NSW Government-Sponsored Clinical Trial: Extended supply of Oral Contraceptive Pills (OCPs) by Community Pharmacists (Intervention study)

Research Protocol

The George Institute for Global Health in partnership with University of Newcastle, the Hunter Medical Research Institute and research consortium

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Contents

1. Administrative information

1.1 Funding

NSW Health is funding the development, implementation, and monitoring of the trial through a grant awarded to a consortium of universities and academics led by Chief Investigator, Dr Sarah Dineen-Griffin from the University of Newcastle, titled *NSW Government-Sponsored Clinical Trial: Management of Urinary Tract Infections by Community Pharmacists to include oral contraception and management of minor skin conditions*. This protocol is to undertake the Intervention study for oral contraception.

1.2 Roles and Responsibilities

1.3 Investigators

The George Institute for Global Health, UNSW Sydney

Name	Project Role	Position, Affiliation	Contact details
Prof David Peiris	Chief investigator (Intervention study evaluation)	Chief Scientist (acting), Director Global Primary Health Care Program	dpeiris@georgeinstitute.org
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University of Newcastle

Name	Project Role	Role, Affiliation	Contact details
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Hunter Medical Research Institute

Name	Project Role	Position, Affiliation	Contact details
Associate Professor Penny Reeves	Health Economist	Associate Director, Health Research Economics Hunter Medical Research Institute & Conjoint Associate Professor, School of Medicine and Public Health, College of Health, Medicine and Wellbeing	penny.reeves@hmri.org.au

Additional Chief Investigators

Name	Position	Organisation
Emeritus Professor Shalom (Charlie) Benrimoj	Co-investigator	Emeritus Professor, The University of Sydney
Associate Professor Kris Rogers	Associate Professor in Biostatistics at University of Technology Sydney, Honorary Senior Research Fellow at The George Institute for Global Health	University of Technology Sydney/ The George Institute for Global Health
Emeritus Professor Julie Byles AO	Emeritus Professor, Research Centre for Generational Health and Ageing, College of Health, Medicine and Wellbeing & Director of the Centre for Women's Health Research & Gerontologist	The University of Newcastle & Hunter Medical Research Institute
Dr Indy Sandaradura	Staff Specialist in Infectious Diseases & Clinical Microbiology, Centre for Infectious Diseases and Microbiology Clinical Senior Lecturer, The University of Sydney School of Medicine	Centre for Infectious Diseases and Microbiology, Westmead Hospital and the Children's Hospital at Westmead
Dr Leanne Holt	Pro Vice-Chancellor Indigenous Strategy	Macquarie University
Dr Kylie Gwynne	Director of Research, Department of Health Sciences, Faculty of Medicine, Health and Human Sciences, and Member, Centre for Global Indigenous Futures	Macquarie University
Professor Kylie Williams	Head of Pharmacy, Faculty of Health	University of Technology Sydney
Dr Helen Benson	Senior Lecturer, Pharmacy, Faculty of Health	University of Technology Sydney
Ms Anna Barwick	Lecturer in Pharmacy, University of New England	University of New England
Associate Professor John Rae	Head, School of Dentistry and Medical Sciences	Charles Sturt University
Dr Joanna Moullin	Senior Research Fellow, School of Population Health Deputy Director WA Country Health Service (WACHS)-Curtin Research and Innovation Alliance Implementation Science Program Lead | Enable Institute	Curtin University
Ms Jan Donovan	Consumer representative	Independent
Dr Terri Foran	Sexual Health Physician and Subject Matter Expert	Independent

Research Staff and Students

Simone Diamandis	Project Manager and Doctoral Candidate	University of Newcastle
Mitchell Budden	Doctoral Candidate	University of Newcastle
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Dr Joy Bowles	Research Assistant	University of New England
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1.4 Steering committee

The Project Steering Committee for the study will comprise representatives from partner organisations. The role of the Project Steering Committee is to provide oversight to the study and advice on the development, implementation, and evaluation of the study.

Role	Person	Organisation
Chair	Ms Jan Donovan	Independent Chair
Committee Member	Dr Sarah Dineen-Griffin	Chief Investigator (Lead), The University of Newcastle
Committee Member	Emeritus Professor Charlie Benrimoj	Chief Investigator
Committee Member	Professor Charlotte Hespe	The Royal Australian College of General Practitioners NSW
Committee Member	Mr Chris Campbell	Pharmaceutical Society of Australia
Committee Member	Ms Catherine Bronger	Pharmacy Guild of Australia NSW
Committee Member	Dr Yann Guisard	Rural Doctors Network NSW
Committee Member	Mr Richard Samimi	Pharmacy Council NSW
Committee Member	Ms Jess Hadley	Pharmaceutical Defence Limited NSW
Committee Member	Dr Kylie Gwynne	Macquarie University
Committee Member	Mr Daniel Gilbertson	Deloitte Australia
Committee Member	Prof David Peiris	The George Institute for Global Health
Committee Member	Dr Elizabeth Deveny	Consumer Health Forum
Observer	Dr Jan Fizzell	NSW Ministry of Health
Secretariat	Ms Simone Diamandis	Research Project Manager

1.5 Glossary of abbreviations and terms

APDC	Admitted Patient Data Collection
CFIR	Consolidated Framework for Implementation Research
ED	Emergency Department
EDDC	Emergency Department Data Collection
EPA	Extended Practice Authority
GDS	George Data Systems
GP	General Practitioner
HREC	Human Research Ethics Committee
ID	Identification
MBS	Medicare Benefits Schedule
MMM	Modified Monash Model
NPT	Normalisation process theory
NSW	New South Wales
OC	Oral Contraception
OCP	Oral Contraceptive Pill
PSA	Pharmaceutical Society of Australia
PBS	Pharmaceutical Benefits Scheme
SEIFA	Socioeconomic indexes for area
TGI	The George Institute for Global Health
UoN	University of Newcastle

2. Protocol Synopsis

On 19 February 2023, the NSW Government announced that its pharmacy prescribing trial would be expanded to include the provision of the oral contraceptive pill (OCP) for women 18-35 years.

The overall aim of this study is to evaluate the clinical and economic impact and implementation of a service model (intervention) delivered by community pharmacists in NSW and 5 pharmacies in ACT, re-supplying specific oral contraceptive pills for a specific patient cohort over a 12-month study period. Women must be aged between 18 to 35 years (inclusive), taking the pill for contraception purposes only, and has seen their GP/nurse practitioner for a review of their low-risk oral contraceptive pill in the last two years.

The specific objectives of this study are to:

1. Assess the accessibility and acceptability for patients managed and/or supplied a low risk contraceptive pill by community pharmacists.
2. Assess implementation uptake of the intervention including the reach, fidelity and adoption of the intervention in community pharmacies, participant characteristics, and variation in uptake by geographic region.
3. Assess the clinical outcomes and patient experience for patients managed by community pharmacists.
4. Assess the safety of the intervention and identify any risks that need to be addressed for future implementation.
5. Qualitatively assess the acceptability and feasibility of the intervention to pharmacists, other care providers and participants using the service.
6. Identify contextual enablers and constraints to access, adoption, fidelity delivery, impact, sustainability, and generalisability of the intervention.
7. Conduct a health economic evaluation to determine the economic benefits.

The study will use a cohort study design to assess the clinical and economic and implementation of the intervention in NSW and ACT over a 12-month study period. The intervention is multicomponent including Pharmacist training and support and a Pharmacy consultation, using an IT program, applying one of two clinical management protocols. Pharmacies and pharmacists must meet the criteria of an 'approved pharmacy' and an 'approved pharmacist' outlined in the NSW Health Authority, or a licence in ACT, to participate.

Primary outcomes will be accessibility and acceptability of the service (based on self-report at 7-day follow up). This will be a composite measure based on patient self-reported data. It includes seven items adapted from existing questionnaires, including a validated questionnaire for perceived service quality in community pharmacies (two items) and studies of pharmacy prescribing for oral contraception, and other medications [1-6]. It will cover the following domains: (a) trust and confidence in health and medical advice provided, (b) convenience, (c) privacy during discussion with pharmacy, and (d) overall satisfaction. Each item is scored on a 7-point Likert scale. Each domain will be equally weighted, and an aggregated score calculated and scaled to a maximum score of 100. Semi-structured interviews with pharmacists and other stakeholders will be conducted to better understand barriers and facilitators to implementation of the service.

3. Introduction

3.1 Background to community pharmacy prescribing

On an international and national basis, the scope of practice for community pharmacists is evolving rapidly. The NSW and ACT Governments have recognised this expanded role community pharmacists could play. The broad approach is to increase the community's access to primary care through:

1. Authorising pharmacists to administer a wider range of public health and travel vaccinations from 14 November 2022, including Japanese Encephalitis, Hepatitis A and Hepatitis B, Poliomyelitis, Typhoid and Zoster.
2. Funding a 12-month trial to evaluate allowing pharmacists to manage uncomplicate urinary tract infections in a specified cohort of females.
3. Funding a 12-month trial to evaluate allowing pharmacists to extend the supply of certain low risk oral contraceptive pills (OCPs).
4. Supporting a state-wide trial where appropriately trained pharmacists can prescribe medications for certain conditions, such as skin ailments [7].

This study protocol refers to the third goal above.

Contraception plays a pivotal role in the well-being and health of women permitting individuals control over their sexuality, fertility, and reproductive choices [8]. The public health and development impact of contraception is well established and so profound that access to contraception is now considered an essential element of the human right to health in the international community [8]. Contraception improves birth outcomes, slows population growth, and improves socioeconomic status [8]. Despite the proven effectiveness and benefits of contraception, advances in contraceptive technology, and the recognition of contraceptive access as a basic human right, the international community is said not to have achieved universal access to contraception [8].

Barriers to access are one reason for inconsistent or non-use of contraception [9, 10]. There are several barriers such as the requirement for a prescription that can prevent women from continuing their contraceptive method of choice [10]. As stated in The Senate Community Affairs References Committee; Ending the postcode lottery: Addressing barriers to sexual, maternity and reproductive healthcare in Australia (May 2023), other key reported obstacles include: regulatory restrictions limiting the role of pharmacists, inadequate incentives for medical practitioners to bulk-bill, contraceptives not available on the PBS, high financial costs, and limited access in rural and remote regions and First Nations communities [10].

Expanding access to contraception allows individuals to safely space and limit their pregnancies and reduces unintended pregnancies, maternal morbidity and mortality [8, 10]. It is accepted at an international level that there is significant potential to increase access to prescription contraceptives in a cost-efficient manner by expanding the scope of practice among a range of allied health professionals, including pharmacists, who with the appropriate training, could help provide contraceptive care [11]. Studies have established that women can self-screen and non-physicians can safely assess for medical contraindications to OCP use [12-16].

Authorising pharmacists to facilitate the continuation of oral contraception in community pharmacy has been shown to be an effective strategy that can increase access to contraception [17]. There is evidence from several countries that suggests pharmacists are well positioned to facilitate the initiation and continuation of hormonal contraception in certain cohorts within the community pharmacy setting. It has become usual practice in some states of the USA [18-28], several regions of the UK [29-32], some provinces in Canada, and New Zealand [33]. Pharmacist supply and continuation of OC offers several advantages, including the alleviation of logistical challenges such as time for appointments, scheduling difficulties, and costs [17]. In addition, pharmacist supply for continuation of contraception can increase access to contraceptives through offering more convenient locations, extended hours of operation, and ability to avoid gaps in medication use when away from home [10, 17]. It is widely believed that since consumers do not require an appointment and pharmacies have expanded hours and locations, direct OCP access through pharmacies may improve contraceptive continuation rates over the traditional standard of care pathway, which requires a clinic visit with a physician or advanced practice clinician [12]. Improving continuation rates may also minimises the risks associated with non-continuance VTE risk.

Moreover, as previously stated by enhancing accessibility to contraceptives, this approach has the potential to effectively decrease unintended pregnancies. It is estimated that one in four Australian women experience an unintended pregnancy during their lifetime, with rates even higher in non-urban areas [10]. Unintended pregnancies are defined as either mistimed (pregnancy occurs earlier or later than desired) or unwanted (pregnancy occurs when no or no more children are desired) [10, 34]. Unintended pregnancies can place

significant physical, social and financial strains on women and their families [10]. This is a major health issue and an area of unmet demand for Australian women [10].

In the Australian context, the NSW and ACT Government have committed to examining the impact of the supply of low-risk oral contraceptive pills to eligible women by community pharmacists under a trial framework to capture robust outcome data to inform the future scope and role of community pharmacists. The implementation of a large-scale trial across NSW (and 5 pharmacies in the ACT) will assist the State Government in better understanding the impact of the service for a specific patient cohort [35].

3.2 Aim and objectives

3.2.1 Aim

The overall aim of this study is to evaluate the clinical and economic impact and implementation of a service model (intervention) delivered by community pharmacists in NSW and 5 pharmacies in ACT, re-supplying specific oral contraceptive pills for a specific patient cohort over a 12-month study period. Women must be aged between 18 to 35 years (inclusive), taking the pill for contraception purposes only, and has seen their GP/nurse practitioner for a review of their low-risk oral contraceptive pill in the last two years.

3.2.2 Objectives

Specific objectives are to:

1. Assess the accessibility and acceptability for patients managed and/or supplied a low risk contraceptive pill by community pharmacists.
2. Assess implementation uptake of the intervention including the reach, fidelity and adoption of the intervention in community pharmacies, participant characteristics, and variation in uptake by geographic region.
3. Assess the clinical outcomes and patient experience for patients managed by community pharmacists.
4. Assess the safety of the intervention and identify any risks that need to be addressed for future implementation.
5. Qualitatively assess the acceptability and feasibility of the intervention to pharmacists, other care providers and participants using the service.
6. Identify contextual enablers and constraints to access, adoption, fidelity delivery, impact, sustainability, and generalisability of the intervention.
7. Conduct a health economic evaluation to determine the economic benefits from the intervention.

4. Methods

4.1 Study hypothesis

The study hypothesis is that an intervention (OCP service) delivered by community pharmacists for women 18-35 years will be acceptable to participants and providers, accessible, cost-effective and not associated with increased safety risks.

4.2 Study design

The study hypothesis will be tested using a cohort study design, applying mixed methods (quantitative and qualitative research) to assess clinical and economic indicators, implementation, and patient experience.

4.3 Pharmacy recruitment

This state-wide study and as part of the contract with the NSW Government, the researchers are obliged to include any approved pharmacy and approved pharmacist in NSW that request participation. Furthermore, as part of the Contract with NSW Health, we have agreed to include 5 pharmacies in the ACT.

In the first instance, the NSW Ministry of Health created an expression of interest (EOI) form on their website (https://www.health.nsw.gov.au/pharmaceutical/Pages/community-pharmacy-pilot.aspx) to which pharmacies were encouraged to complete if interested in participating. Similarly, the Pharmacy Guild of Australia (NSW Branch) and Pharmaceutical Society of Australia (NSW Branch) completed a similar process in seeking EOIs to participate in the research. Details were forwarded to the research team with consent. Pharmacies who submitted an expression of interest were assessed to ensure they meet the eligibility criteria for the project.

NSW pharmacies

The contractual arrangements with the NSW Ministry of Health oblige us to offer participation to all New South Wales pharmacies who had consented to the previous trial (UTI) (ACTRN12623000882628). A formal recruitment letter will be sent via email to those 1109 pharmacies who had already previously consented, including the Participant Information Sheet and Consent forms for both Pharmacy and Pharmacist requesting involvement to be signed and returned electronically (Appendix 5-12). Consent will be sought at the pharmacy level from pharmacy owners, and from the individual pharmacists in those pharmacies consenting to participate in the study.

Pharmacies will be sent Participant Information Sheet and Consent forms electronically via DocuSign and have requested individuals to accept the invitation after 10 days. Pharmacies who do not consent in the timeframe will be sent a follow up, 10 days after the initial invitation. For pharmacies/pharmacists who indicate via email they would like further information or clarification, a follow up email and/or phone call will be made by a member of the research team using a standardised script (Appendix 13).

ACT pharmacies

As per the process in NSW, the 5 participating pharmacies in ACT, which were previously randomly selected to ensure a geographic spread of participation across regions, will be sent a formal recruitment letter including the Participant Information Sheet and Consent forms for both Pharmacy and Pharmacist was sent.

The ACT legislation process has been determined by the acting Chief Pharmacist in ACT. Whilst in NSW the Chief Medical Officer signs an Authority for the change, a licence application will need to be made by participating pharmacies. The discretionary licence (available via PDF) would be issued to authorise the 5 pharmacies in the ACT to participate in the trial (Appendix 29). Further details on the licensing can be found on the ACT website: https://www.health.act.gov.au/businesses/medicine-and-poisons-licences-and-permits

4.3.1 Pharmacy and pharmacist eligibility criteria

Pharmacies and pharmacists recruited must meet the eligibility criteria (defined below) to participate in the study, reflecting the criteria set by Authority under Section 10 Poisons and Therapeutic Good Act 1966 Clauses 170 and 171 of the Poisons and Therapeutic Goods Regulation 2208 (please see the NSW Health Authority – Appendix 1- signed by the Chief Medical Officer). All the pharmacies that have expressed an interest to participate will be sent a copy of the Authority. A summary is detailed below:

1. **Community pharmacies**
    - A community pharmacy in NSW or ACT must have a service room, consulting room, or area consistent with the following (as per the Authority):
        - "Ensures the room or area is not to be used as a dispensary, storeroom, staff room or retail area,

- fully enclosed and provides adequate privacy (a divider or curtain in a dispensary, storeroom, staff room or retail area is not acceptable),
- has adequate lighting,
- is maintained at a comfortable ambient temperature,
- has a hand sanitisation facility,
- has ready access to a hand washing facility, and
- has sufficient floor area, clear of equipment and furniture, to accommodate the person receiving the consultation and an accompanying person, and to allow the pharmacist adequate space to manoeuvre."

Pharmacies must have access to MedAdvisor to complete clinical record keeping for the purposes of the clinical trial assessment.

2. **Pharmacists**
    - A community pharmacist holding general registration employed or engaged in an eligible participating pharmacy in NSW and ACT and:
        - who has successfully completed the following training:
            - Australasian College of Pharmacy Continuation of Oral Contraception Course; or
            - Pharmaceutical Society of Australia NSW – Contraception Essentials; and
            - Training module(s) that have been approved by the Chief Heath Officer for the purposes of the clinical trial.

A pharmacist is eligible to participate if they hold general registration as a pharmacist with the Australian Health Practitioner Regulation Agency (AHPRA). Pharmacists with provisional registration (intern pharmacists) and pharmacists with conditions on their registration are not eligible to participate in the trial. The pharmacy must have at least one eligible pharmacist who is willing to provide their voluntary consent to participate, for the pharmacy to be eligible, and that there is always a pharmacist available, within reason, to deliver the service during all opening hours of the pharmacy.

4.4 Participant recruitment

A flyer has been developed and approved by the NSW Ministry of Health to inform patients of the service and will be displayed in a prominent location in each participating pharmacy. Female patients will be identified on presentation to the community pharmacy requesting re-supply of their oral contraceptive pill. If meeting the below inclusion criteria, the pharmacist will make an offer to the individual to participate in the study. Patients will be asked for their informed consent to participate in the study via an electronic signature (Appendix 15-18).

4.4.1 Participant consent

All participants will require informed consent. Participants will be provided with two consent forms (one for the study and a second form from Services Australia allowing access to MBS and PBS data). They will be given the option of separate consent. The pharmacist will provide the participant with a location specific QR code for scanning on their mobile phone. This will open a secure webform hosted by the George Institute. The participant will then enter their personal details and be asked to review and tick the boxes. They will then provide a finger signature on a signature panel on the screen and click submit for secure submission to The George Institute. The participant will be sent an SMS or email confirmation message with a validation code which they will provide to the pharmacy.

If participants wish to withdraw from the study once it has started, they can do so at any time without having to give a reason. Withdrawing from the study will not affect their relationship with their employers, professional organisations, care providers or receipt of any care or treatment. Participants wishing to withdraw should notify their pharmacist or one of the research team. Once a participant decides to withdraw from the study, no further information will be collected from them. Their information will be removed from study records and will not be included in the study results.

4.4.2 Participant inclusion criteria

Eligible participants must meet all the following criteria, which are included in the clinical management protocols (Appendix 1 & 2):

- Natal, cis females (capable of pregnancy).
- Aged 18 years of age or over and up to and including aged 35 years.
- Present to community pharmacies in NSW or pharmacies in ACT to obtain a continuing supply of their previously prescribed oral contraceptive pill.
- Patient has been initiated on an oral contraceptive pill by their GP (or other authorised prescribing health care professional) primarily for the indication of contraception and has been stabilised on that pill for 2 years continuously.
- Patient is taking an approved oral contraceptive pill listed in the NSW Health Authority.
- Patient has seen their GP (or other authorised prescribing health care professional) for a review of their oral contraceptive pill in the last 2 years.

4.4.3 Participant exclusion criteria

- Individuals who are not female.
- Aged <18 years or >35 years.
- Patient has not been initiated on an oral contraceptive pill by their GP (or other authorised prescribing health care professional).
- Patient is not taking an approved oral contraceptive pill listed in the NSW Health Authority.
- Patient has not seen their GP (or other authorised prescribing health care professional) for a review of their oral contraceptive pill in the last 2 years.

See clinical management protocols (Appendix 1 & 2) for further details.

4.5 Intervention description

The intervention is multicomponent.

4.5.1 Pharmacist training and support

Prior to service delivery, pharmacists will be prepared through a clinical training program (either through the Australasian College of Pharmacy or Pharmaceutical Society of Australia) to apply best practice standard of care. Furthermore, study specific training modules developed by the research team will be completed by pharmacists to ensure efficiency in the consultation process, patient consent, recruitment of patients, timely referral, and quality data collection.

4.5.2 Pharmacy consultation

The pharmacist will undertake a structured consultation with the patient in the community pharmacy guided by an IT program applying one of two clinical management protocols (Combined Oral Contraception and Progestogen-Only Contraception) which encompasses the recommendations from the Australian Therapeutic Guidelines. The clinical management protocol has been subject to co-design between community pharmacists and senior general practitioners with advice from a subject matter expert. This consultation is anticipated to take 10 minutes.
The intervention is provided under the NSW Health Authority allowing participating NSW pharmacists to supply medications as part of the trial. For the ACT, a discretionary licence will be approved for participating pharmacies.

The structured consultation is summarised in Box 1.

BOX 1

- Participant eligibility assessment, in which the pharmacist will assess if the patient meets the inclusion/exclusion criteria to participate in the study.
- Service offering, during which the pharmacist will explain the features of the study and will ask the patient if she/they is willing to participate.
- Electronic provision of the Patient information sheet and informed consent form.
- Patient's clinical assessment. During the assessment the pharmacist will elicit relevant clinical information, including medical conditions, medication history, in line with agreed clinical management protocols. If the patient is a usual patient of the pharmacy, their medication dispensing history may be checked on the computer record, if not the patient medications will be asked. Further information may be obtained from the patients' Electronic Health Record (EHR). Viewing a patients EHR is legally and professionally allowed by pharmacists, with patient consent.
- Clinical measurements of Blood Pressure and BMI will be documented at the initial patient consultation.
- After the clinical assessment, the pharmacist will use one of two clinical management protocols to proceed to resupply.
- Pharmacists may supply a continuation of the oral contraceptive pill (minimum 1 month, and up to 12 months' supply) provided the patient has seen a general practitioner (or other authorised prescribing health care professional in the last 2 years. Pharmacists are not permitted to initiate or change therapy.
- Non-pharmacological management may include:
    - Referral to see their medical practitioner, Family Planning or Sexual Health Clinic for maintaining regular women's health and sexual/reproductive health checks.
    - Counselling on the importance of getting regular cervical screening tests, breast checks, and STI testing done.
    - Counselling on the OCP supplied, i.e.,
        - How to take the OCP;
        - What side effects to expect when taking the OCP;
        - How to manage adverse effects from the OCP;
        - When the OCP is less effective;
        - What to do in event of a missed pill.
    - Provision of a Consumer Medicines Information sheet.
    - Provision of advice if they patient has any concerns regarding the OCP.
    - Provision of advice and referral, of there is a concern that the patient may be at risk for or could have contracted a sexually transmitted disease through unprotected sex, an/ or if the patient indicates that she has been sexually assaulted.
- The pharmacist will facilitate appropriate and timely referral, if required.
- The pharmacist will share a record of the supply with the patient's usual treating medical practitioner or medical practice (via fax, secure messaging software, provision of a letter to the patient, or any other approved secure means by NSW Health), where the patient has one, following consent by the patient.
- The pharmacist complies with the 'Management Protocols', including that the pharmacist makes a record of the consult in MedAdvisor pharmacy software, or an approved system by the Ministry of Health.
- The pharmacist must keep a clinical record for 7 years that contains:
    - sufficient information to identify the patient;
    - the date of the treatment;
    - the name of the pharmacist who undertook the consultation;
    - any information known to the pharmacist that is relevant to the patient's diagnosis or treatment (for example, information concerning the patient's medical history);
    - any clinical opinion reached by the pharmacist;
    - actions taken by the pharmacist;

- particulars of any medication supplied for the patient (such as form, strength and amount);
- notes as to information or advice given to the patient in relation to any treatment proposed by the pharmacist who is treating the patient;
- any consent given by a patient to the treatment proposed.

- Any medications will be dispensed via pharmacy dispensing software and labelled according to the legislative requirements outlined in the Poisons and Therapeutic Goods Regulation 2008.
- The pharmacist will remind the patient they will be followed up by the research team at 7 days. There will be patient reminders if no response, at days 9, 11 and 13 days, with a maximum of 5 attempts.

4.5.3 Implementation strategy

There will be follow up training and ongoing support as part of a translational/implementation strategy through the study period. Practice change facilitators will visit participating pharmacies to provide ongoing support, answer any queries, ensure quality data is being collected, and collect implementation data. The implementation component of the study will be underpinned by the Consolidated Framework for Implementation Research (CFIR), with the use of an adapted implementation model for community pharmacy. Implementation factors (barriers, causes and facilitators) and the Dougherty strategy classification systems, adapted to community pharmacy, will be used.

4.5.4 Considerations for the delivery of the intervention

Cost to patients

NSW - The cost of the consultation with patients ($20) will be paid for by the NSW Government to pharmacies, irrespective of the outcome of the consultation. The patient will meet out of pocket expenses for any medicines or products provided.

ACT - The cost of the consultation with patients will be paid for by the patient receiving the service to pharmacies, irrespective of the outcome of the consultation. The patient will also meet out of pocket expenses for any medicines or products provided.

Legislative considerations

NSW - The legislative approval required for the trial has been developed and executed by the NSW Ministry of Health.

ACT - The ACT legislation process has been determined by the acting Chief Pharmacist in ACT. Whilst in NSW the Chief Medical Officer signs an Authority for the change, a licence application will need to be made by participating pharmacies in ACT. The discretionary licence (available via PDF) would be issued to authorise the 5 pharmacies in the ACT to participate in the trial (Appendix 29). Further details on the licensing can be found on the ACT website: https://www.health.act.gov.au/businesses/medicine-and-poisons-licences-and-permits

Professional indemnity for pharmacists

Pharmaceutical Defence Limited (PDL) is the major provider of professional indemnity and will cover pharmacists as part of their normal indemnity for delivery of this service. Guild Business will cover the liability from the perspective of the pharmacy premises.

4.6 Data sources

4.6.1 Community pharmacy data

During implementation of the intervention, information on health service delivery and program activities will be routinely captured in a case registration form by community pharmacists using the MedAdvisor application which is built into pharmacy software systems. For the purposes of evaluation and study participants (pharmacies and patients) will be assigned a unique study identification number.

The following information will be collected by the community pharmacists:

1. Name of patient
2. Age
3. Address
4. Documented weight, height, and BP on initial contact.
    - BP and BMI will be documented at the first consultation
5. The name, dose, quantity, and manufacturer of the hormonal contraceptive dispensed or administered by the pharmacy
6. The date of dispensing
7. Name of prescriber
8. The name, address, telephone number of the pharmacist (address and phone number of the principal place of practice of the pharmacist is sufficient)

4.6.2 Participant (patients) self-reported data

Participants will be assessed at the registration visit (consultation) described above and this will include basic demographic and clinical information. Those assessed as eligible to participate in the trial will be followed up at Day 7 post registration to assess outcomes. This will include a brief survey administered by the George Institute either via SMS message or phone call with a link to a case report form using George Data Systems (GDS). Appendix 19 provides the case report form for the 7-day follow-up visit.

4.6.3 Implementation data

Practice change facilitators: The collection of the implementation data will be undertaken through visits/contacts (approximately monthly) within the resources available depending on the final number of community pharmacies participating, by practice change facilitators employed as part of the project. An open-ended discussion which, depending on the mode of contact, will vary between 10 to 20 minutes (see Appendix 23 for an implementation checklist to be used by practice change facilitators). Data will be collected using a pre-developed form in REDCap. Practice change facilitators will be trained by an implementation expert on models and frameworks of implementation science with an emphasis on the application of these to this specific study and the use of the checklist for data collection purposes.

Semi-structured interviews: The perspectives and experiences of community pharmacists and participants (patients) will be captured at 6 months and 10 months using semi-structured interviews undertaken by the George institute . Perspectives of other stakeholders will also be sought including general practitioners, professional bodies including the Pharmacy Guild, Pharmaceutical Society of Australia and the Royal Australian College of General Practitioners, and NSW Health administrators.

A maximum variation sampling technique will be used to select a diverse range of pharmacies and patients for interviews, taking into consideration pharmacy level factors such as geography, pharmacy size and participant level factors such as age, geography, presence of comorbid conditions, income status. It is anticipated that around 50 interviews in total will be conducted, however, the final sample size will be determined when it is considered the research team have achieved thematic saturation and few new themes are emerging from the interviews.

For participants (patients), interview questions will focus on experiences of health care and awareness and perceptions of services (Appendix 21). They will take no longer than 45 minutes. For community pharmacists and other stakeholders', questions will focus on implementation and contextual factors which may influence

program outcomes [36-39], sustainability, staff experiences and motivation to engage in the prescribing model (Appendix 26). These interviews will take up to 1 hour.

Data collection will be conducted by members of the research team who are experienced in qualitative research methods. These sessions will take place via telephone, videoconferencing (e.g., Zoom or MS teams), or face-to-face at a community pharmacy, depending on the participants' preference and feasibility and other factors at the time. All sessions will be audio-recorded and transcribed and detailed field notes recorded.

4.6.4 NSW Ministry of Health data

NSW Health will establish a public health register for the purposes of evaluating the trial. The NSW Public Health Act 2010 allows for the Minister for Health to establish public health or disease registers to follow up the care and treatment of patients; for infection control and disease outbreak investigations; disease risk factor monitoring in the population; monitoring the outcomes of population health interventions; and monitoring exposure to chemicals or environmental risk factors. The Centre for Epidemiology and Evidence establishes and manages a range of ad hoc and ongoing registers. Participants will be requested at registration to provide consent to access their data for the evaluation.

4.6.5 Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data

Participants will be requested at registration to provide consent to access their MBS and PBS data for the evaluation. The Services Australia approved patient and information consent form (Appendix 23) will be used to seek consent. Participants will have the option of authorising Services Australia to provide their claim history for MBS, PBS or both.

As the study will be examining how the use of this service impacts consistency of oral contraception adherence, a 3-year lookback will be requested for PBS data. This will allow analysis of prescribing and dispensing habits over multiple prescribing and refill cycles and to assess discontinuation rates pre and post introduction of the service as a proxy to assessing adherence gaps.

4.7 Data management

Only authorised personnel acknowledged and approved by the Human Research Ethics Committees will have access to study data. All study files will be retained for a minimum of 15 years at respective study sites in accordance with the Australian Code for the Responsible Conduct of Research. The final evaluation dataset will be archived at the completion of the project resulting in a single primary data source being retained at the University of Newcastle.

4.7.1 Community Pharmacy Data

Participating pharmacies will record the patient consultation data in a software application (MedAdvisor) installed in each pharmacy. The data are stored centrally on a secure server hosted by MedAdvisor. MedAdvisor will generate an extract of community pharmacy data, and this will be transferred securely to the research team (University/The George Institute) via one of the following ways:

1) Shared via an AWS S3 and The George Institute/University provided with an Access Key/Secret Access
2) Machine-to-Human e.g., a csv that is sent via secure message platform Kiteworks.

Data files will include patient identifiers (Medicare number, patient name, contact details and date of birth), the study identification number, and information collected at the registration visit. Upon receipt of data transfers, the George Institute research team will store the data files on secure servers (more detail below).

4.7.2 Participant self-reported data

7-day follow-up visit data will be collected on GDS case report forms hosted by the George Institute. Participants will be identified only by their study identification number and no identifying information will be collected on these forms.

4.7.3 Participant interviews

Participants will be asked during their consenting process if they may be contacted by the research team with an invitation to participate in an interview. It is not expected that interview topics will cause any harm or distress to participants. During interviews if a participant does experience discomfort from the topics discussed or recollection of their health care experiences, they can ask to stop or pause the interview or skip any questions. If patient/carer participants raise any concerns or have question about symptoms or their health care, they will be directed to discuss this with their usual health care provider or a patient support line. To minimise inconvenience participants will be i) invited to complete the interview at a time best suited to them; ii) patients/carers will be offered a voucher of $20 in recognition of the time taken out of their usual day to participate. Private providers such as Pharmacists and GPs will be offered a $50 voucher for their time, while public health providers, and administrative and service managers will be interviewed within standard working hours, requiring no further compensation as standard practice.

4.7.4 Implementation data

Practice change checklists: Data from the checklists developed by Practice Change Facilitators will be entered into Redcap. A deidentified file including only pharmacy identification number will be securely sent by the UoN research team to the George Institute for analysis.

Interviews: Lists of patient participants that expressed they are willing to be contacted for an interview on the consent form will be generated. A diversity sample will be constructed from these lists to include a range of socio-economic status, living situation (independent/ other), morbidities and engagement with the initiative. Lists of health system administrators and providers will include those directly or indirectly involved in the initiative. The study team will contact eligible participants to invite them to participate and request a time for an interview/focus group. Non-responding eligible participants will be followed up a maximum of two times. At the scheduled interview all participants will be given a full explanation of the study by the research team and provided with an opportunity to ask questions. Consenting participants will be allocated the unique study ID number generated at the baseline registration visit. Interview data will include files of audio and video recordings and transcripts of interviews/focus groups. Audio or videoconference files of interviews will be transcribed verbatim by a professional transcription service after a confidentiality agreement has been signed.

4.7.5 NSW Health Data

The George Institute will provide NSW Health with a list of study participants recruited at each site. This will include a study identification number generated at registration into the trial and the following identifiers: name, date of birth, address. NSW Health will then extract information for these participants on the variables listed in Appendix 28. The data period will include 12 months prior to the study registration date up to the most recent data available in the NSW Health data collections. A deidentified file including only the participant study ID number will then be sent to the George Institute for Global Health using a secure file transfer protocol.

4.7.6 MBS/PBS data

A file of study participants including study identification number and the approved consent forms will be sent to Services Australia for obtaining the claims history for MBS and PBS data.

4.8 Data flow and storage

Table 1 summarises the data sources and flow:

Data	Type	Source	Custodian	Flow	Ethics/ governance considerations
Community Pharmacy registration data	Identified, + participant study ID	Community pharmacy (MedAdvisor)	- MedAdvisor -The George Institute (TGI) -The University of Newcastle (UoN)	-MedAdvisor send identified data to TGI and UoN	-University of Newcastle (UoN) HREC approval -Data access agreement between UoN, TGI and MedAdvisor
Participant 7-day follow-up data	Deidentified, + participant study ID	GDS form hosted by TGI	-TGI	-Data retained by TGI and shared with UoN	-UoN HREC approval
Implementation data	Pharmacy ID Participant study ID	Community pharmacists and participants	-UoN -TGI	-Checklists entered into pre-prepared REDCap form -Interviews professionally transcribed and stored on UoN/TGI password protected server -Data retained by UoN/TGI and not sent to other parties	-UoN HREC approval
NSW Health data	Deidentified, + participant study ID	TGI	-TGI -NSW Health	-TGI sends NSW Health a list of participants -NSW Health sends to Centre for Health Record Linkage (CHeReL) -CHeReL sends deidentified data with participant ID to TGI	-UoN HREC approval -NSW Health establishes a Public Health Register -Data access agreement between TGI and NSW Health
MBS/PBS	Identified data + participant study ID	Community pharmacy (MedAdvisor)	-TGI -Services Australia	-Pharmacy/ MedAdvisor sends paper/electronic Services Australia consent form to TGI --TGI prepares file including participant ID to send to services Australia with electronic/ scanned consent forms -Services Australia	-UoN HREC approval -Services Australia External Request Evaluation Committee

				sends deidentified data with participant ID to TGI	

MedAdvisor is a ISO27001 credentialled company. This information security standard governs the company's handling of how personally identifiable information and health data is securely recorded and stored. Information is accessed by researchers via an extension of the company's information security management system and will be underpinned by a data sharing agreement. Functionally, researchers will be provided data via a secure machine to machine integration or a secure machine to human process. The company utilises the secure transfer software Kiteworks for this purpose. Pharmacy data is restricted within the pharmacy in alignment with the company's existing Pharmacy Licencing Agreement and the ISO27001 framework. The company offers on-premises software to support this data handling.

The George Institute policies pertaining to the secure transfer and storage of study materials and data will be followed. TGI's secure infrastructure is physically located in an ISO 27001 certified data centre in Sydney. Technical controls include access via encrypted network connections, multi factor authentication, data storage on encrypted disks, encryption of all offsite backups, discretionary access controls on project data folders, micro-segmented next generation firewalls, together with a Security Information and Event Management system monitoring network traffic and scanning for Indicators of Compromise. Associated procedural controls are captured in standard operating procedures and Work Instructions.

Pharmacies, pharmacists, and patients will provide consent for data to be transferred from MedAdvisor to the research team.

4.9 Outcomes

Primary outcomes

Primary outcomes will be accessibility and acceptability of the service (based on self-report at 7-day follow up). This will be a composite measure based on patient self-reported data. It includes seven items adapted from existing questionnaires, including a validated questionnaire for perceived service quality in community pharmacies (two items) and studies of pharmacy prescribing for oral contraception, and other medications [1-6]. It will cover the following domains: (a) trust and confidence in health and medical advice provided, (b) convenience, (b) privacy during discussion with pharmacy, and (b) overall satisfaction. Each item is scored on a 7-point Likert scale. Each domain will be equally weighted, and an aggregated score calculated and scaled to a maximum score of 100.

Secondary outcomes

- **On time dispensing rates**: 36 months pre and 12 months post introduction of the intervention (assessed using the proportion of days covered method using PBS data) [40].
- **Primary care utilisation:** MBS records will be used to measure use of general practice services prior up to 36-months pre and 12 months post introduction of the intervention date (MBS data).

- **Safety outcomes**: Adherence rates to Clinical management protocols (assessed by practice change facilitators conducting regular pharmacy monitoring and inspection of data from the patient consultation IT system), hospitalisation for potential pill-related adverse events (e.g., thromboembolic disease) (NSW Health data), rates of STI tests undertaken (MBS pathology data) and adverse events.

- **Implementation outcomes**: Implementation outcomes will also be assessed to examine the fidelity, reach and adoption of the new service, and barriers and facilitators to implementation.

- **Economic outcomes:** Results from the economic analysis will be expressed as (1) net benefit in terms of implementation costs and cost savings arising from more efficient treatment pathways; and (2) cost-consequence results accounting for patient experience measures, relevant safety outcomes and implementation measures. This will be assessed using multiple data sources including MBS records for 36 months pre and 12 months post introduction of the intervention.

4.10 Data analysis

A mixed methods analytic approach will be applied.

4.10.1 Quantitative analysis

Descriptive statistics will be calculated for all study variables. Continuous variables will be reported using the appropriate measure of central tendency. Categorical variables will be summarized as proportions. Analyses will be conducted using SAS and R. The primary and secondary outcomes will be analysed with multivariable regression models adjusted for age, comorbidity count, prior primary care utilisation in the 3 years prior to enrolment and Socio-Economic Indexes for Areas (SEIFA). Sub-group analyses will be conducted to examine variation in outcomes for the cohort to assess a range of demographic and clinical characteristics.

4.10.2 Qualitative analysis

Self-reported patient experience will be examined at 6 and 12 months using qualitative methods. Interview transcripts will be imported into NVivo for thematic analysis. Initial open coding of transcripts will be undertaken iteratively by members of the research team. Themes and care quality measures will be presented to the broader research team and program implementers for final consensus.

4.10.3 Economic analysis

The analysis will be conducted from a health service perspective (base case) and a societal perspective including direct and indirect costs from the health-consumer's perspective - out of pocket expenses for any medicines or products provided, waiting time and travel time to attend treatment, productivity gains or time lost from work.

The scope of the within-study cost analysis is constrained by the design of the cohort study. Cost items associated with the co-design process, research and evaluation will be excluded. Resource use associated with the 2 components, pharmacy enrolment, training and support and pharmacy consultation, will be prospectively identified, measured and valued. In measuring resource use associated with delivery of the intervention, data will be collected from the research team, from the enrolled pharmacies and from the enrolled patients. Labour time will be measured using opportunity costs and valued based on Pharmacy Industry Award rates of pay, and average earnings for patients.

Health care resource use will be captured per the secondary outcomes of the study. Primary care resource use will be measured from MBS records and valued based on current Medicare Benefits Schedule listed prices. Medication use will be valued using Pharmaceutical Benefits Schedule listed prices, over-the counter medication will be valued using market prices. Hospital utilisation will be measured using the APDC and EDDC and valued based on Independent Health and Aged Care Pricing Authority (IHACPA) National Efficient Price tariffs.

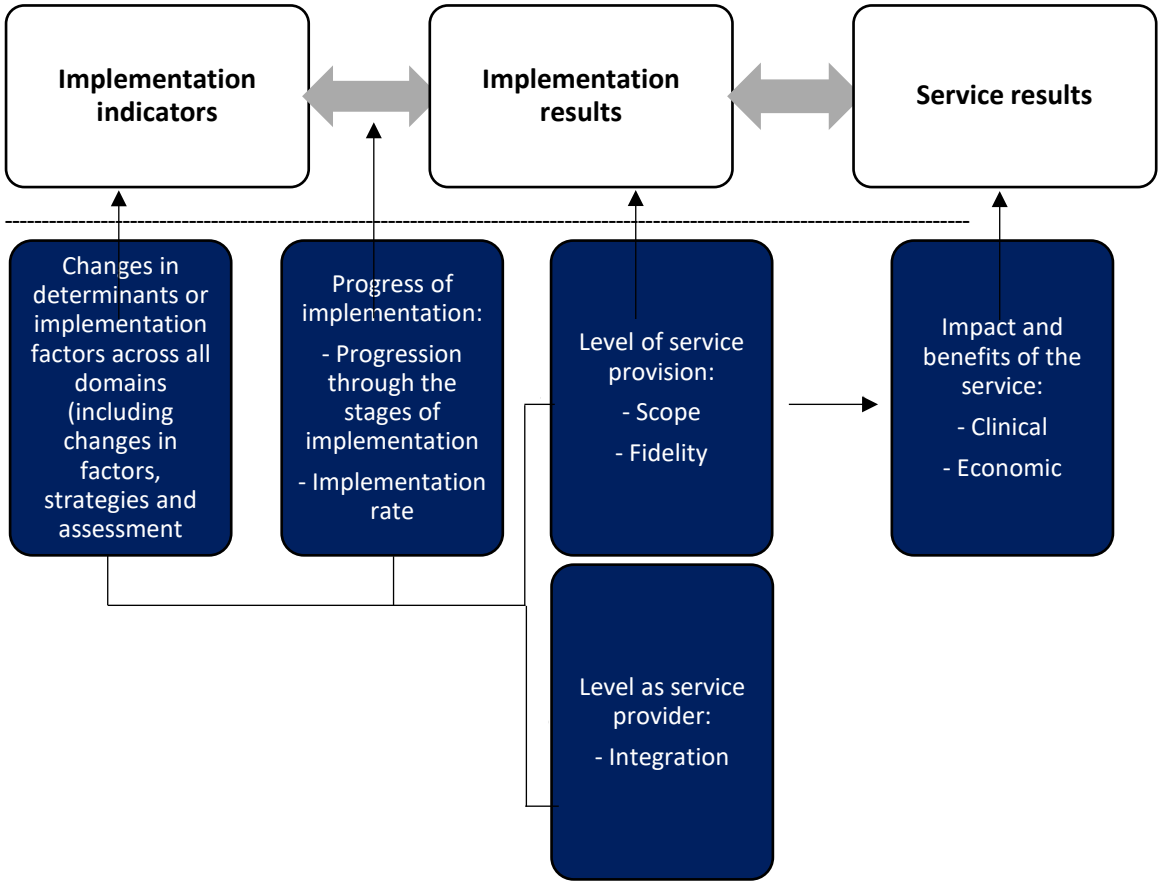
Results from the economic analysis will be expressed as (1) net benefit in terms of implementation costs and cost savings arising from more efficient treatment pathways; and (2) cost-consequence results accounting for patient experience measures, relevant safety outcomes and implementation measures.

Decision uncertainty will be accounted for using parametric and non-parametric bootstrapping to generate uncertainty intervals around the net benefit result.

4.10.4 Implementation outcomes analysis

The implementation component of the study will be underpinned by the Consolidated Framework for Implementation Research (CFIR) [41-44], in particular the use of an adapted implementation model for community pharmacy [45-55]. Implementation factors (barriers, causes and facilitators) (Appendix 3) and the Dougherty strategy classification systems (Appendix 4), adapted to community pharmacy, will be used [45-55]. This will build on the trial outcomes to determine scalability of the intervention. The evaluation framework is set out in Figure 1. The CFIR domains and sub-domains will also be used to organise the data. Descriptive statistics be produced for all implementation outcomes. Links between implementation barriers and facilitators, their cause and implementation strategies will be visually represented using Sankey diagrams. A predictive resolution percentage will be calculated using random forest method for predicting effective strategies for all implementation barriers.

Figure 1 Implementation Evaluation Framework adapted from Moullin, et al. [45]



4.11 Management of serious adverse events

The establishment of a Data Safety Monitoring Board (DSMB) will be an essential step in ensuring the safety and integrity of a research study or clinical trial. The DSMB will be an independent committee responsible for the ongoing monitoring of the study and making informed decisions regarding participant safety. One of the primary functions of the DSMB will be to review and evaluate any serious adverse events that occur during the study. Serious adverse events refer to unexpected or severe adverse reactions, complications, or other medically significant incidents experienced by participants. Furthermore, the DSMB will be responsible for assessing the overall safety profile of the study. It will analyse the frequency and severity of adverse events, identify any emerging patterns or trends, and evaluate whether the study intervention poses any risks that outweigh its potential benefits. The DSMB will also review the safety data in relation to the study's objectives and may make recommendations to modify or discontinue the study if warranted. The DSMB will report its findings and recommendations to the UoN Health Research Ethics Committee (HREC). The DSMB's report to

the HREC will include information on serious adverse events, their assessment, and any recommendations regarding participant safety or modifications to the study protocol. During the period before the establishment of the DSMB, the responsibility for reviewing and reporting serious adverse events falls to the Project Steering Committee. The Project Steering Committee comprises individuals involved in the management and oversight of the study, including principal investigators, study coordinators, and other relevant stakeholders. While the Project Steering Committee assumes this role temporarily, its objective is to ensure that any serious adverse events are promptly addressed, and appropriate measures are taken to protect participant safety.

5. Ethical Considerations

5.1 Research ethics approval

This research protocol was submitted to the University of Newcastle HREC for ethical review and received approval on 25 August 2023 (H-2023-0234). Following HREC approval, The Services Australia External Request Evaluation Committee has reviewed the request for MBS and PBS data linkage, and approval has been received (21 September 2023).

5.2 Protocol adherence

Except for changes to eliminate an immediate hazard to participants, the approved protocol will be followed as specified. Any significant protocol deviation will be documented, and notification sent to the HREC as soon as possible.

5.3 Protocol Amendments

Any significant change in the study protocol will require an amendment. The Chief investigator will submit this to the University of Newcastle HREC for review and approval. The approval letter, signed by the HREC Chair, will refer specifically to the investigator, the protocol number, the protocol title, the protocol amendment number, and the date of the protocol amendment. The protocol amendment may be implemented only after it has been approved by the HREC. If the revision is an administrative change (such as the addition or removal of committee members), a letter explaining the change(s) along with a copy of the amended pages(s) of the protocol will be submitted to the HREC for their information.

5.4 Notification of study closure

In addition to interim reports as required by the HREC, the Coordinating Principal Investigator will complete a final report notifying the HREC of the conclusion of the study. This report will be made within 3 months of completion or termination of the study.

5.5 Records retention

The Site investigator (or The George Institute for Global Health, on behalf of the Investigator) shall retain and preserve one copy of all data generated during the study for 15 years following study closure.

5.6 Confidentiality

All data collected for the purposes of the study will be kept confidential and will only be accessible by Study Personnel. Data will be maintained in accordance with the National Privacy Act 1998 and the NSW Health Records and Information Privacy Act 2002.

5.7 Dissemination Policy

Results will be published in the academic literature and presented at national and international conferences, media articles and newsletters. Publication of the main report from the study will be in the name of the research group, with each individual study investigator named personally at the end of the report.

6. Appendices

A list of appendices will be added as attachments to this application:

Appendix 1	Clinical management protocol – Combined Oral Contraception
Appendix 2	Clinical management protocol - Progestogen-Only Contraception
Appendix 3	Implementation Barriers, Facilitators and Causes
Appendix 4	Dougherty strategy classification systems
Appendix 5	Participant Information Statement (Pharmacy – NSW)
Appendix 6	Consent Form (Pharmacy – NSW)
Appendix 7	Participant Information Statement (Pharmacist – NSW)
Appendix 8	Consent Form (Pharmacist – NSW)
Appendix 9	Participant Information Statement (Pharmacy – ACT)
Appendix 10	Consent Form (Pharmacy – ACT)
Appendix 11	Participant Information Statement (Pharmacist – ACT)
Appendix 12	Consent Form (Pharmacist – ACT)
Appendix 13	Indicative script for initial contact with identified pharmacies
Appendix 14	ACT Health Medicines Poisons Therapeutic Goods New Licence Application
Appendix 15	Participant Information Statement (Patient – NSW)
Appendix 16	Consent Form (Patient – NSW)
Appendix 17	Participant Information Statement (Patient – ACT)
Appendix 18	Consent Form (Patient – ACT)
Appendix 19	Patient follow up data collection template
Appendix 20	Implementation checklist
Appendix 21	Interview questions (Community participants)
Appendix 22	Interview questions (Community pharmacists and other stakeholders)
Appendix 23	Services Australia approved patient and information consent form
Appendix 24	Routinely collected datasets available in NSW Health data
Appendix 25	Participant Information Statement (Stakeholder interviews)
Appendix 26	Consent Form (Stakeholder interviews)

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