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MANAGEMENT OF CHLAMYDIA CASES IN AUSTRALIA (MOCCA): PROTOCOL FOR A NON-RANDOMISED IMPLEMENTATION AND FEASIBILITY TRIAL

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ABSTRACT

Introduction: The sexually transmissible infection chlamydia can cause significant complications, particularly among people with female reproductive organs. Optimal management includes timely and appropriate treatment, notifying and treating sexual partners, timely retesting for reinfection, and detecting complications including pelvic inflammatory disease (PID). In Australia, mainstream primary care (general practice) is where most chlamydia infections are diagnosed, making it a key setting for optimising chlamydia management. High reinfection and low retesting rates suggest partner notification and retesting are not uniformly provided. The Management of Chlamydia Cases in Australia (MoCCA) study seeks to address gaps in chlamydia management in Australian general practice through implementing interventions shown to improve chlamydia management in specialist services. MoCCA will focus on improving retesting, partner management (including patient-delivered partner therapy), and PID diagnosis.

Methods and analysis: MoCCA is a non-randomised implementation and feasibility trial that aims to determine how best to implement interventions to support general practice in delivering best practice chlamydia management. Our method is guided by the Consolidated Framework for Implementation Research and Normalisation Process Theory. MoCCA interventions include a website, flowcharts, factsheets, mailed specimen kits, and autofills to streamline chlamydia consultation documentation. We will work with up to 20 general practices across three Australian states (Victoria, New South Wales, Queensland) to implement the interventions over 12-18 months. Mixed methods involving qualitative and quantitative data collection and analyses (observation, interviews, surveys) from staff and patients will be undertaken to explore our interventions' implementation, acceptability and uptake. De-identified general practice and laboratory data will be used to measure pre-post chlamydia testing, treatment, retesting, reinfection, and PID rates, and to estimate MoCCA intervention costs. Our findings will guide scale up plans for Australian general practice.

Ethics and dissemination: Approval from University of Melbourne Human Research Ethics Committee (Ethics-ID 22665). Dissemination via conference presentations, peer-reviewed publications, and study reports.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The approach is guided by the the Consolidated Framework for Implementation Research and Normalisation Process Theory that together will support understanding of the ways that the implementation processes and the general practice context shape each other.
- A mixed methods approach will facilitate qualitative and quantitative assessment of how interventions for best practice chlamydia management are implemented and used in general practice.
- While this is an implementation and feasibility trial, our sample of 20 clinics should be of sufficient size to detect an increase in chlamydia re-testing from 25% in the 12 months prior to the trial to 40% in the 12 months following implementation.

INTRODUCTION

Chlamydia caused by the pathogen *Chlamydia trachomatis,* is the most common bacterial sexually transmissible infection (STI) globally[1] and the most commonly notified STI in Australia.[2] Usually asymptomatic, chlamydia can cause significant complications if left untreated, particularly among people with female reproductive organs[3], including pelvic inflammatory disease (PID), ectopic pregnancy and infertility. Repeat chlamydia infection plays an important role in progression to complications; increasing the risk of PID by 35%, and up to 4-fold for those aged under 20 years,[4] while severe PID poses a higher risk of tubal infertility than mild-moderate PID.[3, 5]

Chlamydia screening of asymptomatic individuals with the aim of reducing transmission and the harms of untreated infection has been a longstanding and central component of STI control in many countries.[6-8] However, in the absence of definitive evidence showing that widespread testing can reduce chlamydia prevalence or complications in the population,[6, 9, 10] the emphasis of chlamydia control is shifting to optimising management of diagnosed infections to reduce the risk of repeat infection.[11] In the United Kingdom, the National Chlamydia Screening Program now focuses on reducing the harms arising from untreated chlamydia infection that largely impact people with female reproductive organs.[12] In Australia, the National STI Strategy has reduced its focus on testing uptake and places an increasing emphasis on strengthening management of diagnosed infections, in particular toward reducing repeat infections and earliest detection of PID.[8]

General practice is Australia's mainstream primary care setting and where most chlamydia infections are diagnosed and managed;[13, 14] making it a key setting for optimising chlamydia management. However, unlike specialist sexual health services, STI testing and management must compete with other health needs. While most diagnosed infections in general practice are followed up for antibiotic treatment,[15] high reinfection rates of up to 22%[16] suggest missed opportunities for notifying and treating sexual partners. Australian STI management guidelines recommend retesting for reinfection at around 3 months after treatment.[17] Retesting rates in Australian general practice are low; 24.6% within 4 months of treatment in one study.[18] Other Australian data show low PID diagnosis rates in general practice suggesting PID is under-diagnosed in this setting.[9] Furthermore, Australian general practitioners (GPs) have expressed hesitancy in conducting pelvic examinations to support a PID diagnosis, potentially reducing their capacity to diagnose PID.[19] Interventions for strengthening chlamydia management (e.g. mailed specimen kits, links to partner notification websites in chlamydia test results) have improved retesting and uptake of partner notification discussions in specialist sexual health and family planning clinics.[20, 21] Patient-delivered partner therapy (PDPT), a method of expediting partner treatment, has been shown to be effective at reducing reinfection and acceptable to patients and partners.[22, 23] However, to date, these interventions have not been implemented in Australian general practice.

The Management of Chlamydia Cases in Australia (MoCCA) study seeks to address gaps in chlamydia management through implementing interventions that have been found to be

effective at improving chlamydia management in specialist sexual health services. In particular, MoCCA focuses on interventions found to improve testing for repeat infection within recommended timeframes, improve partner management, including use of PDPT where appropriate (eg. PDPT is not recommended for patients at high risk of HIV infection such as men who have sex with men), and increasing clinician confidence in diagnosing PID. In this trial, we aim to determine how best to implement the MoCCA interventions to improve chlamydia case management in general practice. We hypothesise that implementation of the MoCCA interventions will be feasible and acceptable. We will also test the exploratory hypotheses that MoCCA will increase chlamydia re-testing among those diagnosed with chlamydia and increase PID detection. The results of this trial will be used to inform subsequent mathematical and economic modelling of the impact of the MoCCA interventions on chlamydia to guide scaling up the interventions for implementation across Australian general practice.

METHODS

Study design

We will conduct a non-randomised mixed methods implementation and feasibility trial where our primary aim is to implement MoCCA interventions in general practice and measure their uptake by assessing acceptability, adoption, appropriateness, feasibility, fidelity, costs, penetration and sustainability as outlined in Proctors taxonomy of implementation outcomes.[24] As secondary aims, we will explore the impact of the interventions on chlamydia re-testing, re-infection and PID diagnosis in general practice. Our approach is guided by the Consolidated Framework for Implementation Research (CFIR), to assess factors at multiple levels affecting implementation across five domains (intervention characteristics, inner setting, outer setting, characteristics of individuals, process). We will also be guided by Normalisation Process Theory (NPT), to understand how our interventions can be embedded in general practice.[25, 26]

We will conduct the trial in up to 20 general practices across three Australian States (Victoria, New South Wales (NSW) and Queensland). The target population for chlamydia case management will be patients aged 16-44 years attending general practice. Our package of interventions includes a central MoCCA website that provides resources and guidelines, and strategies to improve partner management, re-testing three months following chlamydia treatment, and tools to facilitate the earlier detection of PID (see Table 1 and below for further detail). We will follow the CONSORT checklist for pilot and feasibility trials.[27]

There will be three main study phases; establishment and implementation, operation, and evaluation.

Establishment and implementation phase

Guided by NPT,[25, 26, 28] we will work with each practice individually for 3-6 months to identify which intervention components can be implemented and how best to implement them, focussing on NPT components of coherence, active participation, collective action and reflexive monitoring. We will draw on our experience in applying NPT to implementation of complex chlamydia focussed interventions.[26] Each practice will be asked to nominate a practice champion

who is interested in the study and agrees to be the main point of contact for communication and dissemination of information about the study within the practice. Appointing a practice champion has been effective in supporting implementation of a range of interventions and quality improvements in primary care.[29]

Depending on each practices' preferred communication mode, the research team will meet with staff (either collectively or individually) via zoom or face to face to initiate the study, explain the objectives, interventions, supporting resources, data collection methods, and staff involvement. This implementation meeting will include a tour of the MoCCA website to familiarise staff with the intervention components. Recorded videos and other hard or digital materials with instructional information about the study will also be provided.

While all intervention components will be available to each practice, it will not be feasible for all to be adopted. This will depend to some extent on each practice's interest, priorities and geographical location because there is some variation in STI management program regulations and available resources across Australian states. For example, health authority guidance for PDPT is available for the states of Victoria and NSW but not Queensland so resources to support PDPT will be unavailable for practices in this state.[30, 31] A researcher will work with the practice champion and other relevant staff in each clinic to identify which intervention components will be implemented and establish their implementation. This will be via onsite or virtual meetings, following which clinic staff will be encouraged to liaise with researchers to discuss and troubleshoot any issues as they arise.

Regular communication mechanisms with participating general practices will be established to support ongoing study engagement. The main method will be regular emailed communications (quarterly) that highlight new evidence and resources, provide interim findings and communicate study progress. Anonymous polls will be embedded in these communications as a tool to gain feedback about aspects of the study. For example, we may ask about recent engagement with the study website, which resources have been used and their usefulness. Short vignettes of a patient scenario will also be provided in email communications, and embedded polls will ask brief questions about the type of management GPs might provide. Other communication methods will include individual practice reports and study updates at clinic meetings. Commuincation records with each practice will be maintained.

Operation phase

Following intervention implementation, participating practices will be asked to continue to use the interventions to support management of patients with a chlamydia infection for up to 12 months. Research staff will regularly check in with participating practices to communicate study progress, provide support and troubleshoot any issues. A mix of qualitative and quantitative data collection will be used to measure the implementation outcomes (see table 2 and 3 and below for further detail).

Evaluation phase

Data from the operation phase will be evaluated to identify what worked and what did not, guided by the CFIR and NPT to understand how intervention implementation occurred and the context for implementation. Detail of our implementation outcomes is provided below. The impact of the interventions on chlamydia re-testing, re-infection and PID diagnosis will be assessed as secondary outcomes, acknowledging these estimates will be limited by the non-randomised trial design and sample size.

Participants

Study participants will include general practice staff (GPs, practice nurses, practice managers) and patients attending participating general practices with a chlamydia infection.

Up to 20 general practices will be recruited. Eligible practices must be located in the states of Victoria, NSW or Queensland, use Best Practice™ or Medical Director™ (used widely within Australian general practice) as their electronic medical record (EMR) software (the data extraction software GRHANITE™ (www.grhanite.com/) is validated to work with these EMRs), have at least 2000 active patients aged 16-44 years seen in the last 2 years (to ensure sufficient numbers of patients at risk of STIs and PID), and, diagnose a minimum of 20 chlamydia infections annually.

General practices will be recruited via advertisements in a range of general practice communication networks including those of our project partners (State governments, Primary Health Networks, Family Planning Organisations, Sexual Health Clinics and laboratories). In addition, practices will be approached directly via phone and email by our research team. If eligible, researchers will arrange a meeting (face to face or via Zoom depending on location and COVID-19 restrictions) with practices (including clinical staff and the practice manager) to explain the study further. Consent will be obtained from the general practice management for the clinics' participation in the trial and from a sample of staff (GP, practice nurse, or practice manager) from each clinic to participate in one or more interview about implementation and integration of the interventions.

Patients aged 16-44 years from participating general practices and who have had chlamydia or PID diagnosed and treated at the clinic during the study period will be eligible to participate in a brief anonymous online survey about their experiences of having the infection treated at the general practice. Eligible patients will be invited to participate via several strategies. Survey flyers will be displayed in the general practice waiting area, on the clinic website or directly passed to patients by clinicians at the conclusion of the consultation when chlamydia treatment is prescribed. This flyer will include a QR code that links to an online survey. A plain language statement will comprise the first page of the online survey, and participants will provide consent for participation within the survey prior to commencing the survey questions. Secondly, for practices which use SMS text messaging to communicate with patients, eligible patients will be sent an SMS message including a link to the online survey.

Patients completing the survey will receive a $20 gift voucher. Survey participants will also be asked if they are interested in participating in a semi-structured phone interview to further explore views on how the chlamydia infection was managed at the practice.

Interventions

We have developed a package of interventions that aim to strengthen chlamydia management in general practice. It comprises three main components: strategies to improve partner notification, strategies to increase re-testing following chlamydia treatment and strategies to prompt earlier detection of PID. An overview of the interventions by aspect of chlamydia management is provided in Table 1.

The main component is our study website (www.mocca.org.au/) that outlines best practice chlamydia management and links to key Australian STI management resources and guidelines, and, resources for supporting patient care. Our website was developed in consultation with clinical staff. Firstly, we administered a quantitative survey and conducted interviews with clinical staff to understand chlamydia management practices and inform the website design.[19, 32, 33] Next we conducted think-aloud interviews[34] with clinical staff to assess the usability and acceptability of the prototype website, made modifications to the website and piloted it for 3 months in 3 practices in NSW and QLD. Our pilot results informed further modifications to the website for evaluation in this trial (www.mocca.org.au/about-mocca/research-outputs). Other resources include flowcharts, patient factsheets (developed with health consumer input), mailed specimen kits, autofills for streamlining documentation of the chlamydia consultation, and published educational articles outlining best practice chlamydia management[35-37] including our PID article in which clinicians can take the associated quiz to earn continuing professional development points. A link to the website can be bookmarked within the EMR or search engine allowing easy access during a consultation.

Table 1: Description of the MoCCA interventions, by aspect of chlamydia management

	Intervention	Intervention description
Partner notification	Website	• MoCCA website (or other linked resources) provides information that can support partner notification discussions. • MoCCA website links to online partner notification tools.
	Autofill#	• Chlamydia autofill or shortcut inserted in the EMR that supports documentation of chlamydia management in the patient notes and prompts clinicians to record: ○ Treatment provided ○ If partners were notified ○ If PDPT was provided
	Patient factsheets	• Information about notifying partners is provided to chlamydia positive patients.
	PDPT flowchart	• PDPT flowchart provides an overview of patient eligibility for PDPT, and the process of offering PDPT to eligible and willing patients.
	PDPT prescription template	• A template that can be imported into the EMR and used to generate a PDPT prescription.

	Published article	• PDPT article [37] that provides an overview of the process of offering PDPT and addresses the challenges GPs may face in its provision. • Chlamydia management article[36] outlines best practice to reduce chlamydia associated reproductive complications in women, including partner management.
Retesting	Website	• MoCCA website (or other linked resources) used to support retesting discussion.
	Patient factsheets	• Information about why retesting for reinfection is important is provided to chlamydia positive patients.
	Retesting flowchart	• Provides the rationale for retesting and some options for organising retesting.
	Postal retest	• Patient sent a postal kit by the laboratory for retesting at 3 months.
	Pathology form	• Patient provided a pathology form for retesting in 3 months' time.
	Patient recalls and reminders	• Patient placed on recall system and recalled at 3 months to return for a retest appointment **OR** • Patient placed on reminder system and sent an SMS reminder to visit a pathology collection centre for a chlamydia test
	Published article	• Chlamydia management article[36] provides information about the importance of and options for organising retesting for reinfection.
PID diagnosis	Website	• MoCCA website (and linked resources) provide key PID diagnostic considerations.
	Patient factsheets	• PID factsheet provides a definition of PID, its diagnosis and treatment. • Chlamydia factsheet provides information about symptoms that may indicate complications.
	Published article	• How to Treat PID article[35] that focuses on the diagnosis and management of acute PID in primary care. Taking the associated quiz allows clinicians to earn continuing professional development points.

Autofill, a shortcut for clinical notes for a specific condition that has been pre-populated in the EMR

Patient and public involvement

Health providers and health consumers were involved in the development of this project in a number of ways including surveys, qualitative interviews, focus groups and development and refinement of patient factsheets and health care provider resources. Our findings will be disseminated through our partner organisations including those that provide clinical care to people with a chlamydia infection and also to participating general practices.

Outcomes and data collection

Our primary trial outcomes will relate to the implementation processes and success of implementation and include acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability.[24] To measure our outcomes we will collect qualitative and quantitative data at the general practice, staff and patient level. We will also capture information about costings and effectiveness of the interventions. An overview of our data collection methods, data sources, outcomes and timepoints is provided in table 2 and table 3. Our data collection methods will include:

1. *Practice survey* - to collect baseline information about the practice's structure, staffing, EMR and other management systems, patient demographics, and work processes.

2. *Field notes and logs* – that document researcher communication (via email, telephone, in person) and support provided for participating general practices in implementing the interventions (eg. frequency, nature of support, any modifications).
3. *Minutes* – of study meetings with clinics to provide data to describe implementation procedures, and, understanding of the interventions' acceptability, usefulness and barriers and enablers to its adoption.
4. *Polls and brief surveys* – embedded in quarterly email study communications that ask staff at participating clinics 1-3 questions about the management they might provide in a short chlamydia focussed vignette or their use and views on MoCCA interventions; such as 'have you used the chlamydia autofill to help document chlamydia care in the past 3 months?'.
5. *Interviews with a think aloud component* – in which general practice staff are asked about their views about the MoCCA interventions, their usefulness, how they are integrated into the workflow and why they are or are not being adopted into practice. We will conduct up to 40 interviews across the 20 clinics.
6. *Patient survey* – an online survey asking patients about their experience of having chlamydia or PID diagnosed and treated at the clinic.
7. *De-identified patient attendance and clinical data* – will be collected from participating practices' EMR using GRHANITE™ (www.grhanite.com/) data extraction software and used to measure chlamydia testing, treatment, retesting, reinfection and PID diagnosis rates.
8. *De-identified laboratory data* – for mailed specimen kits will be collected from the relevant laboratory and used to determine request rates for use of postal tests in retesting, return rates and reinfection rates among those retested via this method.
9. *Google analytics* – will be collected monthly to ascertain website usage and pages used.
10. *Costs* – for resources used in delivering the MoCCA interventions that will be collected alongside the study.

Table 2 Data collection method and timepoints

Participant	**Practice**				**Provider**		**Patient**	
Data collection method	**Electronic patient data (GRHANITE)**	**Laboratory data**	**Practice survey**	**Minutes and field notes**	**Poll**	**Interview**	**Survey**	**Interview**
Study phase **Establishment and implementation phase**	X		X	X	X			
Operation phase	X Collected at the end of 12 month operation phase	X Collected 6 monthly		X	X 3 monthly	X 3 and 12 months	X Collected through out the 12 month operation phase	X As per patient preference

Table 3: Outcome description and data sources

Outcome type	Outcome	Description	Data collection method

Implementation	Acceptability	• Acceptability of interventions to general practice staff including a description of barriers and facilitators, how they were implemented and fit with the workflow • Patient satisfaction with chlamydia care	• Observation and field notes • Meeting minutes • Interviews • Polls and surveys
	Adoption#	• Readiness to implement the intervention • Level of use of the interventions	• Interviews • Meeting minutes • Google analytics • Patient attendance and clinical data • Laboratory data
	Appropriateness	• Relevance of interventions to the general practice setting	• Interviews • Meeting minutes • Polls and surveys
	Feasibility	• Extent that the interventions are suitable for use within general practice	• Interviews • Meeting minutes
	Fidelity	Description of how the interventions: • Were implemented • Are being used	• Observation and field notes • Interviews • Meeting minutes
	Implementation costs	• Costs to implement the interventions	• Study protocols and budgets • Interviews with general practice staff
	Penetration	• Level of use of the interventions	• Interviews • Polls and surveys
	Sustainability	• Description of how the interventions are being used	• Interviews • Polls and surveys • Meeting minutes
Impact	Effectiveness	• Chlamydia testing patterns • Chlamydia re-testing rates • Chlamydia reinfection rates • Partner notification practices • PID diagnosis rates	• Patient attendance and clinical data • Laboratory data • Polls and surveys

Sample size

We will implement our intervention in up to 20 general practices, gathering data on our implementation outcomes. We will conduct interviews with up to 40 staff from the 20 general practices to assess our qualitative implementation outcomes. Assuming about 20 people per clinic will be diagnosed with chlamydia during the trial, an estimated 100 patients will complete the quantitative survey, assuming a 25% response rate.

Assuming an annual chlamydia testing rate of 15%, a chlamydia positivity of 7% and average of 2000 16-44 year olds attending each practice per year, a sample size of 20 general practices will generate about 400 chlamydia cases requiring management during the 12 operation phase.[9] This will allow us to estimate an annual chlamydia re-testing rate of 25%[18] to within a 95% confidence interval of +/- 4% (95% CI: 21% to 29%) for the 12 months pre-implementation and estimate a re-testing rate of 40% with a precision of +/- 5% (95% CI: 45% to 55%) for the 12 months after implementation, assuming re-testing increases. While this is an implementation and feasibility

trial, 20 clinics should provide sufficient sample size to detect an increase in chlamydia re-testing from 25% in the 12 months prior to the trial to 40% in the 12 months following implementation, assuming an intra-cluster correlation of 0.02 , an alpha of 0.05 and power of 80%.

Data analysis

We will use a mixed-methods approach, applying quantitative and qualitative methods to assess our study outcomes. NVivo software will be used to manage and facilitate analyses of qualitative data and STATA statistical software to manage and analyse quantitative data.

Our implementation outcomes will be assessed qualitatively using content analysis[38] of data collected in the interviews, free text survey responses and meeting minutes and quantitatively through descriptive analysis. Our qualitative analysis will be largely deductive, and guided by the CFIR to understand the determinants of implementation and NPT to explain how and why changes to support new practices did or did not occur. We will establish an initial coding framework across the five CFIR domains and four NPT components. Additional codes will be developed inductively as needed. Findings from the qualitative analysis will be considered alongside findings from the descriptive analyses of quantitative data including patient attendance and clinical data, google analytics, laboratory data and survey and poll responses. Together, these qualitative and quantitative analyses will allow us to describe:

- Implementation procedures for each best practice chlamydia management intervention
- Barriers and enablers to adoption of best practice chlamydia management interventions
- How interventions and resources to support best practice chlamydia management are integrated into the general practice workflow
- Factors and behaviours associated with sustained adoption of best practice chlamydia management interventions
- The experiences of patients who were treated for a chlamydia infection

We will assess our impact outcomes to inform the design of a future large scale trial through quantitative analyses of patient attendance, clinical and laboratory data. Retesting rates will be measured as the proportion of those diagnosed with chlamydia who are retested within 2-4 months (3 months $\pm$ 1 month). Other outcomes will include chlamydia reinfection rates (proportion of those who re-test chlamydia positive) and PID rates (proportion of women aged 15-44 years diagnosed with PID). We will assess our impact outcomes by comparing outcomes between the 12 month intervention (operation phase) and 12 month pre-intervention periods. Poisson regression models, with a binary indicator for pre- and post-implementation and adjustment for a priori defined potential confounders, and robust standard errors to account for clustering by clinic, will estimate the impact of the intervention immediately post implementation (presented as a Rate Ratio (95% Confidence Interval).

Additional costs to implement and maintain the intervention (compared to the usual care pathway) will be estimated using trial protocols and budgets. We will adopt a 'health care system' perspective to estimate total costs associated with implementation of the MoCCA interventions and calculate costs for MoCCA's three components (partner notification, re-testing,

PID detection) and further break this down into specific interventions (eg. mailed specimen kits). Costs will be grouped by expenditure category such as staffing or consumables and then into 'fixed' vs 'variable' costs, to tease out issues associated with throughput and capacity utilisation. Results will be presented in terms of intervention activities and used to inform subsequent mathematical and economic modelling (protocol to come) of the impact of MoCCA interventions on the population chlamydia burden to guide plans for scale up across Australain general practice.

Ethics and dissemination

Ethical approval has been obtained from the University of Melbourne Human Research Ethics Committee (Ethics ID 22665). For all survey, interview and study data in which participant details are known to researchers, the participants details will be coded using ID codes that will be stored separately from their responses in password protected participant tracking files. All digital data will be stored within a restricted-access folder on a network drive that is internal to the University of Melbourne that has access limited to selected project staff. All hard copy data will be stored in a locked filing cabinet at the University of Melbourne where it is protected with a monitored alarm. Study materials will be kept for 5 years after publication of the study results after which point, they will be destroyed. Findings will be disseminated through conference presentations, peer-reviewed publications, and study reports. All data collected and analysed will pertain to the MoCCA study only.

DISCUSSION

Amid a changing landscape of chlamydia control strategies around the world, the MoCCA study will focus on optimising clinical management of diagnosed chlamydia infections to reduce the risk of repeat infection and chlamydia associated harms. The key areas of emphasis are on implementing interventions in the general practice setting to strengthen retesting for reinfection, partner management, and PID diagnosis. MoCCA will be implemented in Australia's mainstream primary care setting, general practice, being where most chlamydia infections are diagnosed and where the greatest gaps in care are apparent. Importantly this study will determine how best to implement best practice chlamydia management. Guided by the CFIR and NPT our mixed methods design will capture comprehensive qualitative and quantitative data, allowing us to identify the key factors to implementation and use of these interventions in general practice.

As an implementation and feasibility trial, our trial is limited by its sample size and non-randomised design. However, several components of our intervention package including PDPT[39] and re-testing postal kits[20] have been found to be effective in randomised trials. What is now needed, is to determine how they can be best implemented in general practice. Our comprehensive qualitative and quantitative data collection and analyses will allow us to measure the extent of implementation and to understand how and why the interventions are or are not implemented. The main emphasis is on understanding how best to implement these interventions in general practice rather than demonstrating their effectiveness.

The MoCCA study represents a paradigm shift in chlamydia control approaches from a focus on screening to case management. Our study's focus on general practice will provide much needed evidence about how to integrate best practice chlamydia management in the setting where most chlamydia infections are diagnosed in Australia. Our results will have relevance to other similar primary care settings in other countries where chlamydia screening, diagnosis and management take place. Beyond this trial, our findings will feed into mathematical and economic modelling which will explore the cost and impact of MoCCA interventions on a population level and inform a scale-up plan for general practice with potential to improve management for many thousands of Australians diagnosed with chlamydia each year.

Authors' contributions JH, MTS, NC, JAS, JT, CF, RG, BD, DR, MYC, LS, CE, LR, DH, MS were involved in the conceptualisation of the MoCCA study. JG, JC, HB, MTS, and JH were involved in the protocol development, designed all data collection tools and were involved in drafting the manuscript. All authors provided approval of the final version for publication.

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MANAGEMENT OF CHLAMYDIA CASES IN AUSTRALIA (MOCCA): PROTOCOL FOR A NON-RANDOMISED IMPLEMENTATION AND FEASIBILITY TRIAL

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ABSTRACT

Introduction: The sexually transmissible infection chlamydia can cause significant complications, particularly among people with female reproductive organs. Optimal management includes timely and appropriate treatment, notifying and treating sexual partners, timely retesting for reinfection, and detecting complications including pelvic inflammatory disease (PID). In Australia, mainstream primary care (general practice) is where most chlamydia infections are diagnosed, making it a key setting for optimising chlamydia management. High reinfection and low retesting rates suggest partner notification and retesting are not uniformly provided. The Management of Chlamydia Cases in Australia (MoCCA) study seeks to address gaps in chlamydia management in Australian general practice through implementing interventions shown to improve chlamydia management in specialist services. MoCCA will focus on improving retesting, partner management (including patient-delivered partner therapy), and PID diagnosis.

Methods and analysis: MoCCA is a non-randomised implementation and feasibility trial aiming to determine how best to implement interventions to support general practice in delivering best practice chlamydia management. Our method is guided by the Consolidated Framework for Implementation Research and Normalisation Process Theory. MoCCA interventions include a website, flowcharts, factsheets, mailed specimen kits, and autofills to streamline chlamydia consultation documentation. We aim to recruit 20 general practices across three Australian states (Victoria, New South Wales, Queensland) through which we will implement the interventions over 12-18 months. Mixed methods involving qualitative and quantitative data collection and analyses (observation, interviews, surveys) from staff and patients will be undertaken to explore our interventions' implementation, acceptability and uptake. De-identified general practice and laboratory data will be used to measure pre-post chlamydia testing, treatment, retesting, reinfection, and PID rates, and to estimate MoCCA intervention costs. Our findings will guide scale up plans for Australian general practice.

Ethics and dissemination: Approval from University of Melbourne Human Research Ethics Committee (Ethics-ID 22665). Dissemination via conference presentations, peer-reviewed publications, and study reports.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The approach is guided by the the Consolidated Framework for Implementation Research and Normalisation Process Theory that together will support understanding of the ways that the implementation processes and the general practice context shape each other and implementation of our interventions.
- A mixed methods approach will facilitate qualitative and quantitative assessment of how interventions for best practice chlamydia management are implemented and used in general practice.
- While this is an implementation and feasibility trial, our sample of 20 clinics should be of sufficient size to detect an increase in chlamydia re-testing from 25% in the 12 months prior to the trial to 40% in the 12 months following implementation.

INTRODUCTION

Chlamydia caused by the pathogen *Chlamydia trachomatis,* is the most common bacterial sexually transmissible infection (STI) globally[1] and the most commonly notified STI in Australia.[2] Usually asymptomatic, chlamydia can cause significant complications if left untreated, particularly among people with female reproductive organs[3], including pelvic inflammatory disease (PID), ectopic pregnancy and infertility. Repeat chlamydia infection plays an important role in progression to complications; increasing the risk of PID by 35%, and up to 4-fold for those aged under 20 years,[4] while severe PID poses a higher risk of tubal infertility than mild-moderate PID.[3, 5]

Chlamydia screening of asymptomatic individuals with the aim of reducing transmission and the harms of untreated infection has been a longstanding and central component of STI control in many countries.[6-8] However, in the absence of definitive evidence showing that widespread testing can reduce chlamydia prevalence or complications in the population,[6, 9, 10] the emphasis of chlamydia control is shifting to optimising management of diagnosed infections to reduce the risk of repeat infection.[11] In the United Kingdom, the National Chlamydia Screening Program now focuses on reducing the harms arising from untreated chlamydia infection that largely impact people with female reproductive organs.[12] In Australia, the National STI Strategy has reduced its focus on testing uptake and places an increasing emphasis on strengthening management of diagnosed infections, in particular toward reducing repeat infections and earliest detection of PID.[8]

In Australia specialist STI care is provided in sexual health and family planning services. However, these specialist services are at capacity and not widely available outside of metropolitan areas. General practice is Australia's mainstream primary care setting, it is widely accessible and where most chlamydia infections are diagnosed and managed;[13, 14] making it a key setting for optimising chlamydia management. General practice data show that most diagnosed chlamydia infections are followed up for antibiotic treatment.[15] However, high reinfection rates of up to 22%[16] suggest missed opportunities for notifying and treating sexual partners. Australian STI management guidelines recommend retesting for reinfection at around 3 months after treatment.[17] Retesting rates in Australian general practice are low; 24.6% within 4 months of treatment in one study.[18] Where measuredPID diagnosis rates in Australian general practice were 42 per 10,000 consultations for women aged 16-33 years compared with 210 per 10,000 consultations for women aged 16-49 years attending a sexual health clinic.[9, 19] Whilst acknowledging the risk for PID is likely to be higher for women attending sexual health clinics, other Australian data show general practitioners (GPs) have expressed hesitancy in conducting pelvic examinations to support a PID diagnosis, potentially reducing their capacity to diagnose PID.[20] Interventions for strengthening chlamydia management (e.g. mailed specimen kits, links to partner notification websites in chlamydia test results) have improved retesting and uptake of partner notification discussions in specialist sexual health and family planning clinics.[21, 22] Patient-delivered partner therapy (PDPT), a method of expediting partner treatment, has been shown to be effective at

reducing reinfection and acceptable to patients and partners.[23, 24] However, to date, these interventions have not been implemented in Australian general practice.

The Management of Chlamydia Cases in Australia (MoCCA) study seeks to address gaps in chlamydia management through implementing interventions that have been found to be effective at improving chlamydia management in specialist sexual health services. In particular, MoCCA focuses on interventions found to improve testing for repeat infection within recommended timeframes, improve partner management, including use of PDPT where appropriate (eg. PDPT is not recommended for patients at high risk of HIV infection such as men who have sex with men), and increasing clinician confidence in diagnosing PID. In this trial, we aim to determine how best to implement the MoCCA interventions to improve chlamydia case management in general practice. We hypothesise that implementation of the MoCCA interventions will be feasible and acceptable. We will also test the exploratory hypotheses that MoCCA will increase chlamydia re-testing among those diagnosed with chlamydia and increase PID detection. Our results will be used to inform subsequent mathematical and economic modelling of the impact of the MoCCA interventions on chlamydia outcomes at a population level and to understand the potential impacts of scale up of the interventions across general practice. where many thousands of Australians are diagnosed with chlamydia each year.

METHODS

Study design

We will conduct a non-randomised mixed methods implementation and feasibility trial where our primary aim is to implement MoCCA interventions in general practice and measure their uptake by assessing acceptability, adoption, appropriateness, feasibility, fidelity, costs, penetration and sustainability as outlined in Proctors taxonomy of implementation outcomes.[25] As secondary aims, we will explore the impact of the interventions on chlamydia re-testing, re-infection and PID diagnosis in general practice. Our approach is guided by the Consolidated Framework for Implementation Research (CFIR), that provides a framework with five domains; namely i) intervention characteristics, ii) inner setting (eg. culture, communication) iii) outer setting (eg. patient needs, resources), iv) characteristics of individuals (eg. knowledge and beliefs about the intervention), and v) process (eg. planning) to allow us to assess the contextual elements that influence implementation. To complement the CFIR, the Normalisation Process Theory (NPT), will help us understand the cognitive and social processes used by staff to establish and embed interventions into routine practice. [26, 26, 27] Together the CFIR and NPT add explanatory strength for understanding interactions between implementation processes and contextual determinants.[26]

We aim to recruit 20 general practices across three Australian States (Victoria, New South Wales (NSW) and Queensland). The target population for chlamydia case management will be patients aged 16-44 years attending general practice. Our package of interventions includes a central MoCCA website that provides resources and guidelines, and strategies to improve partner management, re-testing three months following chlamydia treatment, and tools to facilitate the

earlier detection of PID (see Table 1 and below for further detail). We will follow the CONSORT checklist for pilot and feasibility trials.[28]

There will be three main study phases; establishment and implementation, operation, and evaluation.

Establishment and implementation phase

Guided by NPT,[26, 27, 29] we will work with each practice individually for 3-6 months to identify which intervention components can be implemented and how best to implement them, focussing on NPT components of coherence, active participation, collective action and reflexive monitoring. We will draw on our experience in applying NPT to implementation of complex chlamydia focussed interventions.[26] Each practice will be asked to nominate a practice champion who is interested in the study and agrees to be the main point of contact for communication and dissemination of information about the study within the practice. Appointing a practice champion has been effective in supporting implementation of a range of interventions and quality improvements in primary care.[30]

Depending on each practices' preferred communication mode, the research team will meet with staff (either collectively or individually) via zoom or face to face to initiate the study, explain the objectives, interventions, supporting resources, data collection methods, and staff involvement. This implementation meeting will include a tour of the MoCCA website to familiarise staff with the intervention components. Recorded videos and other hard or digital materials with instructional information about the study will also be provided.

While all intervention components will be available to each practice, it will not be feasible for all to be adopted. This will depend to some extent on each practice's interest, priorities and geographical location because there is some variation in STI management program regulations and available resources across Australian states. For example, health authority guidance for PDPT is available for the states of Victoria and NSW but not Queensland so resources to support PDPT will be unavailable for practices in this state.[31, 32] A researcher will work with the practice champion and other relevant staff in each clinic to identify which intervention components will be implemented and establish their implementation. This will be via onsite or virtual meetings, following which clinic staff will be encouraged to liaise with researchers to discuss and troubleshoot any issues as they arise.

Regular communication mechanisms with participating general practices will be established to support ongoing study engagement. The main method will be regular emailed communications (quarterly) that highlight new evidence and resources, provide interim findings and communicate study progress. Anonymous polls will be embedded in these communications as a tool to gain feedback about aspects of the study. For example, we may ask about recent engagement with the study website, which resources have been used and their usefulness. Short vignettes of a patient scenario will also be provided in email communications, and embedded polls will ask brief questions about the type of management GPs might provide. Other communication methods will

include individual practice reports and study updates at clinic meetings. Communication records with each practice will be maintained.

Operation phase

Following intervention implementation, participating practices will be asked to continue to use the interventions to support management of patients with a chlamydia infection for up to 12 months. Research staff will regularly check in with participating practices to communicate study progress, provide support and troubleshoot any issues. A mix of qualitative and quantitative data collection will be used to measure the implementation outcomes (see table 2 and 3 and below for further detail).

Evaluation phase

Data from the operation phase will be evaluated to identify what worked and what did not, guided by the CFIR and NPT to understand how intervention implementation occurred and the context for implementation. Detail of our implementation outcomes is provided below. The impact of the interventions on chlamydia re-testing, re-infection and PID diagnosis will be assessed as secondary outcomes, acknowledging these estimates will be limited by the non-randomised trial design and sample size.

Participants

Study participants will include general practice staff (GPs, practice nurses, practice managers) and patients attending participating general practices with a chlamydia infection.

The aim is to recruit 20 general practices. Eligible practices must be located in the states of Victoria, NSW or Queensland, use Best Practice™ or Medical Director™ (used widely within Australian general practice) as their electronic medical record (EMR) software (the data extraction software GRHANITE™ (www.grhanite.com/) is validated to work with these EMRs), have at least 2000 active patients aged 16-44 years seen in the last 2 years (to ensure sufficient numbers of patients at risk of STIs and PID), and, diagnose a minimum of 20 chlamydia infections annually.

General practices will be recruited via advertisements in a range of general practice communication networks including those of our project partners (State governments, Primary Health Networks, Family Planning Organisations, Sexual Health Clinics and laboratories). In addition, practices will be approached directly via phone and email by our research team. If eligible, researchers will arrange a meeting (face to face or via Zoom depending on location and COVID-19 restrictions) with practices (including clinical staff and the practice manager) to explain the study further. Consent will be obtained from the general practice management for the clinics' participation in the trial and from a sample of staff (GP, practice nurse, or practice manager) from each clinic to participate in one or more interview about implementation and integration of the interventions.

Patients aged 16-44 years from participating general practices and who have had chlamydia or PID diagnosed and treated at the clinic during the study period will be eligible to participate in

a brief anonymous online survey about their experiences of having the infection treated at the general practice. Eligible patients will be invited to participate via several strategies. Survey flyers will be displayed in the general practice waiting area, on the clinic website or directly passed to patients by clinicians at the conclusion of the consultation when chlamydia treatment is prescribed. This flyer will include a QR code that links to an online survey. A plain language statement will comprise the first page of the online survey, and participants will provide consent for participation within the survey prior to commencing the survey questions. Secondly, for practices which use SMS text messaging to communicate with patients, eligible patients will be sent an SMS message including a link to the online survey.

Patients completing the survey will receive a $20 gift voucher. Survey participants will also be asked if they are interested in participating in a semi-structured phone interview to further explore views on how the chlamydia infection was managed at the practice.

Interventions

We have developed a package of interventions that aim to strengthen chlamydia management in general practice. It comprises three main components: strategies to improve partner notification, strategies to increase re-testing following chlamydia treatment and strategies to prompt earlier detection of PID. An overview of the interventions by aspect of chlamydia management is provided in Table 1.

The main component is our study website (www.mocca.org.au/) that outlines best practice chlamydia management and links to key Australian STI management resources and guidelines, and, resources for supporting patient care. Our website was developed in consultation with clinical staff. Firstly, we administered a quantitative survey and conducted interviews with clinical staff to understand chlamydia management practices and inform the website design.[20, 33, 34] Next we conducted think-aloud interviews[35] with clinical staff to assess the usability and acceptability of the prototype website, made modifications to the website and piloted it for 3 months in 3 practices in NSW and QLD. Our pilot results informed further modifications to the website for evaluation in this trial (www.mocca.org.au/about-mocca/research-outputs). Other resources include flowcharts, patient factsheets (developed with health consumer input), mailed specimen kits, autofills for streamlining documentation of the chlamydia consultation, and published educational articles outlining best practice chlamydia management[36-38] including our PID article in which clinicians can take the associated quiz to contribute to the continuing professional development requirements. A link to the website can be bookmarked within the EMR or search engine allowing easy access during a consultation.

Table 1: Description of the MoCCA interventions, by aspect of chlamydia management

	Intervention	Intervention description
Partner notification	Website	• MoCCA website (or other linked resources) provides information that can support partner notification discussions. • MoCCA website links to online partner notification tools.
	Autofill#	• Chlamydia autofill or shortcut inserted in the EMR that supports documentation of chlamydia management in the patient notes and prompts clinicians to record:

		○ Treatment provided ○ If partners were notified ○ If PDPT was provided
	Patient factsheets	• Information about notifying partners is provided to chlamydia positive patients.
	PDPT flowchart	• PDPT flowchart provides an overview of patient eligibility for PDPT, and the process of offering PDPT to eligible and willing patients.
	PDPT prescription template	• A template that can be imported into the EMR and used to generate a PDPT prescription.
	Published article	• PDPT article [38] that provides an overview of the process of offering PDPT and addresses the challenges GPs may face in its provision. • Chlamydia management article[37] outlines best practice to reduce chlamydia associated reproductive complications in women, including partner management.
Retesting	Website	• MoCCA website (or other linked resources) used to support retesting discussion.
	Patient factsheets	• Information about why retesting for reinfection is important is provided to chlamydia positive patients.
	Retesting flowchart	• Provides the rationale for retesting and some options for organising retesting.
	Postal retest	• Patient sent a postal kit by the laboratory for retesting at 3 months.
	Pathology form	• Patient provided a pathology form for retesting in 3 months' time.
	Patient recalls and reminders	• Patient placed on recall system and recalled at 3 months to return for a retest appointment **OR** • Patient placed on reminder system and sent an SMS reminder to visit a pathology collection centre for a chlamydia test
	Published article	• Chlamydia management article[37] provides information about the importance of and options for organising retesting for reinfection.
PID diagnosis	Website	• MoCCA website (and linked resources) provide key PID diagnostic considerations.
	Patient factsheets	• PID factsheet provides a definition of PID, its diagnosis and treatment. • Chlamydia factsheet provides information about symptoms that may indicate complications.
	Published article	• How to Treat PID article[36] that focuses on the diagnosis and management of acute PID in primary care. Taking the associated quiz allows clinicians to earn continuing professional development points.

Autofill, a shortcut for clinical notes for a specific condition that has been pre-populated in the EMR

Patient and public involvement

Health providers and health consumers were involved in the development of this project in a number of ways including surveys, qualitative interviews, focus groups and development and refinement of patient factsheets and health care provider resources. Our findings will be disseminated through our partner organisations including those that provide clinical care to people with a chlamydia infection and also to participating general practices.

Outcomes and data collection

Our primary trial outcomes will relate to the implementation processes and success of implementation and include acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability.[25] To measure our outcomes we will collect qualitative and quantitative data at the general practice, staff and patient level. We will also capture information about costings and effectiveness of the interventions. An overview of our data collection methods, data sources, outcomes and timepoints is provided in table 2 and table 3. Our data collection methods will include:

1. *Practice survey* - to collect baseline information about the practice's structure, staffing, EMR and other management systems, patient demographics, and work processes.
2. *Field notes and logs* – that document researcher communication (via email, telephone, in person) and support provided for participating general practices in implementing the interventions (eg. frequency, nature of support, any modifications).
3. *Minutes* – of study meetings with clinics to provide data to describe implementation procedures, and, understanding of the interventions' acceptability, usefulness and barriers and enablers to its adoption.
4. *Polls and brief surveys* – embedded in quarterly email study communications that ask staff at participating clinics 1-3 questions about the management they might provide in a short chlamydia focussed vignette or their use and views on MoCCA interventions; such as 'have you used the chlamydia autofill to help document chlamydia care in the past 3 months?'.
5. *Interviews with a think aloud component* – in which general practice staff are asked about their views about the MoCCA interventions, their usefulness, how they are integrated into the workflow and why they are or are not being adopted into practice. We will conduct approximately 40 individual or group interviews across the 20 clinics, seeking to interview at least one person from each clinic at two interview timepoints (3 and 12 months) during the intervention period. The number of interviews will take into consideration the current context at the time (eg. how busy the clinics are and staff availability for interview), as well as the richness and complexity of the data collected. Concurrent analyses will inform the need for further interviews.
6. *Patient survey* – an online survey asking patients about their experience of having chlamydia or PID diagnosed and treated at the clinic.
7. *De-identified patient attendance and clinical data* – will be collected from participating practices' EMR using GRHANITE™ (www.grhanite.com/) data extraction software and used to measure chlamydia testing, treatment, retesting, reinfection and PID diagnosis rates.
8. *De-identified laboratory data* – for mailed specimen kits will be collected from the relevant laboratory and used to determine request rates for use of postal tests in retesting, return rates and reinfection rates among those retested via this method.
9. *Google analytics* – will be collected monthly to ascertain website usage. These data will include new and total users per month, pages visited, and time spent on the website.
10. *Costs* – for resources used in delivering the MoCCA interventions that will be collected alongside the study.

Table 2 Data collection method and timepoints

Participant	**Practice**				**Provider**		**Patient**	
Data collection method	**Electronic patient data (GRHANITE)**	**Laboratory data**	**Practice survey**	**Minutes and field notes**	**Poll**	**Interview**	**Survey**	**Interview**
Study phase Establishment and implementation phase	X		X	X	X			
Operation phase	X Collected at the end of 12 month operation phase	X Collected 6 monthly		X	X 3 monthly	X 3 and 12 months	X Collected through out the 12 month operation phase	X As per patient preference

Table 3: Outcome description and data sources

Outcome type	Outcome	Description	Data collection method
Implementation	Acceptability	• Acceptability of interventions to general practice staff including a description of barriers and facilitators, how they were implemented and fit with the workflow • Patient satisfaction with chlamydia care	• Observation and field notes • Meeting minutes • Interviews • Polls and surveys
	Adoption	• Readiness to implement the intervention • Level of use of the interventions	• Interviews • Meeting minutes • Google analytics • Patient attendance and clinical data • Laboratory data
	Appropriateness	• Relevance of interventions to the general practice setting	• Interviews • Meeting minutes • Polls and surveys
	Feasibility	• Extent that the interventions are suitable for use within general practice	• Interviews • Meeting minutes
	Fidelity	Description of how the interventions: • Were implemented • Are being used	• Observation and field notes • Interviews • Meeting minutes
	Implementation costs	• Costs to implement the interventions	• Study protocols and budgets • Interviews with general practice staff
	Penetration	• Level of use of the interventions	• Interviews • Polls and surveys
	Sustainability	• Description of how the interventions are being used	• Interviews • Polls and surveys • Meeting minutes
Impact	Effectiveness	• Chlamydia testing patterns • Chlamydia re-testing rates • Chlamydia reinfection rates • Partner notification practices	• Patient attendance and clinical data • Laboratory data • Polls and surveys

		• PID diagnosis rates	

Sample size

We will implement our intervention in up to 20 general practices, gathering data on our implementation outcomes. We will conduct approximately 40 interviews with staff (either as individuals or in groups) from the 20 general practices to assess our qualitative implementation outcomes. Assuming about 20 people per clinic will be diagnosed with chlamydia during the trial, an estimated 100 patients will complete the quantitative survey, assuming a 25% response rate.

Assuming an annual chlamydia testing rate of 15%, a chlamydia positivity of 7% and average of 2000 16-44 year olds attending each practice per year, a sample size of 20 general practices will generate about 400 chlamydia cases requiring management during the 12 month operation phase.[9] This will allow us to estimate an annual chlamydia re-testing rate of 25%[18] to within a 95% confidence interval of +/- 4% (95% CI: 21% to 29%) for the 12 months pre-implementation and estimate a re-testing rate of 40% with a precision of +/- 5% (95% CI: 45% to 55%) for the 12 months after implementation, assuming re-testing increases. While this is an implementation and feasibility trial, 20 clinics should provide sufficient sample size to detect an increase in chlamydia re-testing from 25% in the 12 months prior to the trial to 40% in the 12 months following implementation, assuming an intra-cluster correlation of 0.02 , an alpha of 0.05 and power of 80%.

Data analysis

We will use a mixed-methods approach, applying quantitative and qualitative methods to assess our study outcomes. NVivo software will be used to manage and facilitate analyses of qualitative data and STATA statistical software to manage and analyse quantitative data.

Our implementation outcomes will be assessed qualitatively using content analysis[39] of data collected in the interviews, free text survey responses and meeting minutes and quantitatively through descriptive analysis. Our qualitative analysis will be largely deductive, and guided by the CFIR to understand the determinants of implementation and NPT to explain how and why changes to support new practices did or did not occur. We will establish an initial coding framework across the five CFIR domains and four NPT components. Additional codes will be developed inductively as needed. Findings from the qualitative analysis will be considered alongside findings from the descriptive analyses of quantitative data including patient attendance and clinical data, google analytics, laboratory data and survey and poll responses. Together, these qualitative and quantitative analyses will allow us to describe:

- Implementation procedures for each best practice chlamydia management intervention
- Barriers and enablers to adoption of best practice chlamydia management interventions
- How interventions and resources to support best practice chlamydia management are integrated into the general practice workflow
- Factors and behaviours associated with sustained adoption of best practice chlamydia management interventions
- The experiences of patients who were treated for a chlamydia infection

We will assess our impact outcomes to inform the design of a future large scale trial through quantitative analyses of patient attendance, clinical and laboratory data. Retesting rates will be measured as the proportion of those diagnosed with chlamydia who are retested within 2-4 months (3 months ± 1 month). Other outcomes will include chlamydia reinfection rates (proportion of those who re-test chlamydia positive) and PID rates (proportion of consultations for women aged 15-44 years with a PID diagnosis). We will assess our impact outcomes by comparing outcomes between the 12 month intervention (operation phase) and 12 month pre-intervention periods. Poisson regression models, with a binary indicator for pre- and post-implementation and adjustment for a priori defined potential confounders, and robust standard errors to account for clustering by clinic, will estimate the impact of the overall MoCCA intervention immediately post implementation (presented as a Rate Ratio (95% Confidence Interval).

Additional economic costs to implement and maintain the intervention (compared to the usual care pathway) will be estimated using trial protocols and budgets, along with interviews of general practice staff to estimate clinic staff time and other resources required to set up and deliver the intervention. We will adopt a 'health care system' perspective to estimate total costs associated with implementation of the MoCCA interventions and calculate costs for MoCCA's three components (partner notification, re-testing, PID detection) and further break this down into specific interventions (eg. mailed specimen kits). Costs will be grouped by expenditure category such as staffing or consumables and then into 'fixed' vs 'variable' costs, to tease out issues associated with throughput and capacity utilisation. Results will be presented in terms of intervention activities and used to inform subsequent mathematical and economic modelling (protocol to come) of the impact of MoCCA interventions on the population chlamydia burden to guide plans for scale up across Australian general practice.

Ethics and dissemination

Ethical approval has been obtained from the University of Melbourne Human Research Ethics Committee (Ethics ID 22665). For all survey, interview and study data in which participant details are known to researchers, the participants details will be coded using ID codes that will be stored separately from their responses in password protected participant tracking files. All digital data will be stored within a restricted-access folder on a network drive that is internal to the University of Melbourne that has access limited to selected project staff. All hard copy data will be stored in a locked filing cabinet at the University of Melbourne where it is protected with a monitored alarm. Study materials will be kept for 5 years after publication of the study results after which point, they will be destroyed. Findings will be disseminated through conference presentations, peer-reviewed publications, and study reports. All data collected and analysed will pertain to the MoCCA study only.

DISCUSSION

Amid a changing landscape of chlamydia control strategies around the world, the MoCCA study will focus on optimising clinical management of diagnosed chlamydia infections to reduce the

risk of repeat infection and chlamydia associated harms. The key areas of emphasis are on implementing interventions in the general practice setting to strengthen retesting for reinfection, partner management, and PID diagnosis. MoCCA will be implemented in Australia's mainstream primary care setting, general practice, being where most chlamydia infections are diagnosed and where the greatest gaps in care are apparent. Importantly this study will determine how best to implement best practice chlamydia management. Guided by the CFIR and NPT our mixed methods design will capture comprehensive qualitative and quantitative data, allowing us to identify the key factors to implementation and use of these interventions in general practice.

As an implementation and feasibility trial, our trial is limited by its sample size and non-randomised design. However, several components of our intervention package including PDPT[40] and re-testing postal kits[21] have been found to be effective in randomised trials. What is now needed, is to determine how they can be best implemented in general practice. Our comprehensive qualitative and quantitative data collection and analyses will allow us to measure the extent of implementation and to understand how and why the interventions are or are not implemented. The main emphasis is on understanding how best to implement these interventions in general practice rather than demonstrating their effectiveness.

The MoCCA study represents a paradigm shift in chlamydia control approaches from a focus on screening to case management. Our study's focus on general practice will provide much needed evidence about how to integrate best practice chlamydia management in the setting where most chlamydia infections are diagnosed in Australia. Our results will have relevance to other similar primary care settings in other countries where chlamydia screening, diagnosis and management take place. Beyond this trial, our findings will feed into mathematical and economic modelling which will explore the cost and impact of MoCCA interventions on a population level and inform a scale-up plan for general practice with potential to improve management for many thousands of Australians diagnosed with chlamydia each year.

Authors' contributions JH, MTS, NC, JAS, JT, CF, RG, BD, DR, MYC, LS, CE, LR, DH, MS were involved in the conceptualisation of the MoCCA study. JG, JC, HB, MTS, and JH were involved in the protocol development, designed all data collection tools and were involved in drafting the manuscript. All authors provided approval of the final version for publication.

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Exclusive licence

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MANAGEMENT OF CHLAMYDIA CASES IN AUSTRALIA (MOCCA): PROTOCOL FOR A NON-RANDOMISED IMPLEMENTATION AND FEASIBILITY TRIAL

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ABSTRACT

Introduction: The sexually transmissible infection chlamydia can cause significant complications, particularly among people with female reproductive organs. Optimal management includes timely and appropriate treatment, notifying and treating sexual partners, timely retesting for reinfection, and detecting complications including pelvic inflammatory disease (PID). In Australia, mainstream primary care (general practice) is where most chlamydia infections are diagnosed, making it a key setting for optimising chlamydia management. High reinfection and low retesting rates suggest partner notification and retesting are not uniformly provided. The Management of Chlamydia Cases in Australia (MoCCA) study seeks to address gaps in chlamydia management in Australian general practice through implementing interventions shown to improve chlamydia management in specialist services. MoCCA will focus on improving retesting, partner management (including patient-delivered partner therapy), and PID diagnosis.

Methods and analysis: MoCCA is a non-randomised implementation and feasibility trial aiming to determine how best to implement interventions to support general practice in delivering best practice chlamydia management. Our method is guided by the Consolidated Framework for Implementation Research and Normalisation Process Theory. MoCCA interventions include a website, flowcharts, factsheets, mailed specimen kits, and autofills to streamline chlamydia consultation documentation. We aim to recruit 20 general practices across three Australian states (Victoria, New South Wales, Queensland) through which we will implement the interventions over 12-18 months. Mixed methods involving qualitative and quantitative data collection and analyses (observation, interviews, surveys) from staff and patients will be undertaken to explore our interventions' implementation, acceptability and uptake. De-identified general practice and laboratory data will be used to measure pre-post chlamydia testing, treatment, retesting, reinfection, and PID rates, and to estimate MoCCA intervention costs. Our findings will guide scale up plans for Australian general practice.

Ethics and dissemination: Approval from University of Melbourne Human Research Ethics Committee (Ethics-ID 22665). Dissemination via conference presentations, peer-reviewed publications, and study reports.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The approach is guided by the the Consolidated Framework for Implementation Research and Normalisation Process Theory that together will support understanding of the ways that the implementation processes and the general practice context shape each other and implementation of our interventions.
- A mixed methods approach will facilitate qualitative and quantitative assessment of how interventions for best practice chlamydia management are implemented and used in general practice.
- While this is an implementation and feasibility trial, our sample of 20 clinics should be of sufficient size to detect an increase in chlamydia re-testing from 25% in the 12 months prior to the trial to 40% in the 12 months following implementation.

INTRODUCTION

Chlamydia caused by the pathogen *Chlamydia trachomatis,* is the most common bacterial sexually transmissible infection (STI) globally[1] and the most commonly notified STI in Australia.[2] Usually asymptomatic, chlamydia can cause significant complications if left untreated, particularly among people with female reproductive organs[3], including pelvic inflammatory disease (PID), ectopic pregnancy and infertility. Repeat chlamydia infection plays an important role in progression to complications; increasing the risk of PID by 35%, and up to 4-fold for those aged under 20 years,[4] while severe PID poses a higher risk of tubal infertility than mild-moderate PID.[3, 5]

Chlamydia screening of asymptomatic individuals with the aim of reducing transmission and the harms of untreated infection has been a longstanding and central component of STI control in many countries.[6-8] However, in the absence of definitive evidence showing that widespread testing can reduce chlamydia prevalence or complications in the population,[6, 9, 10] the emphasis of chlamydia control is shifting to optimising management of diagnosed infections to reduce the risk of repeat infection.[11] In the United Kingdom, the National Chlamydia Screening Program now focuses on reducing the harms arising from untreated chlamydia infection that largely impact people with female reproductive organs.[12] In Australia, the National STI Strategy has reduced its focus on testing uptake and places an increasing emphasis on strengthening management of diagnosed infections, in particular toward reducing repeat infections and earliest detection of PID.[8]

In Australia specialist STI care is provided in sexual health and family planning services. However, these specialist services are at capacity and not widely available outside of metropolitan areas.[8, 13] General practice is Australia's mainstream primary care setting, it is widely accessible and where most chlamydia infections are diagnosed and managed;[14, 15] making it a key setting for optimising chlamydia management. General practice data show that most diagnosed chlamydia infections are followed up for antibiotic treatment.[16] However, high reinfection rates of up to 22%[17] suggest missed opportunities for notifying and treating sexual partners. Australian STI management guidelines recommend retesting for reinfection at around 3 months after treatment.[18] Retesting rates in Australian general practice are low; 24.6% within 4 months of treatment in one study.[19] Where measured PID diagnosis rates in Australian general practice were 42 per 10,000 consultations for women aged 16-33 years compared with 210 per 10,000 consultations for women aged 16-49 years attending a sexual health clinic.[9, 20] Whilst acknowledging the risk for PID is likely to be higher for women attending sexual health clinics, other Australian data show general practitioners (GPs) have expressed hesitancy in conducting pelvic examinations to support a PID diagnosis, potentially reducing their capacity to diagnose PID.[21] Interventions for strengthening chlamydia management (e.g. mailed specimen kits, links to partner notification websites in chlamydia test results) have improved retesting and uptake of partner notification discussions in specialist sexual health and family planning clinics.[22, 23] Patient-delivered partner therapy (PDPT), a method of expediting partner treatment, has been shown to

be effective at reducing reinfection and acceptable to patients and partners.[24, 25] However, to date, these interventions have not been implemented in Australian general practice.

The Management of Chlamydia Cases in Australia (MoCCA) study seeks to address gaps in chlamydia management through implementing interventions that have been found to be effective at improving chlamydia management in specialist sexual health services. In particular, MoCCA focuses on interventions found to improve testing for repeat infection within recommended timeframes, improve partner management, including use of PDPT where appropriate (eg. PDPT is not recommended for patients at high risk of HIV infection such as men who have sex with men), and increasing clinician confidence in diagnosing PID. In this trial, we aim to determine how best to implement the MoCCA interventions to improve chlamydia case management in general practice. We hypothesise that implementation of the MoCCA interventions will be feasible and acceptable. We will also test the exploratory hypotheses that MoCCA will increase chlamydia re-testing among those diagnosed with chlamydia and increase PID detection. Our results will be used to inform subsequent mathematical and economic modelling of the impact of the MoCCA interventions on chlamydia outcomes at a population level and to understand the potential impacts of scale up of the interventions across general practice. where many thousands of Australians are diagnosed with chlamydia each year.

METHODS

Study design

We will conduct a non-randomised mixed methods implementation and feasibility trial where our primary aim is to implement MoCCA interventions in general practice and measure their uptake by assessing acceptability, adoption, appropriateness, feasibility, fidelity, costs, penetration and sustainability as outlined in Proctors taxonomy of implementation outcomes.[26] As secondary aims, we will explore the impact of the interventions on chlamydia re-testing, re-infection and PID diagnosis in general practice. Our approach is guided by the Consolidated Framework for Implementation Research (CFIR), that provides a framework with five domains; namely i) intervention characteristics, ii) inner setting (eg. culture, communication) iii) outer setting (eg. patient needs, resources), iv) characteristics of individuals (eg. knowledge and beliefs about the intervention), and v) process (eg. planning) to allow us to assess the contextual elements that influence implementation. To complement the CFIR, the Normalisation Process Theory (NPT), will help us understand the cognitive and social processes used by staff to establish and embed interventions into routine practice. [26, 27, 28] Together the CFIR and NPT add explanatory strength for understanding interactions between implementation processes and contextual determinants.[27]

We aim to recruit 20 general practices across three Australian States (Victoria, New South Wales (NSW) and Queensland). The target population for chlamydia case management will be patients aged 16-44 years attending general practice. Our package of interventions includes a central MoCCA website that provides resources and guidelines, and strategies to improve partner management, re-testing three months following chlamydia treatment, and tools to facilitate the

earlier detection of PID (see Table 1 and below for further detail). We will follow the CONSORT checklist for pilot and feasibility trials.[29]

There will be three main study phases; establishment and implementation, operation, and evaluation.

Establishment and implementation phase

Guided by NPT,[27, 28, 30] we will work with each practice individually for 3-6 months to identify which intervention components can be implemented and how best to implement them, focussing on NPT components of coherence, active participation, collective action and reflexive monitoring. We will draw on our experience in applying NPT to implementation of complex chlamydia focussed interventions.[26] Each practice will be asked to nominate a practice champion who is interested in the study and agrees to be the main point of contact for communication and dissemination of information about the study within the practice. Appointing a practice champion has been effective in supporting implementation of a range of interventions and quality improvements in primary care.[31]

Depending on each practices' preferred communication mode, the research team will meet with staff (either collectively or individually) via zoom or face to face to initiate the study, explain the objectives, interventions, supporting resources, data collection methods, and staff involvement. This implementation meeting will include a tour of the MoCCA website to familiarise staff with the intervention components. Recorded videos and other hard or digital materials with instructional information about the study will also be provided.

While all intervention components will be available to each practice, it will not be feasible for all to be adopted. This will depend to some extent on each practice's interest, priorities and geographical location because there is some variation in STI management program regulations and available resources across Australian states. For example, health authority guidance for PDPT is available for the states of Victoria and NSW but not Queensland so resources to support PDPT will be unavailable for practices in this state.[32, 33] A researcher will work with the practice champion and other relevant staff in each clinic to identify which intervention components will be implemented and establish their implementation. This will be via onsite or virtual meetings, following which clinic staff will be encouraged to liaise with researchers to discuss and troubleshoot any issues as they arise.

Regular communication mechanisms with participating general practices will be established to support ongoing study engagement. The main method will be regular emailed communications (quarterly) that highlight new evidence and resources, provide interim findings and communicate study progress. Anonymous polls will be embedded in these communications as a tool to gain feedback about aspects of the study. For example, we may ask about recent engagement with the study website, which resources have been used and their usefulness. Short vignettes of a patient scenario will also be provided in email communications, and embedded polls will ask brief questions about the type of management GPs might provide. Other communication methods will

include individual practice reports and study updates at clinic meetings. Communication records with each practice will be maintained.

Operation phase

Following intervention implementation, participating practices will be asked to continue to use the interventions to support management of patients with a chlamydia infection for up to 12 months. Research staff will regularly check in with participating practices to communicate study progress, provide support and troubleshoot any issues. A mix of qualitative and quantitative data collection will be used to measure the implementation outcomes (see table 2 and 3 and below for further detail).

Evaluation phase

Data from the operation phase will be evaluated to identify what worked and what did not, guided by the CFIR and NPT to understand how intervention implementation occurred and the context for implementation. Detail of our implementation outcomes is provided below. The impact of the interventions on chlamydia re-testing, re-infection and PID diagnosis will be assessed as secondary outcomes, acknowledging these estimates will be limited by the non-randomised trial design and sample size.

Participants

Study participants will include general practice staff (GPs, practice nurses, practice managers) and patients attending participating general practices with a chlamydia infection.

The aim is to recruit 20 general practices. Eligible practices must be located in the states of Victoria, NSW or Queensland, use Best Practice™ or Medical Director™ (used widely within Australian general practice) as their electronic medical record (EMR) software (the data extraction software GRHANITE™ (www.grhanite.com/) is validated to work with these EMRs), have at least 2000 active patients aged 16-44 years seen in the last 2 years (to ensure sufficient numbers of patients at risk of STIs and PID), and, diagnose a minimum of 20 chlamydia infections annually.

General practices will be recruited via advertisements in a range of general practice communication networks including those of our project partners (State governments, Primary Health Networks, Family Planning Organisations, Sexual Health Clinics and laboratories). In addition, practices will be approached directly via phone and email by our research team. If eligible, researchers will arrange a meeting (face to face or via Zoom depending on location and COVID-19 restrictions) with practices (including clinical staff and the practice manager) to explain the study further. Consent will be obtained from the general practice management for the clinics' participation in the trial and from a sample of staff (GP, practice nurse, or practice manager) from each clinic to participate in one or more interview about implementation and integration of the interventions.

Patients aged 16-44 years from participating general practices and who have had chlamydia or PID diagnosed and treated at the clinic during the study period will be eligible to participate in

a brief anonymous online survey about their experiences of having the infection treated at the general practice. Eligible patients will be invited to participate via several strategies. Survey flyers will be displayed in the general practice waiting area, on the clinic website or directly passed to patients by clinicians at the conclusion of the consultation when chlamydia treatment is prescribed. This flyer will include a QR code that links to an online survey. A plain language statement will comprise the first page of the online survey, and participants will provide consent for participation within the survey prior to commencing the survey questions. Secondly, for practices which use SMS text messaging to communicate with patients, eligible patients will be sent an SMS message including a link to the online survey.

Patients completing the survey will receive a $20 gift voucher. Survey participants will also be asked if they are interested in participating in a semi-structured phone interview to further explore views on how the chlamydia infection was managed at the practice.

Interventions

We have developed a package of interventions that aim to strengthen chlamydia management in general practice. It comprises three main components: strategies to improve partner notification, strategies to increase re-testing following chlamydia treatment and strategies to prompt earlier detection of PID. An overview of the interventions by aspect of chlamydia management is provided in Table 1.

The main component is our study website (www.mocca.org.au/) that outlines best practice chlamydia management and links to key Australian STI management resources and guidelines, and, resources for supporting patient care. Our website was developed in consultation with clinical staff. Firstly, we administered a quantitative survey and conducted interviews with clinical staff to understand chlamydia management practices and inform the website design.[21, 34, 35] Next we conducted think-aloud interviews[36] with clinical staff to assess the usability and acceptability of the prototype website, made modifications to the website and piloted it for 3 months in 3 practices in NSW and QLD. Our pilot results informed further modifications to the website for evaluation in this trial (www.mocca.org.au/about-mocca/research-outputs). Other resources include flowcharts, patient factsheets (developed with health consumer input), mailed specimen kits, autofills for streamlining documentation of the chlamydia consultation, and published educational articles outlining best practice chlamydia management[37-39] including our PID article in which clinicians can take the associated quiz to contribute to the continuing professional development requirements. A link to the website can be bookmarked within the EMR or search engine allowing easy access during a consultation.

Table 1: Description of the MoCCA interventions, by aspect of chlamydia management

	Intervention	Intervention description
Partner notification	Website	• MoCCA website (or other linked resources) provides information that can support partner notification discussions. • MoCCA website links to online partner notification tools.
	Autofill#	• Chlamydia autofill or shortcut inserted in the EMR that supports documentation of chlamydia management in the patient notes and prompts clinicians to record:

		○ Treatment provided ○ If partners were notified ○ If PDPT was provided
	Patient factsheets	• Information about notifying partners is provided to chlamydia positive patients.
	PDPT flowchart	• PDPT flowchart provides an overview of patient eligibility for PDPT, and the process of offering PDPT to eligible and willing patients.
	PDPT prescription template	• A template that can be imported into the EMR and used to generate a PDPT prescription.
	Published article	• PDPT article [39] that provides an overview of the process of offering PDPT and addresses the challenges GPs may face in its provision. • Chlamydia management article[38] outlines best practice to reduce chlamydia associated reproductive complications in women, including partner management.
Retesting	Website	• MoCCA website (or other linked resources) used to support retesting discussion.
	Patient factsheets	• Information about why retesting for reinfection is important is provided to chlamydia positive patients.
	Retesting flowchart	• Provides the rationale for retesting and some options for organising retesting.
	Postal retest	• Patient sent a postal kit by the laboratory for retesting at 3 months.
	Pathology form	• Patient provided a pathology form for retesting in 3 months' time.
	Patient recalls and reminders	• Patient placed on recall system and recalled at 3 months to return for a retest appointment **OR** • Patient placed on reminder system and sent an SMS reminder to visit a pathology collection centre for a chlamydia test
	Published article	• Chlamydia management article[38] provides information about the importance of and options for organising retesting for reinfection.
PID diagnosis	Website	• MoCCA website (and linked resources) provide key PID diagnostic considerations.
	Patient factsheets	• PID factsheet provides a definition of PID, its diagnosis and treatment. • Chlamydia factsheet provides information about symptoms that may indicate complications.
	Published article	• How to Treat PID article[37] that focuses on the diagnosis and management of acute PID in primary care. Taking the associated quiz allows clinicians to earn continuing professional development points.

Autofill, a shortcut for clinical notes for a specific condition that has been pre-populated in the EMR

Patient and public involvement

Health providers and health consumers were involved in the development of this project in a number of ways including surveys, qualitative interviews, focus groups and development and refinement of patient factsheets and health care provider resources. Our findings will be disseminated through our partner organisations including those that provide clinical care to people with a chlamydia infection and also to participating general practices.

Outcomes and data collection

Our primary trial outcomes will relate to the implementation processes and success of implementation and include acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability.[26] To measure our outcomes we will collect qualitative and quantitative data at the general practice, staff and patient level. We will also capture information about costings and effectiveness of the interventions. An overview of our data collection methods, data sources, outcomes and timepoints is provided in table 2 and table 3. Our data collection methods will include:

1. *Practice survey* - to collect baseline information about the practice's structure, staffing, EMR and other management systems, patient demographics, and work processes.
2. *Field notes and logs* – that document researcher communication (via email, telephone, in person) and support provided for participating general practices in implementing the interventions (eg. frequency, nature of support, any modifications).
3. *Minutes* – of study meetings with clinics to provide data to describe implementation procedures, and, understanding of the interventions' acceptability, usefulness and barriers and enablers to its adoption.
4. *Polls and brief surveys* – embedded in quarterly email study communications that ask staff at participating clinics 1-3 questions about the management they might provide in a short chlamydia focussed vignette or their use and views on MoCCA interventions; such as 'have you used the chlamydia autofill to help document chlamydia care in the past 3 months?'.
5. *Interviews with a think aloud component* – in which general practice staff are asked about their views about the MoCCA interventions, their usefulness, how they are integrated into the workflow and why they are or are not being adopted into practice. We will conduct approximately 40 individual or group interviews across the 20 clinics, seeking to interview at least one person from each clinic at two interview timepoints (3 and 12 months) during the intervention period. The number of interviews will take into consideration the current context at the time (eg. how busy the clinics are and staff availability for interview), as well as the richness and complexity of the data collected. Concurrent analyses will inform the need for further interviews.
6. *Patient survey* – an online survey asking patients about their experience of having chlamydia or PID diagnosed and treated at the clinic.
7. *De-identified patient attendance and clinical data* – will be collected from participating practices' EMR using GRHANITE™ (www.grhanite.com/) data extraction software and used to measure chlamydia testing, treatment, retesting, reinfection and PID diagnosis rates.
8. *De-identified laboratory data* – for mailed specimen kits will be collected from the relevant laboratory and used to determine request rates for use of postal tests in retesting, return rates and reinfection rates among those retested via this method.
9. *Google analytics* – will be collected monthly to ascertain website usage. These data will include new and total users per month, pages visited, and time spent on the website.
10. *Costs* – for resources used in delivering the MoCCA interventions that will be collected alongside the study.

Table 2 Data collection method and timepoints

Participant	**Practice**				**Provider**		**Patient**	
Data collection method	**Electronic patient data (GRHANITE)**	**Laboratory data**	**Practice survey**	**Minutes and field notes**	**Poll**	**Interview**	**Survey**	**Interview**
Study phase Establishment and implementation phase	X		X	X	X			
Operation phase	X Collected at the end of 12 month operation phase	X Collected 6 monthly		X	X 3 monthly	X 3 and 12 months	X Collected through out the 12 month operation phase	X As per patient preference

Table 3: Outcome description and data sources

Outcome type	Outcome	Description	Data collection method
Implementation	Acceptability	• Acceptability of interventions to general practice staff including a description of barriers and facilitators, how they were implemented and fit with the workflow • Patient satisfaction with chlamydia care	• Observation and field notes • Meeting minutes • Interviews • Polls and surveys
	Adoption	• Readiness to implement the intervention • Level of use of the interventions	• Interviews • Meeting minutes • Google analytics • Patient attendance and clinical data • Laboratory data
	Appropriateness	• Relevance of interventions to the general practice setting	• Interviews • Meeting minutes • Polls and surveys
	Feasibility	• Extent that the interventions are suitable for use within general practice	• Interviews • Meeting minutes
	Fidelity	Description of how the interventions: • Were implemented • Are being used	• Observation and field notes • Interviews • Meeting minutes
	Implementation costs	• Costs to implement the interventions	• Study protocols and budgets • Interviews with general practice staff
	Penetration	• Level of use of the interventions	• Interviews • Polls and surveys
	Sustainability	• Description of how the interventions are being used	• Interviews • Polls and surveys • Meeting minutes
Impact	Effectiveness	• Chlamydia testing patterns • Chlamydia re-testing rates • Chlamydia reinfection rates • Partner notification practices	• Patient attendance and clinical data • Laboratory data • Polls and surveys

		• PID diagnosis rates	

Sample size

We will implement our intervention in up to 20 general practices, gathering data on our implementation outcomes. We will conduct approximately 40 interviews with staff (either as individuals or in groups) from the 20 general practices to assess our qualitative implementation outcomes. Assuming about 20 people per clinic will be diagnosed with chlamydia during the trial, an estimated 100 patients will complete the quantitative survey, assuming a 25% response rate.

Assuming an annual chlamydia testing rate of 15%, a chlamydia positivity of 7% and average of 2000 16-44 year olds attending each practice per year, a sample size of 20 general practices will generate about 400 chlamydia cases requiring management during the 12 month operation phase.[9] This will allow us to estimate an annual chlamydia re-testing rate of 25%[19] to within a 95% confidence interval of +/- 4% (95% CI: 21% to 29%) for the 12 months pre-implementation and estimate a re-testing rate of 40% with a precision of +/- 5% (95% CI: 45% to 55%) for the 12 months after implementation, assuming re-testing increases. While this is an implementation and feasibility trial, 20 clinics should provide sufficient sample size to detect an increase in chlamydia re-testing from 25% in the 12 months prior to the trial to 40% in the 12 months following implementation, assuming an intra-cluster correlation of 0.02 , an alpha of 0.05 and power of 80%.

Data analysis

We will use a mixed-methods approach, applying quantitative and qualitative methods to assess our study outcomes. NVivo software will be used to manage and facilitate analyses of qualitative data and STATA statistical software to manage and analyse quantitative data.

Our implementation outcomes will be assessed qualitatively using content analysis[40] of data collected in the interviews, free text survey responses and meeting minutes and quantitatively through descriptive analysis. Our qualitative analysis will be largely deductive, and guided by the CFIR to understand the determinants of implementation and NPT to explain how and why changes to support new practices did or did not occur. We will establish an initial coding framework across the five CFIR domains and four NPT components. Additional codes will be developed inductively as needed. Findings from the qualitative analysis will be considered alongside findings from the descriptive analyses of quantitative data including patient attendance and clinical data, google analytics, laboratory data and survey and poll responses. Together, these qualitative and quantitative analyses will allow us to describe:

- Implementation procedures for each best practice chlamydia management intervention
- Barriers and enablers to adoption of best practice chlamydia management interventions
- How interventions and resources to support best practice chlamydia management are integrated into the general practice workflow
- Factors and behaviours associated with sustained adoption of best practice chlamydia management interventions
- The experiences of patients who were treated for a chlamydia infection

We will assess our impact outcomes to inform the design of a future large scale trial through quantitative analyses of patient attendance, clinical and laboratory data. Retesting rates will be measured as the proportion of those diagnosed with chlamydia who are retested within 2-4 months (3 months ± 1 month). Other outcomes will include chlamydia reinfection rates (proportion of those who re-test chlamydia positive) and PID rates (proportion of consultations for women aged 15-44 years with a PID diagnosis). We will assess our impact outcomes by comparing outcomes between the 12 month intervention (operation phase) and 12 month pre-intervention periods. Poisson regression models, with a binary indicator for pre- and post-implementation and adjustment for a priori defined potential confounders, and robust standard errors to account for clustering by clinic, will estimate the impact of the overall MoCCA intervention immediately post implementation (presented as a Rate Ratio (95% Confidence Interval).

Additional economic costs to implement and maintain the intervention (compared to the usual care pathway) will be estimated using trial protocols and budgets, along with interviews of general practice staff to estimate clinic staff time and other resources required to set up and deliver the intervention. We will adopt a 'health care system' perspective to estimate total costs associated with implementation of the MoCCA interventions and calculate costs for MoCCA's three components (partner notification, re-testing, PID detection) and further break this down into specific interventions (eg. mailed specimen kits). Costs will be grouped by expenditure category such as staffing or consumables and then into 'fixed' vs 'variable' costs, to tease out issues associated with throughput and capacity utilisation. Results will be presented in terms of intervention activities and used to inform subsequent mathematical and economic modelling (protocol to come) of the impact of MoCCA interventions on the population chlamydia burden to guide plans for scale up across Australian general practice.

Ethics and dissemination

Ethical approval has been obtained from the University of Melbourne Human Research Ethics Committee (Ethics ID 22665). For all survey, interview and study data in which participant details are known to researchers, the participants details will be coded using ID codes that will be stored separately from their responses in password protected participant tracking files. All digital data will be stored within a restricted-access folder on a network drive that is internal to the University of Melbourne that has access limited to selected project staff. All hard copy data will be stored in a locked filing cabinet at the University of Melbourne where it is protected with a monitored alarm. Study materials will be kept for 5 years after publication of the study results after which point, they will be destroyed. Findings will be disseminated through conference presentations, peer-reviewed publications, and study reports. All data collected and analysed will pertain to the MoCCA study only.

DISCUSSION

Amid a changing landscape of chlamydia control strategies around the world, the MoCCA study will focus on optimising clinical management of diagnosed chlamydia infections to reduce the

risk of repeat infection and chlamydia associated harms. The key areas of emphasis are on implementing interventions in the general practice setting to strengthen retesting for reinfection, partner management, and PID diagnosis. MoCCA will be implemented in Australia's mainstream primary care setting, general practice, being where most chlamydia infections are diagnosed and where the greatest gaps in care are apparent. Importantly this study will determine how best to implement best practice chlamydia management. Guided by the CFIR and NPT our mixed methods design will capture comprehensive qualitative and quantitative data, allowing us to identify the key factors to implementation and use of these interventions in general practice.

As an implementation and feasibility trial, our trial is limited by its sample size and non-randomised design. However, several components of our intervention package including PDPT[41] and re-testing postal kits[22] have been found to be effective in randomised trials. What is now needed, is to determine how they can be best implemented in general practice. Our comprehensive qualitative and quantitative data collection and analyses will allow us to measure the extent of implementation and to understand how and why the interventions are or are not implemented. The main emphasis is on understanding how best to implement these interventions in general practice rather than demonstrating their effectiveness.

The MoCCA study represents a paradigm shift in chlamydia control approaches from a focus on screening to case management. Our study's focus on general practice will provide much needed evidence about how to integrate best practice chlamydia management in the setting where most chlamydia infections are diagnosed in Australia. Our results will have relevance to other similar primary care settings in other countries where chlamydia screening, diagnosis and management take place. Beyond this trial, our findings will feed into mathematical and economic modelling which will explore the cost and impact of MoCCA interventions on a population level and inform a scale-up plan for general practice with potential to improve management for many thousands of Australians diagnosed with chlamydia each year.

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Exclusive licence

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