



Plain Language Statement

Melbourne School of Population and Global Health

Project: Management of Chlamydia Cases in Australia (MoCCA); implementation and feasibility study

Clinic and GP participation

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Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you agree to your general practice taking part in this research.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

The participation of your general practice is voluntary and your general practice is free to withdraw from this project at any time.

What is this research about?

This research is part of a National Health and Medical Research Council funded project entitled Management of Chlamydia Cases in Australia (MoCCA). Led by Professor Jane Hocking at the University of Melbourne, MoCCA is investigating strategies for strengthening management of chlamydia infections in general practice clinics in Australia. In this study, we will implement several interventions designed to strengthen management of genital chlamydia infections into clinics. We will seek to identify which interventions are feasible for use in general practice, and will examine the implementation and uptake of interventions in clinics, as well as their impact on chlamydia outcomes.

The study will include resources to support GPs in managing a patient with a chlamydia infection, including for:

- Notifying and treating the sexual partners of patients with a chlamydia infection,

- Organising for patients to be retested for reinfection around three months after chlamydia treatment
- Supporting GPs to discuss pelvic inflammatory disease with female patients diagnosed with chlamydia

What will I be asked to do?

If you agree for your general practice to participate all GPs (and relevant staff) in the clinic will be asked to use a package of interventions for up to 18 months.

For the study, GPs and relevant staff will be:

- Asked to nominate a 'practice champion' as the main contact point for communication and dissemination of information.
- Asked to meet with researchers (virtually or onsite) to discuss current chlamydia management practices, explain the interventions and how they can be incorporated into your clinic.
- Provided with recorded videos and other hard or digital materials with instructional information about the study.
- Asked to familiarise themselves with the MoCCA website and resources for best practice chlamydia care, to consider using the MoCCA interventions to support chlamydia management and to liaise with researchers about any issues encountered.
- Asked to provide feedback about use of the interventions through participation in short (approx. 5 minutes) anonymous polls/surveys embedded within regular (quarterly) email communications and/or through participation in brief (about 30 minutes) interviews with researchers.

The general practice will be asked to consent to:

- Providing electronic non-identifiable data during the 12-18-month intervention period and preceding 12-18 months that will be used by researchers to determine chlamydia testing patterns, chlamydia positivity rates and retesting practices and pelvic inflammatory disease diagnosis rates. These data will be extracted directly from the electronic medical record using the University of Melbourne's data extraction tool GRHANITE® that will be installed on a computer at your practice. An authorised practice representative will be asked to sign a legal agreement that includes the GRHANITE® software licence and outlines the terms under which your electronic medical record data are provided to the University.
- Researchers accessing electronic, non-identifiable laboratory data from VCS pathology for any postal chlamydia test kits requested for patients by your clinic.
- The practice name being included on study materials including the study website.

What are the possible benefits?

Your general practice's participation will help us to assess whether the interventions are an acceptable and feasible means of supporting chlamydia management in general practice. Improving chlamydia management will benefit patients and will benefit GPs and nurses by improving the efficiency of managing chlamydia infections.

GPs may also have opportunity to participate in education sessions or quality improvement activities that will provide continuing professional development (CPD) points.

What are the possible risks?

There are no anticipated risks of participating in this feasibility study.

Do I have to take part?

No. Participation is completely voluntary. If you do not wish your general practice to take part, you do not have to. You can withdraw at any time and if requested we are able to remove any information you have provided from our records.

Will I hear about the results of this project?

At the end of the 18-months, researchers will provide you with findings for your own and other participating general practices. There will also be publications arising from this project.

What will happen to information about my general practice?

Any information obtained about your general practice during this project will remain confidential and anonymous. We will protect this information and keep it private subject to any legal requirements. The paper-based information collection forms for your general practice will include your clinic's name but not any identifying details for any staff members. These forms will be stored in a locked filing cabinet at the Melbourne School of Population and Global Health, University of Melbourne. This is protected by security, with a monitored alarm. The data collected about your general practice will be transferred to electronic files that will identify your clinic by a code and the contact details of your general practice will be kept in a separate file. All electronic data about your general practice will be kept in password-protected files and kept on a password protected computer, accessible only to the named researchers. The University of Melbourne requires us to keep this data for 5 years after publication before destroying it.

All data collected using the GRHANITE® data extraction tool will be transmitted to the Patron data repository, which is a database of deidentified primary care data managed by the University of Melbourne. All data collected using GRHANITE® are de-identified and encrypted prior to transmission from the practice to Patron, thereby rendering it non-identifiable to researchers. No practitioner or patient personal details are contained in the Patron database. These data will be subsequently securely transferred to the MoCCA research team for storage on a restricted-access folder on a network drive that is internal to the University and operated by IT Services. Access to this folder will be limited to selected researchers on the MoCCA project. Your general practice will be identified by a code (and not clinic name) in the data analysis. All information that comes from this project will be presented in such a way that cannot identify your general practice. The results from this project will be included in a published research paper. If your general practice withdraws from the project any information collected about your general practice can be removed if you wish, just let the researcher know at the time.

If you indicate on the Consent Form that you agree to your clinic being contacted for further research, the general practice details will be kept in a password protected file on a password protected computer only accessible to the named researchers.

Who is funding this project?

This research project is part of a larger project on improving chlamydia management in general practice that is funded by the National Health and Medical Research Council. NSW Ministry of Health, Victorian Department of Health and Human Services, Queensland Health, North West Melbourne Primary Health Network, Central and Eastern Sydney Primary Health Network, and Victorian Cytology Service are partners on this project.

Where can I get further information?

If you would like more information about the project, please contact the researchers; Professor Jane Hocking

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Who can I contact if I have any concerns about the project?

This research project has been approved by the Human Research Ethics Committee of The University of Melbourne (Ethics ID: 22665). If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: HumanEthics-complaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.