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Implementation evaluation of a pharmacist prescribing service for the management of dermatological conditions: a study protocol

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Abstract

Background The scope of practice for community pharmacists is evolving globally. Policy drivers are to increase access to primary care, due to the lack of accessibility to general medical practitioners or inappropriate demand on emergency departments. Most implementation studies in this space have reported on determinants for pharmacist prescribing services. There is a lack of comprehensive evaluations including investigation of the implementation process and outcomes.

Methods A cohort design hybrid type 2 effectiveness-implementation study, applying mixed methods will be carried out between 19th July 2024 and 31st August 2025. This paper is focussed on implementation evaluation components. Pharmacists who participated in either of two previous trials will invite consecutive patients with symptoms suggestive of impetigo, mild to moderate atopic dermatitis, mild plaque psoriasis or herpes zoster to participate. The intervention is a pharmacist-patient consultation utilising codesigned clinical guidelines. Following pharmacist training, the primary implementation strategy will be facilitation, with tailored implementation strategies delivered by implementation facilitators (IFs) based on individual pharmacy and pharmacist level barriers. IFs will be trained and will receive regular feedback from the research team.

The assessment of the implementation impact will include the identification of implementation determinants (Consolidate Framework of Implementation Research, CFIR) and their link to strategies (Expert Recommendations for Implementing Change, ERIC). The evaluation of the implementation process will measure the progression of implementation stages (Exploration, Preparation, Implementation, Sustainment, EPIS). The analysis of implementation outcomes will follow *Proctor* et al. recommendations (acceptability, adoption, appropriateness, feasibility, fidelity and reach). Practical tools for IFs will be used including a checklist to guide the identification, evaluation and documentation of implementation determinants to guide problem-solving solutions and to collect implementation outcomes during encounters with pharmacists. Three reports will be used to provide feedback to IFs. Semi-structured interviews with patients, pharmacists and other key parties will be used to evaluate acceptability, appropriateness and feasibility and sustainment will be explored by using normalisation process theory.

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Discussion This study will contribute to the literature by generating new data on the implementation of pharmacist prescribing services with a detailed facilitation process to support implementers and a detailed process to assess tailored implementation strategies.

Trial registration The trial was registered on 18 July 2024 with the Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12624000877583 (Protocol Version 7, 10 July 2024).

Keywords Implementation science, Health plan implementation, Diffusion of innovation, Health policy, Primary health care, Community pharmacy services, Non-medical prescribing, Skin diseases, Process assessment health care, Clinical trial protocol

Background

The scope of practice for community pharmacists is rapidly evolving globally. Government key policy drivers, regardless of country, include an increase to community's access to primary care [1] due to a lack of accessibility to general medical practitioners [2] or inappropriate demand on emergency departments with costs and health system implications [3]. In countries such as the United States and Canada the scope of practice expansion includes pharmacist prescribing [4, 5]. Pharmacist led prescribing is defined as "an iterative process (carried out by a pharmacists) involving the steps of information gathering, clinical decision making, communication and evaluation which results in the initiation, continuation or cessation of a medicine" [6]. However, there are various types of pharmacists prescribing, e.g., via a structured prescribing arrangement, under supervision, or autonomous prescribing [6]. In this study, the structured prescribing has been used which determines that the service is under an Authority and a structured protocol has to be adhered to, including the type and form of medications that are to be prescribed and/or supplied. On an international basis, there are important differences on the type of medical conditions included in prescribing services ranging from acute conditions such as urinary tract infections, eye or respiratory infections to chronic conditions such as type 2 diabetes or hypertension [7, 8].

Countries such as Canada [9], the United Kingdom [7, 10], Switzerland [11] and Denmark [12] have implemented policies related to pharmacist prescribing. In Canada [9], England [10] and Scotland [7], pharmacists with additional accredited training are allowed to prescribe in collaborative practice agreements with general medical practitioners and autonomously. From 2026 in England, all newly qualified pharmacists will be required to be independent prescribers [10]. Swiss pharmacists are allowed to continue some long-term medicine treatments for selected conditions [13]. Pharmacists in Denmark can re-prescribe medications for conditions such as high blood pressure or high cholesterol for those patients who have been stable for at least one year [12]. Australia has mirrored international trends and recently, state Governments led by Queensland [14] have enabled pharmacist prescribing. Practicing pharmacists in Queensland can prescribe medication for acute conditions (e.g., shingles, eczema, ear infections) and chronic disease management (e.g., high blood pressure, asthma, chronic obstructive pulmonary disease). A similar trend is occurring in other Australian states.

Effectiveness (i.e., blood pressure, blood glucose, cholesterol control), safety (i.e., adverse events, appropriateness of prescribing, prescribing errors, medication omissions) and patient satisfaction have been evaluated for pharmacist prescribing services. There is evidence that pharmacists can maintain or improve patient outcomes while prescribing compared to usual care [15–18].

Implementation determinants for pharmacist prescribing services

Implementation determinants (barriers and facilitators) or contextual factors affect an implementation effort. Most implementation determinants for pharmacist prescribing services reported in the literature have been barriers [4, 11, 19–22]. At an external, system level barriers include a negative perception of pharmacist prescribing by general medical practitioners; at an internal pharmacy level, a lack of pharmacists' time, and at a service level a lack of reimbursement [11, 19–21]. A scoping review in 2019 [22] also suggested inadequate training regarding diagnostic knowledge and skills as a key barrier. However, Dale et al.[4] highlighted that expanding pharmacist prescriptive authority and a culture of support for clinical pharmacists as important facilitators [4]. Other major facilitators identified [23] were competence, self-confidence, and the potential impact on patient care.

Implementation evaluation for pharmacist prescribing services

Moullin et al. suggested a model for the evaluation of pharmacy services including the assessment of the implementation process, impact and outcomes [24]. The implementation process was described as the attainment and movement between implementation stages. The authors promulgated the evaluation of the implementation determinants and how they changed over time, and strategies

used to overcome them, as part of the implementation impact. Implementation outcomes were divided into i) level of service provision (e.g., reach, fidelity) and ii) level as a service provider (e.g., integration) [24]. In published studies there is lack of comprehensive evaluation of the implementation aspects of pharmacy services, with most predominantly focussed on investigating determinants [4, 11, 19–23]. This study has a holistic approach for the overall evaluation of the implementation of a pharmacist prescribing service for dermatology conditions. It builds on another two studies evaluating pharmacist prescribing for urinary tract infections (PATH-UTI) [25] and the resupply of oral contraception pills by community pharmacists (PATH-OC) [26].

Objectives and aims

The overall aim of the research is to evaluate the clinical, economic and implementation outcomes of a pharmacist prescribing service to manage four dermatological conditions. The trial has been registered with Australia New Zealand Clinical Trials Registry (ANZCTR) where the full research protocol is available [27]. This publication is directed to the implementation evaluation objectives which are to:

1. Identify and link contextual implementation determinants to strategies.
2. Evaluate the implementation process and the progression through the implementation stages.
3. Evaluate the implementation outcomes in community pharmacies.

This data will then be used to guide the scale-up of the service across the state and to support the sustainability of the intervention into usual professional practice.

Methods

Study design and setting

The study design of the overarching study is a cohort design hybrid type 2 effectiveness-implementation study [28], using quantitative and qualitative research methods. The trial commenced in July 19th 2024 in the state of New South Wales (NSW, Australia) and was originally planned for 6 months or when a maximum number of 22,857 patient consults was reached; however, it was extended until August 31st 2025.

Pharmacy and pharmacist recruitment

Pharmacies in NSW ($n = 1{,}089$) and ACT ($n = 15$) who participated in at least one of the two previous phases (PATH-UTI and PATH-OC trials) [25, 26] were invited to voluntarily participate. These represent 54.2% of the pharmacies in NSW. New pharmacies that had not participated in the PATH-UTI and/or PATH-OC trials will be required to send an expression of interest and will be reviewed on a case-by-case basis according to the NSW Health Dermatology Authority (Supplementary Material 1). Pharmacy owners from consented pharmacies will be asked to nominate any new employed pharmacists and to remove pharmacists that no longer work at the pharmacy. Existing pharmacists retained from PATH-UTI and/or PATH-OC trials, or new pharmacists will be invited to participate by sending trial information to undertake training requirements. Based on previous trials it is estimated that 2,900 pharmacists will be nominated. For those who complete the training requirements a consent form will be sent for voluntary participation. Figure 1 depicts the recruitment process.

Pharmacies and pharmacists will need to meet the eligibility criteria set by the Authority under Sect. 10 Poisons and Therapeutic Good Act 1966 Clauses 170 and 171 of the Poisons and Therapeutic Goods Regulation 2008 (Supplementary Material 1) or the licence requirement issued by ACT Government (Supplementary Material 2). Some of these legislative requirements include specific training for pharmacists, requirements associated with the consultation room, medications available to be supplied through the service, and use of clinical guidelines by pharmacists (Supplementary Material 1 has full details).

Pharmacies in NSW will be paid a fee for their participation (AUD35 per consultation) by the NSW Government. In addition, both NSW and ACT governments will provide a one-off practice allowance of approximately AUD800 to the pharmacy to meet the costs of the technology infrastructure associated with participation in the trial. Patients will need to pay for any medicines or products provided.

Patient recruitment

Consecutive patients with symptoms suggestive of one of the four skin conditions (impetigo, mild to moderate atopic dermatitis, mild plaque psoriasis and herpes zoster) and either requesting advice or self-selecting a product for their symptoms will be identified on presentation to the community pharmacy. The pharmacist will offer the patient to voluntarily participate in the study if they meet the inclusion criteria i.e. 6 months to 65 years old for mild to moderate atopic dermatitis, 12 months or above for impetigo and 18 years and older for herpes zoster or mild plaque psoriasis. A previous diagnosis by a medical practitioner for mild to moderate atopic dermatitis or mild plaque psoriasis is required to participate in the trial.

The pharmacist will request patient consent with a specific QR code for scanning on the patient's mobile phone or electronic device. A secure webform will become available to enter personal details (name, email, phone

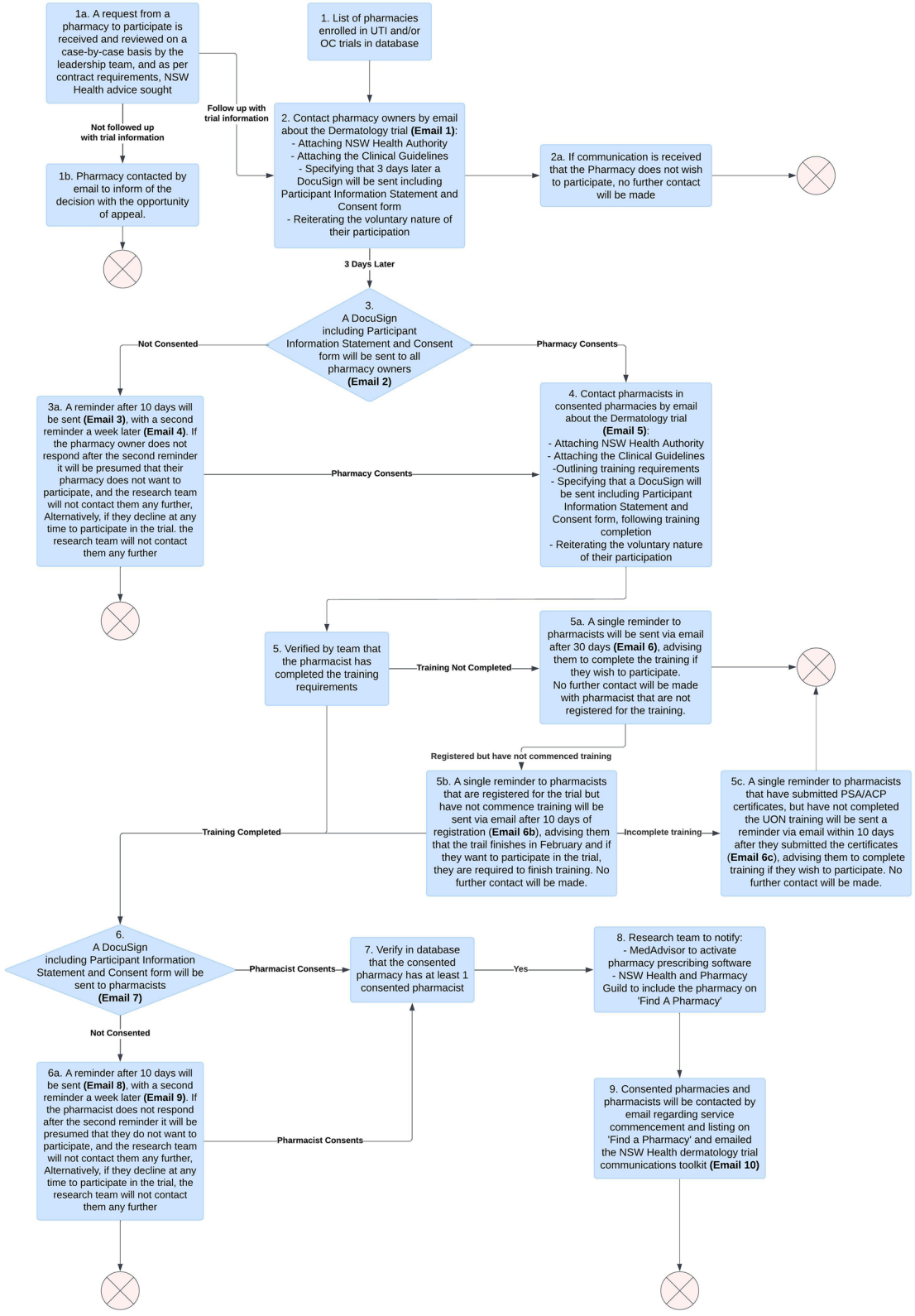

Fig. 1 Pharmacy and pharmacist's recruitment process

number, date of birth, postcode, suburb and the name of their regular general medical practitioner and if they wish the consult information to be transmitted). The patient will be sent an SMS or email confirmation message with a validation code which they will then provide to the pharmacy allowing them to proceed to the IT consultation program.

Intervention: pharmacist-patient consultation

Participant pharmacists will undertake a structured consultation with the patient in an approved community pharmacy applying the codesigned clinical guidelines. The consultation is anticipated to take 10–20 min, and it will be recorded using a secure digital IT platform [29] which includes a secure communication platform (FOXO).

The detailed intervention description (TIDieR template) is included as Supplementary Material 3.

Implementation strategies

Pharmacist initial training

Prior to service delivery, pharmacists will need to undertake clinical online training programs for the treatment of impetigo, mild to moderate atopic dermatitis, mild plaque psoriasis and herpes zoster, either through the Australasian College of Pharmacy (ACP) [30] or Pharmaceutical Society of Australia (PSA) [31]. These to training programs include anatomy, physiology, physiopathology, epidemiology, signs and symptoms, examination skills to confirm diagnosis, differential diagnosis, treatment, scope of practice for pharmacists, legislative framework and workflow comprising documentation, follow up and referral pathways.

In addition, four study specific online training modules developed by the research team will need to be completed by pharmacists. These four modules include the codesigned clinical guideline adapted from the Queensland Government [14] which encompass the treatment recommendations from the Australian Therapeutic Guidelines [32], antimicrobial resistance and stewardship, the trial protocol and an initiation to prescribing module. The training also includes information on the dermatology legislative instruments (NSW) (Supplementary Material 1) and Licence (ACT only) (Supplementary Material 2), and the secure digital IT platform. The IT platform is a prescribing module specifically designed for the trial which includes a secure messaging system to general medical practitioners.

Facilitation process

The key components of the facilitation process are included in Fig. 2 and described below:

- Initial training for implementation facilitators (IFs) Following the Global Implementation Society guide for the developments of IFs competencies, training to four IFs will be deliver by the research team and will involve knowledge about the intervention

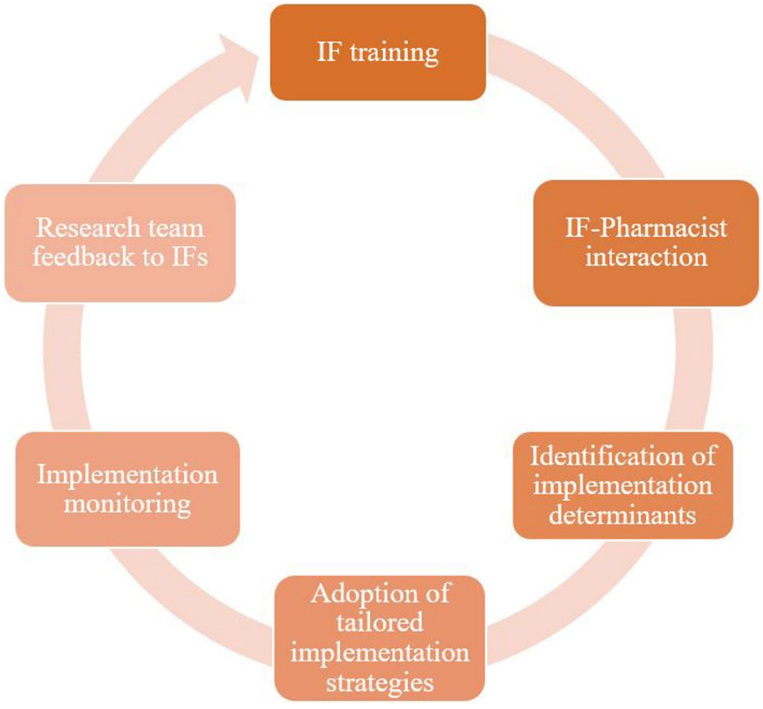

Fig. 2 Implementation facilitator-pharmacist intervention process

and implementation [33] at the commencement of the trial and reinforced fortnightly throughout the study period. To learn about the intervention, IFs will also complete the training required for participant pharmacists (clinical online training and the four study specific training modules). Implementation and facilitation training will include the facilitation process (Expert Recommendations for Implementing Change classification, ERIC) [34], classifications of implementation determinants (Consolidated Framework for Implementation Research, CFIR) [35] and implementation strategies (Expert Recommendations for Implementing Change classification, ERIC) [36], key priorities and triage of requests. This information will be entered by IFs in a predesigned REDCap database [37].

- IF-pharmacist interaction
  As part of the support provided for pharmacists, IFs will be in contact with pharmacists either face to face, through videocalls, phone calls and/or emails to respond to queries and ensure quality of data. The rates of these contacts will be determined by pharmacy commencement, pharmacists-initiated request, data analysis identifying potential issues during its collection as part of the pharmacist-patient consultation, and strategic decisions by the research team depending on the needs and progress of the study.:IFs will identify and evaluate implementation determinants (barriers, facilitators and their causes) during their observations and contacts with participants pharmacists using a checklist (Supplementary Material 4) previously developed through consensus by the research team. This checklist includes two main sections, one to evaluate pharmacist fidelity to clinical guidelines and another to assess and prioritize implementation determinants. These data will be entered in REDCap database [37] by IFs.
- Tailored implementation strategies and monitoring
  IFs will play a crucial role in supporting pharmacists and pharmacy staff through tailoring implementation strategies "as a mean of improving the fit between an intervention and the context in which it is implemented" [38]. IFs will follow a process to select, and report tailored implementation strategies following McHugh et al. [39]. After the identification and prioritization of implementation determinants, IFs will select and execute strategies by matching to determinants according to perceived feasibility and impact of strategies. Assessment of the strategies will be made by mapping determinants, strategies, mechanisms used to execute those strategies and implementation outcomes [40]. The strategic follow up and prioritization of contacts will be based on pharmacy performance in terms of number of consultations, appropriate use of the clinical guidelines and the use of the secure digital IT platform, with at least two contacts per pharmacy anticipated during the trial. Low performing pharmacies will be prioritised for face-to-face visits. Follow up will allow monitoring the strategies and the pharmacists' engagement with the provision of the service [41]. All these data will be entered in REDCap database [37] by IFs.
- IFs audit and feedback
  Pharmacy performance will be monitored by the research team through the community pharmacy data which will be received daily from the secure digital IT platform. The continuous feedback to IFs, at weekly meetings and by the research team through formal reports, will be used to help them prioritize the selection of face-to-face visits to pharmacies.

Continuous individual feedback to IFs by the research team will improve one of the key identified skills for IFs, which is self-development to facilitate implementation [33]. The research team will use three different reports to provide feedback to the IFs: a) weekly activity report to monitor contacts (in situ visits, phone calls, emails) with pharmacies; b) weekly implementation report to monitor the implementation determinants and strategies recorded in REDCap; and c) monthly clinical-implementation report to provide pharmacy performance data. Sankey diagrams, at a study level and individually, will be included on the weekly implementation report to help analyse the success of the strategies. The different reports used for feedback and the agreed checklist provided for IFs to assess implementation determinants and fidelity, are practical tools that could be used for the evaluation and measurement of implementation outcomes for other prescribing services.

Data collection

Patients follow up survey

Patients will receive a follow up survey (Supplementary Material 5) by The George Institute for Global Health (TGI) via their preferred method (SMS and/or email) selected during the consent process. The follow up will occur 7 to 14 days after the pharmacist-patient consultation depending on the condition (7 days in case of herpes zoster, impetigo, and mild plaque psoriasis; and 14 days in case of mild to moderate atopic dermatitis) to elicit adherence to medications, referral advice and service experience. The follow up will be carried out by researchers at The George Institute for Global Health (TGI) [42]. Up to three reminders at two, four and six days after the initial email.

Qualitative interviews

The acceptability, appropriateness and feasibility of the service will be captured at the end of the study (6 months after commencement or when the consultation cap is reached) using semi-structured interviews with patients (Supplementary Material 6), community pharmacists and other key parties (general practice and pharmaceutical professional bodies and NSW Health administrators) (Supplementary Material 7). A maximum variation sampling technique will be used to select a diverse range of pharmacies and patients for interviews. It is anticipated that around 30–40 interviews will be conducted, however, the final sample size will be determined when thematic saturation is considered achieved.

For community pharmacists and other key parties, questions will focus on implementation and contextual factors which may have influenced program outcomes, sustainability, staff experiences and motivation to engage in the prescribing model. Interviews will be conducted by experienced qualitative researchers independent of the study implementation team (TGI). Factors that affect sustainment will be explored by using normalisation process theory (NPT) [43]. The NPT focuses on the work that individuals and groups do to enable an intervention to become normalised. It identifies factors that promote and inhibit the routine incorporation of complex interventions into everyday practice.

Outcome measures

The study outcomes will be measured following the implementation evaluation described by Moullin et al. (Fig. 3).

Objective 1: Identify and link contextual implementation determinants to strategies The implementation determinants and change over time will be identified and recorded by IFs during their contact with pharmacists utilising the CFIR framework [35]. This framework allows the identification of barriers and facilitators at different implementation levels: innovation or, in this case, the pharmacist prescribing service; individuals or pharmacy staff; inner setting or community pharmacies; outer setting or local and state systems (NSW and ACT) and the implementation process. After the identification of the implementation determinants for each pharmacy/pharmacist, tailored implementation strategies will be planned and carried out by IFs. The recording of the strategies will be made using ERIC classification [36].

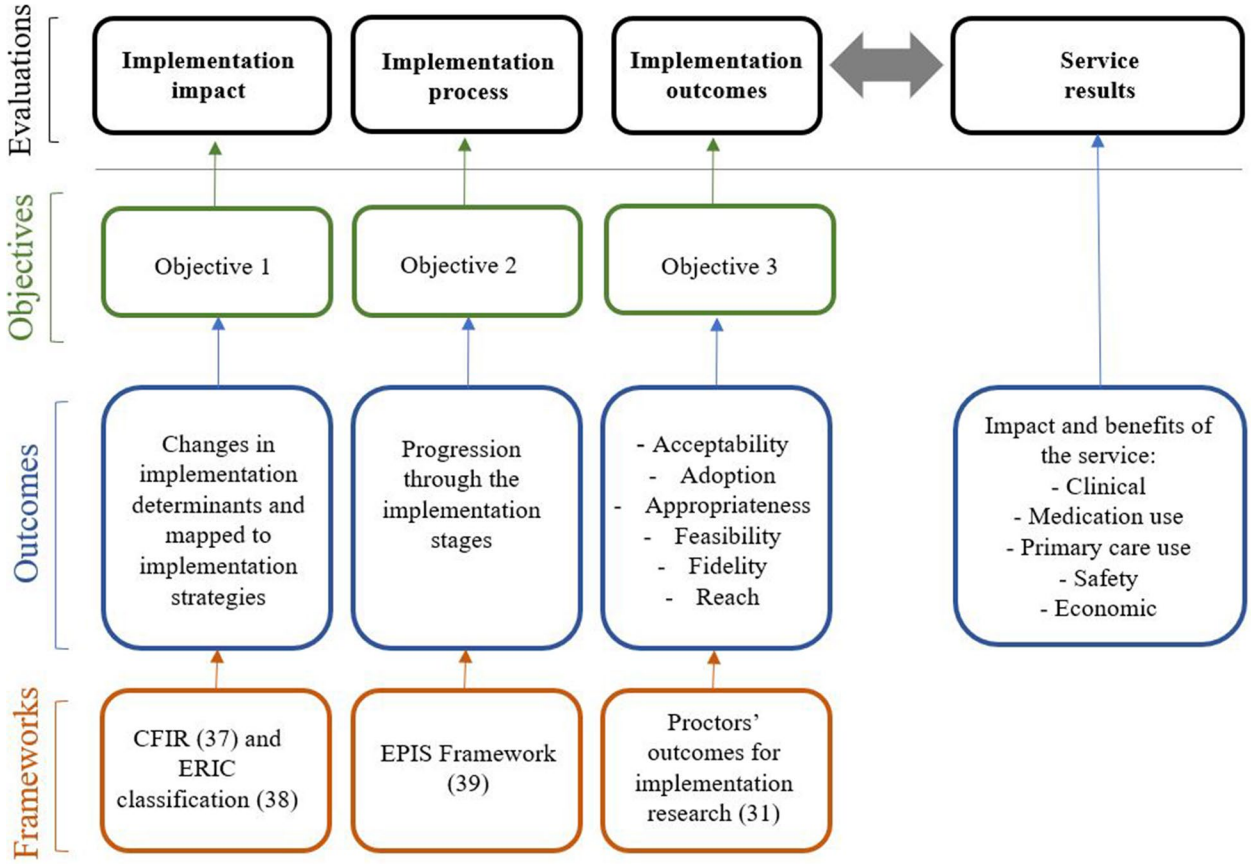

Fig. 3 Implementation evaluation from Moullin et al. [24] aligned with study objectives and theoretical frameworks

Objective 2: Evaluate the process and the progression through the implementation stages The implementation process or pharmacies' progression through the implementation stages will be evaluated quantitatively and qualitatively applying the EPIS Framework [34]. Implementation stages will be measured for "Exploration" by the total number of pharmacies invited to the study to provide the service; "Preparation" by the number of pharmacies with pharmacists completing the educational training; "Implementation" by the number of pharmacies and pharmacists providing the service to at least one patient. "Sustainment" which will not be measured as the study duration is expected to be only six months. Qualitatively the EPIS process will be examined through 30–40 interviews with different key parties which will include assessing the factors which potentially can affect sustainment.

Objective 3: Evaluate the implementation outcomes of the intervention in community pharmacies Implementation results will be assessed using implementation outcomes defined by Proctor et al. [44]. These outcomes, included in Table 1, will determine scalability of the intervention. Service evaluation data will be measured (Fig. 3); however, it is not part of this implementation protocol. Refer to the full protocol for more information (ACTRN12624000877583) [27].

Data management

Six linked databases will be created:

- Community pharmacy data: participating pharmacies and pharmacists'data regarding consent and status for the trial; geographic information including address, postcodes, local government areas (LGAs) and Modified Monash model classification (MMMs); contact information for all participants and training confirmation for pharmacists.
- Clinical consultation data (secure digital IT platform): participating pharmacists will record the patient consultation data in the software application. Three linked data files will include the information about the service recorded during the pharmacist-patient consultation in the pharmacy; the information shared through the secure messaging system between pharmacists and general practitioners; and a treatment summary of the trial medicines prescribed by the pharmacist. Data files will include patient identifiers (Medicare number, patient name, contact details and date of birth).
- Patients follow up data: 7-day or 14-day follow-up (depending on the condition) data will be collected on TGI Data Systems case report forms. Data file will include the information about patients consent, site data (pharmacies and pharmacists' identification) and the information provided by patients during their follow up.
- Protocol violations and deviations: Consultation level data and protocol violations and deviations for pharmacies and pharmacists as related to the approved protocol for the intervention, from a clinical service perspective (i.e. medical referral points, medication prescribing) and an administrative perspective (i.e. pharmacists training and consented status). These as reported by participants, working groups or identified by the researchers through a continuous data validation process.
- IFs data (REDCap® IT platform): This database will include IFs checklists, identified implementation determinants, tailored implementation strategies and fidelity assessments. The rates of these contacts will be determined by pharmacy commencement and/or pharmacists-initiated request, data analysis identifying potential issues as part of the pharmacist-patient consultation, and strategic decision by the research team depending on the needs and progress of the study, with at least two contacts to each pharmacy.
- Participant qualitative interviews data: consenting participants (patients, community pharmacists and other key parties) 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.

Only authorised personnel acknowledged and approved by the Human Research Ethics Committee will have access to study data. All study files will be retained at the University of Newcastle for a minimum of 15 years at respective study sites in accordance with the Australian Code for the Responsible Conduct of Research. All data will be maintained in accordance with the National Privacy Act 1998 and the NSW Health Records and Information Privacy Act 2002.

Data analysis

A mixed methods analytic approach will be applied. Descriptive statistics will be produced for the quantitative implementation outcomes (acceptability, adoption, fidelity and reach), for the implementation process (using the EPIS framework), determinants (using the CFIR framework) and strategies (using the ERIC framework). In addition, links between implementation determinants

Table 1 Implementation outcomes for objective 3 of the study

Name	Definition	Assessment method	Data source	Timepoint
Acceptability	"Perception among implementation stakeholders and patients that the service is agreeable, palatable, or satisfactory"	Two interview guides will be tailored to each group (patient sample, pharmacist the remaining key parties) Patients will be asked about their experiences with the service, including its advantages and disadvantages, and whether they would recommend it to others. Key parties (general practice and pharmaceutical professional bodies and NSW Health administrators) will be asked various questions, focusing on their understanding and interpretation of the service, its perceived benefits to be valuable and its appraisal Patients' interview guide will include service experiences, barriers for care, support with accessing, usefulness of the service, downsides of the service, how the patient heard about the service, recommendation of the service to others and if pharmacists should be allowed to prescribe more (Supplementary Material 5) Key parties' interview guide will include the following sections: acceptability, coherence, cognitive participation, collective action, reflexive monitoring and conclusion (Supplementary Material 6)	Captured by TGI through semi-structured interviews with a sample of patients, pharmacists and other key parties	At the end of the study
		Patients' follow up (Supplementary Material 7, question 15) will be made by the research team and will incorporate seven items including the following domains: (a) trust and confidence in health and medical advice provided, (b) convenience, (c) privacy during discussion with pharmacist, 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	Captured by TGI and completed by patients at follow up	7 and 14-day after the consultation in the pharmacy
Adoption	"Intention, initial decision, or action to try or employ the service"	Absolute number, proportion and representativeness of pharmacies and pharmacists that are willing to initiate the service	Data provided by pharmacists through consent and training certificates	At the beginning, during and end of the study
Appropriateness	"Perceived fit, relevance, or compatibility of the service for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem"	During the qualitative interviews, patients will be asked about their perceived usefulness of the service and any downsides when using it (Supplementary Material 5) Key parties (general practice and pharmaceutical professional bodies and NSW Health administrators) will be asked different questions, focusing on their level of commitment and engagement with the service and its impact on their work (Supplementary Material 6)	Captured by TGI through semi-structured interviews with a sample of patients, pharmacists and other key parties	At the end of the study
Feasibility	"The extent to which the service can be successfully used or carried out within a given agency or setting"	During the qualitative interviews, pharmacist will be asked questions, focusing on the impact of the service on the practice and workflow (Supplementary Material 6)	Captured by TGI through semi-structured interviews with a sample of patients, pharmacists and other key parties	At the end of the study

Table 1 (continued)

Name	Definition	Assessment method	Data source	Timepoint
Fidelity	"Degree to which the service is implemented as it was prescribed in the protocol or as it was intended by the program developers"	Review of pharmacists' adherence to the information included in the clinical guidelines for each of the four conditions in relation to patients' age, allergy check, clear differentiation of the clinical presentation, severity and location check, knowledge and application of the referral criteria and adherence to the antimicrobial stewardship principles	Assessed by IFs on their regular pharmacy interactions using the checklist (Supplementary Material 4) and registered via REDCap	The rates of these contacts will be determined by the research team (at least two per pharmacy)
		Fidelity will be also evaluated through protocol deviations and violations when evaluating pharmacy clinical consultation data, through the evaluation of the clinical database to measure protocol deviations and violations. A protocol deviation is usually an unintended departure from the expected conduct of the trial (with regards to the protocol and/or standard operational procedures). A protocol violation is defined as any departure from the requirements of Good Clinical Practice, the approved clinical trial protocol, trial documents, or any other information relating to the conduct of the study which has the potential to significantly impact the safety or rights of trial participants or the reliability and integrity of the study data. A protocol violation will be considered when the clinical guideline has not been adhered to with the potential to significantly impact patient safety and where there has been a negative outcome to the patient (symptoms worsened, hospitalised, attended an ED/Urgent Care Clinic or reported a Serious Adverse Event) or when the patient outcome is unknown as the patient has not responded to the follow up survey	Captured through the pharmacy consultation data (secure digital IT platform)	Monthly initially and then every two months
Reach	"Target population"	Defined as the absolute number, proportion, and representativeness of consultations in the study sample	Captured through the pharmacy consultation data (secure digital IT platform)	At the end of the study

and 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. For the evaluation of fidelity, we will compare the results obtained through the evaluation of the IFs in their regular contact with pharmacies and the results from the analysis of the database to evaluate protocol deviations and violations. Relationships will be established between the type and frequency of contacts among IFs and pharmacists and implementation outcomes (adoption, fidelity and reach). Additionally, analysis of the comparative results from each one of the four IFs will be undertaken.

As for the qualitative analysis, self-reported patient, community pharmacists and other key parties' acceptability, appropriateness and feasibility will be examined at 6 months. Interviews will be transcribed, deidentified and imported into NVivo for thematic analysis. Initial open coding of transcripts will be undertaken iteratively by two members of the research team. Themes will be presented to the broader research team and program implementers for final consensus.

Ethics approval and consent to participate

Research protocol, following the SPIRIT guidelines (Supplementary Material 8), received approval by the University of Newcastle Human Research Ethics Committee on 27 May 2024 (H-2024–0002). All participants, pharmacists and patients, will be required to provide informed written consent.

Dissemination of results

Results will be published in the academic literature and presented at national and international conferences, media articles and newsletters. Submission of the main report to the sponsor will be in the name of the research group. All participants will be able to request a resume of study outcomes though the trial mailbox, as stated in the consent forms.

Discussion

This is a pragmatic implementation study that involves key parties at a state policy level, service implementers, and academics optimising the integration of implementation science from theory to practice. Health policy is moving towards an increased scope of practice for community pharmacists. This study will contribute to the literature by generating new data on the implementation of

a pharmacist prescribing service and a detailed process to assess tailored implementation strategies.

It has been discussed that too many theoretical implementation frameworks and models have been created [45] and not enough research effort being devoted to real world studies. The present trial will contribute to the literature by adding practical tools (facilitation checklists and reports), for established implementation frameworks, to support the objective measurement of implementation outcomes for prescribing services. An agreed fidelity checklist will allow the evaluation of the intervention by different IFs decreasing variability; it will include pharmacists' adherence to the clinical guidelines, use of the secure messaging system and use of the secure digital IT platform. Such a checklist will also permit tailoring education and support for implementers. In addition, fidelity, identified as one of the key outcomes when implementing prescribing services, will be evaluated by analysing the community pharmacies' databases to search for guideline deviations and violations. Additional evaluation of the fidelity to clinical guidelines, through the IFs' checklist and the database assessment will occur.

The study expands on an earlier project that assessed a pharmacist prescribing service for managing uncomplicated urinary tract infections (PATH-UTI) [25] and resupply of oral contraception treatments (PATH-OC) [26]. However, these services are provided by using agreed protocols via a structured prescribing arrangement while the present study moves further by providing clinical guidelines which need to be applied. A change to guidelines moves professionals from practicing with agreed protocols. The study will add strategies and tools to enable such process change in a safe way.

Study limitations

During the study, patients will be able to obtain recommendations and treatment (when suitable) for any of the four dermatological conditions from pharmacists. Initially, a randomised controlled trial was proposed as study design; however, the NSW Government opted to offer the service to all pharmacies to increase accessibility, thus negating the possibility of a pharmacy control group.

Another limitation of the study is the absence of a comparison group involving general medical practitioners, as obtaining such data was not deemed feasible. Future research could address this by comparing clinical outcomes for patients managed in both settings.

The number of IFs supporting pharmacists during the study will be limited to four. As a large number of pharmacies ($n = 1{,}104$) could be included, there is a risk that facilitators will not be able to visit all pharmacies or make contact as frequently. Contacts other than visits will be allowed (phone and video calls) to overcome this limitation. Additionally, the type of contact will be evaluated in relation to implementation outcomes (adoption, fidelity and reach) to search for patterns. Remote support could reduce costs for scale-up if implementation outcomes are not affected. This study builds on two previous implementation studies of pharmacist prescribing services. Since the same IFs and pharmacists are involved in this third phase, the barriers and strategies might differ from those experienced earlier. However, as this trial is the first to assess implementation for autonomous pharmacist prescribing, it is not a direct continuation of the previous studies. Lastly, sustainment is an important implementation outcome defined as "the extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing, stable operations" [44]; its evaluation will be limited due to the study duration (six months) as a result of resource limitations. Nevertheless, qualitative interviews with different key parties will explore potential for sustainment.

Abbreviations

ACP	Australasian College of Pharmacy
ACT	Australian Capital Territory
AHPRA	Australian Health Practitioner Regulation Agency
AIHW	Australian Institute of Health and Welfare
ANZCTR	Australian New Zealand Clinical Trials Registry
CFIR	Consolidated Framework for Implementation Research
DSMB	Data Safety Monitoring Board
GP	General medical practitioner
IF	Implementation Facilitator
LGA	Local Government Areas
MMM	Modified Monash Model classification
NSW	New South Wales, Australia
PATH-UTI	PATHway to access UTI management
PATH-OC	PATHway to access Oral Contraception
PATH-DERM	PATHway to access skin conditions management
PSA	Pharmaceutical Society of Australia
TGI	The George Institute for Global Health

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12913-025-13128-3.

Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

Supplementary Material 4.

Supplementary Material 5.

Supplementary Material 6.

Supplementary Material 7.

Supplementary Material 8.

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Not applicable

Authors' contributions

All authors have made substantial contributions to the conception and design of the work. They were responsible for the analysis, and interpretation of data.

NAF and SIB are responsible for drafting the manuscript, while FMM, SD, JM, GS, MH and SDG have reviewed the manuscript. All authors have read and approved the final manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This trial was approved by the University of Newcastle Human Research Ethics Committee (Australia) on the 27 May 2024 (approval number H-2024–0002).

Consent for publication
All participants will be required to provide informed written consent, including consent for publication. The consent form includes the following statement "Findings will be reported to the NSW Government, in peer-reviewed publications and conference presentations. Individual participants will not be identifiable in any of the publications generated. Non-identifiable data may be shared with other parties as part of a peer-review process to verify the robustness and integrity of the study, or to contribute to further research and public knowledge".
All participants will be able to request a resume of study outcomes though the trial mailbox, as stated in the participant information sheet and consent forms.

Competing interests
The authors declare no competing interests.

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