Background

Chlamydia is a significant public health problem in Australia with about 4% of under 30 year old men and women infected. While opportunistic chlamydia screening is conducted in several countries, there remains considerable debate about the effectiveness of organized population-based chlamydia screening programs for reducing chlamydia transmission and its associated morbidity.

The Australian Chlamydia Control Effectiveness Pilot (ACCEPt) is a chlamydia testing pilot program that aims to assess the feasibility, acceptability, efficacy, and cost-effectiveness of annual chlamydia testing among 16-29 year olds in the general practice setting. This pilot will assess whether chlamydia testing can lead to a reduction in the burden of chlamydia in the population and will determine whether it is cost-effective for the Government to roll out a national chlamydia testing program. This project has been funded by the Department of Health and Ageing.

We seek your consent to participate in this project

You and your clinic are eligible to participate in this study if your clinic sees at least 100 patients aged 16 to 29 years each year.

This Information Form contains detailed information about the research project. This project is a randomized controlled trial which will run for up to 36 months. This means that some practices will be randomised to an intervention arm and some to a control arm of the project. It is not possible to select the arm to which your practice will be allocated.

Control arm:
If your practice is allocated to the control group you will be given an education package about the diagnosis and management of PID and you will be asked to continue your usual chlamydia testing practice. At the conclusion of the trial, GPs and practice nurses in control clinics will be provided with the chlamydia education package.

Intervention arm:
If your practice is allocated to the intervention arm, you will be asked to offer a chlamydia test to eligible patients aged 16-29 when they present for a consultation for any reason. In order to assist you in this process, your clinic will receive a multifaceted support package designed to assist you in conducting chlamydia testing of eligible patients. At the commencement of the trial, the needs of your practice will be assessed in order to identify how the intervention package can be best tailored to suit the needs and resources of your clinic. The intervention package may include:

- a computer alert within the practice medical records software prompting you to test patients aged 16 to 29 years for chlamydia
- a patient reminder system that will enable your clinic to recall tested patients after 12 months
- chlamydia and pelvic inflammatory disease (PID) education packages for GPs and practice nurses including health education and health promotion materials
- incentive payments for chlamydia testing, and;
- information and support with regular feedback on the testing performance of your practice.

The incentive payments will be paid to you and will be based on:

- $5 per 16 to 29 year old patient screened up to 20% coverage
- $7 per 16 to 29 year old patient screened for between 20% and 40% coverage
- $8 per 16 to 29 year old patient screened over 40% coverage

Your clinic will be provided with technical support to install the computer alerts and to develop the patient reminder system.

What participation will involve for you

Regardless of whether you are in the intervention group or the control group, your clinic will be reimbursed $1200 for participation in the project. You will be asked to:

- Complete a questionnaire to determine your knowledge, awareness and practices in relation to the diagnosis and management of chlamydia prior to the commencement of the trial, at 18 months, and again at 36 months.
- Give your consent to provide anonymous data throughout the trial using a number of different methods, depending on your medical records software. These methods include extracting data from medical records software using a data extraction tool, obtaining data directly from Medicare and retrieving data from pathology providers:
  - The data extraction tool, GRHANITE™, is able to extract consultation data, requested laboratory tests, and the results of these tests in an encrypted form and permit record linkage without disclosing or sharing patient identifiers with any party (including central database administrators or researchers). GRHANITE™ works with most medical records software, but not all.
  - Obtaining data from Medicare and pathology providers. If GRHANITE™ doesn't work, we will seek your consent to obtain your consultation and chlamydia testing data from Medicare and from your pathology provider. We will provide you with a letter for you to sign which will then be sent to Medicare Australia. The ACCEPt study will also request your pathology providers to extract relevant chlamydia test information from their laboratory information system.
- In-depth interview – you may be asked to complete an interview at some stage during the trial. The interview will explore how you feel about chlamydia testing, the trial intervention and any barriers or facilitators to chlamydia testing in your practice. You will be provided with further information about the interview at the time and given the opportunity to agree to the interview or decline. If you consent to do an interview, you will be reimbursed $100 for your time.

Ethics

The ACCEPt trial has been approved by the Royal Australian College of General Practitioners (RACGP) National Research and Evaluation Ethics Committee.

If you have any complaints or concerns about the conduct of this study, please contact the Executive Officer, Royal Australian College of General Practitioners (RACGP) National Research and Evaluation Ethics Committee:
Name:
Contact number:

This project will be carried out according to the National Statement on Ethical Conduct in Research Involving Humans produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Feedback and project results

If your practice is part of the intervention arm of the project, you and your clinic will receive feedback on testing rates on a 3-monthly basis. A summary of the study results will be made available to you at the completion of the project regardless of whether your clinic was part of the intervention or control arm of the trial. It is also likely that the summary results of this project will be published in academic journals and presented at academic conferences.

Privacy, confidentiality and disclosure of information

Your participation in this project is completely voluntary and confidential. You are free to withdraw at any stage by notifying the researchers. A withdrawal of informed consent form will need to be sent to the ACCEPt researchers. Unless otherwise requested, data collected from the clinic up until the time of withdrawal will be included in our final data analysis.
The confidentiality of the information collected as part of this project will be safeguarded subject to any legal limitations. A central database will be established and managed at the Key Centre for Women's Health in Society, University of Melbourne. The confidentiality of records that could identify patients will be protected. All electronic files containing trial data will be password protected with only the research team and statistician having access to these data. Consent forms and clinic data will be stored separately from questionnaire and other study data. In accordance with university regulations, the data will be retained for a period of 15 years. At the end of this time the data will be destroyed.

Further information

If you require further information or if you have any queries relating to this project, please contact the Principal Investigator Dr. Jane Hocking on (03) 8344 0762, email: j.hocking@unimelb.edu.au; or Research Fellow Dr Simone Poznanski on (03) 8344 0792, email: sypozn@unimelb.edu.au.

Email : info@accept.org.au
Website : accept.org.au

How to participate

If you would like to participate, please indicate that you have read and understood this information by signing the accompanying consent form and returning it to the ACCEPt research team.

Investigators: Dr Jane Hocking*, Professor Christopher Fairley, Professor Jane Gunn, Professor Basil Donovan, Professor John Kaldor, Dr Nicola Low, Associate Professor Matthew Law, Associate Professor Meredith Temple-Smith, Dr David Regan, Dr David Wilson, Mr James Ward, Associate Professor John Imrie, Professor Rob Carter, Professor Marian Pitts, Dr Anne Mitchell, Dr Marion Saville, Associate Professor Dorota Gertig, Dr Lena Sanci. Dr Marie Pirotta, Associate Professor Sepehr Tabrizi, Associate Professor Marcus Chen, Associate Professor Margaret Hellard

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Thank you for taking the time to read this information statement.

The Australian Chlamydia Control Effectiveness Pilot

Information for General Practitioners

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