The George Institute for Global Health

HMRI Hunter Medical Research Institute

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

NSW Government-Sponsored Clinical Trial: Management of Dermatology Conditions 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

Version 7 10 July 2024

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NSW GOVERNMENT

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 the dermatology phase.

1.2 Investigators

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Name	Project Role	Role, Affiliation	Contact details
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Additional Chief Investigators

Name	Position	Organisation
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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
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Associate Professor Kylie Gwynne	Director of Research and Senior Research Fellow, Djurali Centre for Aboriginal and Torres Strait Islander Health Research	Heart Research Institute
Professor Kylie Williams	Head of Pharmacy, Faculty of Health	University of Technology Sydney
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Dr Noelia Amador Fernandez	Lecturer in Pharmacy	University of Technology Sydney
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Ms Jan Donovan	Consumer representative	Consultant

Research Staff and Students

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1.3 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	Associate Professor Kylie Gwynne	Heart Research Institute
Committee Member	Mr Daniel Gilbertson	Deloitte Australia
Committee Member	Professor 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

1.4 Glossary of abbreviations and terms

ACT	Australian Capital Territory
APDC	Admitted Patient Data Collection
ARF	Acute rheumatic fever
CARPA	Central Australian Rural Practitioners Association
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
PSA	Pharmaceutical Society of Australia
PBS	Pharmaceutical Benefits Scheme
RHD	Rheumatic heart disease
SEIFA	Socioeconomic indexes for area
TGI	The George Institute for Global Health
UoN	University of Newcastle

2. Protocol Synopsis

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 New South Wales (NSW) and 15 pharmacies in the Australian Capital Territory (ACT), managing four skin conditions for individuals presenting with a suspected diagnosis – Impetigo, Atopic Dermatitis, Mild Plaque Psoriasis and Herpes Zoster.

The specific objectives of this study are to:

1. 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.
2. Assess the clinical outcomes and patient experience for patients managed by community pharmacists.
3. Assess the safety of the intervention and identify any risks that need to be addressed for future implementation.
4. Qualitatively assess the acceptability and feasibility of the intervention to pharmacists, other care providers and participants using the service.
5. Identify contextual enablers and constraints to access, adoption, fidelity, delivery, impact, sustainability, and generalisability of the intervention.
6. Conduct a health economic evaluation to determine the economic benefits.

The study will use a cohort study design to assess the clinical and economic impact and implementation of the intervention in NSW and ACT. Pharmacies will be onboarded from June 2024 to September 2024. This is due to administrative processes associated with MedAdvisor program installation, and the numbers of pharmacies that can be onboarded will be batched over this time. The study will be completed when 22,857 consults are reached or on 28 February 2025, whichever occurs first.

The intervention is multicomponent including Pharmacist training and support, and a Pharmacist-patient consultation, using an IT program, applying clinical guidelines. Pharmacies and pharmacists must meet the criteria of an 'approved pharmacy' and an 'approved pharmacist' outlined in the NSW Health Authority (Appendix 1), or a licence in ACT, to participate.

The 'approved pharmacist' will follow clinical practice guidelines originally developed by Queensland Health (Appendix 2). These guidelines have been through a co-design process (part of a separate low-risk ethics submission approved by HREC – University of Newcastle - H-2023-0448) and their content validated by dermatologists, GPs and NSW Health. These guidelines include a process for the pharmacist to make clinical decisions, and refer to other health professionals, particularly general practitioners.
The 'approved pharmacist' must complete the:

- Australasian College of Pharmacy modules on dermatology conditions; or

- Pharmaceutical Society of Australia module on dermatology conditions; and
- Modules developed by the University of Newcastle.

Pharmacists and pharmacies will be provided follow up support as part of a translational/ implementation strategy. Practice change facilitators will visit/contact these pharmacies during the study to provide ongoing support, answer any queries, ensure quality data is being collected, and collect implementation data. Pharmacies will be divided into low, medium and high contact, and this will depend on the number and nature of consultations delivered throughout the trial period.

The primary outcome will be symptom resolution/relief (completely resolved, improvement, no improvement or worsening) (based on self-report at 7-day or a 14 day follow up (depending on the skin condition)). This will be a composite measure based on patient self-reported data. As symptom resolution/relief time can be different for each of the four conditions, follow-up periods according to the clinical practice guidelines will be:

- 7 days for Impetigo, Psoriasis and Herpes Zoster (Shingles)
- 14 days for Atopic Dermatitis.

There will be several secondary outcomes which will be derived from the IT consultation database, patient follow-up, and an implementation database. In addition, qualitative methodology in the form of semi-structured interviews will be conducted with pharmacists and other stakeholders to better understand barriers and facilitators to implementation of the service (Appendix 3-4).

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 the 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 pharmacists managing uncomplicate urinary tract infections in a specified cohort of females.
3. Funding a 12-month trial to evaluate pharmacists extending 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 [1].

This study protocol refers to the fourth goal above.

International context – The evolution of a community pharmacy in Australia has mirrored international trends. In New Zealand (NZ) there has been an emphasis on integration, spanning primary care and secondary care [2]. This has also occurred in the United Kingdom (UK), where pharmacists are seen as part of the integrated solution to patient and healthcare demands [2]. In the United States, pharmacists are being recognised as part of integrated teams, with opportunities provided by a proliferation of new models such as medical homes, and community-based care teams [3]. Canada, the UK and NZ are more advanced in terms of the enhancing pharmacist roles and scope of practice in areas such as minor ailments or common clinical conditions, pharmacist prescribing, personalised medicines support and screening, and chronic disease prevention [4].

Australian context – An environmental scan provides evidence that at the Australian State and Federal level there has been a significant number of changes. A significant announcement has been the commencement of service delivery in the Queensland pilot trial in May 2024 and that it will be offered statewide and not restricted only to North Queensland. In addition, several other states including Victoria, South Australia and

Tasmania, have made similar announcements. These changes suggest that there is a high probability that pharmacist prescribing in Australia may become usual practice.

In NSW, a urinary tract infection (PATH-UTI) and oral contraceptive pill (PATH-OCP) have commenced. Both trials have been registered with ANZCTR (ACTRN12623000882628 and ACTRN12623001124628, respectively) and previously approved by The University of Newcastle Human Research Ethics Committee (H-2023-0119 on the 27/06/2023 and H-2023-0234 on the 25/08/2023, respectively). The proposal from the NSW Ministry of Health is to implement a third trial on the dermatological conditions (PATH-DERM). These trials have been designed to explore various aspects of pharmacy prescribing and have a secondary objective to lay foundational blocks to prepare the NSW pharmacy workforce. Importantly, it would enable the NSW Government to have community pharmacy and community pharmacists as a resource for the NSW population for the delivery of high-quality primary health care and public health initiatives.

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 New South Wales (NSW) and 15 pharmacies in the Australian Capital Territory (ACT), managing four skin conditions for individuals presenting with a suspected diagnosis – Impetigo, Atopic Dermatitis, Mild Plaque Psoriasis and Herpes Zoster.

Pharmacies will be onboarded from June 2024 to September 2024. This is due to administrative processes associated with MedAdvisor program installation, and the numbers of pharmacies that can be onboarded will be batched over this time. The study will be completed when 22,857 consults are reached or on 28 February 2025, whichever occurs first.

3.2.2 Objectives

The specific objectives of this study are to:

1. 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.
2. Assess the clinical outcomes and patient experience for patients managed by community pharmacists.
3. Assess the safety of the intervention and identify any risks that need to be addressed for future implementation.
4. Qualitatively assess the acceptability and feasibility of the intervention to pharmacists, other care providers and participants using the service.
5. Identify contextual enablers and constraints to access, adoption, fidelity delivery, impact, sustainability, and generalisability of the intervention.
6. Conduct a health economic evaluation to determine the economic benefits.

4. Methods

4.1 Study hypothesis

The study hypothesis is that the community pharmacy delivered services for four skin conditions will: (1) achieve high rates of implementation and adherence to treatment protocols; (2) result in self-reported symptom resolution/relief rates at various time interval depending on the condition; and (3) not be associated with safety risks.

4.2 Study design

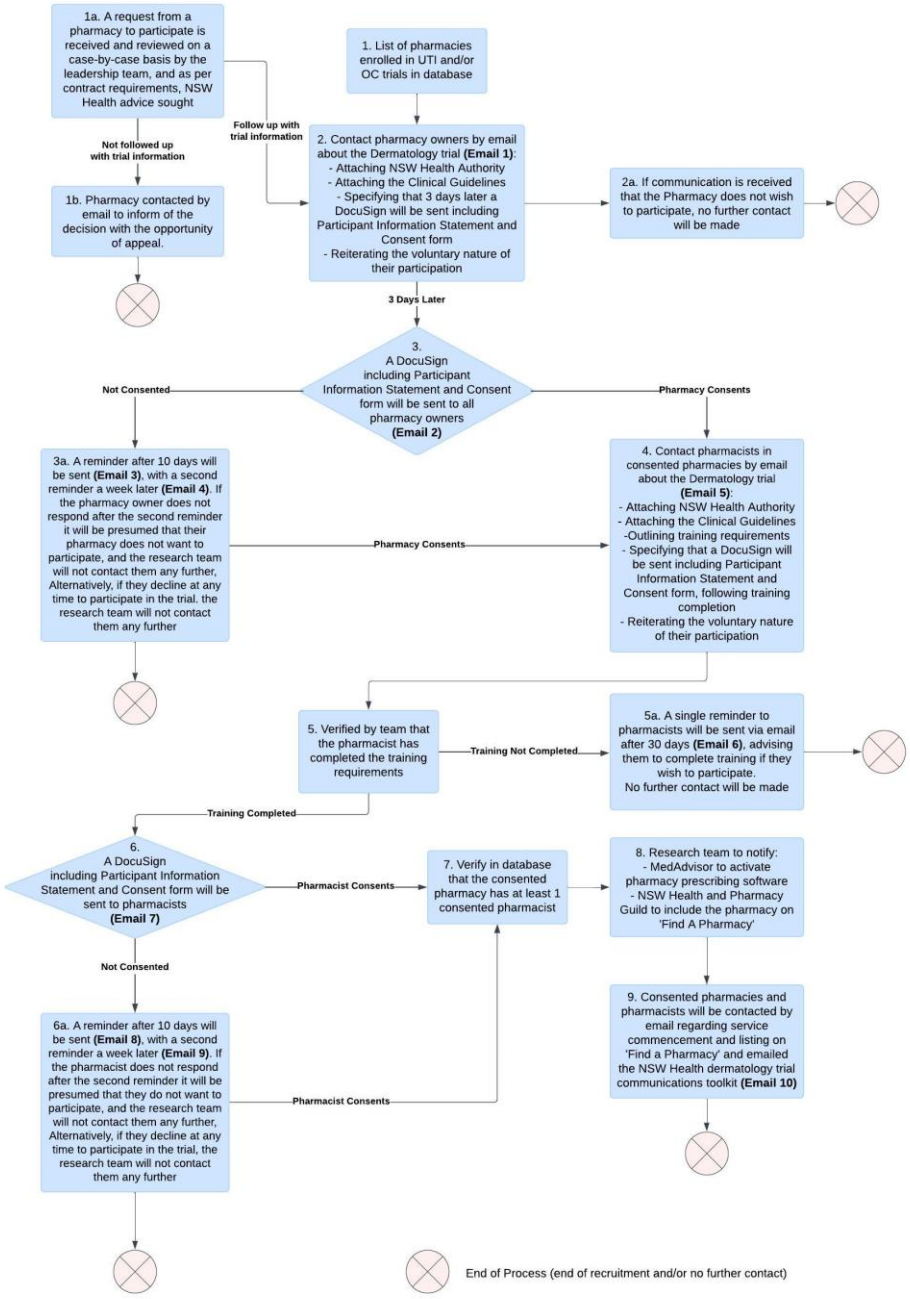
The study hypothesis will be tested using a cohort study design, applying mixed methods (quantitative and qualitative research) to assess clinical and economic indicators, implementation, and patient experience.

4.3 Pharmacy and pharmacist recruitment

Consent will be sought at two levels: the pharmacy level from pharmacy owners, and from the individual pharmacists in those pharmacies to participate in the study.

Please refer to Figure 1 which outlines the process for recruitment and contact with pharmacies and pharmacists. Both NSW and ACT will follow the same process with ACT commencing from Box 2, Figure 1.

Figure 1: Pharmacies and Pharmacists recruitment process for the Dermatology trial



NSW and ACT pharmacies

The contractual arrangements with the NSW Ministry of Health oblige us to offer participation to all NSW pharmacies who had consented to either of the previous trials (PATH-UTI and PATH-OCP) (ACTRN12623000882628 and ACTRN12623001124628, respectively).

Firstly, the list of NSW pharmacies currently participating in the PATH-UTI and/or PATH-OCP trials will be prepared (Box 1, Figure 1). The 15 participating pharmacies in the PATH-UTI and/or PATH-OCP from the ACT will also be added to this list.

An initial email will be sent to pharmacy owners to inform them about the dermatology trial and offer voluntary participation in the trial (Appendix 5, Email 1). This email will provide details of the trial including the NSW Health Authority or ACT Health licence, the Clinical Guidelines and specifying that 3 days later a DocuSign will be sent including Participant Information Statement and Consent form. The voluntary nature of their participation will be reiterated at this point (Box 2, Figure 1). If communication is received at this time that a pharmacy does not wish to participate, no further contact will be made (Box 2a, Figure 1).

A DocuSign will be sent to all pharmacy owners three days after Email 1, providing the Pharmacy Participant Information Statement and Consent form (Appendix 5, Email 2) (Box 3, Figure 1) (Appendices 6-9). The pharmacy owner may include additional pharmacists who have expressed their interest in participating during the consent process by completing the table provided in the pharmacy consent form.

For those pharmacy owners that have not yet provided consent, a reminder after 10 days will be sent (Appendix 5, Email 3), with a second reminder a week later (Appendix 5, Email 4). If the pharmacy owner does not respond after the second reminder it will be presumed that their pharmacy does not wish to participate, and the research team will not contact them any further, Alternatively, if they decline at any time to participate in the trial. The research team will not contact them any further (Box 3a, Figure 1).

Following consent by the pharmacy (Box 4, Figure 1), pharmacists in consented pharmacies will be contacted about the dermatology trial and offer voluntary participation in the trial (Appendix 5, Email 5). This email will provide details of the trial including the NSW Health Authority or ACT Health licence, the Clinical Guidelines and specifying that a DocuSign will be sent including Participant Information Statement and Consent form, following training completion. Details of the required training and how to access will be provided. The voluntary nature of their participation will be reiterated at this point (Appendix 5, Email 5).

Training completion will be verified by a member of the research team in our databases (Box 5, Figure 1), where a DocuSign providing the Pharmacist Participant Information Statement and Consent form will be sent (Appendix 5, Email 7) (Box 6, Figure 1) (Appendices 10-13). For pharmacists who have not completed the training, a single reminder will be sent via email after 30 days (Appendix 5, Email 6). No further contact will be made thereafter.

For those pharmacists that have not yet provided consent despite completion of training, a reminder after 10 days will be sent (Appendix 5, Email 8), with a second reminder a week later (Appendix 5, Email 9) (Box 6a, Figure 1). If the pharmacist does not respond after the second reminder it will be presumed that they do not want to participate, and the research team will not contact them any further, Alternatively, if they decline at any time to participate in the trial, the research team will not contact them any further.

A research team member will verify in our database that a consented pharmacy has at least 1 consented pharmacist (as per the legislative requirements of the NSW Health Authority and ACT Licence) (Box 7, Figure 1). The research team will notify MedAdvisor to activate pharmacy prescribing software in the consented pharmacy and will notify NSW Health for inclusion of the pharmacy to be listed on ‘Find A Pharmacy’ (Box 8, Figure 1). Consented pharmacies and pharmacists will be contacted by email regarding service commencement, listing on 'Find a Pharmacy' and emailed the NSW Health dermatology trial communications toolkit (Appendix 5, Email 10) (Box 9, Figure 1).

Any request form pharmacies not participating in the PATH-UTI and/or PATH-OC trials to participate in the dermatology trial will be reviewed on a case-by-case basis by the leadership team, and as per contract requirements, NSW Health advice will be sought (Box 1a, Figure 1).

4.3.1 Pharmacy and pharmacist eligibility criteria

In NSW, the Chief Medical Officer signs an Authority for the legislative changes allowing approved pharmacists in approved pharmacies to provide the intervention (see Appendix 1a) through participation in the trial.

The ACT legislation process has been determined by the acting Chief Pharmacist in ACT. A licence application will need to be made by participating pharmacies. The licence (available via PDF) would be issued to authorise the 15 pharmacies in the ACT to participate in the trial (Appendix 14) and there will be no licence fee for participating pharmacies. 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/

Pharmacies and pharmacists recruited must meet the eligibility criteria (defined below) to participate in the trial, reflecting the criteria set by the 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) and the ACT licence (Appendix 14). All pharmacies that have expressed an interest to participate will be sent a copy of the Authority or provided the ACT licence. There are minor differences in wording of criteria between the NSW Health Authority and ACT licence. 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 and licence):
        - "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 a Pharmacist Consult form in MedAdvisor developed specifically for the trial 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 modules on dermatology conditions; or
            - Pharmaceutical Society of Australia module on dermatology conditions; and
            - Modules developed by the University of Newcastle for 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.
Prior to service delivery, pharmacists will be prepared through an educational program. This program consists of the following training modules:

- Australasian College of Pharmacy (ACP) modules on Impetigo, Atopic Dermatitis, Mild Plaque Psoriasis and Herpes Zoster; or
- Pharmaceutical Society of Australia (PSA) module on dermatology conditions (Mild Plaque Psoriasis, Impetigo, Herpes Zoster and Atopic Dermatitis); and
- Modules developed by the University of Newcastle for the clinical trial (Introduction, Clinical Practice Guidelines, Antimicrobial Resistance and Stewardship for Impetigo and Herpes Zoster, and Introduction to Prescribing).

Completing this educational program is expected to take between 8 and 10 hours in total.

The modules developed by the University of Newcastle will be provided free to participants, whilst the Australian College of Pharmacy Practice and the Pharmaceutical Society of New South Wales will be offered free to members of the respective organisations, or for non-members there will be a charge associated. MedAdvisor will also provide training to the participating pharmacists as part of the contractual agreement with the University of Newcastle on how to use the software. The study specific training modules will be completed by pharmacists to ensure efficiency in the consultation process, patient consent, recruitment of patients, timely referral, and quality data collection.

The training verification process for pharmacists will be as follows:

- Once pharmacists have completed either the ACP or PSA courses, they will need to upload their certificates of completion during completion of the University of Newcastle modules.
- During the completion on the University of Newcastle modules, pharmacists will complete a self-assessment component after which details of the pharmacist's full name, their AHPRA number and email address.

4.4 Participant (patient) recruitment

A flyer will be 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 (Appendix 15). Patients will be opportunistically recruited in participating community pharmacies. Consecutive patients will be identified on presentation to the community pharmacy with symptoms suggestive one of the four skin conditions and either: presenting symptoms requesting advice or self-selecting a product for symptoms for the conditions included in this study - Impetigo, Atopic Dermatitis, Mild Plaque Psoriasis and Herpes Zoster. 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 (Appendices 16-19).

4.4.1 Participant (patient) consent

All participants will require informed 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 details (name, email, phone number, date of birth, postcode, suburb and the name of their regular General Practitioner if they wish this communication to be passed to them), personal contact preference 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. Alternatively, the pharmacist can provide a device and assist the patient to consent.

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 the research team via the email address provided to them in the consent form. Once a

participant decides to withdraw from the study, no further information will be collected from them, and their information/data will be removed from study records and will not be included in the study results.

4.4.2 Participant (patient) inclusion criteria

The age requirements for participation vary depending on the condition:

- Mild to moderate atopic dermatitis, 6 months to 65 years old
- Herpes Zoster (Shingles), 18 years and older
- Impetigo, 12 month or above
- Mild plaque psoriasis, 18 years and older

If an individual meets the age requirements for their condition, the pharmacist may offer them participation in the trial and provide a consultation. This consultation could lead to (i) referral to a medical professional and/or (ii) an appropriate management and treatment plan, which may involve pharmacotherapy, supportive therapy, and general advice.

Specific referral criteria for each of the four skin conditions are outlined in the co-designed clinical guidelines for NSW/ACT in Appendix 2. These guidelines clearly define when and to whom timely referral should be made.

4.5 Intervention description

The intervention is multicomponent.

4.5.1 Pharmacist-patient consultation

The pharmacist will undertake a structured consultation with the patient in the community pharmacy, anticipated to take 10-20 minutes, applying the co-designed clinical guidelines (Appendix 2) which considers the recommendations from the Australian Therapeutic Guidelines.

The intervention is provided under the NSW Health Authority (Appendix 1) allowing participating NSW pharmacists to supply medications as part of the trial. For the ACT, a free-of-charge discretionary licence will be approved to participating pharmacies.

4.5.2 Implementation strategy

There will be follow up training and ongoing support as part of a translational/implementation strategy. Additional instore training may be required (such as the use of the MedAdvisor software, the clinical assessment process, etc). Practice change facilitators (PCFs) will visit pharmacies to provide any required training, ongoing support, answer any queries, ensure quality data is being collected, and collect implementation data. Since this training will be face-to-face or through remote contact, the PCFs can tailor that to the specific pharmacists/pharmacy.

4.5.3 Considerations for the delivery of the intervention

Cost to patients

NSW - The cost of the consultation with patients ($35) 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 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.

The approved pharmacist will be trained to clearly communicate all costs that may be involved in receiving treatment at the earliest point possible and throughout the consultation. Medicines will not be subsidised by the Pharmaceutical Benefits Scheme (PBS). A statement has been included in the in the patient information statement and consent form so that the patient is fully informed of any costs associated with receiving the service.

Financial support to NSW pharmacies

The NSW Ministry of Health, sponsor of the trial, will provide financial support to NSW pharmacies who consent to participate in the trial, including:

- a one-off 'practice allowance' of $500. The financial support will offset technology infrastructure costs associated with participation in the trial.
- a $35 fee for administration and data recording per consultation, irrespective of the outcome of the service, to offset your time devoted to the trial. Please note that patients will be required to meet the costs of any medications, if supplied.

The criteria for receiving these payments are that pharmacies:

- provide at least one dermatology consultation during the trial.
- have at least one approved pharmacist.
- install the MedAdvisor IT program designed for the trial.
- meet the requirements of the NSW Health Authority.

The practice allowance will be paid directly to the provider of the program and will cover all the costs associated with IT training, installation and maintenance.

The administration and data recording fee per consultation will be paid retrospectively on a 3 monthly cycle.

The study will be completed when 22,857 consults are reached or on 28 February 2025, whichever occurs first.

Cost to ACT pharmacies for IT program

Pharmacies must have access to a Pharmacist Consult form in MedAdvisor developed specifically for the trial to complete clinical record keeping for the purposes of the clinical trial assessment. This program incurs a cost of $500 for participating ACT pharmacies for the duration of the trial. This cost is not covered by ACT Health.

Cost of pharmacist training

The modules developed by the University of Newcastle will be provided free to NSW and ACT participants, whilst the ACP and the PSA online learning modules will be offered free to members of the respective organisations, or for non-members there will be a charge associated.

Legislative considerations

NSW - The legislative approval required for the trial has been developed and is in the process of execution by the NSW Ministry of Health (Appendix 1).

ACT - The ACT legislation process has been determined by the acting Chief Pharmacist in ACT. A licence application will need to be made by participating pharmacies in ACT. The discretionary licence will be issued free to authorise the 15 pharmacies in the ACT to participate in the trial (Appendix 14).

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 as per previous two trials. Guild Business will cover the liability from the perspective of the pharmacy premises. The pharmacy and

pharmacists consent forms have been amended to provide consent for the researchers to pass the names and addresses of the participants in the study for the purposes of indemnity cover.

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 will be assigned a unique study identification number, which will replace personal data sent to the trial team. The list of data that will be collected in these extracts is presented in Table 3.

Table 3: MedAdvisor data collection form included in the prescription software

Patient information	Type of field
Surname	Free text
First Name	Free text
Middle Name	Free text
Address	Free text
Suburb	Free text
Postcode	Free text
State	Drop down
Mobile	Free text
Phone number	Free text
Email	Free text
DOB	Date picker
Sex assigned at birth	Drop down
Gender	Drop down
Medicare number	Free text
Medicare expiry	Free text
DVA	Free text
Main language spoken at home	Free text
Aboriginal and/or Torres Strait Island Status	Drop down
Emergency contact Full name	Free text
Emergency contact Number	Free text
Pharmacist details	Type of field
Consultation date	Date picker
Pharmacist	Drop down
AHPRA number	Free text
Consent	Type of field
Please note age restrictions per service…. The age requirements for participation vary depending on the condition: - Mild to moderate atopic dermatitis, 6 months to 65 years old - Herpes Zoster (Shingles), 18 years and older - Impetigo, 12 month or above - Mild plaque psoriasis, 18 years and older	Text
Participants are required to provide e-consent using their mobile phone. If the patient does not have a mobile device, the pharmacy must provide a device to complete the consent.	Text

Patient has provided e-consent to participate. Consent pertains to this service and collection of their personal information.	Checkbox
Enter the e-consent validation code:	Numeric
Medical and social history	Type of field
Past medical history	Free text
Past surgical history	Free text
Medications from dispense	Table display per dispense record
Current medications	Free text
Allergies and known adverse medication reactions	Free text
Smoking history (including vaping)	Drop down
Alcohol history	Drop down
Standard drinks per day on typical drinking day	Numeric
Recreational drugs	Free text
Relevant family history	Free text
Relevant sexual activity	Free text
Relevant work, hobbies and other information	Free text
Risk factors for referral or treatment	Type of field
If yes to any risk factor, you must provide additional insight during the objective assessment below.	Free text
Is the patient currently pregnant or planning to do so?	Radio buttons
Is the patient currently breastfeeding?	Radio buttons
Does the patient have high blood pressure?	Radio buttons
Is the patient overweight?	Radio buttons
Does the patient have diabetes?	Radio buttons
Does the patient have hepatic impairment?	Radio buttons
Does the patient have renal impairment?	Radio buttons
Does the patient have a fever?	Radio buttons
Clinical Service	Type of field
Presenting symptom (up to four)	Look up to symptom list
Subjective assessment	Free text
Objective assessment	Free text
Diagnosis	Free text
Treatment and plan	Free text
Supporting files and images	NA
Prescribe medication	Type of field
Drug name	Drop-down menu
Generic name	System data
Instructions	Free text
Quantity	Numeric
Created date	System data
Item strength (drug potency)	System data
Reason for prescribing	Free text

Administration route	Drop-down menu
Drug status	Drop-down menu
Notes	Free text
Notifications and referrals	Type of field
Who do you want to notify/refer to?	Drop down
Type of communication	Drop down
Discipline	Auto populate
Subject	Auto populate
Body of the letter	Auto populate
Attached all consultation details to the message as a PDF	Radio buttons
Send secure message	Radio buttons
Download PDF	Drop-down menu
Sent time	System data
Created time	System data
Consultation outcome	Type of field
Consultation length	Drop down
Clinical Service Type	Drop down
Review Clinical Guidelines	Link
Does the patient have a regular GP?	Radio buttons
Consultation summary: (at least one of them must be marked):	
Prescribed clinical trial medication	Check box
Did the patient decide not to purchase the medicines or products recommended as part of this consultation?	Radio buttons
If Yes, please provide further details	Free text
Over the counter treatment	Check box
Non-pharmacological management	Check box
Counselling and education	Check box
No intervention	Check box
Other (please specify)	Check box
Other text	Free text
Referrals - Reason	Type of field
Referral made - Referred to a GP as required by clinical guidelines 'red flag' or 'refer when' criteria	Check box
Referral made - Referred to an Emergency Department as required by clinical guidelines 'red flag' or 'refer when' criteria	Check box
Referral made - Patient may have a condition outside the scope of the trial	Check box
Referral made – Patient may require further investigation or tests, including pathology	Check box
Referral made - Patient may require treatment outside the scope of the trial	Check box

4.6.2 Participant (patient/carer) self-reported data from follow-up

Those assessed as eligible to participate in the trial will be followed up at different time frames depending on the condition. The follow up will include a brief survey administered by The George Institute either via SMS message or email with a link to a case report form using George Data Systems (GDS). Information will be collected on the primary outcome measure of symptom resolution/relief rate, any additional care provided, changes to treatment, service satisfaction and overall experience of care. Basic demographic (educational level, employment status, cultural status) and clinical information (condition, reason for consult, symptom description, other professional visits and other medications use) will also be captured. Appendix 20 provides the case report form for patient follow-up.

The follow up survey will be sent to patients by SMS and/or email, 7 or 14 days after the consultation depending on the condition. Up to 3 reminders will be sent to all patients that do not complete the survey at two, four and six days after the initial sending date. Patients that do not complete the survey after these reminders will be assumed as lost to follow up and will not be contacted further.

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 21 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: A purposive list of stakeholders with in-depth knowledge about the constraints and enablers to successful implementation of the model will be identified using a snowballing method. We will ensure a diverse range of stakeholders are included - general practitioners, and people from professional bodies including the Pharmacy Guild, Pharmaceutical Society of Australia and the Royal Australian College of General Practitioners, and NSW Health administrators. Potential participants will be approached directly by a member of the study team at the University of Newcastle and asked if they are willing to be approached for interview. Names of those willing to be contacted will be provided to the research team at the George Institute, who will provide the potential interviewee with participant information sheets and follow the informed consent process as for the other groups of participants.

The perspectives and experiences of community pharmacists and participants (patients) will be captured at 6 months using semi-structured interviews undertaken by The George Institute (Appendices 22 and 23).
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 22). 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 [5-8], sustainability, staff experiences and motivation to engage in the prescribing model (Appendix 23). 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.

4.7 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.co

Data files will include patient identifiers, 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 and UoN research teams will store the data files on secure servers (more detail below).

4.7.2 Participant (patient/carer) self-reported data

Follow-up 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 (patient/carer) 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 (Appendix 24). 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. Audio or videoconference files of interviews will be transcribed verbatim by Digital & Audio Transcription Services (DAATS), an Australian company with 128-bit SSL servers based in Sydney, after a confidentiality agreement has been signed. Nevertheless, all data regarding interviews will be securely stored in TGI and UON servers.

For participants who participate in interviews conducted by The George Institute, interviews will be recorded and transcribed. Transcriptions will be conducted by DAATS (Digital & Audio Transcription Services), an Australian company, in accordance with their privacy policy and security policy. The George Institute's Privacy Policy can be found at: https://www.georgeinstitute.org/privacy-policy

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 follow-up data	Deidentified, + participant study ID	GDS form hosted by TGI	-TGI -UoN	-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

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. Regarding the contractual arrangements between MedAdvisor and the two subcomponents, Foxo and Hola health, they are only permitted to Process Personal Data (and any other forms of Company Data) for the sole purpose of providing the Services and performing its obligations under this Agreement and the Contractor must not access or use the Personal Data

(or any other Company Data) for any other purpose (including for the Contractor's own purposes) without the Company's prior written consent.
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 outcome
The primary outcome will be symptom resolution/relief (completely resolved, improvement, no improvement or worsening) (based on self-report at various time frames at follow up depending on the condition). This will be a composite measure based on patient self-reported data. As symptom resolution/relief time can be different for each of the four conditions, follow-up periods according to the clinical practice guidelines will be:

- 7 days for Impetigo, Psoriasis and Herpes Zoster (Shingles)
- 14 days for Atopic Dermatitis

Secondary outcomes
Secondary outcomes will be:

- Types of medication supplied for each condition by pharmacists. This is a participant specific outcome.
- Adherence rates to treatment protocol. This is a pharmacy-specific outcome.
- Numbers of patients supplied medications by pharmacists. This is a participant specific outcome.
- Numbers of patients provided self-care advice. This is a participant specific outcome.
- Numbers of patients referred to another health professional. This is a participant specific outcome.
- Reasons for patient referral to another health professional. This is a participant specific outcome.
- Estimated duration of consultation. This is a pharmacy specific outcome.
- Patient follow-up rate. This is a participant specific outcome.
- Patient adverse events. This is a participant specific outcome.
- Patient experience. This is a participant specific outcome.

- **Safety outcomes:** Patient-reported adverse events defined as any unfavourable and unintended sign, symptom or disease associated with the use of a medicine, which does not necessarily have to be caused by that medicine (Appendix 25).

- **Implementation outcomes**
    - Patient and provider program participation rates
        - Patient demographics (gender, DOB, education, employment status)
        - Numbers of patients per pharmacy assessed as eligible for pharmacy medication supply.
        - Numbers of patients supplied medication by pharmacists.
        - Estimated duration of consultation
        - Estimated time to complete all service requirements.
    - Adherence rates to treatment protocol
        - Prescriptions for first-line medications for the four skin conditions /Total medication prescriptions for the four skin conditions
        - Classification of appropriateness of medications for the four conditions as aligned with clinical practice guidelines.

- **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.

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). 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 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.

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.

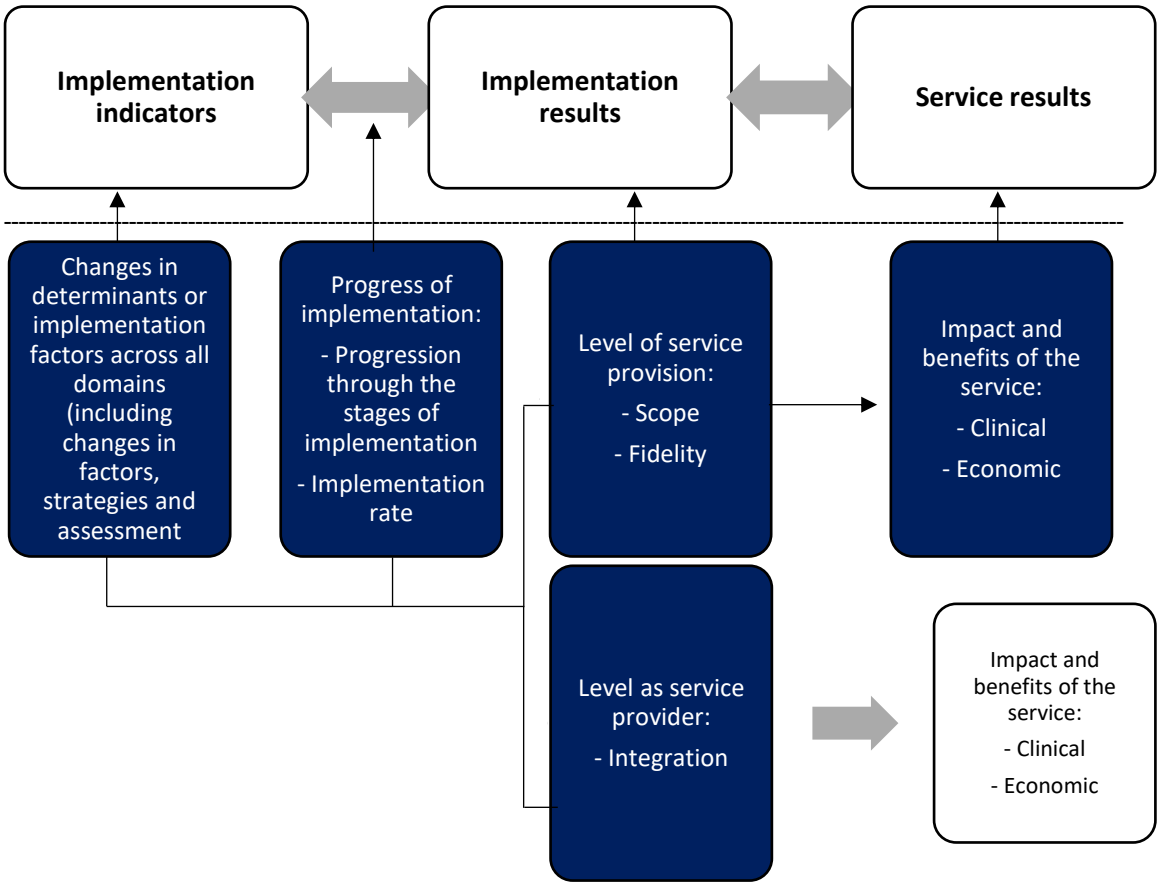
Decision uncertainty will be accounted for using parametric and non-parametric bootstrapping to generate uncertainty intervals around the net benefit result.

4.10.4 Implementation outcomes analysis

The implementation component of the study will be underpinned by the Consolidated Framework for Implementation Research (CFIR) [9-12], the use of an adapted implementation model for community pharmacy [13-23]. Implementation factors (barriers, causes and facilitators) (Appendix 3) and the Dougherty strategy classification systems (Appendix 4), adapted to community pharmacy, will be used [13-23]. 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. [13]



4.11 Oversight and management of serious adverse events

The establishment of a Data Safety Monitoring Board (DSMB) is an essential step in ensuring the safety and integrity of a research study or clinical trial. The DSMB is 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. The internal adverse events policy and procedure for the UTI and OC trials will be extended (Appendix 25) for this trial. 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 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 committee already established for the PATH-UTI and PATH-OCP will be extended to cover PATH-DERM trial.

5. Ethical Considerations

5.1 Research ethics approval

This research protocol will be submitted to the University of Newcastle HREC for ethical review and approval.

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 or violations will be documented, and notification sent to the UoN 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.

All participants will be able to request a resume of study outcomes though the trial mailbox, as stated in the PIS and consent forms.

6. Appendices

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

Appendix 1	NSW Health Authority
Appendix 2	Clinical guidelines
Appendix 3	Implementation Barriers, Facilitators and Causes (CFIR)

Appendix 4	Dougherty strategy classification systems
Appendix 5	Email Communications
Appendix 6	Participant Information Statement (Pharmacy – NSW)
Appendix 7	Consent Form (Pharmacy – NSW)
Appendix 8	Participant Information Statement (Pharmacy – ACT)
Appendix 9	Consent Form (Pharmacy – ACT)
Appendix 10	Participant Information Statement (Pharmacist – NSW)
Appendix 11	Consent Form (Pharmacist – NSW)
Appendix 12	Participant Information Statement (Pharmacist – ACT)
Appendix 13	Consent Form (Pharmacist – ACT)
Appendix 14	Licence form ACT
Appendix 15	Ministry of Health Draft Flyer
Appendix 19	Consent Form (Patient – ACT)
Appendix 20	Patient follow up data collection
Appendix 21	Implementation checklist
Appendix 22	Interview questions (Community participants)
Appendix 23	Interview questions (Community pharmacists and other stakeholders)
Appendix 24	Indicative script for contacting patient participants
Appendix 25	Adverse Events - Policy and Process

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