physician. Therefore, we cannot access the full impact that ECOMPACT could have had on the health of these women. Future studies should aim to create a follow up pathway with this group of women.

Another ethical restriction was that we could not recruit any consumer under the age of 18 years due to guidelines on "consent for a minor". One way of overcoming this barrier in the future may be integrating the Eligibility Assessment Checklist with the PSA EC protocol. This way they would at least be assessed for symptoms of STIs.

Some pharmacies relied on locums on the weekend, and in some cases they were not asked to participate in the study. Therefore we may find that the total number of EC consultations may be under-recorded, leading to an inaccurate recruitment rate. To address this issue, the project co-ordinator sent fortnight emails to remind pharmacists to record all EC consultations and requested their monthly EC stock usage.

6.5 Conclusion

This study has developed a model for pharmacy-based chlamydia screening and established clear evidence that it is feasible in the Australian healthcare setting. Its success is defined by two basic strategies: Firstly, targeted chlamydia screening is an extension of the PSA EC protocol already used in pharmacies. It utilises existing infrastructure within the pharmacy setting to implement a service with minimal disruption to current practice. Taking this a step further, the Eligibility Assessment Checklist could easily be added to the current EC protocol to become a nationwide screening tool for STIs.

Secondly, targeting EC consumers insured that screening is offered to a general population that displays at-risk behaviour for chlamydia and other STIs and may otherwise not have been screened. The findings from this study confirm that these consumers are at risk of undiagnosed chlamydia infections.

Currently, consumers need to make an initial appointment with a physician to get a chlamydia pathology request, and a follow-up appointment if found positive. Our research has shown that the average EC consumer was 24 years old and works full time. They may find it difficult to take time off for a GP appointment, especially if they do not experience any or only mild symptoms. By allowing the pharmacist to request a direct-to-consumer pathology test for chlamydia, pharmacists provide a convenient, easier and more accessible option for this group of women.

This, and the fact that in the process it does not rely on GP's or other health professionals to provide clinical data to the pharmacist (one of the major limiting factors in most chronic disease management studies) ensure that the model is self-contained and sustainable. Pharmacists can play a significant role in sexual health and contribute to primary health care with minimal infrastructure costs to themselves and other healthcare providers.

Future strategies should seek to refine the ECOMPACT model based on suggestions made by consumers, pharmacists and stakeholders. A larger study of this kind conducted across Australia could include measures to identify prevalence rates of chlamydia in the EC population. In addition a well-designed and socially marketed pharmacy-based chlamydia screening program could have the capacity to increase sexual health awareness, and normalise STI screening by attaching itself to pharmacy-based EC, which has already become 'normal'.

ECOMPACT was the first study of its kind in Australia and required a level of participation of pharmacists not seen before. It also tested the willingness of consumers to embrace and use a new service related to sexual health. Considering that almost half agreed to participate, ECOMPACT has shown that pharmacists can provide STI screening services and that their consumers are willing to accept these services.

7 COST OF ECOMPACT

This section discusses the approximate costs of conducting the ECOMPACT study and serves as guidance on the amounts of funds required to support pharmacy-based chlamydia screening to all EC consumers.

The approximate cost of each ECOMPACT Testing Kit issued and returned to pathology was as follows:

Table 4: Cost of ECOMPACT

Cost of ECOMPACT Testing Kit	Low Vaginal Swab (LVS)	\$1.00
	Materials for the kit (leaflet and envelop)	\$2.00
Cost of Pathology Test	NAAT Testing of LVS	\$25.00
	Total	\$28.00
Pharmacists Time	Time taken by pharmacist for eligibility assessment checklist	2 mins
	Time taken by pharmacist for giving out ECOMPACT kit	3-5 mins
	Total time for the study protocol	5-7 mins
	Cost of the pharmacists time of 5-7 minutes@ \$80/hr	≈\$10
Final Total		\$38.00

(Note: The \$80 hourly rate for the pharmacist includes on cost charges)

To ensure that ECOMPACT is effective when implemented as a nationwide screening program, the key roles required are:

- A Programme Lead/ Co-ordinator (based nationally) to establish collaboration networks between family planning, the Royal College of Pathologist of Australia and sexual health physicians in each state;
- A Pharmacy co-ordinator (state or national based) to provide training and support to pharmacists; and
- A sexual health nurse (state based) to disseminate the test results, and refer positive patients for treatment and further investigations.

8 RECOMMENDATIONS

The final stakeholder meeting was held on **26th Oct 2009** at UWA.

The aim of the meeting was to review the quantitative and qualitative analysis of the 6-month ECOMPACT feasibility study and:

- Develop recommendations for the future of ECOMPACT model;
- Explore funding options for the ECOMPACT model and
- Develop guidelines for a national ECOMPACT model.

8.1 Stakeholder driven recommendations

Recommendation 1: Integrate the ECOMPACT Eligibility Assessment Checklist into the existing PSA EC checklist.

The pharmacists identified 13% of consumers as having symptoms of STIs by using the Eligibility Assessment Checklist and were immediately referred to a physician.

We strongly recommend that the 5 questions from the Eligibility Assessment Checklist should be integrated in the PSA's national EC protocol for supply. This should be done without delay.

Recommendation 2: Integrate ECOMPACT model with all EC consultations from all community pharmacies.

769 women requested EC from 20 pharmacies over 6 months. Pharmacists assessed 247 consumers and requested a chlamydia pathology test for 166. These women would otherwise not have had an STI intervention at that point in time. ECOMPACT provides new avenues for screening for chlamydia based on convenience and increased accessibility.

We urge all professional pharmacy bodies to recognise that pharmacies can extend their roles into preventative health care and contribute to chlamydia screening in accordance with the Australian Sexually Transmissible Infections Strategy and work towards integrating the ECOMPACT model with all pharmacy-based EC consultations.

Recommendation 3: Improve the existing ECOMPACT model to increase the uptake and return rates of chlamydia tests.

The barriers identified in the evaluation of ECOMPACT should be addressed and the strategies suggested to improve ECOMPACT should be considered. They are:

- Increase the number of pathology drop-off sites.
- Consider options for postal return for the chlamydia test. Part of this process should include identifying alternative brands of LVS that do not have a transport medium.
- Give the consumer more specific verbal and written instructions.
- Give the consumer options for their preferred method of obtaining their results. This may be done at the point of recruitment in the pharmacy or when the consumer returns their sample to pathology testing, depending on the method of return.
- Provide options for where to obtain treatment for consumers that test positive.

Recommendation 4: Secure funds for the wider availability of ECOMPACT

Pharmacists successfully implemented ECOMPACT and provide chlamydia screening to EC consumers. They provide an easy and accessible alternative to chlamydia screening to women that may not otherwise been tested.

We strongly recommend the Pharmacy Guild of Australia to secure "block funding" for the ECOMPACT model through one of these strategies.

- The second National Sexually Transmissible Infections Strategy;
- The Preventative Health Taskforce; or

- The Fifth Community Pharmacy Agreement.

These agreements are currently in consultation with the Australian Government Department of Health and Ageing and we urge the Pharmacy Guild of Australia to lobby for “block funding” for a national pharmacy-based chlamydia screening service.

The funding should cover:

- The immediate cost of ECOMPACT as illustrated in Table 4 (Section 7),
- Adequate re-imbursement for the pharmacists’ time and involvement in providing the ECOMPACT service. This can be done by determining the appropriate method and value of incentive, such as payments per consultation, returned kit or target incentives (e.g. a one-off payment for every 10 tests returned); and
- The cost of personnel (as outlined in Section 7) required to implement and deliver ECOMPACT.

Recommendation 5: Ensure all pharmacists possess necessary skills and a level of knowledge that will enable them to sexual health services.

To achieve this:

- A higher profile needs to be given to sexual health in the pharmacy curriculum at university level;
- Develop a continued professional development course for pharmacists on sexual health, chlamydia screening, dealing with difficult situations and child protection.
- Develop a training session for ‘front line’ pharmacy assistants and students which includes an initial face-to-face training session and subsequent follow-up (refresher) training, potentially six monthly.
- Use of internet technology, may provide delivery of interactive, problem-based, and accessible training whereby pharmacists and their staff can learn at their own speed.
- Evaluate the effectiveness of the training course prospectively to assess changes in confidence and skills pre-training, post-training and at various times during the study period.

Recommendation 6: Ensure every pharmacy has a private consultation area.

The results of this study demonstrate that consumers want their EC consultation in more private and professional spaces in the pharmacy.

We strongly recommend that all pharmacies should be able to provide an area suitable for discussions on EC and chlamydia screening.

Recommendation 7: The chlamydia screening service and kits should be promoted to service users on the platform of ease of use, convenience and anonymity

Consumers often first learn about the in-pharmacy service through national media and in store promotion.

We recommend that targeted communication strategies and marketing initiatives should be undertaken at national level.

Recommendation 8: Identify and acknowledge other target groups for chlamydia screening from pharmacies.

The potential for pharmacists offering chlamydia screening to other “high-risk” groups should be investigated.

We recommend that future studies should be funded to identify other target groups.

8.2 Framework for guidelines for national pharmacy-based chlamydia screening service

The following framework provides an outline of the issues to consider when setting a pharmacy-based chlamydia screening service. While this framework can be used in consultations for funding, we strongly recommend that key stakeholders from every state are involved prior to the creation of national pharmacy-based chlamydia screening guidelines.

What is ECOMPACT?	<ul style="list-style-type: none"> The Emergency Contraception Mediated Pharmacy Access of Chlamydia Testing (ECOMPACT) model is collaboration between pharmacists, pathology centres, general practitioners (GP), family planning and sexual health services. It provides opportunistic chlamydia screening to all consumers that access Emergency Contraception (EC) from the pharmacy. Pharmacists assess the consumer for eligibility for chlamydia testing using the Eligibility Assessment Checklist. If eligible the pharmacist completes a pathology request form for the chlamydia test and gives the consumer an ECOMPACT Testing Kit that contains a test and instructions for the consumers on how to collect their own sample, where to return it and how to obtain their results.
Pharmacist – Consumer Interaction	
Recruitment Strategy	<ul style="list-style-type: none"> Pharmacist Initiated. After EC consultation. Opportunistic screening for STIs of all EC consumers.
Screening and Assessment	<ul style="list-style-type: none"> Screening for STI symptoms. Refer all consumers with symptoms to a physician. Offer ECOMPACT Testing Kit to all eligible and asymptomatic consumers.
Type of Specimen	<ul style="list-style-type: none"> All tests must use a NAAT platform. Consumer collects their pathology sample. Options include <ul style="list-style-type: none"> Low Vaginal Swab (LVS) First Void Urine (FVU)
Return of Specimen	<p>Examples include:</p> <ul style="list-style-type: none"> All pathology centre drop-off sites All pharmacies Postal mail
Dissemination of Results	<p>Consumer should advise on:</p> <ul style="list-style-type: none"> How they want the results to be disseminated i.e. either calling a designated phone number or getting results in mail / email. Where they want their results to be sent. Options include their own GP, a local family planning or sexual health service.
National and State Based Management	
Infrastructure	<ul style="list-style-type: none"> Provide pharmacists with education on sexual health testing Ensure all physicians are aware that pharmacists are requesting chlamydia tests for pharmacy-based EC consumers. Ensure all pathology centres have the capacity to send the consumers results to the nominated physician.
Key personnel	<ul style="list-style-type: none"> Programme lead/ co-ordinator (Based at National level) Pharmacy co-ordinator (National or State Based) A sexual health nurse (State Based)
Funding	<ul style="list-style-type: none"> “block funding” for pharmacy-based chlamydia testing.

9 APPENDICES

1. a. Minutes of Stakeholder Meetings 1
b. Minutes of Stakeholder Meetings 2
c. Minutes of Stakeholder Meetings 3
2. Pharmaceutical Society of Australia Emergency Contraception Protocol
3. Pharmacist Expression of Interest to Participate Letter
4. Department of Planning Western Australia Metropolitan Regional Scheme
5. Pharmacist Acceptance Letter
6. ECOMPACT Eligibility Checklist and Consent Form
7. Health Review Request Form
8. ECOMPACT 'What you need to know' Leaflet
9. ECOMPACT Reminder Card
10. ECOMPACT Protocol Explanatory Notes
11. a. ECOMPACT Pharmacist Training Course Program
b. ECOMPACT Pharmacist Training Course Presentation Slides
12. a. Summary Form S1
b. Summary Form S2
13. CATI Telephone Interview
14. Consumer Invitation to Focus Group Letter
15. Pharmacist Invitation to Focus Group Letter
16. Consumer Focus Group Themes
17. Pharmacist Focus Group Themes
18. Consumer Focus Group Information Sheet and Consent Form
19. Pharmacist Focus Group Information Sheet and Consent Form
20. Patient Demographic Survey
21. Demographics of Participating Pharmacies
22. a. Number of Telephone Surveys
b. Demographics of Consumers Interviewed
23. a. Demographics of Consumers at the ECOMPACT Focus Group
b. Demographics of Pharmacists at the ECOMPACT Focus Group

Appendix 1a: Minutes of Stakeholder Meeting 1

ECOMPACT

Minutes

Purpose of the meeting:	ECOMPACT Stakeholder Meeting
Meeting No:	1
Location:	Room 203, Pharmacy, UWA
Date / Time:	07/02/08 at 2pm
Attendees:	Rhonda Clifford/ University of Western Australia Lewis Marshall/ Sexual Health Physician, Fremantle Hospital Xuan Li Yow/ female consumer Jila Misaghian/ female consumer Sajni Gudka/ University of Western Australia
Apologies	Alison Creagh, Family Planning Western Australia

Item No.	Description	Action
Introductions	RC opened the meeting and welcomed the group Members introduced themselves SG presented the outline of meeting	
Ethics Application	SG has made an ethics application for the pharmacy-based chlamydia study. Ethics have responded back with queries on the content of the telephone survey. SG to create the telephone survey, and respond back to Ethics by Friday 8 th Feb.	SG Friday 8 th Feb.
Recruiting Pharmacies	This is the first project of its kind in Australia. Not possible to calculate power. Pharmacies that have more EC consultations per month should be recruited so that more tests get issued. SG to prepare to letter for expression of interest for pharmacists and send it out to all pharmacies in Perth.	SG
EC consumers recruitment	XLY said that consumers would be happy to talk to pharmacist about chlamydia, but it should be done in conversation style. SG highlighted that according to PSA EC protocol, pharmacists should be discussing STIs with all women. LM agreed that the study protocol should link with existing workload.	
Pathology Lab Pathology Testing Kit	LM will contact Western Diagnostics and Path West to arrange meetings with them. First Void Urine (FVU) or Low Vaginal Swab (LVS). SG presented evidence that both samples have their advantages but LVS is more stable at room temperature and urine sample can not be posted. RC and LM raised the issue of rural and regional Australia where access to a pathology lab may not always be possible. XLY and JM said that women would not shy away from LVS and it is a simple process. Decision was made that a LVS test will be used.	LM SG
Obtaining results	SG to create a leaflet explaining in detail the way to use a LVS – illustrated if possible LM said that Fremantle Hospital Sexual Health Clinic would set up a free-phone number that can be used in the study. Sexual health nurse will be responsible for giving out the results SG to arrange to meet her and explain the study process to her, and her involvement.	SG
Project Materials	SG to create all materials for the study: 1. Patient recruitment process 2. Pharmacy recruitment process 3. Patient Information Leaflet and Consent Form 4. Pharmacy Data Collection Sheets	SG
Pharmacist Training	SG discussed that a training program should be set up for pharmacists LM, RC and SG to meet to create the training session Will include summaries of relevant literature reporting prevalence and risks associated with chlamydia, and practical issues on talking to women. Main barriers of pharmacy practice research will be discussed – and problem solved prior to the session.	LM, RC and SG
Advertising	XLY asked if there will be an advertising campaign to tell women to access chlamydia test from these pharmacies. RC highlighted that since it was linked with EC, the Poison's Law does not permit advertising EC to the public.	
Next Meeting	It was agreed that the next meeting will be at 11am on 17 th March 2008 at UWA.	

Appendix 1b: Minutes of Stakeholder Meeting 2

ECOMPACT

Minutes

Purpose of the meeting:	ECOMPACT Stakeholder Meeting
Meeting No:	2
Location:	Room 203, Pharmacy, UWA
Date / Time:	17/03/08 at 11am
Attendees:	Rhonda Clifford/ University of Western Australia Lewis Marshall/ Sexual Health Physician, Fremantle Hospital Alison Creagh, Family Planning Western Australia Xuan Li Yow/ female consumer Sajni Gudka/ University of Western Australia
Apologies	Jila Misaghian/ female consumer

Item No.	Description	Action
Introductions	RC opened the meeting and welcomed the group and introduce AC SG presented the outline of meeting	
Ethics Application	SG informed the group that a full ethics has been approved.	
Recruiting Pharmacies	SG to present the letter for expression of interest for pharmacists to the group for feedback and comments. SG will collate all comments and finalise the letter and post to all pharmacies.	SG to send letter by 20 th March 2009
Pathology Testing Partner	LM said Western Diagnostics have expressed interest in the study.SG and LM to meet Geraldine Ormonde/ Business Development Manager for WD at 1pm today.	
Pathology Testing Kit	SG presented the leaflet explaining in detail the way to use a LVS. AC and XLY suggested a BL size triple folded style leaflet. SG to get printing quotes.	SG
Referral Pathways for ineligible women	RC wanted a document referral pathway, and all parties mentioned as referral site to be aware of the study. AC will send through all family planning clinic times and details, and a list of all other sexual health providers in Perth to SG. SG will compile them and contact each one to inform them of the study	AC SG
Private consultation areas	XLY raised concerns about private areas in the pharmacy to have chlamydia discussion. RC agreed that this may be a barrier. It was suggested that pharmacies with private consultation areas should be given preference in the study.	
Obtaining results	SG met the sexual health nurse and was happy to have her involvement in the study. The free-phone number is working and has been tested.	
Project Materials	SG presented draft materials for the study to the group <ol style="list-style-type: none"> 1. Patient recruitment proces3 2. Pharmacy recruitment process 3. Patient Information Leaflet and Consent Form 4. Pharmacy Data Collection Sheets 	SG
Pharmacist Training	SG will send out revised versions for final comments 1 week before the next meeting LM, RC and SG had met and created an outline for the training session LM and SG to continue writing the training course LM is unavailable for training courses during last week of April and first week of May.	LM and SG
Tracking progress	Discussion on how to track women that have been issued a chlamydia kit through the process of doing the test, pathology and results to discussed at length. SG will be responsible for ensuring that all infrastructures at pharmacy level, western diagnostics and Fremantle hospital are linked and working. A unique patient ID code needs to be created in the pharmacy, and the patient must be tracked on that code over the study protocol. SG to investigate options for this.	SG
Next Meeting	It was agreed that the next meeting would be at 11am on 13 th May 2008 at UWA.	

Appendix 1c: Minutes of Stakeholder Meeting 3

ECOMPACT

Minutes

Purpose of the meeting:	ECOMPACT Stakeholder Meeting
Meeting No:	3
Location:	Room 203, Pharmacy, UWA
Date / Time:	13/05/08 at 11am
Attendees:	Rhonda Clifford/ University of Western Australia Lewis Marshall/ Sexual Health Physician, Fremantle Hospital Alison Creagh, Family Planning Western Australia Xuan Li Yow/ female consumer Sajni Gudka/ University of Western Australia Jila Misaghian/ female consumer

Item No.	Description	Action
Introductions	RC opened the meeting and welcomed the group SG presented the outline of meeting	
Recruiting Pharmacies	20 Pharmacies have been recruited. All pharmacies have attended at 2 hours training session. They are very enthusiastic about the study.	
Pathology Testing Partner	SG and LM to meet Geraldine Ormonde/ Business Development Manager for WD on 17 th March GO suggested that we use the normal long shaft swab – APTIME GENE PROBE – NAAT-RNA and will have a transport medium to increase stability. SG and LM chatted with the WD IT department of dealing with ways and means for sending our patient results directly to LM at Fremantle Hospital. Various options were discussed and trialled. We agreed to use a system whereby LM will be given a code to log into the WD database. WD will add all our patients' results on his profile. WD and Fremantle Hospital will use the unique ID code given at the pharmacy level. This system will be in place by end of May. LM will test the system by sending a pathology sample through before the start of the study. A Health Review Request Form will be created by GO for the study to use. All her staff at all WD will be informed of this Form and shown how to input the information on LM profile and bulkbill on a monthly basis to UWA chlamydia grant. An account code will be set up.	Various steps for GO, LM and SG
Pathology Testing Kit	SG has created the leaflet with SUKIYA and will be sent to uniprint next week	SG
Project Materials	All project materials have been finalised and will be sent to uniprint next week	SG
Name for study	XLY and JM said that a catchy name for study would make it easier of women rather than being called pharmacy chlamydia project. XLY had prepared a list of acronyms that she presented to the group. The group agreed on Emergency Contraception Mediated Pharmacy Access of Chlamydia Testing – ECOMPACT. SG will brand all materials with the ECOMPACT title.	
Pharmacist Training	SG, LM and AC conducted 3 training session over 5 th May and 8 th May (last week) More staff and locums have expressed interest for further training sessions – SG will facilitate this	LM and SG
ECOMPACT protocol	The ECOMPACT pilot study will start on the 1 st of June 2008. SG will create all the materials, pharmacy files and a demonstration box. SG will assemble all ECOMPACT screening kits. She will deliver the materials and files to all pharmacies prior to 1 st June 2008.	SG by 1 st June 2008
Summary	A summary process to presented: Patient comes in pharmacy asking for EC. Pharmacist completed the EC consultations and discusses the important of contraception and that EC will protect them for STIs. They will introduce the ECOMPACT study – offering women a chance to do a free chlamydia test. If women agrees, pharmacists will use a paper-based assessment tool to ensure they are eligible. All women with symptoms will be referred. All asymptomatic women will be given an ECOMPACT testing kit. Women does the test, returns it to pathology, and calls the free-phone number 7 days later to get her results. If negative – no follow up. If positive – full sexual health check, treatment and partner notification by physician. All stakeholders agreed on this process. RC thanked all stakeholders for their time over the last 3 months. It was agreed that SG will send bi-monthly updates – and that she will arrange a meeting with them at the end of the pilot period to discuss the results of the study.	SG

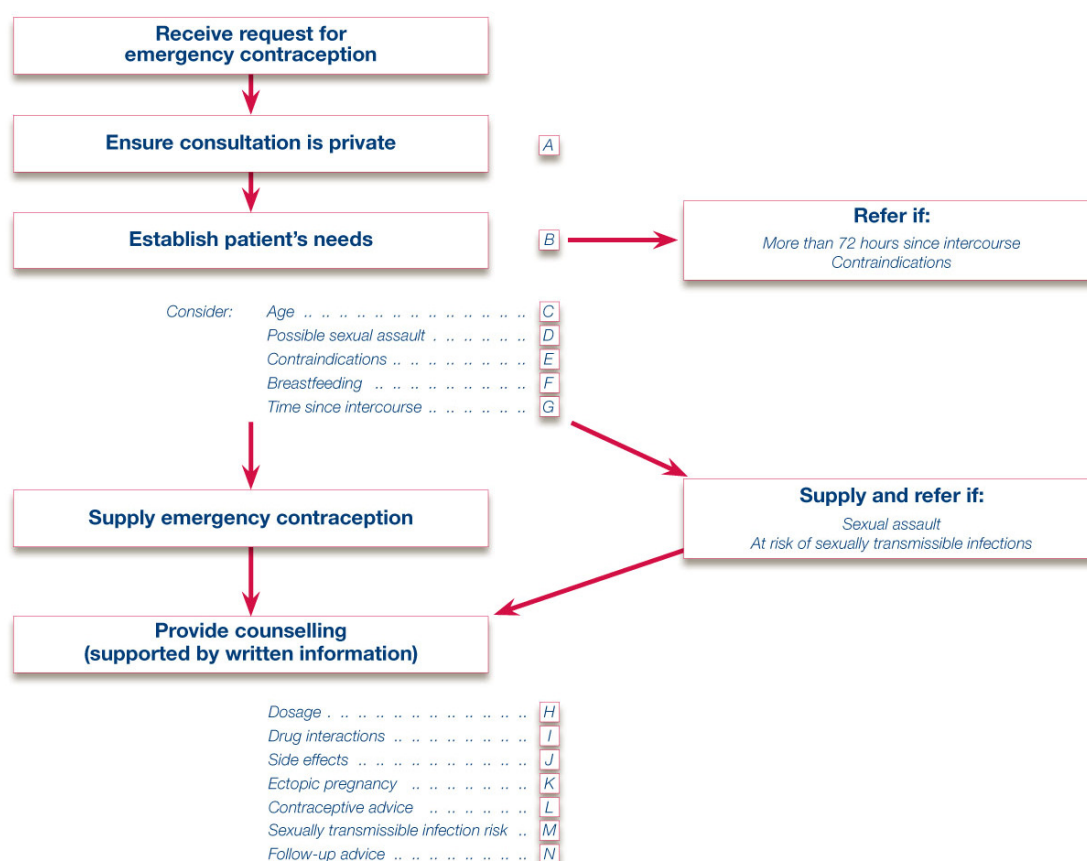
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Appendix 2: Pharmaceutical Society of Australia Emergency Contraception Protocol



Direct product request protocol *Supply of levonorgestrel as a Pharmacist Only medicine¹ for emergency contraception (EC)*

October 2008



Explanatory notes

Pharmacists are expected to exercise professional judgement in adapting the guidance provided to specific presenting circumstances.

A. Privacy issues

Pharmacists will be aware of their obligations in relation to respecting the patient's privacy and confidentiality in the provision of a *Pharmacist Only* medicine and associated patient counselling.²

B. Supply to a third party

Pharmacists must meet the relevant standard for the provision of *Pharmacist Only* medicines when a product for EC is requested through a third party.²

C. Age

There is limited data available regarding the use of levonorgestrel for EC in females of child-bearing potential aged 14–16 years.

It may be advisable to refer someone who is very young to a children's hospital, family planning clinic³ or medical practitioner of her choice. In such cases it is part of a pharmacist's duty of care to assist with arranging an urgent appointment for the patient.

D. Sexual assault

Where sexual assault is suspected, the pharmacist should offer support and assistance with reporting the incident to the

police and facilitating a referral to a medical practitioner or a sexual assault referral centre⁴ for more comprehensive help and advice. One suggested approach if an assault is suspected is for the pharmacist to ask if the sexual intercourse was consensual.

E. Contraindications

Levonorgestrel for EC should not be used if the patient is already pregnant.^{5,6} However, pharmacists should note this contraindication reflects a lack of benefit rather than any risk to the pregnancy, and it will not terminate an existing pregnancy.

The pharmacist should assess the likelihood of the patient already being pregnant

(e.g. menstruation is late or was lighter than normal). If in doubt, a pregnancy test can be undertaken prior to the provision of EC, or the patient can be referred to a medical practitioner or family planning clinic.³

Other contraindications are unexplained vaginal bleeding and current breast cancer. Referral to a medical practitioner or family planning clinic³ is advised.

F. Use in lactation

The use of levonorgestrel for EC is safe for nursing mothers.⁶ The amount that can be transferred to the infant through breastfeeding is about 0.1% of the maternal dose.

G. Efficacy

Pharmacists must advise patients there is clear evidence that EC is not 100% effective. The time elapsed since intercourse is a critical factor and relates to percentage of expected pregnancies prevented as:⁷

<24 hours = 95%
24–48 hours = 85%
48–72 hours = 58%

Efficacy continues to decrease with time after 72 hours.

Overall, the frequency of unintended pregnancy with EC taken within 72 hours of unprotected sex is 1.5%. This can be compared with the frequency of pregnancy after unprotected sex without EC, which varies during the menstrual cycle from 2–4% to 20–30%.⁸

In some circumstances EC is unlikely to be effective e.g. where the patient:

- Vomits within two hours of taking a tablet. In this case the 'lost' dose needs to be replaced as soon as possible;
- Has already engaged in unprotected sex prior to the event for which EC is being sought; or
- Has further unprotected sex after taking EC.

H. Dosage and administration

EC can be taken at any time during the menstrual cycle.

There are two approved regimens for EC:

- One tablet containing 750 micrograms of levonorgestrel to be taken orally as soon as possible and within 72 hours of unprotected intercourse, followed by a second 750 microgram tablet 12 hours after the first dose.

- One tablet containing 1.5mg of levonorgestrel to be taken orally as soon as possible and within 72 hours of unprotected intercourse.

Recent published research showed that a single dose of 1.5mg levonorgestrel (i.e. two 750microgram tablets taken at once within 72 hours of unprotected intercourse) was as effective as the 12-hourly dose.⁸

If the two-dose regimen is supplied, the doses should be timed for optimum convenience to the patient in order to minimise the risk of missing the second dose.

I. Drug interactions⁵ and other considerations

- *Warfarin:* The use of levonorgestrel for EC has been associated with a marked increase in INR within three days of administration. Therefore, close monitoring of INR is recommended and adjustment to the dose of warfarin may be required.
- *Hepatic enzyme-inducing drugs:* Medicines such as primidone, phenytoin, carbamazepine, rifampicin, ritonavir, griseofulvin and St John's wort can increase the metabolism (and therefore reduce the efficacy) of levonorgestrel. Refer to APF for a full list of CYP3A4-inducing drugs.
- *Crohn's disease and irritable bowel syndrome:* EC can be used but may be less effective due to reduced absorption.

If the patient has current or ongoing acute diarrhoea or vomiting, the efficacy of EC may be reduced.

J. Side effects^{6,7}

Most commonly reported side effects are nausea (23%) and vomiting (5–6%). Less common effects include breast tenderness, vaginal bleeding and headache.

There are no known reports of adverse effects on foetal development where EC has failed.⁵

No statistically or clinically significant differences in side effects between the two dosing regimens have been observed, except for more cases of headache with the single-dose regimen.⁹

K. Ectopic pregnancy

There may be a slightly increased risk of ectopic pregnancy following the use of EC.

Severe abdominal cramping following EC treatment requires immediate referral to a medical practitioner.

The patient must be advised that if pregnancy does result she should inform a medical practitioner as soon as possible that she has taken EC during the last cycle.

L. Contraceptive advice

While no adverse effects have been reported, the use of EC products as a 'routine' method of contraception is not recommended.

Where appropriate, the pharmacist should offer the patient general information about the appropriate use of contraception or facilitate referral to a medical practitioner.

M. Sexually transmissible infection risk

The use of a product for EC does not protect against sexually transmissible infections (STIs).

Undiagnosed or untreated STIs can lead to serious complications (including infertility) and/or the need for more intensive treatment after diagnosis.¹⁰ For these reasons, all patients at risk of STIs (this includes anyone requesting EC who is not in a monogamous STI-free relationship) should be encouraged to visit their doctor or a sexual health service for testing within 2–3 weeks after unprotected sex, rather than waiting to see if symptoms develop.¹¹

N. Follow-up actions

It is important for pharmacists to provide information to the patient about what follow-up actions should be taken. These include the following:

- After a course of EC, the patient's menstrual period should occur around the (previously) anticipated date but can be up to one week earlier or later.
- If menstruation does not occur within one week after the expected date or if the period is lighter than normal or intermittent, the patient should conduct a pregnancy test and/or consult a medical practitioner or family planning clinic.³
- A course of EC does not provide ongoing protection against pregnancy. Other forms of contraception (e.g. abstinence, barrier method, continuation of the oral contraceptive pill within 12 hours of taking EC) must be employed until the next period starts and regular contraception can be instituted. If the patient continues the oral contraceptive pill (i.e. does not wait until the next menstrual cycle before starting it), she should conduct a pregnancy test in three weeks to ensure the EC was effective.¹¹

Notes/References

1. At the time of publication, products available in Australia for EC are: a two-tablet pack (each tablet containing 750 micrograms of levonorgestrel) and a one-tablet pack (the tablet containing 1.5mg levonorgestrel).
2. Pharmaceutical Society of Australia. Standards for the provision of Pharmacy Medicines and Pharmacist Only Medicines in community pharmacy. In: Professional Practice Standards (version 3). Canberra: PSA, 2006.
3. The contact details for Family Planning Australia are listed below. Pharmacists may also find local family planning clinics which would be more convenient for the patient to access.
ACT: Sexual Health Family Planning ACT 02 6247 3077
NSW: FPA Health 02 8752 4300 or Healthline 1300 658 886
NT: Family Planning Welfare Association of NT 08 8948 0144
Qld: Family Planning Qld 07 3250 0240
SA: Sexual Health information networking and education (Shine SA) 08 8431 5177 or Sexual Healthline 1800 188 171
Tas: Family Planning Tasmania Inc 03 6228 5244 or Healthline 1300 358 886

4. The telephone numbers for sexual assault centres are listed below. Pharmacists may also find local centres which would be more convenient for the patient to access.
ACT: Rape crisis centre 02 6247 2525
NSW: Rape crisis centre 02 9819 7357 or Counselling Line Freecall 1800 424 017
NT: Darwin Centre Against Rape 08 8945 0155
Qld: Sexual assault helpline 1800 01 01 20
SA: Rape and sexual assault service 1800 817 421
Tas: Sexual assault support service 03 6231 1811
Vic: Centre against sexual assault (CASA) 1800 806 292
WA: Sexual assault resource centre 1800 199 888
5. Australian drug information for the health care professional, 2nd ed. Canberra: Therapeutic Information Resources Australia, 2002.
6. Australian Medicines Handbook. Adelaide: AMH Pty Ltd, 2008.

7. Task force on postovulatory methods of fertility regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 1998;352:428–33.
8. Von Hertzen H, Piaggio G, Ding J, et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. *Lancet* 2002; 360:1803–10.
9. Cheng L, Gülmezoglu A, Piaggio G, Ezcurra E, Van Look P. Interventions for emergency contraception. *Cochrane Database of Systematic Reviews* 2008, Issue 2. Art. No.: CD001324. DOI: 10.1002/14651858.CD001324.pub3.
10. National sexually transmissible infections strategy 2005–2008. Canberra: Commonwealth of Australia, 2005.
11. Contraception: an Australian clinical practice handbook. Sydney: Sexual Health and Family Planning Australia, 2006.

Appendix 3: Pharmacist Expression of Interest to Participate Letter



INVITATION TO PARTICIPATE IN CHLAMYDIA RESEARCH PROJECT: THE ECOMPACT STUDY

Dr Rhonda Clifford and Sajni Gudka of the Pharmacy Programme, the University of Western Australia, Dr Lewis Marshall from the Department of Infectious Disease, Fremantle Hospital and Alison Creagh, Medical Educator from Family Planning Western Australia (FPWA) invite you to take part in the research of the feasibility of Chlamydia Screening from Community Pharmacies.

Chlamydia *trachomatis* is the most common notifiable sexually transmitted infection in Australia. In Western Australia alone, the total number of Chlamydia notifications increased more than six-fold over the last decade. Eighty-five percent of Chlamydia carriers are asymptomatic and consequently spread the infection unknowingly to their partners.

It has been shown that women attending pharmacies for Emergency Hormonal Contraception (EHC) were significantly more likely to test positive for Chlamydia than those of a similar age using family planning services. This offers pharmacists a unique opportunity to offer a screening test to women that have had unprotected sexual intercourse.

We have developed an **Emergency Contraception Mediated Pharmacist Access of Chlamydia Testing (ECOMPACT)** practice model and we plan to pilot this from 20 pharmacies in the Perth metropolitan region over a 6-month period. The pilot study will be implemented in May 2008.

A Free Chlamydia Screening Kit will be offered to consumers requesting EHC. The Kit will contain a low-vaginal swab test that the consumer completes and returns to any Western Diagnostic Pathology Centre. Dr Lewis Marshall, Fremantle Hospital, will handle all the test results in a confidential and appropriate manner.

The Research Team will provide all participating pharmacies with a training session, materials and equipment (Free Chlamydia Screening Kits) to carry out this pilot study. On going support will also be provided through out the pilot study.

A "Readiness Fee" of \$1000 is available to each participating pharmacy to support staff training and promotional activities. There is also a \$15 re-imbursement fee payable to the pharmacy for every screening test returned to pathology by the patient.

In order to register and participate in ECOMPACT, your pharmacy will need to have:

1. **Access to at all times to a pharmacist that is willing to provide an EHC consultation.**
2. **At least 8 EHC requests a month.**
3. **Have at least ONE pharmacist attending the ECOMPACT study training session (see below for dates).**

The pilot study will allow pharmacists to become an integral part of the current public health taskforce. It will give you an opportunity to raise awareness of a serious public health issue, and enhance pharmacist-patient relationships.

If you are interested in participating in the ECOMPACT study, please complete and post/fax the attached Expression of Interest form to me by Tuesday 22nd April 2008.

Do not hesitate to contact me for further information or clarification on (08) 6488 7516 or via email: sajni.gudka@uwa.edu.au

Sajni Gudka BPharm MRPharmS, MPS

The Project is funded by the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia. The project has been approved by the Human Research Ethics Committee of The University of Western Australia.



THE UNIVERSITY OF
WESTERN AUSTRALIA

EXPRESSION OF INTEREST FOR CHLAMYDIA RESEARCH PROJECT: THE ECOMPACT STUDY

1. Name of Pharmacy _____
2. Address of Pharmacy _____

3. Telephone _____
4. Contact person _____

5. Confidentiality of counseling:

☐

Consultation room

☐

Screened area

☐

Other _____

6. Approximate Number of Emergency Hormonal Contraception (EHC) consultations per month:

☐

More than 8

☐

More than 12

7. Preference for the compulsory 2hr ECOMPACT training session. (At least one representative should be present)

Monday 5th May 6.30pm to 8.30pm ☐

Tuesday 6th May 7.30pm to 9.30pm ☐

Wednesday 7th May 6.30pm to 8.30pm ☐

Post/Fax your completed expression of interest by Tuesday 22nd April 2008 to:

Sajni Gudka, Pharmacy Programme,
School of Biomedical, Biomolecular and Chemical Sciences
M315/35 Stirling Highway, The University of Western Australia, Crawley 6009
T: (08) 6488 7516
F: (08) 6488 7532



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Appendix 5: Pharmacist Acceptance Letter



THE UNIVERSITY OF
WESTERN AUSTRALIA

Mrs Sajni Gudka BPharm, MRPharmS, MPS
Research Fellow
Pharmacy Programme
School of Biomedical, Biomolecular and Chemical Sciences
M315/35 Stirling Highway
The University of Western Australia
Crawley 6009
T: 6488 7516
F: 6488 7532
E: sajni.gudka@uwa.edu.au

Date: 22nd April 2008

Dear

ACCEPTANCE INTO THE ECOMPACT STUDY

Congratulations! You have been successfully accepted into the ECOMPACT study to pilot a Chlamydia Screening Model from Community Pharmacies.

To complete the selection process, and register for the study, you need to attend a compulsory ECOMPACT training course. I strongly recommend that all pharmacists, regular locums, 2000 hr students and any other staff member dealing with Emergency Hormonal Contraception (EHC) in your pharmacy to attend this course. This is because the Chlamydia Kit will be given out during an EHC consultation.

The details of the ECOMPACT training course are as follows:

Dates:	Monday 5 th May	6.30pm to 8.30pm
	Tuesday 6 th May	7.30pm to 9.30pm
	Wednesday 7 th May	6.30pm to 8.30pm

Location: Building 345, Pharmacy Building, University of Western Australia 6009.
(Map in post with this letter)

Parking: Enter University via Hackett Drive Entry 2. Turn left and find a RED parking bay.

To organize catering and handouts, please confirm the number of people attending the course, and the preferred sessions via phone, fax or email.

I look forward to meeting you at the ECOMPACT training course.

Do not hesitate to call or email me if you have any queries.

Yours faithfully,

Sajni Gudka

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Appendix 6: ECOMPACT Eligibility Checklist and Consent Form

FRONT:

ECOMPACT

Eligibility Checklist and Consent Form

UNIQUE ID CODE: 0101

Pharmacist to determine: (please tick)

Is the consumer under 18 years of age? (Date of Birth: / /)

Does the consumer have any of the following symptoms:

Abnormal bleeding? (irregular timing, heavy menstruation, more painful periods)

Lower abdominal pain?

Unusual vaginal discharge?

Pain during/after sex?

Burning or pain when passing urine?

Has the consumer had a positive chlamydia test in the last 4 weeks?

If YES to ANY of the above - Consumer is INELIGIBLE for ECOMPACT chlamydia testing: (Tick if INELIGIBLE)

Reason(s) for ineligibility (please state):

If symptomatic, strongly encourage consumer to make a doctor's appointment for further investigation

If NO to ALL of the above - Consumer is ELIGIBLE for ECOMPACT chlamydia testing: (Tick if ELIGIBLE)

Appropriate issues discussed with the client: (please tick)

What is chlamydia?

What is ECOMPACT? (chlamydia test only, kit contents, patient consent)

How to take a vaginal swab (refer to patient information leaflet)

Pathology testing (where to take the sample, appropriate handling conditions & delivery time)

How to obtain results (contact details for Fremantle Hospital)

Available treatment options and outcomes for positive & negative results

Statement by Consumer

I hereby voluntarily agree to take part in the ECOMPACT pilot study. I have read the information sheet provided and any questions I have asked have been answered to my satisfaction. I am aware of the purpose of this project and what my involvement entails. I have been informed of my rights to question any part of the procedure or withdraw from the project at any time without reason and without prejudice to my future care. I understand that any information collected for the purpose of this study will remain strictly confidential and will not be released by the investigators unless required to by law. I have been advised as to what data is being collected, the purpose of collecting this data, and what will be done with it upon completion of the study. I agree that the information obtained from this study may be used in future research or published, provided my name is not used. I understand how to proceed with the testing and the advice given to me by the pharmacist.

Participant's Name: Signature: Date:

Pharmacist's Name: Signature: Date:

Please indicate if we can contact you for a confidential discussion about ECOMPACT at the end of the pilot: YES / NO

If YES, please provide a contact/mobile number that you can be contacted on: Postcode:

For more information about the ECOMPACT study, contact Sajni Gudka at the Program of Pharmacy, M315 /35 Stirling Highway, University of Western Australia, Crawley 6009. Phone: (08) 6488 7516

Approval for the conduct of this study has been granted by the Human Research Ethics Committee, University of Western Australia, and will be carried out in a manner conforming to the principles set out by National Health and Medical Research Council (NHMRC).

All data collected will be kept confidential and subsequently destroyed. All reports or articles will be de-identified and your identity will be safeguarded at all times. Only those directly involved in the study will have access to your personal details. If you would like a report of the study on completion please ask the investigator and the report (that may consist of positive and negative findings) will be forwarded to you. Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Research Ethics Committee, Registrar's Office, University of Western Australia, on (08) 6488 3703 (Telephone) or in writing at 35 Stirling Highway, Crawley, WA 6009.

The 'Best Practice Community Pharmacy Chlamydia Screening Model' Research Project has been developed in collaboration with the Pharmacy Guild of Australia and the Department of Health and Ageing. The Project is funded by the Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement.

BACK:

Emergency Contraception Mediated Pharmacy Access of Chlamydia Treatment (ECOMPACT study)

Participant Information Sheet and Consent Form

We invite you to participate in a research study supported by the University of Western Australia. If you decide to take part in ECOMPACT, it is important that you understand its purpose, what you can gain from it and what will be expected of you. Information about the study and its potential benefits are explained below. You will be given a copy of this Participant Information Sheet and Consent Form to keep.

What is the nature and purpose of the study?

Chlamydia trachomatis is the most common notifiable sexually transmitted infection in Australia. 85% of Chlamydia carriers do not have any symptoms and consequently spread the infection unknowingly to their partners. Chlamydia is easy to diagnose and treat.

The aim of this study is to determine if, the trust people have in the pharmacist, the accessibility and regularity of use of the community pharmacy makes it appropriate setting for screening for Chlamydia.

We have asked you to participate in this study because you have requested emergency hormonal contraception (EHC). The study will focus on screening women requesting EHC from their community pharmacist as they represent an accessible target group and as they are already approaching the pharmacist for a service related to sexual health.

Your participation in this study will not affect your EHC consultation and supply now or at any time in the future. Your pharmacist should have already discussed your EHC supply with you prior to introducing you to this study.

Who is carrying out the study?

Senior Lecturer Rhonda Clifford (Principal Investigator) and Sajni Gudka (Research Fellow) from the School of Biomedical, Biomolecular and Chemical Sciences, University of Western Australia; Dr Lewis Marshall from Infectious Disease Department, Fremantle Hospital and Alison Creagh, Medical Educator from Family Planning Western Australia (FPWA).

What does the study involve?

If you decide to participate in ECOMPACT, by signing the Consent Form, you will be given a FREE Chlamydia Testing Kit containing a vaginal swab test and instruction leaflet to take home and complete.

You then need to return the swab to a Western Diagnostics Pathology Centre near you for sampling. They will require your name, address, contact phone number (mobile number) and your Medicare number.

Your results will be sent to Dr Lewis Marshall, Sexual Health Physician at Fremantle Hospital. Your pharmacists will not be made aware of any test results. Their role is solely to distribute the test to you and counsel you on how to use the test.

7-days after leaving your sample at Western Diagnostics, you need to call a confidential **1-800-628-909** to obtain your results. The number is operational Monday to Friday **8.30am to 12.3pm** and from **1.30pm to 4.30pm** and is directed to a sexual health nurse.

You will need to identify yourself as a **“Participant of the Pharmacy Study”** when you call.

Dr Marshall will review all results and will ensure that positive results are dealt with in accordance with the Department of Health Guidelines on Testing and Managing Chlamydia.

He will also be required to notify the Department of Health details of all positive participants, however the Department of Health will not contact you without your consent.

We will be conducting discussions with participants and pharmacists to evaluate this study. Please indicate your preference below. If you agree, we will require your name and at least one contact option.

What are the benefits of the study?

This study enables you to receive Free Chlamydia testing. If you think that you may have been at risk of contracting Chlamydia at any time, this study will provide an accessible, confidential and convenient way of obtaining a test. You will receive a free test, which can be carried out by yourself in the comfort and privacy of your home.

If the test is positive, a sexual health nurse from Fremantle Hospital will contact you to arrange a consultation with Dr. Marshall. However, the consultation with Dr Marshall and the necessary treatment is not part of our study, and you will not be asked to provide any further information about yourself or the treatment.

Are there any discomforts and risks?

Generally, the screening test does not cause any discomfort.

As with all tests, a low rate of false positive (2%) and false negatives (4%) could be possible. A false positive is someone who tests as positive but is actually negative. A false negative is someone who tests negative but is actually positive. All participating pharmacists will be trained and competent to provide any advice and assistance you may need.

Do you have a choice?

Your participation in this study is entirely voluntary and it will not affect you from obtaining your EHC. You may also withdraw from this study at any time, for whatever reason. Your decision to withdraw will not affect your future care.

For more information about the ECOMPACT study, contact Sajni Gudka at the Program of Pharmacy, M315 /35 Stirling Highway, University of Western Australia, Crawley 6009. Phone: (08) 6488 7516

Approval for the conduct of this study has been granted by the Human Research Ethics Committee, University of Western Australia, and will be carried out in a manner conforming to the principles set out by National Health and Medical Research Council (NHMRC).

All data collected will be kept confidential and subsequently destroyed. All reports or articles will be de-identified and your identity will be safeguarded at all times. Only those directly involved in the study will have access to your personal details. If you would like a report of the study on completion please ask the investigator and the report (that may consist of positive and negative findings) will be forwarded to you. Any person with concerns or complaints about the conduct of a research study can contact the Secretary of the Human Research Ethics Committee, Registrar's Office, University of Western Australia, on (08)6488 3703 (Telephone) or in writing at 35 Stirling Highway, Crawley, WA 6009.

The 'Best Practice Community Pharmacy Chlamydia Screening Model' Research Project has been developed in collaboration with the Pharmacy Guild of Australia and the Department of Health and Ageing. The Project is funded by the Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement.

Appendix 7: Health Review Request Form

FRONT:

Health Review Request Form



74 McCoy Street Myaree WA 6154
Telephone (08) 9317 0999
Facsimile (08) 9317 1536



SURNAME Mr Mrs Ms		FIRST NAMES		BIRTH DATE		SEX	
ADDRESS				POST CODE		PHONE No.	
FAMILY RECORD No.							UNIQUE ID CODE
1. HEALTH SCREEN NAME 2. INVESTIGATIONS REQUESTED <input type="checkbox"/> FASTING <input type="checkbox"/> NON FASTING UWA Community Pharmacy Study							
Data Entry CHP				Date of Referral: (date when kit given out) _____			
ACCOUNT TO (Monthly)		REQUESTING DOCTOR'S NAME AND INITIALS, ADDRESS & PROVIDER NUMBER					
UWAC Attn: Rhonda Clifford Pharmacy M315 UWA, Crawley 6009		Dr Lewis Marshall (UWAC) Infectious Disease Dept Fremantle Hospital Phone 9431 2376					
LABORATORY USE				COPY TO			
TUBES		THERAPEUTIC DRUG MONITORING		COLLECTOR		Date	
		Last Dose		Date		Time	
				ToC			

Sensitive information is collected, stored, used and accessed with due regard for privacy in accordance with the
Private Policy in Community Pathology published by the Australian Association of Pathology Practices. A handout is available on request and you should have this explained to you.
AME Medical Services Pty Ltd (APA) ABN 88 009 136 118 trading as Western Diagnostic Pathology

BACK:

PATIENTS MAY BE REFERRED TO:

ARMADALE

240 Seville Drive Medical Centre
Telephone (08) 9497 5594
Monday - Friday 8.00am - 4.30pm
(Close between 1.00pm - 2.00pm)

BALGA

95 Princess Road
Telephone (08) 9344 3435
Monday - Friday 8.00am - 5.30pm
Saturday 8.00am - 11.00am

BASENDEAN

15 Old Perth Road (Cnr Parker)
Telephone (08) 9279 1610
Monday - Friday 8.30am - 5.00pm
(Close between 1.00pm - 2.00pm)
Saturday 8.30am - 11.30am

BAYSWATER

7/488 Walter Road East
Telephone (08) 9377 0599
Monday-Friday 8.00am - 4.30pm
(Close between 1.00pm - 2.00pm)

BELDON

Unit 6 Belridge Shopping Centre
Cnr Ocean Reef Road & Eddystone Avenue
Telephone (08) 9402 0224
Monday - Friday 7.30am - 5.00pm
(Close between 12.30pm - 1.00pm)
Saturday 7.30am - 11.00am

BELMONT

373 Belgravia Street (Cnr Gabriel Street)
Telephone (08) 9277 1610
Monday - Friday 8.00am - 11.00am

BENTLEY

Unit 1, 10-16 Mills Street
Telephone (08) 9458 1102
Monday - Friday 8.00am - 4.30pm
Monday - Friday 12.15pm - 12.45pm
Saturday 8.30am - 11.30am

BULLCREEK

Cnr Parry Avenue & Bullcreek Drive
Telephone (08) 9310 7383
Monday-Friday 7.00am - 5.00pm
Saturday 8.30am - 12.30pm

CANNING VALE

Unit 9, 98 Waratah Boulevard
Telephone (08) 9256 2389
Monday-Friday 8.30am - 4.30pm
(Close between 12.30pm - 1.30pm)
Saturday 8.00am - 10.30am

CARINE

56 Almadine Drive
Telephone (08) 9246 2355
Monday-Friday 8.00am - 5.00pm
(Close between 1.00pm - 2.00pm)
Saturday 8.00am - 11.00am

CLAREMONT

Bethesda Hospital
25 Queenslea Drive
Telephone (08) 9385 0037
Monday-Friday 8.00am - 5.00pm
Saturday 8.00am - 12.00noon

CLARKSON

U6/5 Ebb Way
Telephone (08) 9407 8614
Monday-Friday 8.00am - 4.00pm
(Close between 1.00pm - 1.30pm)

DUNCRAG

Glenagary Medical Suites
Suite 4/60 Anisdale Road
Telephone (08) 9246 5800
Monday - Friday 8.00am - 7.00pm
Saturday 8.00am - 12.00noon

EAST VICTORIA PARK

(Near Park Centre)
4/779 Albany Highway
Telephone (08) 9361 9383
Monday - Friday 8.00am - 5.00pm
Saturday 8.00am - 11.00am

FREMANTLE

Unit 5, 18 Parry Street
Telephone (08) 9430 5510
Monday-Friday 8.00am - 5.00pm
(Close between 12.30pm - 1.00pm)
Saturday 8.00am - 11.00am

FREMANTLE

Ellen Street Family Practice
59 Ellen Street
Telephone (08) 9430 8533
Monday-Friday 8.00am - 4.00pm
(Close between 1.00pm - 1.30pm)

FREMANTLE - EAST FREMANTLE

East Fremantle Medical Centre
12 Silas street
Telephone (08) 9319 9845
Monday-Friday 8.00am - 4.00pm
(Close between 1.00pm - 1.30pm)

FREMANTLE - SOUTH FREMANTLE

Unit 8, 219 Hampton Road
Telephone (08) 9430 9020
Monday-Friday 8.30am - 4.30pm
(Close between 12.30pm - 1.00pm)

GLEN FORREST

4 Hardey Road
Telephone (08) 9298 8188
Monday-Friday 8.00am - 5.00pm
(Close between 1.00pm - 2.00pm)
Saturday 8.00am - 11.00am

GREENWOOD

Unit 6, 9 Coolibah Drive
Telephone (08) 9246 7152
Monday-Friday 8.00am - 5.00pm
(Close between 1.00pm - 2.00pm)
Saturday 8.00am - 11.00am

HIGH WYCOMBE

Unit 8, 431 Kalamunda Road
(Located in Maids Vale Shopping Centre)
Telephone (08) 9352 8675
Monday - Friday 8.00am - 4.00pm
(Close between 12.30pm - 1.00pm)

HILLARYS

17B/110 Hillarys Shopping Centre
Flinders Avenue
Telephone (08) 9403 7013
Monday - Thurs 8.00am - 7.00pm
Friday 8.00am - 6.00pm
Saturday 8.00am - 12.30pm

JANDAKOT

850 North Lake Road
Telephone (08) 9417 9841
Monday-Friday 8.00am - 5.00pm
(Close between 12.30pm - 1.00pm)
Saturday 8.00am - 11.00am

JONDALUP LABORATORY

Jondalup Health Campus
Cnr Grand Boulevard & Shenton Avenue
Telephone (08) 9400 9810
Fax (08) 9400 9811
Monday - Friday 8.00am - 5.30pm
Saturday 8.00am - 12.00noon
(Closed on public holidays)

KELMSCOTT

2968 Albany Highway
Telephone (08) 9495 1236
Monday - Friday 8.00am - 5.30pm
(Close between 1.00pm - 1.30pm)
Saturday 8.00am - 11.00am

MADDINGTON

Shop 4, 64 Attfield Street
Telephone (08) 9493 7506
Monday - Friday 8.00am - 4.30pm
(Close between 1.00pm - 2.00pm)
Saturday 8.00am - 11.00am

MEDINA

8-10 Pace Road
Telephone (08) 9419 7761
Monday - Friday 8.00am - 6.00pm

MIDLAND

New centre opening soon
Telephone (08) 9274 4398

MIDLAND

280 Great Eastern Highway
Telephone (08) 9274 8703
Monday - Friday 8.00am - 6.00pm
Saturday 8.00am - 12.00noon

MORLEY

Unit 5/11-13 Marchant Way
Telephone (08) 9375 1116
Monday - Friday 7.30am - 5.00pm
Saturday 8.00am - 11.30am

MORLEY GALLERIA

Shop R1, Centro Medical Centre
Galleria Shopping Centre
Telephone (08) 9376 1285
Monday - Friday 8.00am - 4.00pm
(Close between 12.30pm - 1.00pm)

MT HAWTHORN

391 Oxford Street
Telephone (08) 9444 1499
Monday - Friday 8.00am - 5.00pm
(Close between 1.30pm - 2.00pm)
Saturday 8.00am - 11.00am

MT PLEASANT

Unit 5, 16 Queens Road
Telephone (08) 9315 4152
Monday - Friday 7.30am - 4.00pm
(Close between 12.00noon - 1.00pm)

MYAREE LABORATORY

74 McCoy Street
Telephone (08) 9317 0999
Monday - Friday 7.00am - 7.00pm
Saturday 7.30am - 1.00pm

NEDLANDS

Unit 3, 55 Hampden Road
Telephone (08) 9389 8669
Monday - Friday 7.30am - 4.30pm
(Close between 12.30pm - 1.00pm)
Saturday 8.00am - 12.00noon

NORANDA

36 Benara Road
Telephone (08) 9375 3945
Monday - Friday 8.00am - 6.00pm
(Close between 1.00pm - 1.30pm)
Saturday 8.00am - 11.00am

NORTH PERTH

373 Fitzgerald Street
(opp Bell's Pharmacy)
Telephone (08) 9228 2607
Monday - Friday 8.00am - 4.00pm
(Close between 12.30pm - 1.00pm)

OCEAN REEF

Beaumaris Family Practice
Constellation Drive
Telephone (08) 9300 4780
Monday - Thurs 8.00am - 7.30pm
Friday 8.00am - 5.00pm
Saturday 8.00am - 12.00noon

O'CONNOR

Unit 7/386 South Street
Telephone (08) 9337 5162
Monday - Friday 8.00am - 5.00pm
(Close between 1.00pm - 1.30pm)
Saturday 8.00am - 12.00noon

PARKWOOD

Unit 1, 2 Madeira Road
(behind Riverton Forum)
Telephone (08) 9457 5415
Monday - Friday 7.30am - 5.00pm
(Close between 12.30pm - 1.30pm)
Saturday 8.00am - 11.00am

PARMELIA

Cnr Parmelia Avenue & Sutherland Pde
Telephone (08) 9430 3720
Monday - Friday 8.00am - 5.00pm
(Close between 12.30pm - 1.00pm)
Saturday 8.00am - 11.00am

PERTH

110 William Street
(above Hight Centre)
Telephone (08) 9321 3448
Monday - Friday 8.00am - 4.00pm
(Close between 2.00pm - 2.30pm)

PERTH LABORATORY

Mount Hospital
Mount Medical Centre
Suite 11, 146 Mounts Bay Road
Telephone (08) 9321 3300
Monday - Friday 8.00am - 6.00pm

ROCKINGHAM

Hunston House,
Suite 1, 11 Council Avenue
Telephone (08) 9528 3013
Monday - Friday 7.45am - 5.00pm
Saturday 8.00am - 11.00am

ROCKINGHAM

Woodbridge Medical Centre,
37 Elsona Drive
Telephone (08) 9528 5447
Monday - Friday 7.45am - 8.00pm
Saturday/Sunday 8.00am - 1.00pm

ROCKINGHAM

Port Kennedy
Unit 2, Cnr Discovery Cres & Endeavour Dve
Telephone (08) 9524 6982
Monday-Friday 8.00am - 5.00pm
(Close between 1.00pm - 2.00pm)
Saturday 8.00am - 11.30am

SORRENTO

Seacrest Medical Centre
28 Seacrest Drive
Telephone (08) 9246 5225
Monday - Thurs 8.00am - 8.30pm
Friday 8.00am - 7.00pm
Saturday 8.00am - 1.30pm
Sunday 8.30am - 1.30pm

SPEARWOOD - COCKBURN

Seawood Cockburn Medical Centre
316 Rockingham Road
Telephone (08) 9434 1540
Monday - Friday 8.00am - 5.00pm
(Close between 1.00pm - 2.00pm)
Saturday 8.00am - 11.30am

THORNLEE

Spencer Road Medical Centre
Cnr Spencer & Warton Roads
Telephone (08) 9493 2033
Monday - Friday 7.30am - 6.00pm
Saturday 8.00am - 12.30pm
Sunday 9.00am - 12.00noon

TUART HILL

217 Wanneroo Road
Telephone (08) 9344 4994
Monday - Friday 7.30am - 6.00pm
Saturday 8.00am - 12.00noon

WANNEROO

Wanneroo Specialist Medical Centre
Unit E, 771 Wanneroo Road
Telephone (08) 9306 5563
Monday - Friday 8.00am - 5.00pm
(Close between 12.30pm - 1.30pm)
Saturday 8.00am - 11.00am

WEBBLEY

Post Office Medical Centre
339 Cambridge Street
(Cnr Jersey & Cambridge Streets)
Telephone (08) 9284 1898
Monday - Friday 8.00am - 6.00pm
(Close between 12.00pm - 1.00pm)
Saturday 8.00am - 11.00am

WEMBLEY DOWNS

16 Bournemouth Crescent
Telephone (08) 9245 3877
Monday - Friday 8.00am - 5.00pm
(Close between 12.30pm - 1.30pm)
Saturday 8.00am - 12.00noon

WEST PERTH

36 Parliament Place
(opposite HBF and ANZ Bank)
Telephone (08) 9321 3031
Monday - Friday 7.30am - 5.00pm
(Close between 12.30pm - 1.00pm)

COUNTRY CENTRES**ALBANY**

Shop 4/22-23 Albany Highway
(opposite HBF and ANZ Bank)
Telephone (08) 9842 3471
Monday - Friday 7.30am - 5.00pm
(Apts between 7.30am - 8.30am)
Saturday 9.00am - 10.30am
(Appointments preferable)

Spencer Park

Spencer Park
(next to Dalorane Pastries)
Telephone (08) 9841 7138
Monday - Friday 7.30am - 4.00pm
(Apts between 7.30am - 8.30am)

BEVERLEY

106 Forrest Street
Telephone (08) 9646 0149
Mobile 0411 406 913
Monday - Friday 8.00am - 1.00pm
(Close between 12.00noon - 2.00pm)

BROOME

26 Robinson Street
Telephone (08) 9192 3534
Monday - Friday 8.00am - 5.00pm
Saturday 8.00am - 10.30noon

BUNBURY

122 Spencer Street
Telephone (08) 9791 9240
Monday-Thurs 8.00am - 6.00pm
Friday 8.00am - 5.00pm
Saturday 8.00am - 11.30am

BUSSELTON

21 Albert Street
Telephone (08) 9752 2452
Monday - Friday 8.00am - 5.30pm
Saturday 8.00am - 11.30am

BUSSELTON - BROADWATER

4 Broadwater Boulevard
Telephone/Fax (08) 9751 4223
Monday - Friday 8.00am - 4.00pm
(Close between 1.00pm - 2.00pm)

CAPEL

21 Properjohn Road
Telephone/Fax (08) 9727 1798
Monday 8.30am - 12.00noon
Wed - Friday 8.30am - 12.00noon
Tuesday 1.30pm - 4.30pm

DENMARK

64 Strickland Street
Telephone (08) 9848 3093
Monday - Friday 7.30am - 3.00pm
(Close between 11.30pm - 12.00noon)

DUNSBOROUGH

Seymour House
Dunn Bay Road
Telephone/Fax (08) 9756 8851
Monday - Friday 8.30am - 4.15pm
(Close between 1.00pm - 2.00pm)

ESPERANCE

Home visit service
Telephone 0408 429 858

GERALDTON

30 Holland Street
Telephone (08) 9965 5901
Monday - Friday 7.30am - 5.00pm
Saturday 7.30am - 11.00am

Batavia Health

361 Marine Terrace
Telephone (08) 9965 8190
Mobile 0418 784 045
Monday - Friday 8.30am - 4.30pm

KALGOORLIE

Goldfields Medical Centre
Cnr Cassidy & Egan Streets
Telephone (08) 9021 4833
Monday - Friday 8.00am - 5.30pm
Saturday 8.30am - 12.00noon

Boulder

49 Burt Street
Telephone (08) 9080 8617
Monday - Friday 8.30am - 5.00pm

KARRATHA

Lot 2609 Sharpe Avenue
Telephone (08) 9185 1140
Monday - Friday 7.00am - 6.00pm
Saturday 8.00am - 12.00noon

MANDURAH

Unit 2, 21 Sholl Street
Telephone (08) 9535 5189
Monday - Friday 8.00am - 4.30pm

Dudley Park Medical Centre

15 Anstruther Road
Telephone (08) 9535 9128
Monday - Friday 8.00am - 4.30pm
(Close between 1.00pm - 2.00pm)

Halls Head Medical Centre

Cnr Glencoe and Peelwood Parades
Telephone (08) 9535 5928
Monday - Friday 8.00am - 4.30pm
(Close between 1.00pm - 2.00pm)

Murray Medical Centre

Cnr Lakes Road and Minilaya Parkway
Telephone (08) 9586 8117
Monday - Friday 8.00am - 4.30pm
(Close between 1.00pm - 2.00pm)

Peel Health Campus Laboratory

Lakes Road
Telephone (08) 9531 8510
Monday - Friday 8.00am - 6.00pm
Saturday 8.00am - 12.00noon

Gemini Medical - Erskine

102 Oakleigh Dr
Telephone (08) 9534 7137
Monday - Friday 8.00am - 4.30pm
(Close between 1.00pm - 2.00pm)

Gemini Medical - Pinjarra

26 Forrest Street
Telephone (08) 9531 3412
Monday - Friday 8.00am - 4.30pm
(Close between 1.00pm - 2.00pm)

Mandurah Doctors

34 Boundary Road, Dudley Park
Telephone (08) 9535 2463
Monday - Friday 8.00am - 4.30pm
(Close between 1.00pm - 2.00pm)

MOUNT BARKER

44 Langton Road
Telephone (08) 9427 604 267
Monday - Friday 8.00am - 4.00pm
(Thursdays - Mobile collection)

SOUTH HEDLAND

South Hedland Community Health Centre
Colebatch Way
Telephone (08) 9140 1200 or
0417 916 190
Monday - Friday 8.00am - 4.00pm
Saturday 8.30am - 12.30pm

YORK

Avon Terrace
Telephone (08) 9641 2689
Monday - Friday 8.30am - 1.30pm

Current as at March 2008. Times indicated may be subject to change.

Appendix 8: ECOMPACT 'What you need to know' Leaflet



ECOMPACT

what you need to know

what is ECOMPACT?

ECOMPACT is a 6 month pilot study conducted by the University of Western Australia in selected community pharmacies in the Perth metropolitan area.

We have asked you to participate in this study because you have requested the Emergency Hormonal Contraception "Morning after Pill"

This study will provide an accessible, confidential and convenient way of obtaining a test which can then be carried out by yourself in the comfort and privacy of your own home.

how will my information be used?

Your participation in the ECOMPACT study will help design a pharmacy-based chlamydia program that can be used throughout Australia. In order for us to determine the best practice model for this program in the future, we would like to speak with you about your experiences and opinions of ECOMPACT.

All information obtained will be confidential and all personal information will be de-identified.

If you have already given consent to be contacted at the end of the project, the research team will be in touch shortly to listen to your comments and talk about your experiences.

If you have NOT given consent, but would like to give feedback on the study or would like more information about ECOMPACT, please contact Sajni Gudka on (08) 6488 7516

If you would like to learn more about the prevention of chlamydia, talk to your GP or any of the sexual health providers listed on the reverse side of this leaflet. Remember, this test is for chlamydia only; it won't tell you if you have been exposed to other infections.

useful contacts

Fremantle Hospital
Infectious Diseases, B2 Clinic
Alma Street, Fremantle
T: (08) 9431 2149

Royal Perth Hospital
Sexual Health Clinic
Wellington Street Perth
T: (08) 9224 2178

Rockingham Clinic
(Thursday 3-6pm)
City of Rockingham Youth Health Services
9 Baralda Court, Rockingham
T: (08) 9527 7464

FPWA (Family Planning WA)
70 Roe Street, Northbridge
T: (08) 9227 6177

Sexual Health Helpline
T: (08) 9227 6178
1800 198 205 toll-free

Quarry Health Centre
(For under 25s)
Rear, 7 Quarry Street, Fremantle
T: (08) 9430 4544

Women's Health Care House
100 Aberdeen Street, Northbridge
T: (08) 9227 8122
1800 998 399 toll-free

Debarl Yerrigan Health Service
(Perth Aboriginal Medical Service)
256 Wittenoom Street, Perth
T: (08) 9421 3888

for more information please contact:

Mrs. Sajni Gudka
Research Fellow
p. (08) 6488 7516
e. sajni.gudka@uwa.edu.au



THE UNIVERSITY OF WESTERN AUSTRALIA
Aspiring International Excellence

The Pharmacy Guild of Australia

Australian Government
Department of Health and Ageing

This program is funded by the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia.

This program has been approved by the Human Research Ethics Committee of the University of Western Australia

what is chlamydia?

Chlamydia is a sexually transmitted infection (STI) caused by a bacteria that can affect both men and women. It is the most common notifiable STI in Australia.

how do you get chlamydia?

You can be infected with chlamydia, or pass it on to someone else during sex - through semen or vaginal fluids. Chlamydia cannot be passed on through kissing or by sharing towels, cutlery, cups and plates, or toilet seats.

why should I get tested?

Most people have no symptoms and don't know they have chlamydia - and so the infection is passed on to others. If left untreated, chlamydia can cause health problems such as pelvic pain or painful sex. It may also lead to infertility if left untreated.

how do I find out if I have chlamydia?

As part of the ECOMPACT study, you will be given a FREE chlamydia testing kit. In addition to this leaflet, the kit contains:


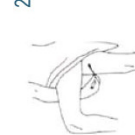
- One unisex collection swab
- GEN-PROBE/PTIMA swab transport medium tube (2.9ml)
- A Health Review Request Form (yellow form)
- A bio-hazard bag
- ECOMPACT Reminder Card

what do I have to do?

You need to collect your own low-vaginal swab. It's very easy to do, in fact it's easier than inserting a tampon. The swab can be done in the privacy of your home or at any Western Diagnostics Lab.

how do I use the swab?

just follow these simple steps:

- 
- 
1. Hold the swab at the break point and put the tip of the cotton swab about 2cm (approximately one finger-joint) inside your vagina.
2. Turn the swab around once making sure to touch all sides.
3. Leave the swab stick in the vagina for 10 seconds.
4. Remove cap from the specimen transport tube and immediately place the swab inside the tube.
5. (Do not pierce the silver foil under any circumstances). Carefully break the swab shaft against the side of the tube at the score-line and discard the top portion of the shaft (use care to avoid splashing contents).
6. Re-cap the transport tube tightly.
7. Label the tube with your name and the date of swab.
8. Place the tube into the sealed compartment of the plastic bio-hazard bag provided, together with the Health Review Request Form ready for delivery.

where do I return my swab for testing?

Take your swab to ANY Western Diagnostics Pathology Lab. A list of all the Western Diagnostic sites can be found on the reverse side of your Health Review Request Form.

To ensure satisfactory testing conditions, the swab MUST be:

- Delivered within 72hrs (3 days) of testing
- Stored at room temperature (15°C-30°C)

Do NOT refrigerate or store at temperatures above 30°C

what information will I need to provide?

Western Diagnostics will require your completed Health Review Request Form with your name, address, date of birth and contact details. We need these details in order to identify you when you call for your results. This information will be kept confidential by Western Diagnostics and Fremantle Hospital.

where do I return my swab for testing?

Your results will be made available to you over the phone by contacting the Fremantle Hospital 7 days after delivering your swab to Western Diagnostics. To obtain your results, please call:

**1800 628 909 (toll-free)
Monday - Friday**

**Between the hours of:
8.30am - 12.30pm and 1.30pm - 4pm**

**You MUST identify yourself as:
"A Participant of the Pharmacy Study"**

The nurse will ask for your full name and date of birth. This is to ensure that only you can call for your results.

what does a negative result mean?

Great News! A negative result means that your swab did not have any traces of chlamydia infection.

what does a positive result mean?

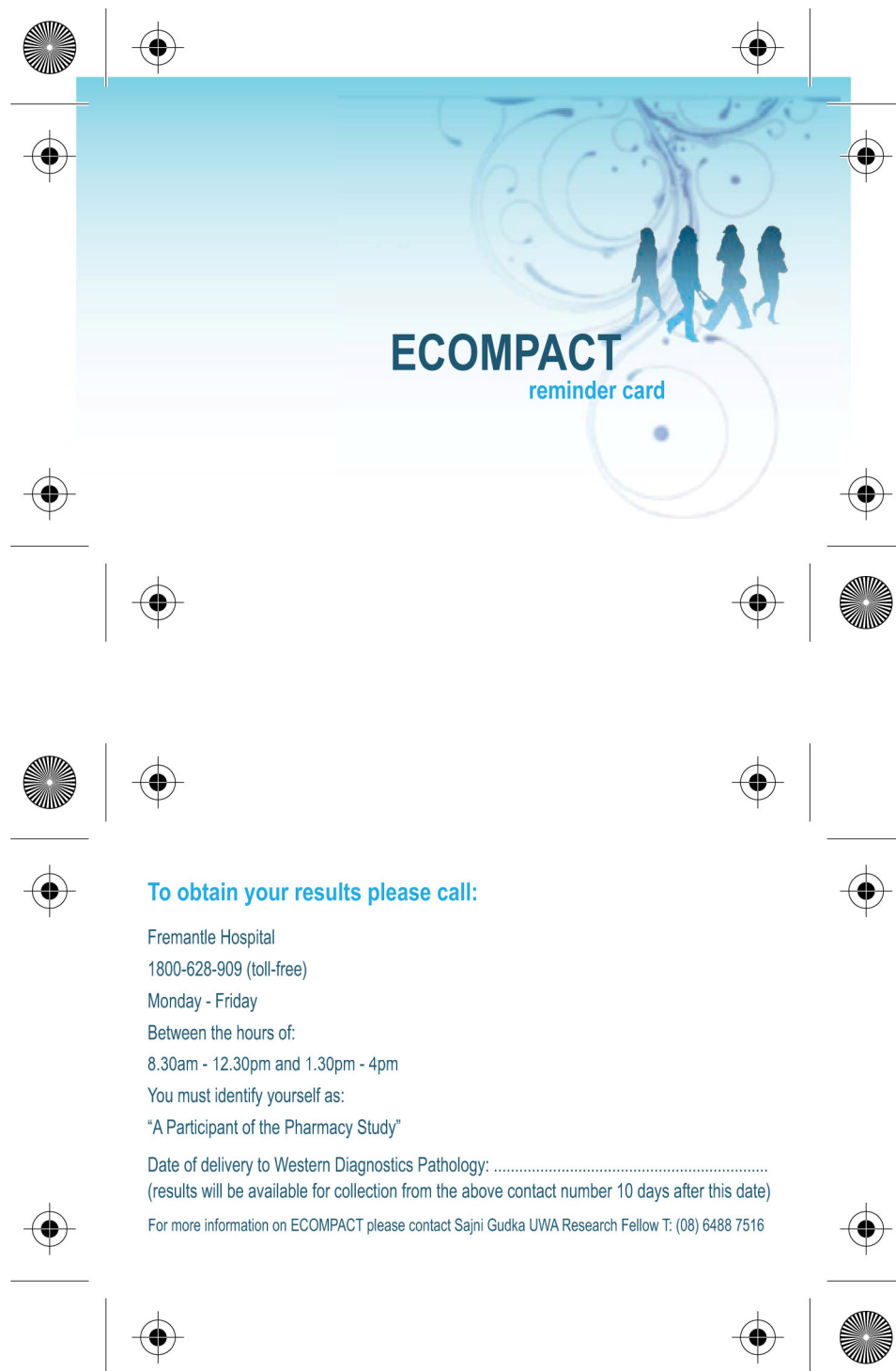
A positive result means that you either have chlamydia, or have been in contact with someone who has chlamydia. Your options for treatment and consultation with a physician will be discussed with you when you call for you results.

The good news is that chlamydia is easy to treat, but it should be treated as early as possible to prevent further complications.

During your consultation, you will be asked about the people you have recently had sex with. Because chlamydia is spread through unprotected sex, your partner(s) may be infected and need treatment.

You will be given help and advice on the best way to approach them. This can be arranged anonymously without any mention of your name to them.

Appendix 9: ECOMPACT Reminder Card



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Appendix 10: ECOMPACT Protocol Explanatory Notes

Explanatory Notes for ECOMPACT screening protocol

A. Section M of PSA EC protocol

Section M of PSA EC protocol (Appendix 5) recommends that pharmacists should make the consumer aware that the EC does not protect them from STI's and that the consumer should be encouraged to get an STI test. Inform the consumer about chlamydia, including the following:

- it is the most common STI in Australia
- it is asymptomatic
- it can lead to serious complications if left untreated.

Determine if they would be interested in carrying out a free self-collected chlamydia test as part of their EC consultation.

B. Screen consumer for STI symptoms

Symptoms of STI include:

- Abnormal bleeding (irregular timing, heavy menstruation, more painful periods than usual)
- Lower abdominal pain
- Unusual vaginal discharge
- Pain during or after sex
- Burning or pain when passing urine

Consumers showing any of the above symptoms should be promptly referred either to their general practitioner or to Family Planning Western Australia for a full sexual health check.

C. Assess consumer's eligibility for chlamydia testing

To be eligible, all of the following criteria need to be met. The consumer:

- Must have requested EC from your pharmacy
- Must be over 18 years of age
- Must be able to give their full name, address and contact number for pathology screening.
- Must not have had a positive chlamydia test in the last four weeks.

Ineligible Consumers

Those outside the above inclusion criteria should be given sexual health advice and must not be invited to participate in the study. Eligibility and Consent Form F1 (Appendix 6)

Form F1 is a one-page form that has been printed on No Carbon Required (NCR) duplicates, bound together in a pad with common front and back, with one copy to be given to the consumer and one copy to be kept in the pharmacy for collection by the research team.

It has been designed to reduce the quantity of paperwork, and make the data collection process quick and user friendly. Each form contains:

- A unique Patient Identification Code used to key the data and de-identify the consumer
- A checklist of eligibility criteria [see also Explanatory Note C]
- A list of points the pharmacist should discuss with the consumer
- The Participation Information Sheet
- The Participation Consent Form
- A section to obtain additional consent for future contact and contact details

D. Explain ECOMPACT study and procedure

Once a consumer has been identified as eligible, refer them to the information on the back of F1 under the heading ECOMPACT "Participant Information Sheet". To ensure that the consumer fully understands what is required from them, the following points must be pointed out to the consumer:

- ECOMPACT is a UWA pharmacy research project funded by the Pharmacy Guild of Australia and Department of Health.
- It is a feasibility study to assess the process and acceptance of a pharmacy-based chlamydia screening service to women seeking EC.
- The consumer will need to collect their own low vaginal swab either at home or at any Western Diagnostics drop-off sites.
- The swab should be returned to any Western Diagnostics drop-off sites for testing.
- The results will be available from Fremantle Hospital on 1800 628 909.
- Treatments options available if tested positive.

Refer to the quick reference guide of appropriate issues to discuss with the consumer on the front of F1.

E. Obtain consumer consent for study

Explain to the consumer that their involvement is voluntary and all data collected as part of the study is treated with strictest confidentiality. The consumer will need to read and sign the "Statement by Consumer" section on F1.

If consumer does not want to participate in the study, give the consumer sexual health advice as per section M of the PSA protocol before ending consultation.

F. Complete Health Review Request Form F2 (Appendix 7)

Form F2 was designed in consultation with Western Diagnostics Pathology Centres and Fremantle Hospital. Form F2 has patient information and clinical data on one side and a list of Western Diagnostic drop-off sites on the reverse.

Clearly fill in the following sections for the consumer:

- Surname
- First Name
- Residential Address
- Date of Birth
- Contact phone number
- Date of referral or when ECOMPACT kit was given
- Unique ID code from top right hand corner of F1

G. Give and explain consumer ECOMPACT kit

The ECOMPACT kit includes the following items in a plain white A5 envelope:

- 1 x ECOMPACT "what you need to know" leaflet (Appendix 8)
- 1 x GEN-PROBE APTIMA unisex collection swab
- 1 x GEN-PROBE APTIMA swab transport medium tube
- 1 x biohazard bag
- 1 x ECOMPACT Reminder Card (Appendix 9)

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Appendix 11a: ECOMPACT Pharmacist Training Course Program



ECOMPACT Training Session

7.30pm – 7.40 am *Sajni Gudka*
Registration & Welcome

SESSION 1: CHLAMYDIA OVERVIEW

7.40 pm – 8.00pm *Lewis Marshall – Sexual Health Physician*
Key Issues in Chlamydia – Overview and Prevalence

8.00 pm – 8.15 pm *Jila Misaghian, UWA Student*
Types of Screening Test

8.15PM TO 8.20 PM Tea Break

SESSION 2: PHARMACY BASED CHLAMYDIA SCREENING

8.20pm – 8.45pm *Xuan Li Yow*
Evidence for Pharmacy Based Chlamydia Screening
Introduction to ECOMPACT
Patient Journey


8.45pm – 9.20pm *Sajni Gudka*
Pharmacist Process
Motivational Interviewing
Confidentiality
House Keeping

9.20pm – 9.30pm Question Time




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Appendix 11b: ECOMPACT Pharmacist Training Course Presentation Slides


ECOMPACT



Emergency
CONtraception
Mediated
Pharmacy
Access of
Chlamydia
Testing

 The Pharmacy Guild of Australia  THE UNIVERSITY OF WESTERN AUSTRALIA  Australian Government
Department of Health and Ageing

Program



- Chlamydia Overview – Dr Lewis Marshall (20mins)
- Types of Screening Tests – Jila Misaghian (15mins)
- Evidence for Pharmacy Chlamydia Screening – Xuan Li Yow (10mins)
- Consumer Journey– Xuan Li Yow (15mins)
- Pharmacist Process – Sajni Gudka (20 mins)
- Motivational Interviewing, Confidentiality, House Keeping – Sajni Gudka (15 mins)

Investigators




- Dr Rhonda Clifford (Senior Lecturer) UWA;
- Sajni Gudka (Research Fellow) UWA;
- Dr Lewis Marshall, Department of Infectious Disease, Fremantle Hospital; and
- Alison Creagh, Medical Educator, Family Planning Western Australia (FPWA)

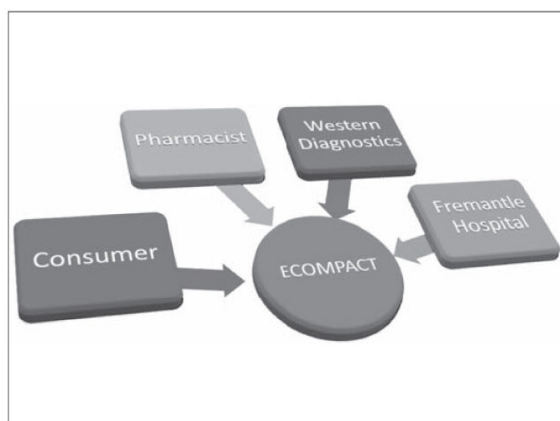
AND

Jila Misaghian and Xuan Li Yow,
Master of Pharmacy Students, UWA.

Aims



- Develop a model of a community pharmacy Chlamydia screening program which best meets consumer, health care professional and community needs - ECOMPACT
- Pilot the model in 20 pharmacies across Perth over 6 months
- Evaluate ECOMPACT via qualitative & quantitative analysis
- Construct an evaluation framework to monitor the uptake of the program and a subsequent increase in Chlamydia awareness
- Utilise experience gained from the pilot to develop a national program

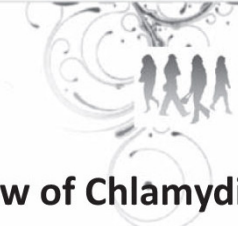


Item	Completed by:
Acceptance of a Chlamydia Screening Program in Community Pharmacies. <small>Published: Journal of Pharmacy Practice and Research Volume 37, No. 4, 2007</small>	April 2007
Developing a chlamydia screening program for community pharmacy - ECOMPACT	November 2007
Ethics approval for ECOMPACT	February 2008
Creating the process of ECOMPACT, flow charts, consumer information leaflets, kits, pharmacy recruitment	April 2008
Start pilot – 20 pharmacies – 6months	May – Nov 2008
Consumer and pharmacist evaluation, focus groups	January 2009
Data analysis and review, report writing and future recommendations for sustainable models for pharmacy-based chlamydia screening	May 2009



ECOMPACT is funded by the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia.

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Department of Health and Ageing



1. Overview of Chlamydia

Dr Lewis Marshall

About Chlamydia

- Slow growing intracellular organism
 - 2 phases intracellular reproductive and extracellular infectious phases
- Needs cell culture to grow
 - Reproduces 48-72 hours
- Nucleic Acid testing now preferred

RISK FACTORS

- NUMBER OF LIFETIME PARTNERS
- HIGH RATE OF PARTNER CHANGE
- HIGH NUMBER CASUAL PARTNERS
- INFECTIVITY OF PARTNERS
- USE OF CONDOMS
- LATE PRESENTATION
- POOR COMPLIANCE
- PARTNER NOT TREATED

Chlamydia symptoms

No symptoms - many cases are asymptomatic (as many as 85% of female cases and 40% of male cases)

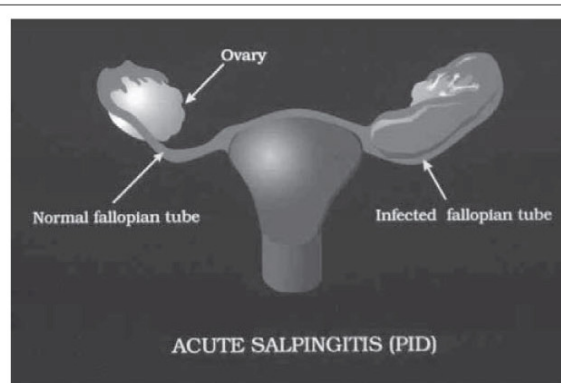
- Vaginal discharge
- Penile discharge
- Pain while urinating
- Light vaginal bleeding
- Vaginal bleeding after intercourse
-

Chlamydia symptoms

- Symptoms of a milder chronic infection:
 - Yellow vaginal discharge
 - Smelly vaginal discharge
 - Lower abdominal or back pain
 - Lower abdominal or back pain worse during menstruation
 - Spotting after sex

Chlamydia Importance

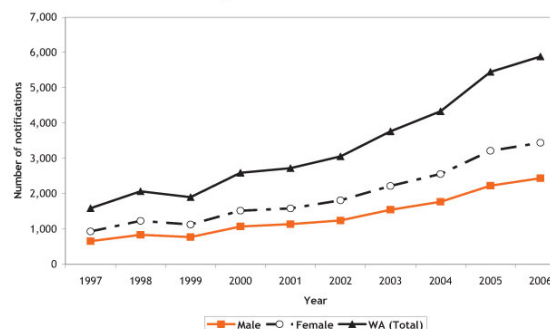
- PID AND INFERTILITY
 - C/T 8-10% PID Worse with repeat infections
 - Responsible for 50% of PID
 - 10-15% Of those with PID have tubal infertility
- Increasing evidence of reduced fertility in men
- PID AND ECTOPIC PREGNANCY
 - 7% RISK AFTER ONE EPISODE PID
 - 15% AFTER 2 AND 40% WITH >2
- POOR PERINATAL OUTCOMES
- SOCIAL OUTCOMES



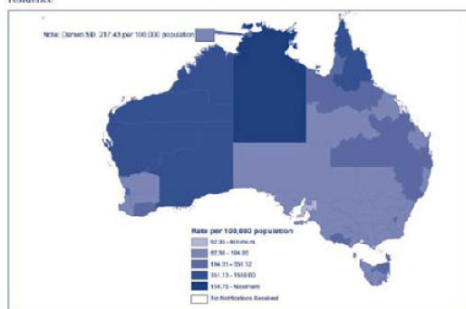
epididymitis (a complication of gonorrhea) www.healthac.org



Number of chlamydia notifications by sex, WA, 1997 to 2006



Map 3. Notification rate for chlamydial infections, Australia, 2005, by Statistical Division of residence



ASR of chlamydia and gonorrhoea notifications by region, WA, 2006

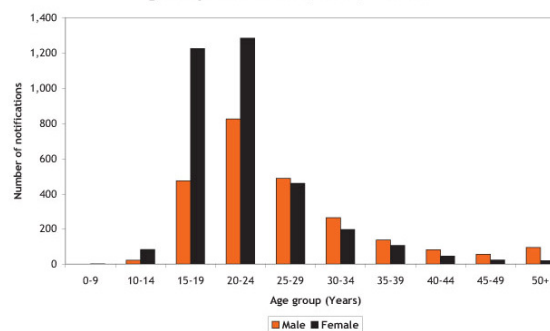
Region	ASR per 100,000	
	Chlamydia	Gonorrhoea
Goldfields	607.9	373.7
Great Southern	253.5	24.9
Kimberley	1,295.3	1,423.8
Midwest	375.8	86.7
North Metropolitan	236.3	26.1
Pilbara	786.0	902.6
South Metropolitan	244.9	27.9
South West	196.0	11.6
Wheatbelt	172.3	12.6
WA (Total)	284.6	81.5

WHO HAVE THE HIGHEST RATES?

➤ Behaviour and prevalence determine risk

- Age <25
- THOSE WHO HAVE CHANGED PARTNERS
- INJECTING DRUG & ALCOHOL ABUSERS
- PREVIOUS STIs
- MSM
- INDIGENOUS AUSTRALIANS
- PSYCHIATRIC ILLNESS
 - PARTICULARLY DISINHIBITING DISORDERS

Number of chlamydia notifications by age group and sex, WA, 2006

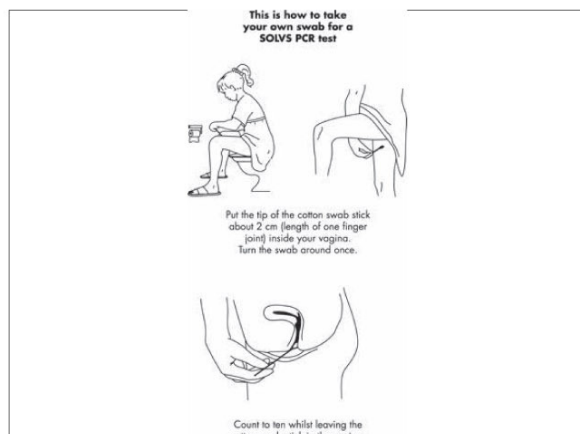


Necessary conditions for screening

- Important disease
- Reliable test
- Cost effective test
- Good intervention
- Intervention changes the disease process

WHAT TESTS?

- MEN
 - FIRST VOIDED 20MLS OF URINE
- WOMEN
 - SELF OBTAINED LOW VAGINAL SWAB
 - URINE
 - Urine alone misses up to 10% of infections



Treatment Options

- For uncomplicated infection
 - Azithromycin 1000mg stat; or
 - Doxycycline 100mg bd for 7 days. (not for use in pregnancy or breast feeding)
- In pregnancy:
 - Azithromycin 1000mg stat (Category B1); or
 - Amoxicillin 500mg tds for 10 days (Category A); or
 - EES 800mg bd for 10 days (Category A)

Notification

- Laboratories automatically notify
- Doctors have a legal responsibility to also notify
- Action taken depends on the disease
- Chlamydia not always actively contact traced
 - Partner initiated contact important

CONTACT TRACING OBJECTIVES

- Interrupt Transmission
- Prevent re-infection
- Identify early those with infection who may be asymptomatic
- Provide early treatment to reduce complications
- Provide individual education and counselling

Referrals

Fremantle Hospital
Infectious Diseases, B2 Clinic
Alma Street, Fremantle
T: (08) 9431 2149

FPWA (Family Planning WA)
70 Roe Street, Northbridge
T: (08) 9227 6177
Sexual Health Helpline
T: (08) 9227 6178

Royal Perth Hospital
Sexual Health Clinic
Wellington Street Perth
T: (08) 9224 2178

Rockingham Clinic
(Thursday 3-6pm)
City of Rockingham Youth Health Services
9 Baralda Court, Rockingham
T: (08) 9527 7464

Quarry Health Centre
(For under 25s)
Rear, 7 Quarry Street, Fremantle
T: (08) 9430 4544

$$R = \beta \times C \times D$$

R is reproductive rate

β is infectivity

C is change of partners

D is duration of infection

2. Types of Screening Tests

Jila Misaghian

Types of Screening Tests Available for *Chlamydia trachomatis*

Direct Detection of *Chlamydia trachomatis*

Non Direct Detection of *Chlamydia trachomatis*

Direct detection of *Chlamydia trachomatis*

➤ Cell Culture

- Most specific method for diagnosis of *Chlamydia trachomatis* → 100%
- Specimens are added to cultures of susceptible cells
 - Infected cells are examined for the presence of iodine-staining inclusion bodies
 - Presence of iodine-staining inclusion bodies → Specific for *C. trachomatis*

Cell Culture

➤ Disadvantages

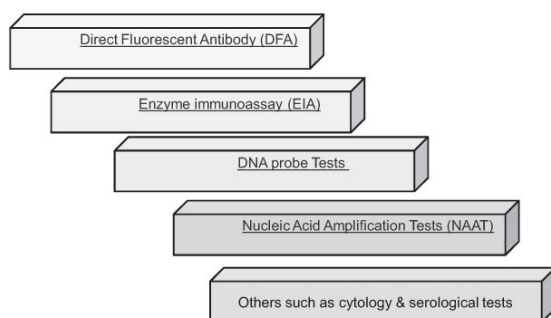
- Low sensitivity → 56.1%
- Expensive
- Time consuming → 48-72 hours
- Technically difficult
- Not standardized
- Requires careful specimen collection and pelvic examination
- Requires stringent transport conditions
- Can only be provided by a few laboratories

Direct Detection of *Chlamydia trachomatis*

Non Direct Detection of *Chlamydia trachomatis*

➤ Non culture tests

- Do not require viable organisms
- Avoid some of the collection and transport problems
- Rapid diagnosis



Next

Direct Fluorescent Antibody (DFA)

Works by detecting species-specific epitope

DFA

Advantages

- Less expensive than culture
- Results within 30 minutes
- Avoids technical difficulties encountered with culture handling

Disadvantages

- Pelvic examination for endocervical specimen
- Marked inter-laboratory variability of results
- Not suitable for screening large populations

Non-direct detection of *Chlamydia trachomatis*

Enzyme Immunoassays (IE)

- Uses a polyclonal or a monoclonal antibody directed against the genus-specific lipopolysaccharide (LPS) antigen

➤ The use is appropriate when:

- Patient's return for treatment is not predictable
- Practitioner needs rapid diagnosis to commence treatment

Enzyme Immunoassays (IE)

EIA

Advantages

- Suitable for processing large numbers of specimens
- Very rapid

Disadvantages

- Cannot be used in screening program as it has a low sensitivity

Sensitivity and specificity can increase to >99% by blocking tests

Enzyme immunoassay (EIA)

DNA Probe Test

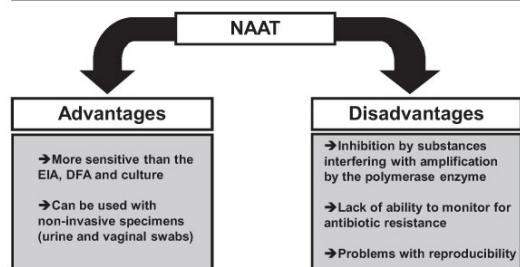
- Uses a direct nucleic acid probe
 - Hybridizes to a species-specific sequence of chlamydial rRNA
- Sensitivity ➔ 75% to 80%
- Specificity of > 99%
- Advantage:
 - Ability to batch process many specimens

DNA probe Tests

Nucleic Acid Amplification Tests (NAAT)

- Most recent generation of diagnostic tests
- Most widely used NAAT include:
 - Polymerase Chain Reaction (PCR)
 - Ligase Chain Reaction (LCR)
 - Transcription Mediated Amplification (TMA)

Nucleic Acid Amplification Tests (NAAT)



Nucleic Acid Amplification Tests (NAAT)

How accurate are these tests?

Test method	Sensitivity	Specificity
Direct Detection		
Cell Culture	50% to 56%	100%
Non Direct Detection		
Direct Immunofluorescence Assays (DFA)	70%-90%	95%-99.9%
Enzyme Immunoassay (EIA)	64.2%-80%	98%-99.1%
Nucleic Acid Amplification Tests (NAAT)	85%-95%	92%-99.8%

Sensitivity and specificities of NAAT on various specimens

Specimen Type	Sensitivity	Specificity
Endocervical swab	64-100%	96-100%
Urine	49-100%	90-100%
Vaginal swabs	90-97%	99-100%

Test method	Specimen type	Skill & time required
Direct Detection		
Cell Culture	Urethral and cervical swab	Need for specialized culture medium, culture conditions and skilled staff, 72 hours
Non Direct Detection		
Direct Immunofluorescence Assays (DFA)	Urethral and cervical swab	Simple to process, subjective results, need for skilled staff, 30 minutes
Enzyme Immunoassay (EIA)	Urethral and cervical swab	Easy to perform and interpret, 3 hours
Nucleic Acid Probe (NAP)	Vulval, cervical or urethral swab	Easy to perform and interpret, 3 hours
Nucleic Acid Amplification Tests (NAAT)	Vulval, cervical or urethral swab, first void urine	Need for specialized equipment and qualified staff, 4-24 hours

First Catch Urine (FCU) vs. Self Collected Vaginal Swab (SVS)

- ➔ FCU
- Can be done by both the Gene Probe and PCR
 - Reliable detection method
 - Studies comparing DFA, PCR and LCR concluded
 - PCR has the highest sensitivity followed by LCR, DFA
 - Studies comparing LCR, PCR and TMA
 - Highest sensitivity for PCR followed by TMA and LCR

- ➔ SVS
- » Superior to endocervical swabs and urine samples
 - » Higher number of positive test results
 - » Feasible alternative to cervical specimen
 - » Less labor intensive ➔ Doesn't need a centrifugation step
 - » Easy transport by post
 - » More stable in room temperature

First Catch Urine (FCU) & Self Collected Vaginal Swab (SVS)

- Advantages of both
- Non or minimally invasive
 - More acceptable both in terms of acceptability compared to endocervical swabs
 - Reduced need for the trained personnel and material required for pelvic examination
 - A study found that 51% of participants wouldn't do endocervical swabs and they would have preferred FVU or LVS

What do women prefer?

- Several studies have shown:
 - SVS & FCU accepted by women after they have performed the tests
 - Slight number of women preferred FCU than SVS (<10% difference)
- Preference of FCU
 - Cultural barriers
- Preference of SVS
 - Being white
 - History of sexual risk behavior
- Study done in Perth Metropolitan area (n:50)
 - Women prefer urine specimen
 - Women were asked about the type of test they prefer
 - Not given any information on both type of tests available
- Another study currently being trialed where women are given more information about the testing methods

Self Collected Lower Vaginal Swab

- Can be collected at the patient's house or at the laboratory
- Should be stored at 4°C to 30°C
- Needs to be taken to pathology within 72 hours of collection (ideal)
- Could be posted by mail (without medium)
- Has a sensitivity of 90% to 97% and a specificity of 99% to 100%



- Remove the cap off the tube
Place the swab into the transport tube
Snap off the shaft of the swab & screw on the transport tube lid firmly
Label the tube with your full name and time of collection
Place the tube into the plastic specimen bag, with the pathology request form
Deliver the sample to your nearest pathology collection centre within 72 hours
Store sample at room temperature (Between 2°C to 30°C) prior to delivery to the collection centre

Self Collected First Void Urine

- Collected by providing 25 mL of first void urine into a specimen jar
- Requires not passing urine for 2 hours before collecting the specimen
- Can be collected at the patient's house or at the laboratory
- Should be stored at 2°C to 30°C
- Needs to be taken to pathology within 24 hours of collection
- Cannot be posted to the pathology in mail
- Has a sensitivity of 49% to 100% and a specificity of 90% to 100%



3. Evidence for Pharmacy Chlamydia Screening and ECOMPACT

Xuan Li Yow

Why screen for chlamydia?

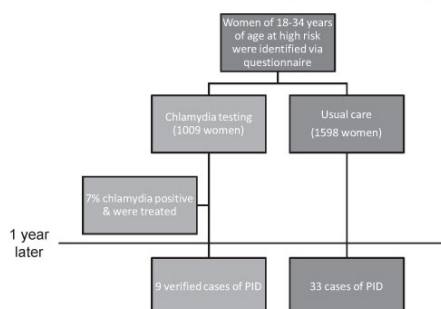
Screening is often necessary to detect chlamydia due to its asymptomatic nature

Chlamydia screening successfully fulfils the Wilson-Junger criteria for screening (WHO)

Internationally, screening programs have been introduced as a strategy to reduce the number of people infected & the rate of complications

Implementation of opportunistic chlamydia screening models in both Australian and overseas settings have proven to be cost effective

Randomized controlled trials showed reductions in PID from screening



Scholes D, Stergachis A, Heidrich FE, Ansell H, Holmes KK, Stamm WE. Prevention of pelvic inflammatory disease by screening for cervical chlamydial infection. *N Engl J Med*. 1996 May 23;334(21):1392-6.

Programmes demonstrate decreases in prevalence from screening

Disadvantaged women aged 16-24
Entering a national job training program for economically disadvantaged youths in the U.S.

Women entering the program were routinely screened for chlamydia due to it's high prevalence in adolescents, minorities, low SES.

Prevalence declined from 14.9% in 1990 to 10.0% in 1997 ($P < .001$).

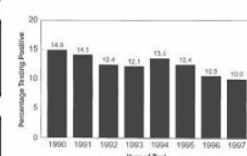


FIGURE 1—Prevalence of chlamydial infection in women aged 16 through 24 years entering a national job training program 1990–1997, by year of test.

Mertz KJ, Ransom RL, St Louis ME, Groseclose SL, Hadgu A, Levine WC, et al. Prevalence of Genital Chlamydial Infection in Young Women Entering a National Job Training Program, 1990–1997. *Am J Public Health*. 2001 August 1; 91(8):1287-90.

Models show it's cost-beneficial & cost-effective

Literature review on cost-effectiveness of screening for chlamydia

Asymptomatic sexually active women, < 30 y/o in a primary care setting.

Intervention: Screening for lower genital tract infection with chlamydia

Outcomes studied: cases of C trachomatis detected, cases of PID prevented, & associated costs.

10 studies included - all were modelled scenarios and all found screening to be more cost effective than simply testing symptomatic women

Honey E, Augood C, Templeton A, Russell J, Paavonen J, March PA, et al. Cost effectiveness of screening for Chlamydia trachomatis: a review of published studies. Sex Transm Infect. 2002 December 1; 78(6):406-12.

Evidence for ECOMPACT

Chlamydia screening internationally

Pharmacy-based chlamydia screening has been implemented in the U.S., Sweden the U.K. And Australia

Most success has been achieved in the U.K.

Two major screening programmes (Boots & NCSP), as well as many independent projects

Extensive evaluation is yet to come for many of these projects

Pharmacy Chlamydia Screening Pathfinder



Free-to-user pharmacy based screening of 16-24 y/o males & females

Launched in 2005 by the UK DoH

200+ Boots pharmacies in 31 PCTs

21,793 screens undertaken between 14/11/05 (launch) & 30/06/07

8% positive (7% females, 10% males)

Typical consumer profile was older

- 58% were 22-24 years of age

29% were not using condoms during the previous two months

- other forms of contraception or not using any contraception

43% had 2 or more partners in the previous 12 months

- Suggests that consumers were participating in high-risk behaviours

National Chlamydia Screening Programme (UK)

Opportunistic testing of individuals under 25 years of age

Various health care settings: Sexual health & G.P. clinics, pharmacies, prisons

Each programme area tailors screening to local needs.

Hull PCT (from 01/08/06 to 30/04/07)

- 20 pharmacies, consumers <25 y/o
- Kits supplied: 141
- Kit return rate: 57% (63% of these were 19-21 years of age)
- Positive tests: 18.5%

Lambeth & Southwark PCTs: 01/08/05 – 30/11/05

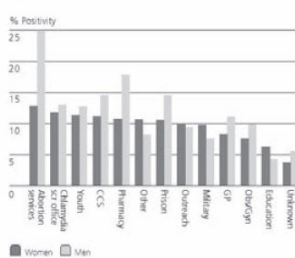
- 90 tests were provided. 9.5% positive
- 52% were under 25
- 60% of those who accessed the service had accessed an EHC service

Overall evaluation of the NCSP will be available this year.

National Chlamydia Screening Programme (UK)

Abortion services, prisons and pharmacies had one of the highest incidences of positive screens

Figure 3: Chlamydia positivity by venue type and sex (year 4: 01/04/06–31/03/07)



Data as of 22 August 2007 and may not reflect all screens performed.

4. Consumer Journey

Xuan Li Yow

Emergency contraception (EHC)

Consumer requests for EHC contraception at the pharmacy.

After the consultation, the pharmacist will explain what the Chlamydia Screening Project is about.

Pharmacist to determine whether or not you are eligible for testing.

If consumer is eligible

The pharmacist will explain what to do next.

Consumer will receive a test kit containing a self-collected vaginal swab & transport tube, instructions on how to collect the vaginal swab sample, a Health Review Request Form (yellow form) & a bio-hazard bag.

Consumer will also receive a copy of the Chlamydia testing checklist.

Perform sample swab

Perform the swab either at home OR at a Western Diagnostics Lab OR nearest toilet facilities.

Follow the step-by-step instructions to collect the sample.

Take to Western Diagnostics within 72 hours (3 days) Or return to pharmacy if courier organized.

The sample should NOT be exposed to temperatures higher than 30C (do not leave it in the car).

Call the hotline



If WD – Call 7 days later;
If Pharmacy – Call 10 days later

Call 1800 628 909 Mon-Fri between 8.30-am- 12.30pm or 1.30pm -4.00 pm to get your results.

Consumer MUST state that you are part of the "Pharmacy Chlamydia Study"

Results

POSITIVE for Chlamydia: Make a free appointment for treatment & sexual health check at Fremantle Hospital. If consumer would rather visit their own GP, must let the hotline staff know.

NEGATIVE for Chlamydia: Great news! Consumers' journey ends here.

Treatment if you are positive for Chlamydia

Antibiotics given to treat Chlamydia.

Full sexual health check.

Partner notification (with consumer's permission).

Feedback

Consumer may be contacted for a telephone survey 4-6 weeks after visiting the pharmacy.

This survey will be about their experience of the Chlamydia Screening Project.



Western Diagnostics

Sample processed within 72 hours (RNA test of vaginal swab sample)

Results sent to Infectious Disease Department of Fremantle Hospital for action

Positive results are notified to the Health Department



Fremantle Hospital

Receives test results from Western Diagnostics

Consumer should call 1800 hotline 7 days after returning their sample to obtain their results

If consumer tests positive, Fremantle Hospital shall call the consumer A.S.A.P.

- If consumer is unable to be reached, FH shall leave a text message

If consumer tests negative and does not call within 14 days after dropping off the sample

- Fremantle hospital shall send a text message



Fremantle Hospital

Negative result

- Sexual health promotion; No further action

Positive result

- Consumer encouraged to make an appointment with Dr Lewis Marshall at FH
- Chlamydia treatment (Azithromycin 1g STAT as a single dose)
- Full STI examination offered
- Sexual partner notification discussed
- Sexual health promotion
- Follow up 3 months after treatment
- If consumer prefers to be treated by GP, test results shall be forwarded to GP
- Hotline staff document reasons for preference
- Positive results notified to the health department

Inconclusive result

- Repeat test as per laboratory instructions

Follow up - evaluation



- Random consumer sample shall be contacted by project researchers via telephone for a sample questionnaire
- If consumer consents, shall participate in a focus group regarding the screening project

5. Pharmacist Process

Sajni Gudka

When do you recruit?

Complete EHC consultation

Introduce ECOMPACT (regardless of EHC given or not given)

Complete ECOMPACT Eligibility Checklist

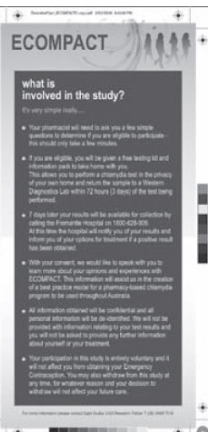
If eligible, fill in Consent Form, and Pathology Review Request Form (yellow form)

Give consumer ECOMPACT KIT, Pathology Review Request Form and copy of ECOMPACT eligibility form

How do I introduce ECOMPACT?

- ECOMPACT is a "study" by UWA, DOH and Pharmacy Guild.
- Trialing new sexual health service for community pharmacists
- Pilot study from 20 pharmacies in Perth (6 months)
- Offering consumers a chance to carry out a FREE self collected chlamydia test

result



ECOMPACT Eligibility Checklist

- To assess if patient is symptomatic or asymptomatic
- To address consumer eligibility in the study
- A memory aid for pharmacists to discuss all relevant information about ECOMPACT – to ensure compliance and higher return rates (\$)

ECOMPACT
Eligibility Checklist and Consent Form

UNIQUE ID CODE: 0101

Pharmacist to determine: (please tick)

Is the consumer over 18 years of age? (Date of Birth: / /) ☐

Does the consumer have any of the following symptoms:

Abnormal bleeding? (irregular timing, heavy menstruation, more painful periods) ☐

Lower abdominal pain? ☐

Unusual vaginal discharge? ☐

Pain during/after sex? ☐

Burning or pain when passing urine? ☐

Has the consumer had a positive chlamydia test in the last 4 weeks? ☐

IF YES to ANY of the above - Consumer is **INELIGIBLE** for ECOMPACT chlamydia testing: (Tick if INELIGIBLE) ☐

Reason(s) for ineligibility (please state):

If symptomatic, strongly encourage consumer to make a doctor's appointment for further investigation

IF NO to ALL of the above - Consumer is **ELIGIBLE** for ECOMPACT chlamydia testing: (Tick if ELIGIBLE) ☐

What is chlamydia?

What is ECOMPACT? (chlamydia test only, kit contents, patient consent)

How to take a vaginal swab (refer to patient information leaflet)

Pathology testing (where to take the sample, appropriate handling conditions & delivery time)

How to obtain results (contact details for Fremantle Hospital)

Available treatment options and outcomes for positive & negative results

What is the Unique ID Code

- Every patient gets a unique ID code
 - Track their progress in the study.
- Monitor uptake from pharmacies
- Indication of return rates to pathology (\$)
 - Timescales
- Information about when they call for results
- Indication of positive and negative results

ALL ESSENTIAL FOR MONITORING UPTAKE AND SUCCESS – FUTURE FUNDING

Consumer Information Sheet and Consent Form

- Legal requirement by University of Western Australia Human Research Ethics Committee
- ALL consumers must
 - Give written “consent”
 - Keep a copy of “Information and Consent Form”
 - Be willing to give their name, address, DOB and mobile number (Pathology Review Request Form)

Consumer Consent Form

Statement by Consumer

I hereby voluntarily agree to take part in the ECOMPACT pilot study. I have read the information sheet provided and any questions I have asked have been answered to my satisfaction. I am aware of the risks and benefits of the study and I understand that the study will remain strictly confidential and will not be released by the University of Western Australia without my written consent. I agree that the information obtained from this study may be used for research purposes and I understand how to proceed with the testing and the results.

Participant's Name: _____ Signature: _____

Pharmacist's Name: _____ Signature: _____

Please indicate if we can contact you for a confidential discussion about ECOMPACT at the end of the pilot: YES / NO

If YES, please provide a contact/mobile number that you can be contacted on: _____ Postcode: _____

PLEASE ENCOURAGE AS MANY CONSUMERS AS POSSIBLE TO LEAVE THESE DETAILS – VERY IMPORTANT FOR FEEDBACK AND STRENGTHENING MODEL FOR FUTURE FUNDING AND SUSTAINABILITY.

Health Review

1. HEALTH SCREEN NAME

2. INVESTIGATIONS REQUESTED

☐ TYPING

☐ NON-TYPING

UWA Community Pharmacy Study **CHP**

ACCOUNT TO (Monthly)

UWAC Attn: Rhonda Clifford Pharmacy M315 UWA, Crawley 6009

Dr Lewis Marshall (UWAC) Infectious Disease Dept Fremantle Hospital Phone 9431 2376

DATE OF REFERRAL: (date when kit given out)

What's in the “KIT”?

- One unisex collection swab
- One tube containing GEN-PROBE APTIMA swab transport medium (2.9ml)
- A bio-hazard bag
- Patient Information Leaflet on ECOMPACT

what is chlamydia?

Chlamydia is a sexually transmitted infection (STI) caused by a bacteria that can affect both men and women. It is the most common STI in Australia.

how do you get chlamydia?

You can be infected with chlamydia, or pass it on to someone else during sex. Through oral or vaginal sex. Chlamydia cannot be passed on through kissing or by sharing towels, clothing, cups and glasses, or toilet seats.

why should I get tested?

Most people have no symptoms and don't know they have chlamydia. And so the infection is passed on to others. If left untreated, chlamydia can cause health problems such as pain and infertility if left untreated.

how do I find out if I have chlamydia?

As part of the ECOMPACT study, you will be given a FREE chlamydia testing kit in addition to this swab. The kit contains:

- One unisex collection swab
- One tube containing GEN-PROBE APTIMA swab transport medium (2.9ml)
- Health Review Request Form (yellow form)
- A bio-hazard bag

what do I have to do?

You need to collect your own (or your partner's) swab. It's very easy to do. In fact it's easier than inserting a tampon. The swab is used to collect the swab from your vagina or your partner's penis.

how do I use the swab?

1. Put the tip of the swab into your vagina or your partner's penis. 2. Turn the swab around and make sure it is inside of the vagina or penis. 3. Push the swab into the vagina or penis. 4. Remove the swab from the vagina or penis and immediately place it into the bio-hazard bag. 5. Do not use the swab for anything else. 6. Carry the swab to the lab and place it into the box at the back of the bag. 7. Seal the box and place it into the bio-hazard bag. 8. Place the bio-hazard bag into the box and place it into the box. 9. Place the box into the box and place it into the box. 10. Place the box into the box and place it into the box.

where do I return my swab for testing?

Take your swab to APTIMA Diagnostics Pathology Lab. A list of all the APTIMA Diagnostics Pathology Lab can be found on the reverse side of your Health Review Request Form.

what information will I need to provide?

Health Review Request Form will require your completed Health Review Request Form with your name, address, date of birth, contact details and mobile number. The swab from the kit is used to identify you when you call for your results. The information will be held confidentially by APTIMA Diagnostics and Fremantle Hospital.

what does a positive result mean?

A positive result means that you or your partner have chlamydia. Chlamydia is a sexually transmitted infection. It can be treated with antibiotics. Your partner should also be treated with antibiotics. You should avoid sex until you and your partner have been treated with antibiotics.

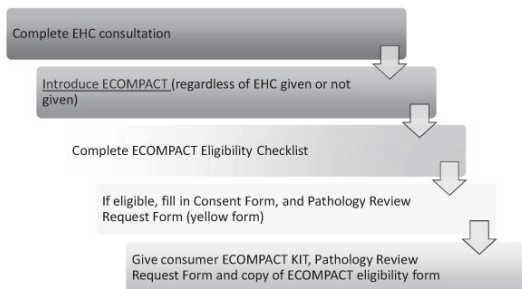
what does a negative result mean?

A negative result means that you or your partner do not have chlamydia. Chlamydia is a sexually transmitted infection. It can be treated with antibiotics. Your partner should also be treated with antibiotics. You should avoid sex until you and your partner have been treated with antibiotics.

List of items to give to consumer

- 1. ECOMPACT KIT**
 - Completed and signed
- 2. Health Review Request Form (yellow form)**
 - Appropriate sections filled out
 - Esp Unique Identification Code

When do you recruit?



Data collection sheets

- Track EHC request, chlamydia acceptance, patient ID, and demographics

ECOMPACT STUDY - EMERGENCY CONTRACEPTION MEDIATED PHARMACY ACCESS OF CHLAMYDIA TESTING
PHARMACY PROGRAMME, UWA - SAJINI GUDKA T: 6488 7516 E: sajini.gudka@uwa.edu.au

PHARMACY: _____

MONTH: _____

Date	Prescription	OTC request	EHC given	Chlamydia Test Offered	Accepted	Patient ID code	Age	Postcode

6. Strategies of Increasing Compliance

Sajni Gudka

Strategies to increase return rates

- Advice on importance of test
- Tell them how easy it is to carry out – no consultations, and FREE
- Encourage them to:
 - Find the nearest toilets (shopping centre, medical centre)
 - Use facilities at Western Diagnostics

Motivational Interviewing Techniques

- Structuralist model of healthcare
 - aetiology, symptoms, treatment
- BUT psychosocial factors are not considered
 - Beliefs and attitudes

Nature of problem	Levels of personal participation in health care
Severity	Perceived benefits of screening/ treatment
Consequences	Cure/Control

Motivational Interviewing Techniques

- Extremely important in health promotion
 - Can be patient centered, but not directive
- ↓
- Allows patients to explore pro and cons of behavior or information given
 - Very important in public health and screening models – opportunistic and targeted

Motivational Interviewing Techniques

- Other ways are enhance opportunistic screening:
 - Understanding the “sick role”
 - Knowing that consumer accessing EHC is already a “proactive consumer”
 - Easier for opportunistic targeting

7. Confidentiality

Sajni Gudka

Confidentiality



- 15-25 year old women have the highest rate of Chlamydia of any age group
- Improving young people's trust in the confidentiality of a pharmacy setting is crucial for professional pharmacy – based services
- Consultation rooms, screened areas should display confidentiality "clauses"
 - E.g. "hear to listen, not to tell"

Confidentiality



- What is "consent"?
 - If a patient consents to the ECOMPACT study, it means that she agrees to carry out the tasks required of her.
- What is "confidentiality"?
 - A pharmacist will not disclose anything learned from the patient who has consulted them, without that patients agreement.

Confidentiality



- Does your practice have a policy on confidentiality?
- Is this a written policy?
- Are there notices in your pharmacy which explain the confidentiality policy?

8. House Keeping

Sajni Gudka

Monies and Payments



- \$1000 readiness fee
 - Payable 8 weeks after start of pilot
- \$15 per every swab returned to pathology
 - tracked through the unique ID code
 - paid at the end of the project

Importance of counseling and encouraging testing!!

ECOMPACT file



- | | |
|---|--|
| ➤ Data collection sheet | ➤ About the project |
| ➤ PSA EHC checklist | ➤ Pharmacist flow chart |
| ➤ ECOMPACT eligibility checklist and Consent Form (carbon copy) | ➤ Master copy of paperwork (laminated and highlighted) |
| ➤ Health Review Request Form (yellow form) | ➤ Flyer and leaflets |
| ➤ Sexual health referral sites | |

ECOMPACT

Emergency
Contraception
Mediated
Pharmacy
Access of
Chlamydia
Testing



The Pharmacy Guild of Australia



Australian Government
 Department of Health and Ageing

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Appendix 13: CATI Telephone Interview

Telephone Survey for ECOMPACT

Can I talk to <name> please?

Ensure speaking to correct person

Good morning/afternoon/evening, my name is Sajni Gudka and I am telephoning regarding the ECOMPACT (Pharmacy Chlamydia Screening) study.

You have given your details for a telephone survey.

I'm calling to see if you are still willing to take part in a telephone interview. It is <enter the number of questions> and will take approximately <enter time> minutes.

Is this a convenient time, or would you like to schedule for a more suitable time?

The aim of the interview is to discuss the pharmacy Chlamydia screening service and to hear your views/experience about it.

All information you give me will be immediately de-identified and your identity will not be disclosed in any reports.

This interview is NOT tape-recorded.

Do you have any questions before we begin?

1	Which of the following describes your current situation?	Student Working full time Working part time Parent or carer Looking for work Other Refuse	1 2 3 4 5 6 7	
2	What is the highest qualification you have completed?	No formal qualifications Year 12 or equivalent Trade/apprenticeship Certificate/diploma University degree Post Graduate Degree	1 2 3 4 5 6	
3	Have you had any STI tests in the last 12 months?	Yes No	1 2	
4	What regular contraception, if any, do you use?	Condoms Contraceptive Pill Implant Another method No contraception	1 2 3 4 5	

The next two questions are rated on a scale of 1-5. I will ask the question first, and then explain the scale for each question.

5. Do you think pharmacy based Chlamydia screening is a convenient service?

(1 being very inconvenient, 3 being neutral, and 5 being very convenient)

Very inconvenient Neutral Very convenient

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

6. How comfortable did you feel when you were offered a Chlamydia screening kit in the pharmacy?

(1 being very uncomfortable, 3 neutral, and 5 very comfortable)

Very Uncomfortable Neutral Very Comfortable
1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

Please answer Yes or No to the next two questions.

7	Have you used the Chlamydia Screening Kit?	Yes No	1 2	If YES - Go to Q23 Continue with Q8
8	Are you going to use it?	Yes No	1 2	If YES - Go to Q16 Continue with Q9

If you are not going to use the kit, I would like to explore some of reasons for your choice.

Please answer yes/no to the following questions.

9	Did the pharmacist give you enough information about ECOMPACT and the screening process?	Yes No	1 2	
10	Did you have any concerns about confidentiality in the pharmacy?	Yes No	1 2	

The next two questions are rated on a scale of 1-5. I will ask the question first, and then explain the scale for each question.

11. Were the instructions difficult/easy to follow?

1 being very difficult, 3 being neither difficult/easy, and 5 being very easy

Very Difficult Neither Difficult/ Easy Very Easy
1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

12. Overall did you find the process difficult/easy?

1 being very difficult, 3 being neither difficult/easy, and 5 being very easy

Very Difficult Neither Difficult/ Easy Very Easy
1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

13. Are there any other reasons why you have chosen NOT to use the KIT?

14. Are there any further suggestions/comments you would like to make?

15. Finally, is there anything else you would like to ask (that has not been previously covered)?

Thank you very much for your time and input. Your comments have been noted, and will help us in evaluating our process

.....Continue from Q8.

Note to interviewer: The following questions are for consumers that have NOT used the KIT, but are still thinking about using the KIT

Please answer yes/no to the following questions.

16	Is there any reason why you have not used the KIT yet?	Yes No	1 2	<i>Please explain</i>
17	Did the pharmacist give you enough information about ECOMPACT and the screening process?	Yes No	1 2	
18	Did you have any concerns about confidentiality in the pharmacy?	Yes No	1 2	
19	Do you have any suggestions for improvement for this process?	Yes No	1 2	<i>Please make suggestions.</i>
20	With your permission, I would like to re-contact you in a couple of weeks to get more information about your experience of the screening process (i.e. once you have used the KIT)	Yes No	1 2	<i>When? (If no timescale given suggest one week)</i>

21. Are there any further suggestions/comments you would like to make?

22. Finally, is there anything else you would like to ask (that has not been previously covered)?

Thank you very much for your time and input. Your comments have been noted, and will help us in evaluating our process.

.....Continue from Q7.

Note to interviewer: The following questions are for consumers that have used the KIT.

23	Where did you carry the test out?	In the pharmacy premise At home At Western Diagnostics	1 2 3	
24	Where did you return the KIT?	Not returned it yet At the pharmacy At Western Diagnostics	1 2 3	
25	Would you have preferred to return the KIT by post?	Yes No	1 2	
26	Did the pharmacist give you enough information about ECOMPACT and the screening process?	Yes No	1 2	

27	Did you have any concerns about confidentiality in the pharmacy?	Yes No	1 2	
----	--	-----------	--------	--

The next four questions are rated on a scale of 1-5. They are all based on how difficult or easy you found each step.

1 being very difficult, 3 being neither difficult/easy, and 5 being very easy

28. Overall did you find the process difficult/easy?

Very Difficult Neither Difficult/ Easy Very Easy

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

29. How difficult/easy was the KIT to use?

Very Difficult Neither Difficult/ Easy Very Easy

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

30. Were the instructions difficult/easy to follow?

Very Difficult Neither Difficult/ Easy Very Easy

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

31. How difficult/easy did you find the process of getting your results from Fremantle Hospital

Very Difficult Neither Difficult/ Easy Very Easy

1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐

And finally, I have some open questions in which you can make suggestions.

32. Would you be willing to pay for such a service in the future? How much?

33. Are there any further suggestions/comments you would like to make?

34. Finally, is there anything else you would like to ask (that has not been previously covered)?

Thank you very much for your time and input. Your comments have been noted, and will help us in evaluating our process.

Appendix 14: Consumer Invitation to Focus Group Letter

INVITATION FOR FOCUS GROUP DISCUSSION

Thank you for participating in the pharmacy chlamydia screening study (ECOMPACT).

We would like to offer you a chance to earn \$80 for 1.5 hours of your time.

Your experience with ECOMPACT is crucial in helping us to evaluate this study. To assist us in this process and to ensure that your opinions have been represented as accurately as possible, we would like to invite you to attend ONE focus group session in the coming weeks.

Session:	Date:	Day:	Time:
ONE	20/04/09	Monday	6.30-8pm
TWO	22/04/09	Wednesday	6.30-8pm
THREE	29/04/09	Wednesday	6.30-8pm

Where will it be held?

Pharmacy Building at the University of Western Australia (map attached).

How long will it take?

The focus groups last approximately ONE hour. Refreshments will be provided.

Do I get an incentive for participating?

To show our appreciation for your time and input, every participant in attendance will be given \$80.

If you would like to attend, you will need to do the following prior to Friday the 17th of April 2009:

1. Read the attached information and consent sheet.
2. RSVP via email or using the enclosed slip stating your preferred date/ session.

On behalf of everyone involved with ECOMPACT, we would like to thank you again for your participation in ECOMPACT.

We look forward to hearing from you soon in order to confirm your attendance.

Kind regards,

Sajni Gudka BPharm MRPharmS, MPS

For further information, contact Sajni Gudka on (08) 6488 7516 or via email: sajni.gudka@uwa.edu.au

Investigators: Sajni Gudka and Dr Rhonda Clifford of the Pharmacy Programme, the University of Western Australia, Dr Lewis Marshall from the Department of Infectious Disease, Fremantle Hospital and Alison Creagh, Medical Educator from Family Planning Western Australia (FPWA).

RSVP TO THE FOCUS GROUP AT UWA

Please complete this slip by Tuesday, April 14th

I _____ will/ will not be attending the focus group discussion at UWA.

*Please number your preferred session time in order of preference; 1 being the most favored option, 3 being the least favored option
Please indicate any days which you would be unable to attend:*

20/04/09	Monday	6.30-8.30pm
22/04/09	Wednesday	6.30-8.30pm
29/04/09	Wednesday	6.30-8.30pm

I understand the session will be audio taped and that all the information provided will be confidential.

Contact Phone Number _____

Dietary requirements: ☐ Vegetarian ☐ Non-Vegetarian Other _____

Please complete and return to Sajni Gudka by Friday the 17th of April 2009:

Phone: (08) 6488 7516 Fax: (08) 96488 7532 Email: sgudka@uwa.edu.au

**Mail: Attn: Sajni Gudka (M315)
The University of Western Australia
35 Stirling Highway
Crawley WA 6009**

Appendix 15: Pharmacist Invitation to Focus Group Letter

EXPRESSION OF INTEREST TO PARTICIPATE IN ECOMPACT FOCUS GROUP: YOUR EXPERIENCE AS A PHARMACIST

Dear Pharmacist,

Thank you for participating in Emergency Contraception Mediated Pharmacy Access of Chlamydia Testing (ECOMPACT) study last year.

Aga Palecka and Linda Nguyen (co-ordinators) would like to warmly invite you to focus group session to discuss your experiences with ECOMPACT.

This is the first pharmacy chlamydia screening project in Australia, so it is imperative to evaluate this pilot and discuss possibly sustaining this in the future. Your input is a critical component in obtaining future funding for a longer and wider project, and for creating national guidelines for pharmacists in chlamydia screening.

Focus groups have been scheduled as follows:

Date: Wednesday 8TH APRIL 2009.
Time: 6.30 pm for 7.00 pm start.
Venue: University of Western Australia.
Refreshments: Plenty! From 6.30 pm onwards

The focus group will run for a maximum of 1.5 hrs. To analyse the discussions, the conversation will be audio taped. Opinions expressed during the focus groups will not be attributed to identifiable individuals in any subsequent reports.

RSVP to Sajni by Thursday 2nd April 2009 (email to Sajni Gudka (sajni.gudka@uwa.edu.au) or fax 6488 7532.)

Sajni Gudka BPharm MRPharmS, MPS

RSVP TO THE FOCUS GROUP AT UWA (please complete this slip by Thursday, April 2 and fax to (08)964887532)

I _____ will be attending the focus group discussion on Wednesday the 8th of April at UWA.

I understand the session will be audio taped and that all the information provided will be confidential.

Name of Pharmacy _____ Contact Phone Number _____

Dietary requirements: ☐ Vegetarian ☐ Non-Vegetarian Other _____

The Project is funded by the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia.
The project has been approved by the Human Research Ethics Committee of The University of Western Australia.

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Appendix 16: Consumer Focus Group Themes

Investigators: Dr Rhonda Clifford and Sajni Gudka of the Pharmacy Programme, the University of Western Australia, Dr Lewis Marshall from the Department of Infectious Disease, Fremantle Hospital and Alison Creagh, Medical Educator from Family Planning Western Australia (FPWA).

EMERGENCY CONTRACEPTION MEDIATED PHARMACY ACCESS OF CHLAMYDIA TESTING (ECOMPACT) – SOCUS GROUPS

Discussion Guide for ECOMPACT Patient Focus Group

The Project is funded by the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia.

Introduce self, co-ordinators (Linda and Aga) and main theme for discussion in focus group

Emergency Contraception Mediated Pharmacy Access of Chlamydia Testing (ECOMPACT)

No right or wrong answers

Explain audio taping

Signed consent form

The project has been approved by the Human Research Ethics Committee of The University of Western Australia.

Reassure regarding confidentiality (Data Protection Act)

Self introduction of participants (name, job or hobbies – used for recognition of voice during transcription if any reassurance required)

Patient Themes

EXPERIENCE

1. What has been your overall experience with ECOMPACT?

PROBE: Strengths and weaknesses

PROBE: Would you use this service in future if it becomes permanent in pharmacies?
(Seek examples)

2. How did you feel when you were offered the Chlamydia screening kit in the pharmacy?

a. Environment

PROBE: Pharmacy layout, consultation room, privacy issues
(Seek examples)

b. Professionalism

PROBE: How did the pharmacist approach you?

PROBE: Pharmacists' attitude towards you
(Seek examples)

3. What made you accept and do the screening test?

PROBE: What factors made you NOT do the test?

PROBE: What could be done differently?
(Seek examples)

PATIENT JOURNEY IN ECOMPACT

4. About the kit

a. Method of sample collection – **SWAB**

PROBE: was it easy to use?

PROBE: were the instructions to follow?

PROBE: was there enough information?

PROBE: what other information could be added?

b. How was your experience with **Western Diagnostics**?

PROBE: Barriers/Facilitators

PROBE: Did you have any concerns?
(Seek examples)

- c. How was your experience with **Fremantle hospital**?

PROBE: Barriers/Facilitators
(Seek examples)

- d. How can we increase the number of **people returning the kit**?
- i. Patient understanding
 - ii. Enough information provided
 - iii. Method of testing (Low Vaginal Swab, Urine test)
 - iv. Return of sample at pharmacy? Pathology? Options?

FUTURE DIRECTIONS

- 5. Would you like to receive the Chlamydia screening kit from pharmacies in future?**

PROBE: the service as it is or modified form?
PROBE: to all customers, not just EC users?

- 6. Would you be willing to pay for such a service in the future?**

PROBE: how much are you willing to pay for such a service?

- 7. Is there anything else you would like to add to the discussion that might help to improve screening program implementation into pharmacies or any other comment that you would like to make that we haven't addressed?**

SUMMARY

Facilitator to briefly summarise key ideas raised

- What improvements can be made?

THANK YOU FOR YOUR PARTICIPATION

Quick Survey to be completed

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Appendix 17: Pharmacist Focus Group Themes

Investigators: Dr Rhonda Clifford and Sajni Gudka of the Pharmacy Programme, the University of Western Australia, Dr Lewis Marshall from the Department of Infectious Disease, Fremantle Hospital and Alison Creagh, Medical Educator from Family Planning Western Australia (FPWA).

EMERGENCY CONTRACEPTION MEDIATED PHARMACY ACCESS OF CHLAMYDIA TESTING (ECOMPACT) – SOCUS GROUPS

Discussion Guide for Pharmacists Focus Group

The Project is funded by the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia.

- Introduce self, co-ordinators (Linda and Aga) and main theme for discussion in focus group
- Emergency Contraception Mediated Pharmacy Access of Chlamydia Testing (ECOMPACT)
- No right or wrong answers
- Explain audio taping
- Signed consent form
- The project has been approved by the Human Research Ethics Committee of The University of Western Australia.
- Reassure regarding confidentiality (Data Protection Act)

Self introduction of participants (name, job or hobbies – used for recognition of voice during transcription if any reassurance required)

1. What has been your overall experience with ECOMPACT?

PROBE: Strengths and Weaknesses
 PROBE: As a pharmacist
 PROBE: From staff
 PROBE: Customer – feedback (good or bad)
 Seek Examples

2. Engaging/recruiting ECOMPACT patients?

a. What environmental factors with engaging/recruiting

i. ENGAGING

PROBE: Staff issues (Level of confidence in staff, number of staff)
 PROBE: Time issues
 Seek Examples

ii. RECRUITING

PROBE: Pharmacy layout (private areas)
 Seek Examples if appropriate

b. What professional factors with engaging/recruiting

i. ENGAGING

PROBE: What strategies did you use?
 a. What worked?
 b. What didn't work?
 PROBE: Barriers
 PROBE: Facilitators
 Seek Examples

ii. RECRUITING

PROBE: Tell us about why patients accepted / refused ECOMPACT?
 PROBE: Barriers - Were customers offended?
 PROBE: Facilitators
 Seek Examples

3. How to improve ECOMPACT

PROBE: How can we increase the number of **people accepting** the kit?

a. Pharmacist view

- i. Training (what do you want?)
- ii. Incentive (payment for kit, how much?)

b. Patient view

- i. Awareness
- ii. Facilities to have test done in pharmacy

- PROBE: How can we increase the number of **people returning** the kit?
 - Patient understanding
 - Enough information provided
 - Method of testing (Low Vaginal Swab, Urine test)

4. Future Direction

a. Would you like to provide this service in the future?

PROBE: the service as it or modified form

PROBE: To all customers, not just EC users?

PROBE: Would re-numeration for the service make it more appealing in the long term?

b. What challenges do you anticipate would be encountered in adopting this responsibility?

5. Is there anything else you would like to add to the discussion that might help to improve screening program implementation into pharmacies or any other comment that you would like to make that we haven't addressed?

Summary

Facilitator to briefly summarise key ideas raised

- What improvements can be made?

THANK YOU FOR YOUR PARTICIPATION

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Appendix 18: Consumer Focus Group Information Sheet and Consent Form



THE UNIVERSITY OF
WESTERN AUSTRALIA

Investigators: Dr Rhonda Clifford and Sajni Gudka of the Pharmacy Programme, the University of Western Australia, Dr Lewis Marshall from the Department of Infectious Disease, Fremantle Hospital and Alison Creagh, Medical Educator from Family Planning Western Australia (FPWA).

EMERGENCY CONTRACEPTION MEDIATED PHARMACY ACCESS OF CHLAMYDIA TESTING (ECOMPACT) – SOCUS GROUPS

PARTICIPANT INFORMATION SHEET

TO BE USED IN CONJUNCTION WITH THE CONSENT FORM

1. Invitation

You are invited to take part in this research project because of your involvement with ECOMPACT. The participant information sheet contains detailed information about the research project. It is important that you understand its purpose, what you can gain from it and what will be expected of you. Once you understand what the project is about, and if you agree to participate, please sign the consent form. You will be given a copy of the information sheet and consent form to keep as a record.

2. What is the purpose of this study?

Last year, you participated in the ECOMPACT study. Your feedback is very important to us, and therefore we want to hear about experiences with this study. The focus group discussions will be tape-recorded, transcribed, coded and analysed for key themes in line with qualitative techniques.

3. Why have I been chosen?

You are invited to participate because you were involved in the ECOMPACT study.

4. Do I have to take part?

Your participation in this project is entirely voluntary and you may withdraw at any time, for whatever reason.

5. What happens when the research is completed?

Once the study is completed and the results are known, the researchers have to write a report to the Pharmacy Guild of Australia (part of the funding criteria). If you would like to receive this information when the project is completed, please contact the researcher and a summary of the key results will be posted to you.

6. Will me taking part in this study be kept confidential?

All data collected will be kept confidential and subsequently destroyed after 7 years. All reports or articles will be de-identified and your identity will be safeguarded at all times. Only those directly involved in the project will have access to your personal details.

7. Ethics approval?

The University of Western Australia Human Research Ethics Committee has granted ethics approval for this study.

8. Who do I contact for further information?

If you require further information or if you have problems concerning this study, you can contact Sajni Gudka (6488 7516) at the Pharmacy Program at the University of Western Australia.



THE UNIVERSITY OF
WESTERN AUSTRALIA

Investigators: Dr Rhonda Clifford and Sajni Gudka of the Pharmacy Programme, the University of Western Australia, Dr Lewis Marshall from the Department of Infectious Disease, Fremantle Hospital and Alison Creagh, Medical Educator from Family Planning Western Australia (FPWA).

EMERGENCY CONTRACEPTION MEDIATED PHARMACY ACCESS OF CHLAMYDIA TESTING (ECOMPACT) – SOCUS GROUPS

CONSENT FORM

I have **read the information sheet** provided and any questions I have asked have been answered to my satisfaction.

I am **aware of the purpose** of this project and what my involvement entails.

I freely **agree to participate** in this project according to the conditions in the information sheet.

I have been informed of my rights to question any part of the procedure or **withdraw** from the project at any time without reason and without prejudice to my future care.

I agree for the **focus groups to be tape recorded**.

I have been **advised as to what data is being collected**, the purpose of collecting this data, and what will be done with it upon completion of the study.

I understand that any information collected for the purpose of this study will remain **strictly confidential** and will not be released by the investigators unless required to by law.

I agree that the information obtained from this study may be used in future research or published, provided my name is not used.

Consent to participate Yes No

Participant's Name (printed) _____

Signature _____ Date _____

Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood the explanation.

Researcher's Name (printed) _____

Signature _____ Date _____

Appendix 19: Pharmacist Focus Group Information Sheet and Consent Form



THE UNIVERSITY OF
WESTERN AUSTRALIA

Investigators: Dr Rhonda Clifford and Sajni Gudka of the Pharmacy Programme, the University of Western Australia, Dr Lewis Marshall from the Department of Infectious Disease, Fremantle Hospital and Alison Creagh, Medical Educator from Family Planning Western Australia (FPWA).

EMERGENCY CONTRACEPTION MEDIATED PHARMACY ACCESS OF CHLAMYDIA TESTING (ECOMPACT) – SOCUS GROUPS

PARTICIPANT INFORMATION SHEET

TO BE USED IN CONJUNCTION WITH THE CONSENT FORM

1. Invitation

You are invited to take part in this research project because of your involvement with ECOMPACT. The participant information sheet contains detailed information about the research project. It is important that you understand its purpose, what you can gain from it and what will be expected of you. Once you understand what the project is about, and if you agree to participate, please sign the consent form. You will be given a copy of the information sheet and consent form to keep as a record.

2. What is the purpose of this study?

Last year, you participated in the ECOMPACT study. Your feedback is very important to us, and therefore we want to hear about experiences with this study. The focus group discussions will be tape-recorded, transcribed, coded and analysed for key themes in line with qualitative techniques.

3. Why have I been chosen?

You are invited to participate because you were involved in the ECOMPACT study.

4. Do I have to take part?

Your participation in this project is entirely voluntary and you may withdraw at any time, for whatever reason.

5. What happens when the research is completed?

Once the study is completed and the results are known, the researchers have to write a report to the Pharmacy Guild of Australia (part of the funding criteria). If you would like to receive this information when the project is completed, please contact the researcher and a summary of the key results will be posted to you.

6. Will me taking part in this study be kept confidential?

All data collected will be kept confidential and subsequently destroyed after 7 years. All reports or articles will be de-identified and your identity will be safeguarded at all times. Only those directly involved in the project will have access to your personal details.

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THE UNIVERSITY OF
WESTERN AUSTRALIA

Investigators: Dr Rhonda Clifford and Sajni Gudka of the Pharmacy Programme, the University of Western Australia, Dr Lewis Marshall from the Department of Infectious Disease, Fremantle Hospital and Alison Creagh, Medical Educator from Family Planning Western Australia (FPWA).

EMERGENCY CONTRACEPTION MEDIATED PHARMACY ACCESS OF CHLAMYDIA TESTING (ECOMPACT) – SOCUS GROUPS

CONSENT FORM

I have **read the information sheet** provided and any questions I have asked have been answered to my satisfaction.

I am **aware of the purpose** of this project and what my involvement entails.

I freely **agree to participate** in this project according to the conditions in the information sheet.

I have been informed of my rights to question any part of the procedure or **withdraw** from the project at any time without reason and without prejudice to my future care.

I agree for the **focus groups to be tape recorded**.

I have been **advised as to what data is being collected**, the purpose of collecting this data, and what will be done with it upon completion of the study.

I understand that any information collected for the purpose of this study will remain **strictly confidential** and will not be released by the investigators unless required to by law.

I agree that the information obtained from this study may be used in future research or published, provided my name is not used.

Consent to participate Yes No

Participant's Name (printed) _____

Signature _____ Date _____

Declaration by researcher: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood the explanation.

Researcher's Name (printed) _____

Signature _____ Date _____

Appendix 20: Patient Demographic Survey

ECOMPACT Patient Demographic Survey

Age: _____

Post code: _____

What is your highest level of education?

- ☐ Year 10
- ☐ Year 12
- ☐ TAFE
- ☐ Bachelor
- ☐ Post-graduate

What is your current occupation? (Tick one or more box)

- ☐ Student
- ☐ Working part time
- ☐ Working full time
- ☐ A parent or carer
- ☐ Unemployed

Chlamydia is the most common notifiable STI in Australia. It has no symptoms, so you won't know if you or your partner(s) have it. Chlamydia is easily tested for and easy to treat – you don't need to be examined. You just need to give a urine sample or vaginal swab.

Would you accept a Chlamydia screening kit from a pharmacy if a national screening model is introduced?

- ☐ Yes
- ☐ No

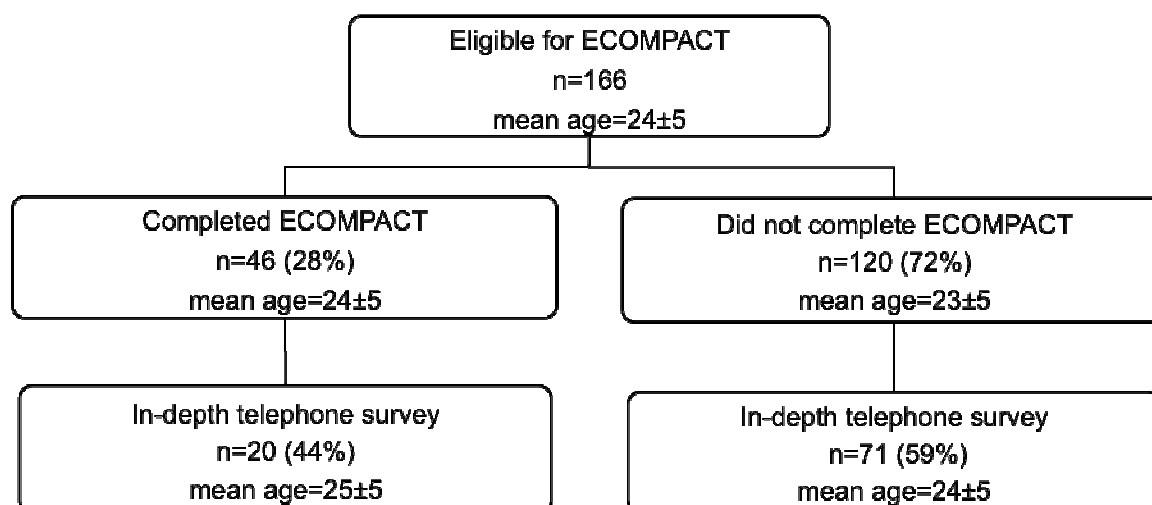
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Appendix 21: Demographics of Participating Pharmacies

Pharmacy ID	Attended the ECOMPACT training session			Type of consultation area
	Pharmacists	Pharmacy Students	Pharmacy Assistants	
01	1			Screened area
02	2	1		Consultation room
03	4			Consultation room
04	5	1		Consultation room
05	1			Consultation room
06	1			Consultation room
07	1	2		Screened area
08	1	1	1	Consultation room
09	1			Screened area
10	1			Screened area
11	2	1		Consultation room
12	2			Consultation room
13	2			Screened area
14	1		1	Screened area
15	2	1		Screened area
16	2			Consultation room
17	4			Consultation room
18	1			Counter
19	1			Counter
20	1	2		Screened area
TOTAL	36	9	2	

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Appendix 22a: Number of Telephone Surveys



Appendix 22b: Demographics of Consumers Interviewed

	Completed ECOMPACT n=20 (%)	Did Not Complete ECOMPACT n=71(%)	Total CATI survey results n=91 (%)
Mean age ± SD	24±5.	23±5	24±5
Occupation status			
Student	5 (25%)	17 (24%)	22 (24%)
Working full-time	12 (60%)	41 (58%)	53 (58%)
Working part-time	2 (10%)	6 (9%)	8 (9%)
Parent / Carer	1 (5%)	4 (6%)	5 (6%)
Looking for work	0 (0%)	3 (4%)	3 (3%)
Qualifications			
No formal qualification	1 (5%)	2 (3%)	3 (3%)
Year 12 / Equivalent	3 (15%)	23 (32%)	26 (29%)
Certificate / Diploma	10 (50%)	22 (31%)	32 (35%)
University degree	5 (25%)	21 (30%)	26 (29%)
Post graduate	1 (5%)	3 (4%)	4 (4%)
STI test in last 12 months			
Yes	10 (50%)	34 (48%)	44 (48%)
No	10 (50%)	37 (52%)	47 (52%)
Usual method of contraception			
Condoms	11 (55%)	41 (58%)	52 (57%)
Contraceptive pill	10 (50%)	36 (50%)	46 (51%)
Implant	1 (5%)	2 (3%)	3 (3%)
Other	1 (5%)	3 (4%)	4 (4%)
None	1 (5%)	6 (9%)	7 (8%)

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Appendix 23a: Demographics of Consumer at the ECOMPACT Focus Group

Age	Highest level of education	Current Occupation	Completed Test
26	Bachelor	Working full time	Yes
24	Bachelor	Working part time	No
19	TAFE	Working full time	Yes
21	Year 12	Student	No
27	Year 12	Working full time	No

Appendix 23b: Demographics of Pharmacists at the ECOMPACT Focus Group

Gender	Age	Occupation	Years qualified	Consultation area
Female	37	Pharmacy Owner/Partner	14	Consultation Room
Female	28	Pharmacy Manager	7	Screened Area
Male	27	Employee Pharmacist	1	Consultation Room
Male	29	Pharmacy Owner/Partner	3	Consultation Room
Male	25	Pharmacy Manager	3	Consultation Room
Male	35	Pharmacy Owner/Partner	16	Private Area

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10 LOGOS



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11 REFERENCES

1. Department of Health and Ageing. Number of notifications of Chlamydia infection, received from State and Territory health authorities in the period of 1991 to 2006 and year-to-date notifications for 2007; 2007.
2. Stamm W. Toward control of sexually transmitted infections. *Annals of Internal Medicine*. 1993;199:3.
3. Stamm W. Diagnostic tests should be used for sexually transmitted chlamydia (editorial). *Western Journal of Medicine*. 1990;153:2.
4. Paavonen J, Vesterinen E. Chlamydia trachomatis in cervicitis and urethritis in women. *Scandinavian Journal of Infectious Diseases*. 1982;32(suppl):2.
5. Miller K. Diagnosis and treatment of *Chlamydia trachomatis* infection. *Am Fam Physician*. 2006;73:1411-1416.
6. Watson E, Templeton A, Russell I, et al. The accuracy and efficacy of screening tests for *Chlamydia trachomatis*: a systematic review. *J Clin Microbiol*. 2002;51:1021-1031.
7. Hillis SD, Nakashima A, Amsterdam L, et al. The impact of a comprehensive chlamydia prevention program in Wisconsin. *Fam Plann Perspect*. May-Jun 1995;27(3):108-111.
8. Herrmann B, Egger M. Genital Chlamydia trachomatis infections in Uppsala County, Sweden, 1985–1993: declining rates for how much longer? *Sex Transm Dis*. 1995;22:253-260.
9. Department of Health. Looking back, moving forward: Annual report of the National Chlamydia Screening Programme in England, 2004/05. London; 2005.
10. TNS Healthcare. *Pharmacy Chlamydia Screening Pathfinder Evaluation (PCSPf) Final*. London: Department of Health; 2007.
11. Baraitser P, Pearce V, Holmes J, Horne N, Boyton P. Chlamydia testing in community pharmacies: evaluation of a feasibility pilot in south east London. *Qual Saf Health Care*. 2007;16:303-307.
12. RPSGB. *Practice guidance: Azithromycin*. London: Royal Pharmaceutical Society of Great Britain; 2008.
13. *National Sexually Transmissible Infections Strategy*. Canberra: Commonwealth of Australia; 2005.
14. Hocking J. Chlamydia screening - Australia should strive to achieve what others have not. *Medical journal of Australia*. 2008;188(2):106-108.
15. Kong F, Guy R, Boyle DJ, et al. Chlamydia testing rates in general practices across Australia: The Australian Collaboration for Chlamydia Enhanced Sentinel Surveillance (ACCESS). *Australasian Sexual Health Conference*. Perth Convention Centre: Australasian Chapter of Sexual Health Medicine; 2008:74.
16. Taylor K, Clifford R, Marshall L. Acceptance of a chlamydia screening program in community pharmacies. *Journal of Pharmacy Practice and Research*. 2007;37(4):287-288.
17. Gudka S, Scook P, Clifford R. Who Accesses Pharmacy-Based Emergency Hormonal Contraception. *Federation International Pharmacy*. Istanbul; 2009.
18. Gudka S, Yow X, Clifford R. A Review of International of Pharmacy Based Chlamydia Screening Models. *Australasian Pharmaceutical Science Association*. Canberra; 2008.
19. Pojski C, Atkin L, Williams H. *Review of Sexual Health Clinical Services in Victoria*: Family Planning Victoria; 2006.
20. NHMRC. National Statement on Ethical Conduct in Human Research: Australian Government; 2007.
21. BreastScreen Australia Evaluation Progress and Status Report. *Department of Health and Ageing*. Available at: <http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/breastscreen-about>. Accessed 6th November 2009.
22. National Bowel Cancer Screening Program. *Department of Health and Ageing*. Available at: <http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/bowel-about>. Accessed 7th November 2009.

23. Brabin L, Thomas G, M H, O'Brien K, Roberts S. Delivery of chlamydia screening to young women requesting emergency hormonal contraception at pharmacies in Manchester, UK: a prospective study. *BMC Women's Health*. 2009;9:7.
24. Kong F, Guy R, Boyle DJ, et al. Chlamydia testing rates in general practices across Australia: The Australian Collaboration for Chlamydia Enhanced Sentinel Surveillance (ACCESS). *Australasian Sexual Health Conference*. Perth Convention Centre: Australasian Chapter of Sexual Health Medicine; 2008:74.
25. Williams H, Tabrizi SN, Lee W, Kovacs GT, Garland S. Adolescence and other risk factors for Chlamydia trachomatis genitourinary infection in women in Melbourne, Australia. *Sex Transm Infect*. 2003;79:31-34.
26. Waller S, Salkeld G, Donovan B. The cost effectiveness of screening for genital Chlamydia trachomatis infection in Australia. *Sex Health*. 2006;3(4):225-234.
27. Gen-Probe, Gen-ProbeGen-Probes. GEN-PROBE APTIMA COMBO 2 Assay.
28. Pavlin NL, Gunn JM, Parker R, Fairley CK, Hocking J. Implementing chlamydia screening: what do women think? A systematic review of the literature. *BMC Public Health*. 2006;6:221.
29. Armour C, Brilliant M, Krass I. Pharmacists' views on involvement in pharmacy practice research: Strategies for facilitating participation. *Pharmacy Practice*. 2007;5(2):8.