FINAL REPORT

NSW Government Sponsored Trial: Resupply of Oral Contraception by Community Pharmacists

Evaluation of PATH-OC

MAY 2026

UNIVERSITY OF NEWCASTLE AUSTRALIA

ISBN: 978-0-7259-0847-8 (print)
ISBN: 978-0-7259-0846-1 (electronic/online)

Acknowledgements

The University of Newcastle acknowledges the traditional custodians of the lands within our university footprint areas: Awabakal, Darkinjung, Biripai, Worimi, Wonnarua, Gomeroi and Eora Nations. We pay respect to the wisdom of our Elders past and present. We also acknowledge and pay respect to the other Aboriginal and Torres Strait Islander nations from which our research partners, students, staff and community are drawn.

NSW Health is funding the development, implementation, and monitoring of the trial through a grant awarded to a research consortium led by the University of Newcastle, titled NSW Government Sponsored Trial: Resupply of Oral Contraception by Community Pharmacists. This report serves as the final project deliverable, summarising the trial outcomes, key findings and recommendations for potential integration into broader healthcare policy and practice.

The University of Newcastle extends its gratitude to all partners, members of the governance structure, research participants, community pharmacists and community pharmacy owners for their invaluable contributions. We especially acknowledge and deeply appreciate the Indigenous knowledge holders whose wisdom and insights have enriched this research.

A generative AI tool (Microsoft Copilot) was used as a writing aid to support drafting, structural editing, summarisation, and clarity improvements. The tool was not used for decision-making or to replace author judgement. In line with NHMRC guidance, we exercised caution regarding information entered into the system and ensured that all statements were human reviewed; the author team verified quantitative figures and claims against the underlying data and/or cited sources and remains accountable for the accuracy of the final report.

National Health and Medical Research Council. (2025, February 27). Artificial intelligence (AI) transparency statement. NHMRC.

Citations

Full Report Citation

Dineen-Griffin, S., Martinez Mardones, F., Benrimoj, S. I., & Collaborators. (2026). Resupply of Oral Contraception by Community Pharmacists*: Evaluation of PATH-OC – Final report*. College of Health, Medicine and Wellbeing, The University of Newcastle, Newcastle, in collaboration with The George Institute for Global Health; University of New South Wales; Hunter Medical Research Institute; and University of Technology Sydney. https://doi.org/10.71862/3cvv-1c53

For specific chapters, please cite the relevant authors and chapter titles individually, as follows:

- Dineen-Griffin, S., Martinez Mardones, F., & Benrimoj, S. I. (2026). Executive Summary. Resupply of Oral Contraception by Community Pharmacists*: Evaluation of PATH-OC – Final report.* College of Health, Medicine and Wellbeing, The University of Newcastle, Newcastle.
- Chisari, V.S., Budden, M., Martinez Mardones, F., Xenos, K., Dineen-Griffin, S., & Benrimoj, S. I. (2026). Introduction. Resupply of Oral Contraception by Community Pharmacists*: Evaluation of PATH-OC – Final report* (Chap. 1). College of Health, Medicine and Wellbeing, The University of Newcastle, Newcastle.
- Gilbertson, D., Chung, S., Chisari, V.S., Martinez Mardones, F., Palominos Veas, C., Benrimoj, S. I., & Dineen-Griffin, S. (2026). Co-design of PATH-OC. Resupply of Oral Contraception by Community Pharmacists*: Evaluation of PATH-OC – Final report* (Chap. 2). College of Health, Medicine and Wellbeing, The University of Newcastle, Newcastle.
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EXECUTIVE SUMMARY

UNIVERSITY OF NEWCASTLE AUSTRALIA

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Executive Summary

International evidence indicates that pharmacist-led resupply of low-risk oral contraceptive pills (OCPs) is feasible, acceptable, and safe when delivered within defined eligibility criteria, standardised clinical screening, and clear referral pathways. This occurs alongside continued recognition that long-acting reversible contraception (LARC) remains the preferred first-line option, and that pharmacist-led resupply serves a different purpose - supporting continuity of supply for established OCP users. In the United Kingdom (UK), a service encompassing 741 consultations reported consistently positive user experiences in relation to comfort discussing contraception, privacy and overall satisfaction, with combined OCPs [1]. A UK clinical audit found supplies under a patient group direction to be clinically appropriate with appropriate referrals when indicated, supporting the reliability of pharmacist decision-making under structured directives [1]. A United States (US) cohort evaluating pharmacist supply of hormonal contraception (pills, patch, ring) showed 91% of women supplied at consultation and 70% continuation of use at 12 months, with high convenience and satisfaction, and referrals for further care where warranted [2]. A US comparative analysis of medical contraindications to combined hormonal contraception found lower potential contraindication ("error") rates under pharmacist management than under other clinicians in protocolised settings [1]. These data collectively suggest that pharmacist-delivered OCP resupply can maintain continuity for eligible users safely, provided pharmacists operate within clear clinical processes and escalation pathways.

PATH-OC employed a prospectively registered mixed methods cohort design in community pharmacies across New South Wales (NSW) and 15 Australian Capital Territory (ACT) sites over 12 months to evaluate this continuation model with safety as the primary outcome (27 September 2023 – 27 September 2024). The protocol was prospectively registered and overseen by a multi-institutional consortium, with independent analyses and ethics approvals. The evaluation aimed to determine whether pharmacist-led resupply could safely and acceptably maintain continuity of low-risk OCP use among individuals with an existing prescription from a medical practitioner. Safety was the primary outcome, supported by analyses of participant experience, implementation outcomes, economic impacts, and equity considerations, including a dedicated stream focused on Aboriginal and Torres Strait Islander peoples' perspectives.

Eligibility targeted assigned female at birth (AFAB) women aged 18–35 years, on the same OCP for ≥2 years, and reviewed by a medical practitioner or nurse practitioner within 24 months. Trained pharmacists delivered a protocolised consultation with blood pressure (BP) and body mass index (BMI), algorithmic triage, and 1–12 months resupply where appropriate, coupled with brief counselling, medical practitioner notification (with consent), and referral when indicated. Data sources comprised pharmacy consultation records, a follow-up participant survey at day 7 (exploring experience, use, side effects, out-of-pocket costs), and, where consented, linked administrative datasets (including NSW/ACT hospital and emergency department (ED) records; Medicare Benefits Schedule (MBS)/Pharmaceutical Benefits Scheme (PBS) claims), covering 12–36 months pre- and up to 6–12 months post-consultation depending on the dataset.

Co-design of PATH-OC

Clinical management protocols were produced through a structured process that combined a targeted review of international and Australian practice models with a multidisciplinary workshop involving medical practitioners, community pharmacists and women's health experts. The protocols embedded medical eligibility criteria, BP and BMI measurements, and a colour coded risk triage (green, orange, red) dictating supply versus referral. The protocols allowed 1–12 months of resupply for eligible consultations, required documentation and general practitioner (GP) notification (with participant consent), and specified the delivery of contraception and sexual health counselling. The guiding principle was feasibility in routine community pharmacy without compromising safety, underpinned by clear escalation and referral mechanisms for any elevated risk or protocol exclusions.

Clinical Evaluation of PATH-OC

Of 1,299 consenting pharmacies, 528 (40%) delivered at least 1 consultation, with a median of 3 consultations per active site (IQR 1–5), reflecting heterogeneity in local uptake and capacity. Across the trial, 1,946 unique participants underwent 2,209 pharmacist-led OCP resupply consultations. The patient cohort was predominantly metropolitan (79.3% in Modified Monash Model (MMM) 1) and skewed younger (largest stratum 18–25 years, approximately 48%), with a distribution that leaned towards higher socioeconomic quintiles by residential postcode, an important consideration for generalisability and equity. In terms of medicines, combined OCPs were supplied in 86.2% of consultations and progestogen-only pills in 6.6%; 7.2% resulted in no supply. The mean duration of resupply was 5 months, and 6.9% of participants were referred to a GP.

All enrolled participants consented to linkage with NSW/ACT hospital and ED datasets; 81.1% contributed follow-up to the data cut-off used for the main analyses, and 33.2% contributed data at 6months post-consultation given the rolling nature of enrolment and the fixed administrative cut-off. Consent to MBS/PBS linkage was 94.6%, with those datasets extending to 31 December 2024; 81.3% of participants had 6-month follow-up in at least 1 of the Commonwealth datasets. This mixed, time-bounded coverage necessarily shapes the interpretation of longitudinal indicators and underlines the importance of careful windowing and denominator management in the analyses.

In the linked data, there were no detected OCP related hospitalisations or ED presentations following pharmacist resupply. All-cause hospitalisations and ED attendances in the 4 weeks after consultation were very low in absolute terms, and where small cell counts arose, values were suppressed per privacy guidance; the narrative synthesis indicates the absence of emergent safety concerns attributable to the intervention. At the point-of-care, 57 consultations (2.6%) triggered elevated risk flags: 48 were red (high risk) and 9 were orange (moderate risk). No red flag consultations resulted in resupply, and 81.2% of red flag cases were referred to general practice; reasons for non-referral in the remainder were documented and addressed in governance narratives. All orange flag cases received resupply and referral, reflecting the protocol's intent to combine risk mitigation with continuity where clinically permissible. At 7-day follow-up, 6 consultations documented self-reported, expected non-serious side effects (for example, bleeding changes, nausea, mood effects).

Participants reported very high satisfaction with pharmacist consultations. Among 1,751 completed 7-day surveys (79.2% of consultations), the mean composite experience score was 91.6/100, with consistently positive ratings for trust and confidence, privacy, and convenience. Resupply was reported in 95.2% of these follow-ups, and 90.5% reported taking the OCP as recommended at 7 days. Medication continuity improved materially with the proportion of days covered (PDC) increased from 0.60 in the pre-consultation period to 0.84 post-consultation, and the proportion achieving ≥80% coverage rose from 44.1% to 65.3%. These changes are consistent with the service's core purpose, uninterrupted access to an already established method, and were observed alongside a modest reduction in mean monthly medical practitioner visits. Exploratory subgroup analyses of the experience outcome suggested higher odds of a high composite satisfaction score among women aged 26–30 relative to those aged 18–25 (adjusted odds ratio (OR) 1.78), and among those attending medium or small towns relative to metropolitan settings (adjusted OR 1.88). By contrast, consultations that did not result in resupply were associated with lower odds of a high satisfaction score (adjusted OR 0.36), indicating the intuitive link between achieving the intended outcome and perceived service quality. These findings relate specifically to experience and do not imply differences in safety outcomes by stratum.

Reported fidelity to the clinical protocol was very high, supported by standardised software-guided workflows and training. The evaluation notes a temporary coding error early in the period that incorrectly green-flagged 26 consultations at specific BP/BMI thresholds; the issue, its rectification, and implications are documented, and no safety signal was observed as a result.

The model did not generate evidence of harm in linked administrative outcomes and improved continuity of medication access and use. The strong satisfaction signals align with the practical benefits reported in interviews: timeliness, convenience, and perceived value. These findings should not be generalised beyond the low-risk continuation context, nor should they be interpreted as evidence for

initiation or for populations outside the eligibility criteria.

Economic Evaluation

The economic analysis compared the pre-PATH-OC landscape of OCP resupply (dominated by GP pathways) with the PATH-OC landscape that includes a pharmacy resupply option. The modelling adopted a partial societal perspective, explicitly quantifying Commonwealth outlays and patient out-of-pocket payments across plausible pharmacy uptake scenarios. NSW consultations carried no pharmacist service fee for the patient during the trial (participants paid for medication only), whereas ACT consultations may have included a pharmacist fee. The model did not include productivity impacts, long-term health outcomes, or full provider implementation costs, keeping inference appropriately conservative.

The analysis simulated episodes of resupply under competing pathways, pharmacy, GP, and online GP services, and assigned pathway specific unit costs (patient and Commonwealth components), based on observed or published fee schedules. The base-case pharmacy uptake was set at approximately 13% (with sensitivity tests at 10–50%), reflecting realistic early-stage adoption rather than fully mature integration. Illustrative costs per episode demonstrate the shift in payer mix: a pharmacy episode (where a service fee applies) is predominantly a patient cost; a GP episode entails both Commonwealth and patient shares; and an online GP service episode typically charges the patient and, in some settings, attracts a smaller Commonwealth component. These structural differences are fundamental to interpreting who saves and who pays when pharmacy resupply scales.

At ≈13% pharmacy uptake, the model estimated Commonwealth savings of about $11.9 million per annum due to substitution away from GP and online GP service pathways, accompanied by an increase in aggregate patient-of-pocket of roughly $3.5 million driven by pharmacy service fees (where applicable), partially offset by reduced copayments in other pathways. When uptake was increased in sensitivity analyses to 25% and 50%, projected Commonwealth savings rose accordingly (up to approximately $44.5 million at 50%), while patient costs increased to around $8 million and $16 million, respectively.

In 7-day follow-up surveys across NSW and ACT, participants reported a mean total spend of $28, encompassing medicine costs in NSW and medicine plus consultation fee in ACT; 8.5% indicated that cost may be a barrier to using the service again. While this sentiment was a minority, it was concentrated among users more sensitive to out-of-pocket expenses, underscoring the need for careful fee setting and mitigations (for example, fee caps or targeted subsidies) to prevent two-tiered access by income or geography as services transition from trial to routine practice.

The economic modelling outcome data is internally consistent: introducing a pharmacy pathway for low-risk continuation reduces Commonwealth expenditure, by substituting some GP activity but can shift part of the cost burden to patients if fees are levied at point-of-care. The public savings are compelling at scale, yet affordability safeguards are essential to preserve equitable access, particularly for young, rural, and low-income users who already face structural barriers. Given that LARC remains first-line, referral integration and transparent information about options and costs should accompany any scale-up to support informed choice and minimise unintended financial obstacles.

An Evaluation of Implementation Fidelity and Effectiveness

Forty percent of consenting pharmacies delivered consultations, 915 pharmacists provided services, and protocol fidelity approached 100%, supported by standardised digital workflows, training, and Practice Change Facilitator (PCF) input (coaching, audit/feedback, and local problem solving). Barriers commonly reflected training/credentialing, equipment/space, patient awareness and demand generation, and workflow/time in community settings; facilitators included pharmacist capability, private consultation spaces, and decision support tools. The geographic pattern of activity was concentrated in MMM 1–5, with no MMM 6–7 pharmacies delivering services; this differential access aligns with broader remote workforce and infrastructure constraints and signals a priority area for any uptake. It was interesting to note that an alternative method of resupply, under PBS authority, which did not have extensive protocol driven requirements was mentioned by participants. This alternative model may have had negative implications for the number of consultations.

Aboriginal and Torres Strait Islander Perspectives and Access

A dedicated mixed-methods component engaged Aboriginal and Torres Strait Islander community members, Aboriginal Community Controlled Health Organisation (ACCHO) staff, and pharmacists through yarning and complementary data sources. Although representation within the quantitative follow-up sample was small, several consistent themes emerged. Participants valued the proximity and timeliness of pharmacy access and often described positive rapport with local pharmacists. Nonetheless, cultural safety, privacy, continuity of care, and affordability were recurring concerns, and emphasis was placed on the need for clear, trusted referral pathways to LARC, which remains first-line and typically sits outside pharmacy scope. In small samples, satisfaction scores were lower than the overall cohort, and some users declined resupply and were referred appropriately. These signals argue for co-design with ACCHOs, culturally safe practice, transparent information, and fee mitigation as preconditions for equitable benefit in Aboriginal and Torres Strait Islander communities.

Overall Discussion

When delivered within the trial's safety parameters of stable users, standardised screening, documented thresholds, and clear referral processes, pharmacist-led OCP resupply was safe, highly acceptable, and implemented with very high fidelity in community pharmacies. Linked administrative data revealed no OCP related serious adverse events, while continuity of use improved substantially, and participant experience was uniformly positive. The model achieved these gains without the potential of using the first-line status of LARC, which remains central to contraceptive care and at this stage requires coordinated referral pathways from pharmacy to medical services.

At the same time, there are important caveats. Reach and equity were constrained by eligibility criteria, product inclusion, and the metropolitan concentration of participating pharmacies; remote and very remote communities were not represented among service-delivering sites. The economic analysis, while favourable to the public payer, indicates potential cost shifting to consumers unless fee structures are calibrated with equity safeguards. Finally, the time-bounded follow-up in linked datasets and the absence of a control group limit causal inference for some outcomes. Future work should track longer-term endpoints (such as unintended pregnancy), expand geographic coverage, and deepen integration with ACCHOs and LARC providers to align access with first-line recommendations.

The evaluation has several limitations that should be considered when interpreting findings. The absence of a control group limits causal inference from pre-post comparisons, particularly given the short 7-day follow-up for primary safety outcomes. Data completeness varied across linked administrative datasets: hospital and ED records were only available to 30 June 2024, providing follow-up data for 81.1% of participants and 6-month follow-up for only 33.2%. In contrast, MBS/PBS data were available to 31 December 2024 with higher consent rates (94.6%), enabling 81.3% 6-month follow-up.

External validity is also constrained. Activity was concentrated in metropolitan areas (79.3% MMM 1), with no MMM 6–7 sites and a socioeconomic skew toward more advantaged communities. The continuation only, low risk eligibility criteria, enhance safety but limit generalisability beyond established OCP users. The economic evaluation used a partial perspective (excluding productivity and long-term outcomes) and was sensitive to assumptions about uptake and fees. Additionally, small Aboriginal and Torres Strait Islander samples and limited rural and remote participation restrict equity generalisability, and qualitative findings remain subject to selection bias.

Evidence from the evaluation supports scaling up pharmacist-led resupply of low risk OCPs under the same safety parameters, including accredited training, structured decision support, audit and feedback mechanisms, and defined referral thresholds, while concurrently addressing equity levers (fee design, rural access, cultural safety) and integration with LARC and primary care. Monitoring should include longitudinal safety, continuity of use, unintended pregnancy, out-of-pocket burden, and geographic/priority population coverage, so that benefits are sustained and shared across diverse settings and communities.

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Glossary

ACCHO	Aboriginal Community Controlled Health Organisation
ACT	Australian Capital Territory
ACT APDC	ACT Admitted Patient Data Collection
ACT EDDC	ACT Emergency Department Data Collection
ACT RBDM	ACT Registry of Births, Deaths and Marriages
AGREE II	Appraisal of Guidelines for Research and Evaluation II
AIHW	Australian Institute of Health and Welfare
ANZCTR	Australian New Zealand Clinical Trials Registry
APDC	Admitted Patient Data Collection
ABS	Australian Bureau of Statistics
BP	Blood Pressure
CFIR	Consolidated Framework for Implementation Research
CHC	Combined hormonal contraception
CHRI	Co-Design Health Research and Innovation
CI	Confidence Interval
CHeReL	Centre for Health Record Linkage
COC(s)	Combined oral contraceptive(s)
CTG	Close the Gap
CUP	Consumer User Panel
DMPA	Depot medroxyprogesterone
DPMQ	Dispensed Price for Maximum Quantity
EC	Emergency contraception
ECPs	Emergency contraceptive pills
EDDC	Emergency Department Data Collection
ED	Emergency department
ERIC	Expert Recommendations for Implementing Change
GP	General practitioner
HPV	Human papillomavirus
IQR	Interquartile range
LARC	Long-acting reversible contraception
MACS	Minor Ailments and Contraception Service
MEC	Medical Eligibility Criteria
MBS	Medicare Benefits Schedule
MMM	Modified Monash Model
NAP	Non-Admitted Patient Data Collection

NHS	National Health Service
NIPVIP	National Immunisation Program Vaccinations in Pharmacy
NPT	Normalisation Process Theory
NSW	New South Wales
NZ	New Zealand
OC(s)	Oral contraceptives
OCP(s)	Oral contraceptive pill(s)
OR	Odds ratio
PATH-OC	Trial evaluating pharmacist resupply of OCPs in NSW (and 15 ACT pharmacies) for women aged 18–35
PATH-UTI	Trial evaluating pharmacist management of uncomplicated UTI in women aged 18–65
PCF	Practice Change Facilitator
PCS	Pharmacy Contraception Service
PBS	Pharmaceutical Benefits Scheme
PDC	Proportion of days covered
PGD	Patient group directive
PDL	Pharmaceutical Defence Limited
PPMAC	Pharmacist Prescribing for Minor Ailments and Contraception
POP(s)	Progesterone-only pill(s)
PSA	Probabilistic sensitivity analysis
RACGP	Royal Australian College of General Practitioners
RBDM	Registry of Births, Deaths & Marriages
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
STI(s)	Sexually transmitted infection(s)
SURE	Secure Unified Research Environment
UK	United Kingdom
UKMEC	UK Medical Eligibility Criteria for Contraceptive Use
UNSW	University of New South Wales
US	United States
USMEC	US Medical Eligibility Criteria for Contraceptive Use
UTI	Urinary tract infection
uUTIs	Uncomplicated urinary tract infections

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INTRODUCTION

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-OC
PATHWAY TO ACCESS: ORAL CONTRACEPTION

Chapter 1: Introduction

Contraception

There is growing recognition of the need to prioritise women's health, driven by several important factors [3, 4]. According to the Australian Institute of Health and Welfare (AIHW), women make up just over 51% of Australia's population [5], which highlights their significant contribution to society. Access to safe, effective, affordable, and high-quality sexual and reproductive health services remains a global challenge [4].

Contraception is a fundamental component of sexual and reproductive health and is regarded as a human right according to the World Health Organization (WHO) [6–8]. The prevention of unintended pregnancies lowers maternal morbidity and mortality, improves birth outcomes [8, 9], improves socioeconomic status [8], slows population growth and improves educational and employment opportunities for women [10]. The global landscape of contraceptive use has undergone significant transformation over the past several decades. Since the 1970s, the prevalence of contraceptive use among women of reproductive age (15–49 years) who are married or in union, has increased from just under 40% to over 65% by 2022, driven largely by the expansion of access to modern methods of contraception [11]. Modern methods, including hormonal contraception such oral contraceptive pills (OCP), subdermal implants; intrauterine devices (IUDs), male and female condoms and fertility-awareness based methods, are now used by over three-quarters of contraceptive users globally [11]. The number of women seeking contraception has increased from 900 million in 2000 to nearly 1.1 billion in 2021 [12], and an additional 70 million is expected by 2030 [12, 13].

Among modern contraceptive methods, hormonal contraceptives are by far the most utilised method worldwide [11]. These include various types of OCP, injectable contraceptives, subdermal implants, transdermal patches, hormonal IUDs, emergency contraceptive pills (ECPs), and the vaginal ring [11]. The popularity of hormonal methods has been attributed to their high effectiveness, reversibility, and the degree of user autonomy they provide [11]. The introduction of the oral contraceptives (OCs) in the 1960s marked a pivotal moment in reproductive autonomy and played a significant role in reshaping traditional gender dynamics [11, 14, 15]. Oral contraceptives are known to be the most widely used contraceptive method internationally [16–18] and remains the most used contraceptive method among Australian women [19]. Their popularity is due to their non-invasive and easy administration compared to methods which require vaginal insertion or intramuscular injection for example, their reversibility, and additional non-contraceptive benefits such as controlling acne, hirsutism, and other menstrual-related symptoms [20–22]. It should be noted that, long-acting reversible contraceptives (LARCs) are widely recommended by professional bodies and the WHO as first-line contraception for young women as they are safe, effective and reversible.

The literature has reported several barriers to the access of the OCP. Smith *et al.* reported that one of the most common reasons was being unable to access a new pack of contraceptive pills for the beginning of a new cycle [23]. A 2006 survey of 811 women aged 18–44 years in the United States (US), who were at risk for unintended pregnancy, found that 28% of women had problems with obtaining a prescription for contraception [24]. In addition, 20% of women said the cost of a visit to the doctor was an obstacle in obtaining a prescription contraceptive [24]. In a 2022 nationally representative survey conducted in the US, among women who experienced challenges or delays obtaining contraception, the most common reasons were logistical barriers (38.2%) and cost or insurance-related barriers (35.8%) [25].

Contraception in Australia and Barriers to Access

Access to contraception remains a significant public health challenge in Australia [26]. It is estimated that 1 in 4 Australian women experience an unintended pregnancy during their lifetime, with rates even higher in non-urban areas [27, 28]. It is suggested that funding for contraception, abortion, and miscarriage care in Australia is uneven and insufficient, which may create inequitable access [26]. Unintended pregnancies are often linked to

issues relating to access to contraception such as non-use, inconsistent use, or contraceptive failure, and can result in serious physical, emotional, and financial strain for women and their families [27]. Unintended pregnancies contribute to short interpregnancy intervals, which are associated with increased risks of preterm birth, low birth weight, and maternal complications [27].

Multiple barriers have been identified that can prevent women from starting and/or continuing their contraception method [29, 30]. One key barrier is the need to obtain a prescription from an appropriate healthcare practitioner, such as a medical practitioner [23, 24, 31]. According to data from the Australian Bureau of Statistics (ABS), in 2024–2025, 26% of people felt they waited longer than acceptable for a general practitioner (GP) appointment, down from 28% the previous year. Those in outer regional or remote areas, females, people aged 35–44, people with long-term conditions, and those in more disadvantaged areas, were more likely to report unacceptable waits [32]. Urgent care waiting times were largely unchanged, with about 42% seen within 4 hours and nearly half waiting 24 hours or more [32]. People without long-term conditions and those in major cities were more likely to be seen quickly, while younger adults were more likely to wait 4–24 hours [32]. These barriers may contribute to inconsistent contraceptive use and increase the risk of unintended pregnancies.

Emergency contraception (EC), commonly referred to as “the morning after pill”, serves as an important back-up method to prevent pregnancy after unprotected intercourse or contraceptive failure [33, 34]. In Australia, levonorgestrel and ulipristal acetate ECPs are available over the counter in community pharmacy. Pharmacists are required to perform a consultation with the person requesting the EC to provide advice on suitability, safety and important information on efficacy. The accessibility of EC in community pharmacy has empowered women to avoid unintended pregnancies, however, its use raises important questions about continuity and effectiveness of regular contraceptive use [33, 34].

Internationally, studies have shown that many OC users report concurrent or recent use of EC [33, 35, 36]. Evidence from Denmark, Norway, and Sweden found that up to 30% of ECP users were also using OCs, indicating issues related to missed pills, incorrect use, or perceived method failure [37]. This pattern suggests that even among regular users, adherence challenges and lack of backup planning may drive EC use. Similarly, data from the US further supports these trends where in women aged 15–44 who were OC users, almost 50% used EC due to concerns that the regular method had failed, for example missed contraceptive pill(s) and condom breakage [36]. Although EC is designed as an occasional method, repeat use is not uncommon. Research shows that many ECP users, particularly younger women, report using emergency contraception multiple times within a single year. [36]. This may reflect ongoing barriers to initiating or maintaining regular contraception, including difficulty accessing care, cost, stigma, or side effects from hormonal methods. LARCs have been suggested as a potential solution for access and adherence to contraception [36]. As such, EC use may serve as a proxy indicator for gaps in contraceptive service delivery, especially in populations with poor access to routine care [36]. Whilst EC is a vital safety net, its frequent use among women who are already using or intend to use regular contraception points to systemic gaps in awareness, knowledge of the importance of adherence and importantly, access to contraception.

Expanding Scope of Practice of Pharmacists

Improving access to effective contraception is a critical public health goal, with the intention to reduce unintended pregnancy and abortion rates [38]. One strategy to improving contraceptive access is increasing the scope of non-medical health professionals to include supply of hormonal contraceptives [10, 28, 39, 40]. Due to their accessibility, community pharmacists have been authorised to supply OCPs in many countries including states and/or provinces in Canada [41, 42], the US [43-54], the United Kingdom (UK) [55–59], New Zealand (NZ) [60, 61] and recently, in some states of Australia [62–64]. The supply of hormonal contraceptive pills by pharmacists is part of the broader initiative to expand accessibility to the public through community pharmacies [65–70]. Expanded services also include management of specific common ailments, chronic disease management, preventive health interventions such as immunisations as well as resupply of contraceptives [70]. Globally, this expansion of practice is being pursued as part of broader health system reforms to improve access to primary care and leverage the full potential of the health workforce in response to

increased demand for primary health care services, the integration of digital technologies, and lessons learned from the COVID-19 pandemic [38, 71].

Community pharmacists often serve as the first point of contact in the healthcare system [72]. In Australia, individuals visit community pharmacies more frequently than any other health professional, averaging 18 visits per person annually [73]. Pharmacists have long played a central role in delivering a range of primary care services such as medication management and preventative care [74] and are increasingly being recognised as well-positioned to expand their role in the provision of contraceptive care [38]. A core responsibility of pharmacists is the dispensing of both prescription and non-prescription medications, accompanied by patient counselling. In the context of women's health, this includes guidance on contraceptives, hormone replacement therapies, and over-the-counter treatments for menopause, perimenopause, and infertility [74]. Pharmacists, as part of the primary healthcare team, provide general advice on prenatal vitamins, supplements during pregnancy, and the safe use of medications during pregnancy and breastfeeding [74]. Pharmacists also contribute to women's health through screening, such as for sexually transmitted infections (STIs), in addition to referral, and treatment of conditions [75]. Pharmacists are authorised to administer the human papillomavirus (HPV) vaccine through the National Immunisation Program Vaccinations in Pharmacy (NIPVIP) program [76]. In Australia, pharmacists are authorised to dispense medications for early medical abortion, specifically the MS-2Step regimen (mifepristone and misoprostol), for pregnancies up to 63 days gestation [77]. Regulatory changes introduced in 2023 removed the requirement for pharmacists to be registered to dispense MS-2Step, and GPs no longer need mandatory training or registration to prescribe it. Additionally, the prescribing process by approved providers was simplified by moving MS-2Step to a Streamlined Authority category under the Pharmaceutical Benefits Scheme (PBS) [77]. These changes are expected to enable greater access to medical abortion, particularly for people living in rural and remote areas where access to trained providers has historically been limited [78].

International Research Overview of Pharmacist-Prescribed Contraceptives

Supply of contraceptives by community pharmacists has been identified as a strategy to improve access and has been adopted by health systems in the last 2 decades [10, 79, 80]. At an international level, there is evidence to support increased access to OCs in pharmacy without a prescription from a medical practitioner or an authorised prescriber [1, 2]. A 2013 review by Grindley *et al.* analysed the availability of OCs in community pharmacy across 147 countries [81]. Access to OCs in pharmacy was categorised into 4 groups; (a) informally available without a prescription (b) legally available without a prescription where there is no screening required by the pharmacist (c) legally available without prescription where screening is required by a health professional, and (d) only available with a medical prescription [81]. Fifty six countries (38.1%) had OCs informally available without a prescription, 35 countries (23.8%) had OCs legally available without a prescription (no screening by the pharmacist required), 11 countries (7.5%) had OCs legally available without a prescription where screening by the pharmacist is required, and 45 countries (30.6%) had OCs only available with a medical prescription [81].

In a study involving pharmacist supply of OCPs in the UK, a total of 741 consultations were conducted and 92.2% of total consultations were provided to women aged under 30 years [1, 82]. Combined OCPs were mostly supplied with nearly half (46.1%) of initial supplies to first-time pill users. Microgynon® 30 (30 mcg ethinylestradiol and 150 mcg levonorgestrel) constituted 65.1% (n=471) of consultations where a combined OCP was supplied. Progesterone-only pills (POPs) were less commonly supplied (196 packs) with desogestrel 75 mcg being the most common progesterone only pill supplied, constituting 64.3% (n=126). Of patients who completed the questionnaire, most (87.5%; 84/96) reported being very satisfied with the service they had received. When asked whether they felt comfortable talking to the pharmacist about contraception, 96.9% (94/96) reported being comfortable or very comfortable [1, 82]. All respondents were satisfied with privacy afforded [1, 82].

A study in the US reported on the outcomes of pharmacist supply of hormonal contraception including oral pills, patches and vaginal rings [2]. Overall, 91% (n=195) of women were supplied contraceptives, and after 12 months, 70% of women reported their continuing use of hormonal contraceptives. In the study, 38.9% (n=76) of women were referred by the pharmacist for other care as per the protocol. Referrals were made for 57 pelvic examinations, and 6 patients were referred for evaluation by a medical practitioner that resulted from pharmacist screening. One hundred and seventy-five patients responded to the interview held 1 month after their consultation, 97.7% (n=171) reported that they were satisfied or very satisfied with the experience and 97.1% reported they would recommend the service to a friend. Nearly all respondents (97.7%) found it convenient or very convenient to obtain hormonal contraception from a pharmacist, compared to accessing it through other providers such as family-planning clinics [2].

Studies from the UK and the US have demonstrated the safety of community pharmacists supply of hormonal contraceptives [1, 83]. The study conducted in the US compared the prevalence of medical contraindications to combined hormonal contraceptive use provided by pharmacists and those provided by other clinicians [83]. It included supply of combined hormonal contraceptives pills, patches and rings. The study examined instances of supply to women with a Medical Eligibility Criteria (MEC) Category 3 or 4 condition. The proportion of women with potential contraindications to combined hormonal contraception was lower among those supplied by pharmacists (0.90%) compared to clinicians (4.25%). Similarly, error rates were also lower among pharmacists (0.74%) than clinicians (2.11%) [83]. In the study from the UK, a clinical audit of 24% (n=180) of the total number of consultations was conducted in pharmacists supplying OCs [1], and showed pharmacist's adherence to the patient group directive (PGD) (or protocol) for supplied contraceptives was deemed clinically appropriate, and patients were appropriately referred in all cases [1].

Studies from the UK and the US have indicated that community pharmacists can safely screen for medical contraindications to hormonal contraceptives [2, 83] and can appropriately prescribe contraceptives [82]. A study from the US evaluated the cost effectiveness of pharmacist prescription of hormonal contraception through an estimation of unintended pregnancies averted and the evidence indicated an aversion of an estimated 51 unintended pregnancies and saving of $1.6 million dollars [84, 85]. These services have shown to improve access by offering lower costs, reduced wait times, no need for appointments, convenient locations, and extended hours of operation [1, 86, 87]. Evidence has shown that pharmacist-prescribed contraception is associated with higher continuation rates and increased uptake among new users [84, 85]. Additionally, patients report high levels of satisfaction with pharmacist-provided contraceptive care [1, 2].

A widely adopted international model of care involves pharmacists conducting structured clinical screening to assess patient eligibility and ensure the safety and effectiveness of contraceptive therapy prior to prescribing [10, 79, 80]. Screening is the process of assessing a patient's medical history, current health status, and personal preferences to determine the safest and most appropriate contraceptive method [88]. This process is essential to ensure that the chosen method of contraception does not pose health risks and aligns with the individual's reproductive goals to support reproductive autonomy through informed choice [88]. Pharmacist prescribing services distinguish between initiation and resupply of contraceptives. Initiation refers to prescribing by a pharmacist commencing hormonal contraceptive medication for a patient who has not previously been prescribed a hormonal contraceptive. Resupply, or continuation, involves providing a further or additional supply to a patient already using the hormonal contraceptive, most likely initially commenced by a GP or nurse practitioner. Initiation and resupply services improve contraceptive access by meeting the distinct needs of new and continuing users. The evidence indicates that initiation services increase contraceptive usage in women who are not currently taking a contraceptive [24], and resupply services improve continuation rates in women who are currently using contraception [84]. Together, these services contribute to broader and more sustained contraceptive coverage [89].

Regulatory change is needed to support the expansion of community pharmacists' scope of practice to include prescribing. In some countries, regulations define this expanded role through the use of clinical protocols that outline the scope and requirements of pharmacist-delivered services. These protocols are intended to support clinicians, patients, and the broader healthcare system by improving clinical decision-making, promoting

consistency of care, and enhancing patient safety [90–92]. Terms such as guidelines, clinical guidelines, and clinical management protocols are often used interchangeably to describe these clinical protocols.

Overview of Educational Requirements for Pharmacists

Education is also a key component of comprehensive patient care and forms part of the broader considerations involved in extending scope of practice. Components of pharmacist education in contraception typically include training on how to prescribe, education on the physiology of the menstrual cycle and associated hormonal changes, an overview of the drug mechanisms affecting menstrual function, and development of clinical skills. In Canada, pharmacy undergraduate programs have increasingly incorporated contraception prescribing, with pharmacist prescribing recognised as a significant update to sexual and reproductive health education over the last 5 years. Additionally, continuing education tailored to jurisdiction-specific requirements for contraception prescribing is offered throughout the country [42]. Provinces like British Columbia have a Minor Ailments and Contraception Service (MACS), where pharmacists must complete the Pharmacist Prescribing for Minor Ailments and Contraception (PPMAC) Regulatory Education module to provide the service [93]. In the US, the duration of required training programs for pharmacists to prescribe contraception differs by state, typically ranging from 2–6 hours of mandatory instruction [42, 94]. In 2023, National Health Service (NHS) England commissioned the Pharmacy Contraception Service (PCS) allowing the ongoing supply of OCs from community pharmacies. From December 2023, the service expanded to include both initiation and ongoing supply of OCs. The recommended training and education involve a core package focusing on the skills required to provide clinical services which safeguard vulnerable adults, young people and children [95]. The NHS provides a further breakdown of the different set of educational requirements for resupply and initiation. For resupply, this includes topics such as EC, contraceptive choice and sexual health, and for initiation, topics such as health history, risk assessment and managing contraceptive complications such as bleeding problems in women using contraceptives, side effects and other complications [95]. Separately, pharmacists in the UK may complete accredited training to become independent prescribers. They must practise within their competence, while identifying a defined area of expertise. From 2026, all newly qualified UK pharmacists will be registered as independent prescribers [96].

Australian Policy Changes

Australia has introduced pharmacist prescribing of contraceptives, including initiation or resupply, with the exact scope varying by state. A 2022 Australian Federal Government Inquiry found that regulatory restrictions continue to limit access to contraceptives across the country [27]. These barriers included the requirement to obtain a prescription, commonly through a GP or other authorised prescribing professional such as a nurse practitioner [27]. Several recent reports suggest that Australian pharmacists are not currently practicing to their full scope, including the prescribing of medicines [97, 98]. Expanding the scope of practice for pharmacists to include the supply of hormonal contraceptives has been recognised as a viable strategy to mitigate these challenges and has already been implemented in Queensland [10, 79, 80, 99]. These initiatives are expected to enhance equitable access to contraception, particularly for individuals in rural, remote, or underserved urban areas [10, 79, 80, 99].

In October 2023, Victoria launched the Community Pharmacist Statewide Pilot which authorised pharmacists to resupply selected OCPs without a prescription for women aged 16–50 over a 12-month period (October 2023 to October 2024) [100]. From July 2025, this service became part of routine practice, with publication of an evaluation summary [100]. In August 2024, Queensland introduced the Community Pharmacy Scope of Practice Pilot, including the Hormonal Contraception Pilot, implemented between August 2024 to June 2025 [101]. This pilot authorised pharmacists to initiate and resupply contraceptives to women including OCPs, vaginal rings and intramuscular injections [102]. From July 2025, these services were made permanent, reflecting broader recognition of pharmacists as prescribers for several acute conditions and preventive care services [103].

South Australia and Western Australia both commenced pharmacist resupply of the OCP in May 2024 [104, 105], followed by Tasmania in July 2024 [106]. Across these states and territories, services

are restricted to resupply only. At the time of this report, Queensland covers a more advanced scope than the rest of the country permitting both initiation and continuation of multiple contraceptive methods [102]. At the time of drafting this report, there are no published results from the Queensland Scope of Practice Pilot, including the Hormonal Contraceptive Pilot.

Oral Contraceptive Trial: NSW and ACT

Research contract

In 2022, the NSW Government commissioned a 12-month trial to evaluate pharmacist-led resupply of OCPs (PATH-OC). Under this trial, trained community pharmacists were authorised to provide continued supplies of selected OCPs to eligible women [107]. This trial forms part of a broader NSW Health funded research program comprising 3 pharmacist-led initiatives: (a) management of uncomplicated urinary tract infections (uUTIs), (b) resupply of OCPs, and (c) management of selected dermatological skin conditions, including exacerbations of atopic dermatitis and mild plaque psoriasis, impetigo and herpes zoster (shingles) [108]. Each trial ran for 12-months, commencing at different time points between 2022 and 2024. The PATH-OC trial was conducted from 27 September 2023 – 27 September 2024. The trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) (ACTRN - 12623001124628), with the protocol publicly available.

Aim, objectives and timing

The primary objective of the PATH-OC trial was to evaluate the clinical and economic impact, as well as the implementation, of a pharmacist-led service model (intervention) for resupplying selected OCPs. The intervention was delivered by community pharmacists across New South Wales (NSW) and 15 pharmacies in the Australian Capital Territory (ACT) over a 12-month period. Eligible participants were women aged between 18–35 years (inclusive), who were taking the OCP for contraception only and had seen their GP or nurse practitioner for review of a low-risk OCP within the previous last 2 years. An implementation science framework was applied to assess the delivery, uptake and sustainability of the service model.

The specific objectives of the OC trial (PATH-OC) were to:

1. Assess patient accessibility and acceptability of pharmacist-led management and resupply of low risk OCPs.
2. Evaluate implementation uptake, including reach, fidelity, adoption in community pharmacies, participant characteristics, and geographic variation.
3. Assess clinical outcomes and patient experience.
4. Evaluate safety and identify any risks for future implementation.
5. Explore the acceptability and feasibility of the service among pharmacists, other healthcare providers and participants through qualitative methods.
6. Identify contextual enablers and barriers affecting access, adoption, fidelity, delivery, impact, sustainability, and generalisability.
7. Conduct a health economic evaluation to determine the economic benefits.

The NSW Government highlighted the following specific objectives for the OCP resupply trial:

- incorporate pharmacist-led resupply of selected OCPs for eligible patients within the broader trial of pharmacist management;
- evaluate the benefits of pharmacist-led OCP resupply using both qualitative and quantitative methods; and
- identify potential risks and provide recommendations to support safe and effective broader implementation of pharmacist managed OCP supply across NSW following the trial.

Research team and governance

A governance structure was established to support collaboration among key stakeholders and health professionals and to ensure independent quality oversight of the project. A team of 18 Chief Investigators collaborated with 13 project partners to undertake and advise on the research (Appendix 1.1). Chief Investigators were responsible for overseeing the research components and providing advice to the lead Chief Investigators. The governance structure (Appendix 1.2) organised project partners into groups aligned with 3 phases of

the research: co-design, implementation, and evaluation.

Study hypothesis

The study hypothesised that a pharmacist-led OCP resupply service for women aged 18–35 years would be acceptable to both patients and providers, improve access, be cost-effective and not increase safety risks.

To test this hypothesis, the following studies were conducted:

- an independent co-design process with stakeholders, undertaken by Deloitte Consulting (Chapter 2);
- an independent formative and summative evaluation of clinical outcomes, patient satisfaction, and implementation, conducted by The George Institute for Global Health (Chapter 3);
- an economic evaluation undertaken by the Hunter Medical Research Institute (Chapter 4);
- an implementation evaluation, undertaken by the University of Newcastle and the University of Technology Sydney (Chapter 5); and
- a qualitative study undertaken for Aboriginal and Torres Strait Islander peoples by the Co-Design Health Research and Innovation (CHRI) team at the University of New South Wales (UNSW) (Chapter 6).

02

CO-DESIGN OF PATH-OC

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-OC
PATHWAY TO ACCESS: ORAL CONTRACEPTION

Chapter 2: Co-design of PATH-OC

Introduction

Co-design processes are now key aspects of any service or intervention design and implementation, as it allows stakeholders to input their experience and improves aspects related to collaborative care. Services protocols or models which are conceptualised through co-design usually gain more support from the service providers (including other healthcare professionals involved with the service) and from patients, particularly in relation to motivation and attituded towards change [109]. It also assists with service adoption and sustainability, leading to more successful service models and interventions. The co-design process with stakeholders was managed by Deloitte Consulting. A separate consultation process was undertaken for Aboriginal and Torres Strait Islander people (please see Chapter 6).

A literature review of international and national clinical protocols was undertaken to inform the development of evidence-based clinical protocols for pharmacist-supplied contraceptives (Appendix 2.1). The results of the literature review were used as the basis for discussion at a stakeholder workshop with the intent of developing and agreeing on final protocols and a service model for implementation in the New South Wales (NSW) setting (Appendix 2.2), as set out in the NSW Health Authority (Appendix 2.3).

Objectives

The primary aim of this component of the project was to develop evidence-informed consensus-based clinical management protocols that enable pharmacists in NSW to resupply oral contraceptive pills (OCPs; including specific combined oral contraceptives (COCs) and progesterone only pills (POPs)) to eligible patients in a safe and effective manner. These protocols were intended to be trialled to evaluate the safety and feasibility of pharmacist resupply of specific low dose OCPs.

The objectives were to:

- conduct a comprehensive review of national and international clinical management protocols governing pharmacist-led OCP supply;
- synthesise and compare relevant guidelines, formulary inclusions, and safety mechanisms including use of the United States Medical Eligibility Criteria for Contraceptive Use (USMEC) and the United Kingdom Medical Eligibility Criteria for Contraceptive Use (UKMEC);
- engage diverse stakeholders in a workshop-based co-design process to ensure practical applicability; and
- generate consensus-based clinical management protocols suitable for trial implementation within NSW and Australian Capital Territory (ACT) pharmacies, as part of the NSW Health Authority.

Methods

The co-design process involved a workshop where stakeholders helped shape critical aspects of the clinical protocols. Importantly, the sequencing of activities ensured that findings from the review informed the workshop discussions. The combined input from both formats was synthesised to create a trial and service delivery model that was evidence-based and responsive to the needs of healthcare providers and patients.

Phase 1: Literature review

A systematic search of the peer-reviewed literature identified a limited number of relevant studies, reflecting that many existing protocols are primarily reported in grey literature sources such as organisational websites and reports. To ensure comprehensive coverage of available evidence, a narrative review of grey literature was undertaken. These findings provided a valuable foundation for protocol development and informed discussions during the co-design workshop.

Search strategy

- A comprehensive search of grey literature was undertaken to identify relevant protocols and guidelines. Sources included established grey literature databases such as OpenGrey and National Health Service (NHS) Evidence, as well as Australian and international health department websites.

- Searches were also conducted using Google Scholar, government portals, and customised Google search engines. The following search terms were applied:
  - ("pharmacies" OR "pharmacist" OR "pharmacists" OR "community pharmacy" OR "pharmacy") AND ("contraceptive" OR “Hormonal Contraception”) AND (“guidelines” OR “clinical guidelines” OR “protocol” OR “Evaluation”)
- In addition, targeted consultation was undertaken through direct email correspondence with clinical experts and policymakers across Australia, Canada, New Zealand (NZ), and the United Kingdom (UK) to identify relevant protocols not publicly available.

Eligibility criteria

- Inclusion criteria: documents were included if they described guidelines or protocols enabling community pharmacists to initiate or continue hormonal contraception. Eligible documents were required to be published in English and released from 2010 onwards.
- Exclusion criteria: protocols were excluded if they were restricted to hospital settings, general practice, or specialist care and did not involve community pharmacy service delivery.

Data extraction

The following data were extracted from each included protocol:

- country and jurisdiction;
- type of contraceptives authorised (COCs, POPs, depot medroxyprogesterone (DMPA), vaginal ring);
- whether pharmacists' initiation and/or continuation was permitted;
- age limits or eligibility requirements;
- risk assessment frameworks applied (e.g., UKMEC);
- requirements for review by a general practitioner (GP) or other health care professional; and
- Clinical measurements required (e.g., blood pressure (BP), body mass index (BMI)).

To ensure methodological rigour, all included protocols were appraised using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument for quality assurance [110].

Phase 2: Co-design workshop

Following the literature review, a workshop was held on June 9, 2023, at Deloitte Offices in Sydney. The 3-hour session brought together key stakeholders including academics, representatives from the Ministry of Health, community and clinical pharmacists, general practitioners, and clinicians with expertise in women’s and sexual health. The workshop was chaired and facilitated by Deloitte. The process was underpinned by principles of patient safety, clinical effectiveness, equitable access, and integrated care. Interactive breakout sessions and consensus discussions were used to refine and validate the final clinical management protocol.

The workshop aimed to present findings from the systematic review, refine patient eligibility criteria for pharmacist resupply of OCPs, identify key clinical red flags and contraindications, and develop treatment algorithms, referral pathways, and workflow processes. It was structured into 5 sections: an overview of the project and background; presentation of international evidence and protocol comparisons; discussion of clinical risk, eligibility, and pharmacist roles; real-time refinement of the draft treatment algorithm and flowcharts; and a final consensus session to agree on red flags, required clinical measurements, and documentation standards.

Results

Outcomes are presented from both the narrative review of clinical management protocols for pharmacist resupply of OCPs and the stakeholder workshop. These combined findings informed the development of a draft protocol for trial implementation in NSW and 15 pharmacies in the ACT.

Phase 1: Literature review results

The findings of the review have been published by Chisari *et al.*, in the journal *Contraception* titled *Pharmacist-prescribed contraception using clinical protocols: A review of the grey literature* [111] (Appendix 2.1).

A total of 600 records were identified through Overton and Google searches. After removal of

duplicates, 593 records were screened. An additional 12 records were identified through professional and government websites, and 9 through consultation with international experts. In total, 30 clinical protocols met the inclusion criteria. These were primarily from the United States (US), with additional protocols from the UK, Canada, NZ, and Australia. All protocols were published from 2016 onward.

Protocols were categorised according to whether pharmacists were authorised to initiate and/or continue contraceptives. In 27 protocols, both initiation and continuation were authorised, while 3 protocols were limited to continuation or resupply only. Most protocols, particularly from the US and Canada, applied the same criteria to both initiation and continuation. However, 6 protocols, including those from Australia, the UK, Canada and the US, applied distinct criteria. Some protocols restricted initial supply to 3 months but allowed continuation for up to 12 months. Common requirements prior to supply included age restrictions (93%), BP measurement (97%) and BMI assessment (93%). Patient-completed screening tools were required in 77% of protocols, alongside adherence to established clinical guidelines. Fourteen protocols also required prior review by a healthcare professional, such as a GP, reproductive health providers, or advanced practice nurses, before pharmacists could initiate or continue contraceptives.

There was variation in the types of contraceptives authorised. Twelve protocols permitted all methods, while 13 included POPs, COCs, and combined hormonal contraception (e.g., vaginal ring and transdermal patch) but excluded DMPA. Five protocols were limited to oral contraceptives (OCs) only.

Quality appraisal using the AGREE II instrument identified several weaknesses across the protocols. *Editorial Independence* scored 0%, while *Applicability* (12%) and *Rigour of Development* (10%) were also low. Higher scores were observed for *Clarity of Presentation* (64%) and *Scope and Purpose* (57%). Overall, eligibility criteria were primarily age-based, while clinical requirements varied depending on the contraceptive methods authorised, as outlined in Table 2-1.

Table 2-1: Main criteria identified in protocols for the provision of contraceptives by pharmacists.

Requirement/ process	Total number of clinical protocols		Clinical protocols							
			POP (total number of protocols = 29)		COC (total number of protocols = 29)		CHC* (total number of protocols = 25)		DMPA (total number of protocols = 13)	
			Present (%)		Present		Present		Present	
	%	N	%	N	%	N	%	N	%	N
Age restrictions	93	28	93	27	93	27	92	23	85	11
Measurement of BP	97	29	93	27	97	28	96	24	92	12
Measurement of BMI	93	28	90	26	93	27	92	23	85	11
The use of patient self-completed screening tool	77	23	79	23	79	23	88	22	77	10
Mandatory review interval by a healthcare professional other than the pharmacist	47	14	48	14	48	14	44	11	31	4

**CHC = combined hormonal contraception (includes vaginal ring and transdermal patch)*

Phase 2: Co-design workshop results

Thirteen stakeholders participated in the workshop: 2 general practitioners (GPs; including a representative from the Royal Australian College of General Practitioners (RACGP)), 4 practicing pharmacists, 5 members from the University of Newcastle research team and 2 members from Deloitte's team who directed the session. The workshop featured multi-disciplinary representation and aimed to translate evidence from the review into an implementable protocol. Key outcomes from the discussion included:

- Decreasing the age of eligibility to 18–35 years (down from the original 18–39).
- Authorising pharmacist resupply (not initiation) of OCP.
- Requiring patients to have been on the same OCP continuously for 2 years.
- Requiring a GP review within the past 24 months.
- Permitting supply of up to 12 months, subject to eligibility and clinical parameters.
- Designing a specific protocol and referral criteria for COCs and POPs due to the different safety aspects.

The UKMEC was identified as a key reference for developing the NSW clinical management protocol. It informed the majority of criteria used to guide referral decisions and determine eligibility for resupply of medication. The group also finalised core protocol components, including eligibility screening, identification of red flags, referral criteria, required clinical measurements (BP and BMI), and pharmacist counselling and documentation requirements.

Consideration was given to the practical application of the protocol in community pharmacy settings.

Table 2-2: Clinical eligibility and risk assessment criteria for OCP resupply (NSW trial)

Criterion	Requirement
Age	18–35 years (inclusive)
Sex	Assigned female at birth AFAB women
Current OC use	Continuously on same product for 2 years
Recent GP review	Seen for contraception within past 24 months
Missed OC for 4+ weeks	Must refer to GP, no supply
Missed OC 2–4 weeks	Supply 1 month + refer
Red flag criteria (VTE, breast cancer, etc.)	Refer to GP (with/without 1-month supply)

The workshop resulted in the development of a clear, safety-focused clinical algorithm for the resupply of OCPs in women aged 18–35 years. This algorithm was incorporated into clinical management protocols tailored to each contraceptive type included in the trial, with separate guidance for COCs and POPs (Appendix 2.2).

Table 2-3 outlines the specific risk factors identified during the co-design process, alongside the corresponding referral and resupply criteria. Red flags requiring referral were clearly defined and systematically categorised by contraceptive type to ensure safe and consistent clinical decision-making.

Table 2-3: Risk factors and referral criteria (NSW trial)

Risk factor	COC	POP
Red flags (high risk factors)		
Breast Cancer	Refer only	Refer only
Adenoma or malignancy	Refer only	Refer only
Multiple CVD risk factors (> 3)	Refer only	Resupply up to 12 months
Migraine	Refer only	Resupply up to 12 months
Cirrhosis	Refer only	Refer only
Surgery with immobilisation	Refer only	Refer only

Risk factor	COC	POP
Red flags (high risk factors)		
Age 35 smoker	Refer only	Resupply up to 12 months
Previous CVD	Refer only	If while using POP - Refer only If unrelated to POP – Resupply up to 12 months
HT SBP ≥ 145 or DBP ≥ 90 mmHg	Refer only	Resupply up to 12 months
Heart disease	Refer only	Resupply up to 12 months
VTE/Thromboembolism	Refer only	Resupply up to 12 months
Antiphospolipids antibodies	Refer only	Resupply up to 12 months
Thrombogenic mutations	Refer only	Resupply up to 12 months
Diabetes with complications	Refer only	Resupply up to 12 months
Gall bladder disease	Refer only	Resupply up to 12 months
BMI ≥ 35	Refer only	Resupply up to 12 months
Missed pills > 4 weeks	Refer only	Refer only
Orange flags (moderate risk factors)		
Drug Interactions + St John's wort	Refer and resupply 1 month	Refer and resupply 1 month
Missed pills > 2 weeks < 4 weeks	Refer and resupply 1 month	Refer and resupply 1 month

CVD=cardiovascular diseases; DBP=diastolic blood pressure; HT=hypertension; SBP=systolic blood pressure; VTE=venous thromboembolism.

Discussion

The combined use of literature synthesis and stakeholder engagement enabled the development of clinical protocols grounded in international evidence and tailored to the NSW context. The decision to restrict the model to continuation, rather than initiation, reflects a pragmatic balance between improving access and addressing patient safety concerns raised by key stakeholders, including GPs and health regulators.

Several practical issues were also resolved during the workshop, including management of missed doses, referral responsibilities, pharmacist training, and incorporation of clinical measurements. UKMEC provided a robust and standardised framework to guide clinical decision-making. Importantly, the workshop surfaced concerns around risk exposure if protocols were not properly adhered to, highlighting the need for high-quality training and audit mechanisms.

The review findings demonstrated broad international consensus that appropriately trained pharmacists, supported by structured risk assessment tools, can safely supply hormonal contraception. However, successful implementation will require clear clinical guidelines, decision support tools, defined escalation pathways, and integration with digital health systems.

Conclusion

This 2-phase approach to protocol development for pharmacist-led resupply of OCPs integrated evidence-based safety measures, clearly defined scope of practice, and established referral pathways for higher-risk patients. The co-designed protocol represented a critical first step in implementing the service in NSW and the ACT. Its evaluation is presented in the subsequent chapters.

03

CLINICAL EVALUATION OF PATH-OC

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-OC
PATHWAY TO ACCESS: ORAL CONTRACEPTION

Chapter 3: Clinical Evaluation of PATH-OC

Introduction

This chapter of the report provides a detailed description of the methods and results of the clinical evaluation of PATH-OC, drawing upon data from the PATH-OC trial, data linkage, and the available literature. Data collected from the trial were combined with external data sources through a comprehensive data linkage process to provide a robust analysis.

The analysis was conducted by The George Institute for Global Health with feedback from the University of Newcastle team.

Objectives

The overall aim of this study was to evaluate the clinical impact, implementation, and safety of a service delivery model delivered by community pharmacists in New South Wales (NSW) and 15 pharmacies in Australian Capital Territory (ACT), re-supplying specific oral contraceptive pills (OCPs) for women aged between 18–35 years over a 12-month study period. Specific objectives were to:

- assess the accessibility and acceptability for people resupplied an oral contraceptive (OC) by community pharmacists;
- 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;
- assess the clinical outcomes and participant experience for people managed by community pharmacists;
- assess the safety of the intervention and identify any risks that need to be addressed for future implementation;
- qualitatively assess the acceptability and feasibility of the intervention to pharmacists, other care providers and participants using the service; and
- identify contextual enablers and constraints to access, adoption, fidelity, delivery, impact, sustainability, and generalisability of the intervention.

Methods

A cohort study design, applying mixed methods (quantitative and qualitative research) to assess clinical indicators, implementation, participant experience, and safety was adopted. A cohort study design, applying mixed methods (quantitative and qualitative research) to assess clinical indicators, implementation, participant experience, and safety was adopted. The complete list of methods, including eligibility criteria and objectives can be found in the Australian New Zealand Clinical Trials Registry (ANZCTR; ACTRN12623001124628).

Pharmacy and pharmacist recruitment

Pharmacy/pharmacist recruitment for this trial was as per the procedure used in the previous urinary tract infection (UTI) intervention study. Pharmacies who had consented to the PATH-UTI trial (ACTRN12623000882628) were sent a formal recruitment pack inclusive of the Participant Information Sheet and Consent forms for both Pharmacy and Pharmacist. In the ACT, the 15 pharmacies participating in the UTI trial were sent a similar recruitment pack, tailored for the ACT and each pharmacy had to apply for a license to participate in the trial (https://www.act.gov.au/business/health-licenses-and-inspections/medicines-and-poisons-licences/apply-for-a-medicines-poisons-therapeutic-goods-licence-permit). Full details of requirements and definitions for pharmacies, pharmacists and patients are outlined in the NSW Health Authority for the trial (Appendix 2.3).

Pharmacy eligibility criteria

In NSW, participating community pharmacies were required to have a service room, consulting room, or area meeting the following requirements as per the Authority. Equivalent requirements were specified under the formal licence application process in the ACT. These spaces were required to:

- not to be used as a dispensary, storeroom, staff room or retail area;

- be fully enclosed and have adequate privacy (a divider or curtain in a dispensary, storeroom, staff room or retail area was not acceptable);
- have adequate lighting;
- be maintained at a comfortable ambient temperature;
- have a hand sanitisation facility available and ready access to a hand-washing facility; and
- have 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.

In addition, each participating pharmacy was required to have at least 1 eligible pharmacist willing to deliver the service during standard business hours.

Pharmacist eligibility criteria

A community pharmacist was required to hold general registration as a pharmacist with the Australian Health Practitioner Regulation Agency and be employed by, or engaged with, an eligible participating pharmacy in NSW and ACT. They were also required to have successfully completed the following training:

- Australasian College of Pharmacy Continuation of Oral Contraception Course; or
- Pharmaceutical Society of Australia NSW – Contraception Essentials; and
- training module(s) that have been approved by the NSW Chief Heath Officer for the purposes of the trial.

Pharmacists with provisional registration (intern pharmacists) and pharmacists with conditions on their registration were not eligible to participate in the trial.

Participant recruitment

Participants were recruited from enrolled pharmacies by scanning a location specific QR code on their mobile phone, which opened a secure e-consent webform hosted by The George Institute. This code was visible at the pharmacy for patient to scan when asking to participate in the trial or being invited by the pharmacist. Two consent forms were presented – 1 for the study and the second for Services Australia data linkage (to allow access to Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) data). Once this e-consent was completed and submitted, the participant received a text message confirmation with a validation code to provide to the pharmacy to confirm their consent. If the participant subsequently withdrew from the study, no further information was collected from them and their information was removed from study records and not included in the study results.

Participant inclusion criteria

As stated in the clinical management protocols for this trial, eligibility criteria included:

- Assigned females at birth (AFAB) women (capable of pregnancy).
- Participants aged 18 up to (and including) 35 years.
- Presented to participating community pharmacies in NSW or ACT to obtain a re-supply of their previously prescribed OCP.
- Participant had been initiated on an OCP by their general practitioner (GP; or other authorised prescribing health care professional) primarily for the indication of contraception and had been stabilised on that pill for 2 years continuously and not discontinued use for ≥ 1 month.
- Participant was taking an approved OCP listed in the NSW Health Authority.
- Participant had seen their GP (or other authorised prescribing health care professional) for a review of their OCP in the last 2 years.

Participant exclusion criteria

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

Intervention

This multicomponent intervention commenced with training and support for the pharmacist through a clinical training program (either through the Australasian College of Pharmacy or Pharmaceutical Society of Australia) to apply best practice standard of care. Furthermore, study specific training modules developed by the University of Newcastle research team were completed by pharmacists to ensure efficiency in the consultation process, participant consent, recruitment of participants, timely referral, and quality data collection. Once training was completed, the pharmacist performed a structured consultation with the participant in the community pharmacy guided by an IT program (developed by MedAdvisor®), applying 1 of 2 clinical management protocols (Combined Oral Contraception (COC) and Progestogen-Only Contraception (POC)), which encompassed the recommendations from the Australian Therapeutic Guidelines. The clinical management protocol was co-designed between community pharmacists and GPs with advice from a subject matter expert (see Chapter 2). Follow-up training and ongoing support was provided by 4 practice change facilitators (PCFs) throughout the period (see Chapter 5).

The intervention had 2 components:

1. Pharmacist enrolment, preparatory training program prior to service delivery for pharmacists to ensure efficiency in the consultation process, participant consent, recruitment of participants, timely referral, and quality data collection. In addition, there was follow-up training and ongoing support as part of a translational/implementation strategy.
2. Structured consultation with the participant in the community pharmacy undertaken by the pharmacist, anticipated to take 10 minutes, applying a co-designed clinical management protocol.

Clinical consultation conducted by pharmacist

- Participant eligibility assessment, in which the pharmacist assessed if the participant met the inclusion/exclusion criteria to participate in the study.
- Service offering, during which the pharmacist explained the features of the study and verified if the person was willing to participate.
- Electronic provision of the participant information sheet and informed consent form.
- Participant clinical assessment including gathering of relevant clinical information such as medical conditions, medication history, medication dispensing history (if a regular attender of that pharmacy).
- Clinical measurements of blood pressure (BP) and body mass index (BMI).

For the clinical assessment, the pharmacist used 1 of 2 clinical management protocols to resupply (Appendix 2.2). Participants were assessed into three colour coded categories: (1) those in the red category required a GP referral without an OC resupply; (2) those in the orange category required a referral but could still receive an OC resupply; and (3) those in the green category could receive an OC resupply without referring.

Pharmacists could supply a continuation of the OCP (minimum 1 month, up to 12 months' supply) provided the participant had seen a GP (or other authorised prescribing health care professional) in the last 2 years. Pharmacists were not permitted to initiate or change therapy. Non-pharmacological management could include:

- Referral to see their medical practitioner, family planning or sexual health clinic for maintaining regular women's health and sexual/reproductive health checks.
- Counselling on the importance of getting regular cervical screening tests, breast checks, and sexually transmitted infection (STI) testing done.
- Counselling on the OC supplied including the following:

  - how to take the OC;
  - what side effects to expect when taking the OC;
  - how to manage adverse effects from the OC;
  - when the OC is less effective; and
  - what to do in event of a missed pill.
- Provision of a Consumer Medicines Information sheet.
- Provision of advice if the participant had any concerns regarding the OC.
- Provision of advice and referral if there was a concern that the participant may be at risk of or could have a STI through unprotected sex, and/ or if the participant indicated that they had been sexually assaulted.
- The pharmacist facilitated appropriate and timely referral, if required.
- A record of the supply was shared with the participant's usual treating medical practitioner or medical practice (via fax, secure messaging software, provision of a letter to the participant, or any other approved secure means by NSW Health), where the participant had one, following consent by the participant.
- The pharmacist made a record of the consult in MedAdvisor® pharmacy software.

The pharmacist was required to keep a clinical record for 7 years that contained:

- sufficient information to identify the participant;
- the date of the treatment;
- the name of the pharmacist who undertook the consultation;
- any information known to the pharmacist that was relevant to the participant's diagnosis or treatment (for example, information concerning the participant's medical history);
- any clinical opinion reached by the pharmacist;
- actions taken by the pharmacist;
- particulars of any medication supplied for the participant (such as form, strength and amount);
- notes as to information or advice given to the participant in relation to any treatment proposed by the pharmacist who is treating the participant;
- any consent given by a participant to the treatment proposed; and
- any medications dispensed and labelled according to the legislative requirements outlined in the Poisons and Therapeutic Goods Regulation 2008.

The pharmacist also reminded the participant they would receive a follow-up survey from The George Institute, including reminders if the survey remained incomplete at days 9, 11 and 13.

In developing the intervention, the following considerations were accounted for:

- **Cost to participants** – these were no cost to patients for the consultation; however, pharmacies were provided $20 per patient as reimbursement for the required data collection. The participant paid for any medicines or products provided. In the ACT the cost of the consultation was suggested to be paid for by the participant receiving the service irrespective of the outcome of the consultation. The participant also paid for any medicines or products provided.
- **Legislative considerations** – in NSW, the legislative approval required for the trial was developed and executed by the NSW Ministry of Health. In ACT, the legislation process was determined by the acting Chief Pharmacist and the licensing process (as described above) implemented, with an agreement that the discretionary licence would be issued to authorise the 5 pharmacies in the ACT to participate in the trial.
- **Professional indemnity for pharmacists** – Pharmaceutical Defence Limited (PDL; the major provider of professional indemnity) covered pharmacists as part of their normal indemnity for delivery of this service. Guild Business covered the liability from the perspective of the pharmacy premises.

Data sources

Community pharmacy data

During implementation of the intervention, information on the consultation was recorded in a case registration form completed by the pharmacist using the MedAdvisor® application built into pharmacy software systems. This included demographic information on participants, presence of allergies, responses to eligibility questions, whether the OCP was resupplied and the type of OCP supplied, whether a referral was made to the GP and any other education provided.

Participant self-reported surveys

A survey was sent to eligible participants 7 days after their pharmacy consultation. Three reminders were sent every 2 days thereafter if the survey was not completed. Survey variables included: participant demographic information; care experience questions, details of what OCP was supplied and if it was taken as intended, presentation of any medication side effects; and treatment costs.

Qualitative data

Qualitative data sources included semi-structured interviews with pharmacists and participants, and feedback emails. A purposive sampling technique was used to select a diverse range of pharmacies and participants for interviews, considering pharmacy level factors such as geography, engagement, and provision of trial services, and participant level factors such as age, geography, and utilisation and outcomes of pharmacy services. All interviews were conducted via phone call or video conferencing, audio recorded, deidentified and professionally transcribed.

Pharmacists interviewed for the PATH-UTI trial evaluation were also asked questions about the OCP resupply trial due to parallel implementation periods. This allowed comparison of the patient experience with each service. The recruitment method is described in the PATH-UTI evaluation. Most interviews were conducted between January 2024 and March 2024, 3– 5 months into the intervention period. An additional 2 interviews were conducted in August 2024 and October 2024 incorporating perspectives from pharmacists who had implemented the OCP resupply trial for a longer period. The final sample included pharmacists from pharmacies across 5 Modified Monash Model (MMM) remoteness regions and a range of business types and included ‘high’ or ‘low’ recruiters based on the numbers of OC consultations provided (see Table 3-7). There were no interviews from pharmacists within MMM 6 or MMM 7 as there were no participants enrolled in these regions. Interview questions focused on implementation and contextual factors which may influence program outcomes, including sustainability considerations, staff experience and motivation to engage in the OC resupply model, perceived barriers for uptake and similarities and differences of their experiences of delivering other pharmacy-led interventions.

Participants were asked when obtaining trial consent if they were willing to be contacted further about their experiences with the service via an interview, and participants were selected for interview from those who agreed. Participants interviewed tended to have only used the OC resupply service, however during interviews participants were opportunistically asked about their perceptions and willingness to engage with other pharmacy-led interventions to

contextualise experiences and perceptions. To minimise recall bias, participants with a recent encounter date were invited (no more than 2 months since encounter). Participant interview questions focused on experiences of health care, awareness and perceptions of services, including perceived barriers and facilitators for use, and effectiveness of the new service.

A dedicated email address for the trial evaluation was provided to participants on the consent documentation to facilitate another avenue for consumer feedback and support. Emails were deidentified and incorporated into the thematic analysis.

NSW and ACT Health administrative data

NSW and ACT Health administrative data provided information on hospital sector utilisation for participants enrolled in the trial. The NSW Centre for Health Record Linkage (CHeReL) performed the linkage of trial data sets with NSW and ACT administrative records. The following NSW and ACT data collections were linked:

- NSW Admitted Patient Data Collection (APDC);
- NSW Emergency Department Data Collection (EDDC);
- NSW Registry of Births, Deaths & Marriages (RBDM);
- NSW Non-Admitted Patient Data Collection (NAP);
- ACT Admitted Patient Data Collection (ACT APDC);
- ACT Emergency Department Data Collection (ACT EDDC); and
- ACT Registry of Births, Deaths and Marriages (ACT RBDM).

For APDC and EDDC data (for both NSW and ACT), data were available from Sept 2022 (12 months prior to the start of the study) to June 30, 2024. For NSW RBDM-Deaths, ACT RBDM-Deaths, and NSW NAP data, data were requested from Sept 2023 (start of the study) to June 30, 2024.

MBS/PBS data

Participants consent was requested to access MBS and PBS data for a 4-year period (from 36 months prior to registration to 12 months post registration) using the Services Australia approved Participant and Information Consent Form. A file of consenting study participants was sent to Services Australia for obtaining the claims history in early January 2025.

Outcomes

Primary outcome

The primary outcome was a composite measure based on participant self-reported experience. It included 7 items adapted from existing questionnaires, including a validated questionnaire for perceived service quality in community pharmacies (2 items) and studies of pharmacy resupply of OC, and other medications [112–117]. Questions related to trust and confidence in the advice provided, convenience, privacy, and overall satisfaction. Each item was scored on a 7-point Likert scale, each question equally weighted, with an aggregated score calculated and scaled to a maximum score of 100.

Secondary outcomes

Participant experience

- Self-reported response to individual participant experience questions at day 7 post-pharmacy consult.
- Self-reported response to the service provided:
  - proportion resupplied an OCP by the pharmacist;
  - proportion who took the resupplied OCP; and
  - proportion experiencing any side effects or other complications from the OCP resupplied by the pharmacist.
- Median (interquartile range) treatment cost for the pharmacy service:
  - proportion stating cost would be a barrier to using the service again.

Primary care and medication utilisation (see Appendix 3.1 Table 3-1-1 for MBS codes)

- Number of GP consultations for enrolled participants in the 36 months pre-enrolment vs the number of GP consultations in the following 6 months post-enrolment

- On time OC dispensing rates up to 24 months pre- and up to 6 months post-introduction of the intervention. Two outcome measures were used:
  - PDC* by any OC (Appendix 3.1 Table 3-1-2 for medication codes) for each participant 24 months pre-enrolment, reported as a mean and standard deviation (SD; or median, interquartile range (IQR) as appropriate) vs up to 6 months post-enrolment; and
  - number (%) of people with a proportion of days covered by >80% in the period 24 months pre-enrolment vs the period up to 6 months post-enrolment.

*PDC is a metric used to assess medication adherence by calculating the percentage of days a person has access to their medication over a specific time period [118]. To calculate the PDC the numerator is the number of days a patient has medication available (based on prescription fill dates and days supplied) and the denominator is the total number of days in the observation period.

PDC: number of days covered / total number of days in the observation period.

The PDC per person was capped at 1, indicating complete coverage for the period evaluated. A higher PDC, typically 0.80 or greater, is often considered a high level of adherence to a medication. For more information on how PDC is calculated see here [link].

Implementation outcomes

- Participant and pharmacist participation rates and trends over time at 6 and 12 months from registration. This includes the following service outcomes obtained from MedAdvisor® data:
  - participant demographics (gender, age, date of birth, education, employment status);
  - numbers of people declining participation and reasons for declining;
  - numbers of people per pharmacy assessed as eligible for pharmacy OCP resupply;
  - numbers of participants supplied OCPs by pharmacists;
  - numbers and types of OCPs supplied;
  - numbers of participants provided self-care advice;
  - numbers of participants referred to another health professional;
  - reasons for participant referral to another health professional;
  - estimated duration of consultation;
  - classification of appropriateness of OCP resupply as aligned with management protocol; and
  - loss to follow-up rates.

Safety outcomes

Adherence to clinical management protocol (MedAdvisor® data)

- Number of participants identified as “red” and “orange” based on the clinical management plan.
- Number of “red” and “orange” participants referred to GP.
- Number of “red” and “orange” participants receiving OCP resupply.

Self-reported adverse events

- Tabulated responses to the self-reported question: Did you experience any side effects or other complications from the oral contraceptive pill (the pill) re-supplied by the pharmacist?

Hospital admissions

- APDC data was used to assess hospitalisation trends over the 12-months pre-enrolment and up to 6 months post-enrolment.
- All-cause hospitalisations per 100 persons.
- Hospitalisation for potential pill-related adverse events (Appendix 3.1 Table 3-1-3 for International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED) codes).

Emergency department presentations

- EDDC data was used to assess emergency presentation trends over the 12-month pre-enrolment and up to 6 months post-enrolment.
- Total presentations per 100 persons.

- Total presentations for triage 3, 4 and 5 per 100 persons (only available for NSW emergency presentations).
- Emergency presentations for potential pill-related adverse events (see Appendix 3.1 Table 3-1-3 for ICD-10 and SNOMED codes).

Pathology tests for sexually transmitted infections (MBS data)

- Number of pathology tests requested for a sexually transmitted infection in the 36 months pre-enrolment vs the number of requests in the following 6 months post-enrolment.
- Average per month pre-enrolment (as observed over the past 36 months).
- Average per 6 months pre-enrolment (as observed over the past 36 months).
- Average per month post-enrolment (as observed over the 6 months post enrolment).
- Average per 6 months post-enrolment (as observed over the 6 months post enrolment).

MBS pathology services for STIs include:

- Chlamydia trachomatis (69316, 73813, 73825).
- Gonorrhoea (69317, 73813, 73825).
- Human immunodeficiency virus (HIV) serology (69384, 69387, 69390, 69393, 69396, 69405, 69408, 69411, 69413, 69415) or RNA or genotype testing (69378, 69380, 69381, 69382).
- Syphilis serology (69387).
- Hepatitis B serology or DNA testing (69405, 69408, 69411, 69413, 69415, 69475, 69482, 69483, 69484).

Serious adverse events

A serious adverse event was defined as any potential pill-related adverse event that involves either an emergency presentation or a hospitalisation.

Analysis

Quantitative analyses

Figure 3.1 outlines the data flows for each of the datasets generated from the study.

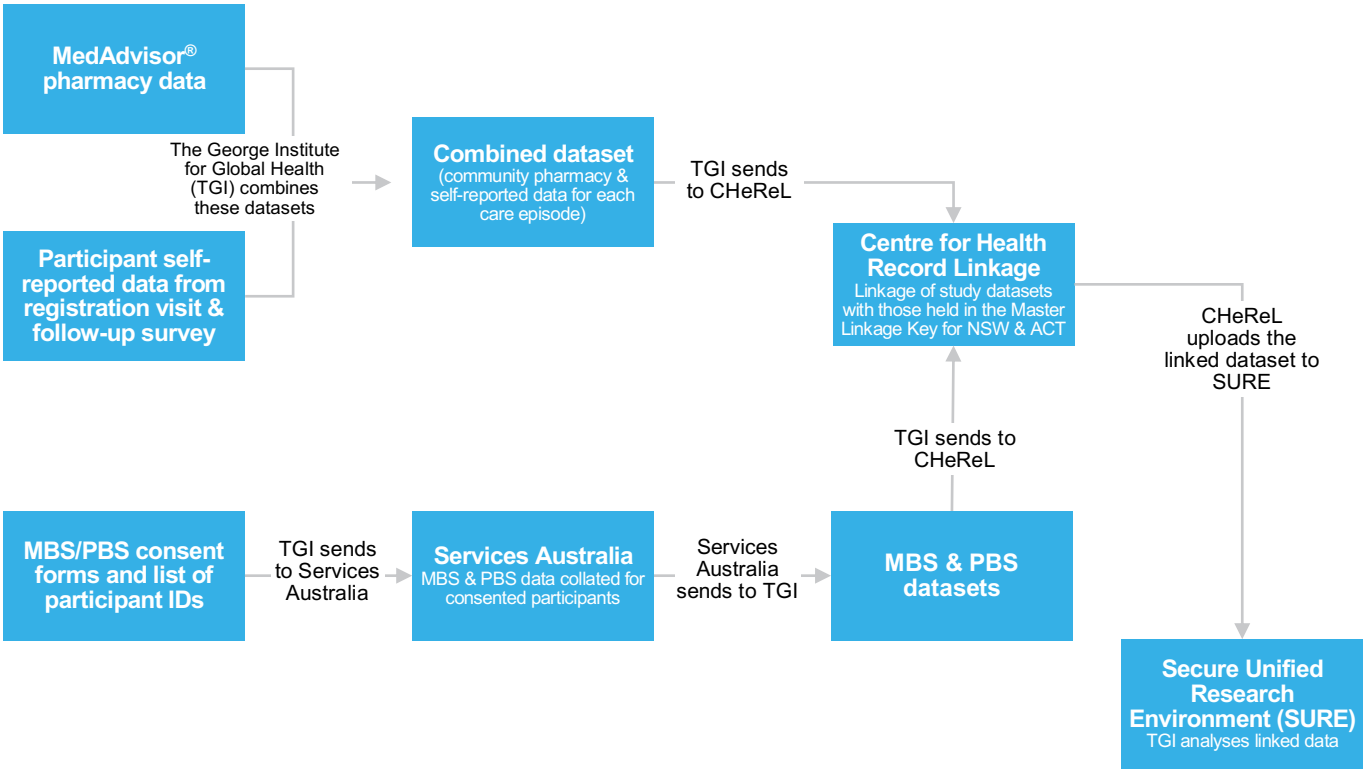


Figure 3.1: Study data flow

For linked data analyses, the CHeReL employs probabilistic record linkage methods to link multiple data sources [119]. They ensure privacy by separating identifying details from health-related content and using encoded personal information to create linkage keys. This process involves matching records from different datasets based on common identifiers, such as names and dates of birth, while maintaining confidentiality. The CHeReL's probabilistic linkage procedures are designed to achieve a false positive rate around 5/1,000. The deidentified linked dataset was then uploaded to the Secure Unified Research Environment (SURE) facility hosted by the Sax Institute for analysis. Analyses were conducted primarily using Statistical Analysis System (SAS) software (Version 9.3 or above) or R Software (Version 4.3.1). The primary analysis used all available data with no imputation. The proportion of missing data was reported within the analysis where appropriate. Discrete variables were summarised by frequencies and percentages. Percentages were calculated according to the number of participants in whom data were available. Continuous variables were summarised using mean, standard deviation and 95% confidence interval (CI) where appropriate, and median and IQR (Q1–Q3). Experience outcomes were visualised using Likert type illustrations per survey response. MBS data were used to assess the proportion of the participants who accessed GP services in the first month after participating in the study as well as over the 12 months pre-enrolment and 6 months-post enrolment. PBS data were used to assess the proportion of days covered for the various OCP medications used in the trial. The NSW APDC and EDDC were used to analyse use of the NSW health services. Weekly rates of hospital service utilisation were calculated for the 12 months before and 6 months after the consultation.

The following sub-group analyses were conducted to understand variation in the primary outcome:

- age [18–25, 26-30, 31–35 years];
- MMM remoteness category of pharmacy;
- location of pharmacy (NSW vs ACT);
- COC vs progesterone-only-pills (POP) resupply; and
- referred to general practice vs not referred.

Qualitative analyses

Qualitative analyses were conducted by researchers who were independent of the main trial. The process began with familiarisation of transcripts, and an initial coding framework was developed using a combined inductive and deductive approach.

This framework was iteratively refined over multiple coding rounds as patterns, inconsistencies, and new insights emerged. Based on the analysis, and repeated questioning of the data, explanations about service providers' and women's experiences of the trial, and how, why, and for whom the OCP resupply trial achieved its effects in different local contexts were formulated. Findings were contextualised using Normalisation Process Theory (NPT) and Weiner's theory of organisational readiness to change [113, 114]. NPT focuses on processes by which practices become routinely embedded. Weiner's theory identifies preconditions to organisational readiness to change as being change valence (valuing the change), and information appraisal (organisational members assessment of task demands, resource availability, and situational factors).

Ethical considerations

Approval was obtained from the University of Newcastle Health Research Ethics Committee (H-2023-0234), the NSW Health Population Health Services Research Ethics Committee (2024/ETH01457/2023.37) and the Services Australia Executive Committee (RMS3297). The trial is registered with the ANZCTR (ACTRN12623001124628).

Results

Participants

Pharmacy recruitment

The trial commenced on 27 September 2023 with the last participant recruited on 27 September 2024 (Figure 3.2). A total of 1,533 pharmacies expressed interest in trial participation from whom 1,299 consented to participation – with 528 of those consenting pharmacies (40%) conducting at least 1 consultation with an eligible participant. Figure 3.2 provides the geographic distribution of actively recruiting pharmacies.

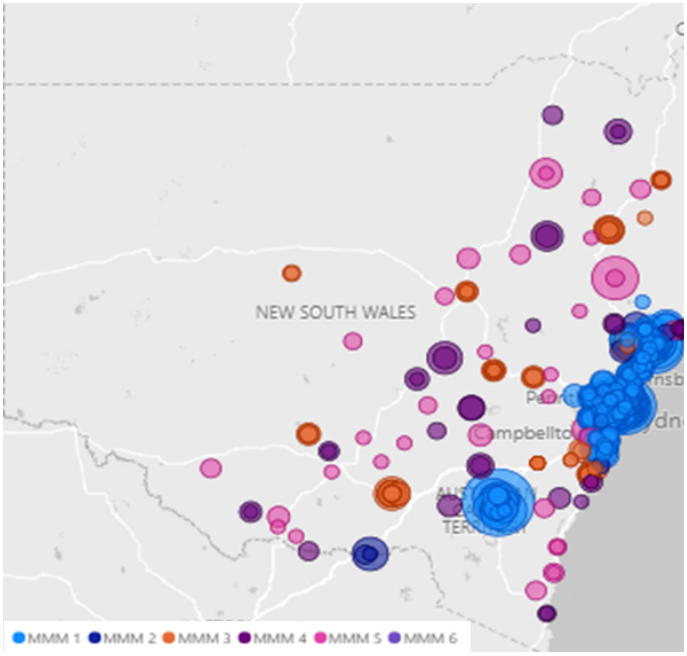


Figure 3.2: Geographic distribution of actively recruiting pharmacies

(MMM 1=metropolitan, MMM 2=regional centre, MMM 3= large town, MMM 4=medium town, MMM 5=small town, MMM 6= remote).*
**There were no pharmacies recruited from MMM 7 (very remote communities).*

Participant recruitment

A total of 2,959 self-filled consent forms were completed by participants expressing interest to be involved in the trial (Figure 3.3). Of these, 1,946 participants proceeded to enrolment in the study and for these participants 2,209 pharmacy consultations were completed – 1,725 (88.6%) people had 1 consultation, 182 (9.4%) with 2 consultations, 36 (1.8%) with 3 consultations, and 3 people (0.2%) with 4 consultations. The median number of consultations conducted per actively recruiting pharmacy over the trial period was 3 (IQR 1–5). For 57 (2.7%) consultations, participants were assessed as being in the red or orange category based on the management protocols (Appendix 2.2). For the 2,209 pharmacy consultations conducted, participants completed the follow-up survey for 1,751 (79.2%) of these. Trial recruitment rates steadily increased over the study period (Figure 3.4).

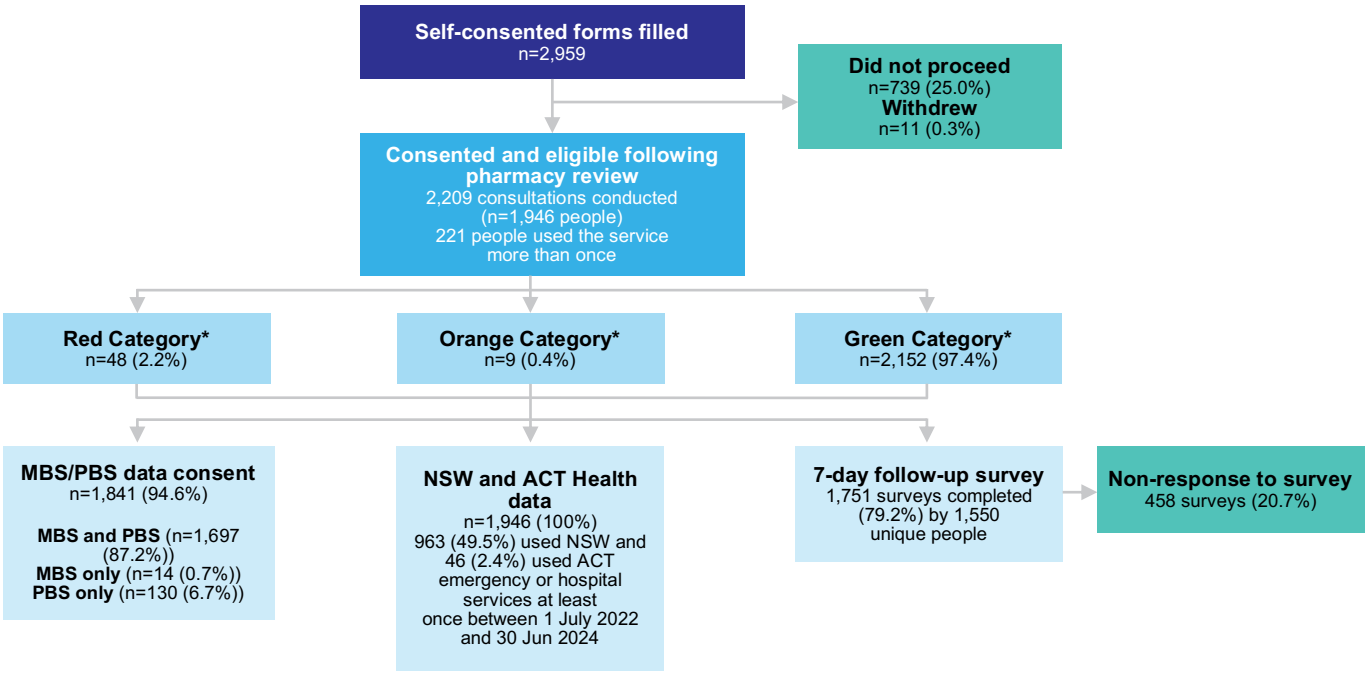


Figure 3.3: Participant flowchart

**See Appendix 2.2 for red, orange and green criteria as per the protocol, defined during codesign (please see Chapter 2). As per the management protocol, participants in the red category required a GP referral without an OCP resupply. Participants in the orange category required a referral but could still receive an OCP resupply. Participants in the green category could receive an OCP resupply without referring. Due to a coding error, pharmacists were not alerted to 26 participants who were incorrectly assigned a green flag (see Chapter 7 Discussion). This error was related to exclusion of BP values at the cut-points and a lack of inclusion of the BMI criterion.*

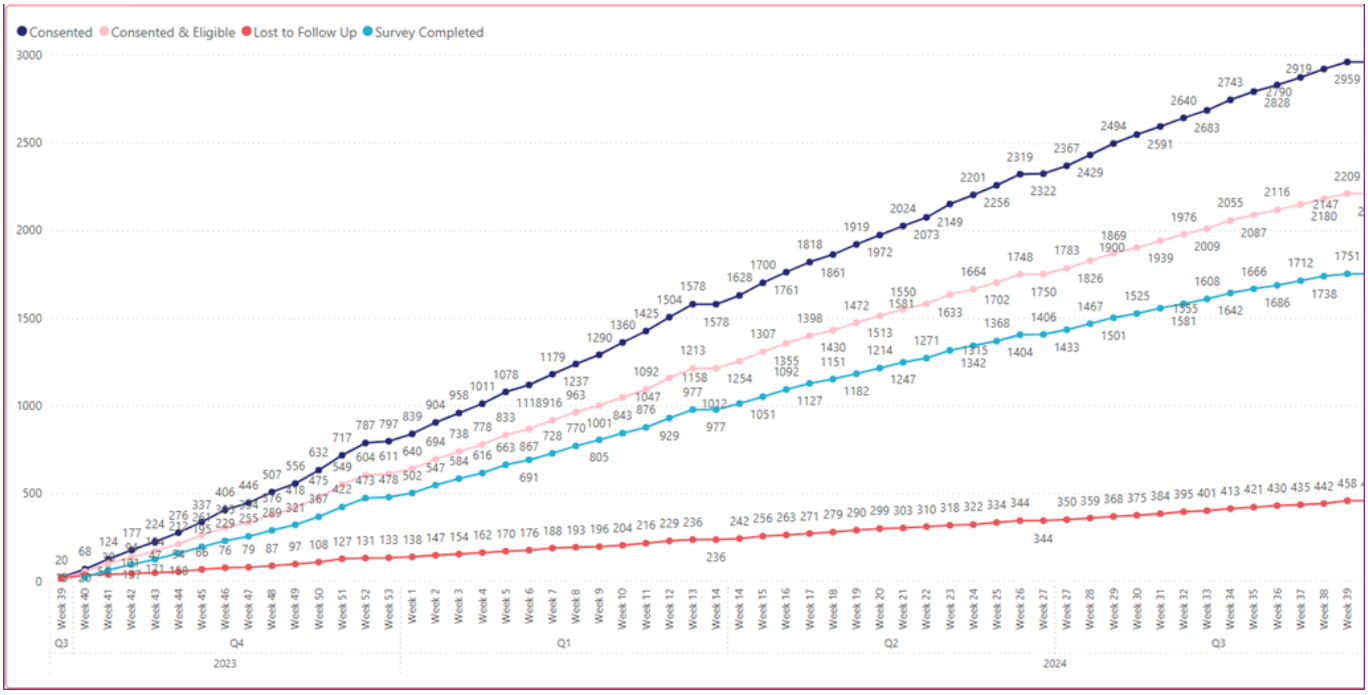


Figure 3.4: Participant recruitment over the study period

Participant characteristics

Participant characteristics are provided for the 1,946 unique participants. The majority lived within MMM area 1 (Metropolitan) (79.3%). The most common participant age group was 18–25 years (48.0%). A total of 6.9% of participants were referred to a GP (Table 3-1). A total of 176 consultations were provided in the ACT and 2,033 in NSW. Appendix 3.1 Table 3-1-4 provides data on the participants by jurisdiction. There was a greater proportion of younger participants in the ACT compared to NSW and few other differences in socio-demographic characteristics. Appendix 3.1 Table 3-1-5 provides more details on baseline characteristics by MMM area.

Based on participant self-reported postcode information provided at the initial pharmacy consultation, we calculated the index of socio-economic advantage and disadvantage for the 2,209 consultations. The proportion of people in each quintile was as follows: 1st quintile (most disadvantaged 7.2%), 2nd quintile (13.5%), 3rd quintile (16.7%), 4th quintile (14.4%) and 5th quintile (most advantaged 46.5%) with a further 1.6% with missing postcode information. Most ACT participants resided in the most advantaged areas (Appendix 3.1 Table 3-1-5).

A total of 134 (6.9%) unique participants were referred to the GP based on the referral criteria with most related to responses to the screening questions asked at the initial pharmacy assessment.

Table 3-1: Participant baseline characteristics (n=1,946)

Characteristic	n=1,946
Age (years) mean (SD)	26 (5)
Age groups	
18–25 years	934 (48.0%)
26–30 years	636 (32.7%)
31–35 years	376 (19.3%)
Location of pharmacy	
Metropolitan (MMM 1)	1,543 (79.3%)
Regional centres (MMM 2)	29 (1.5%)
Large rural town (MMM 3)	192 (9.9%)
Medium rural town (MMM 4)	98 (5.0%)
Small rural town (MMM 5)	84 (4.3%)
Remote/very remote communities (MMM 6/7)	0 (0.0%)
BP	
Systolic blood pressure (mmHg) mean (SD)	118 (11)
Diastolic blood pressure (mmHg) mean (SD)	78 (9)
Missing[1]	649 (33.3%)
BMI	
Underweight: < 18.5	60 (3.1%)
Normal Weight: 18.5–24.9	962 (49.4%)
Overweight: 25.0–29.9	329 (16.9%)
Obese: >= 30	165 (8.5%)
Missing[1]	430 (22.1%)
Referred to GP	
Total participants referred to GP	134 (6.9%)[3]
Based on screening questions	70 (3.6%)
Based on clinical measurements	39 (2.0%)
Other referral criteria[2]	25 (1.3%)
Employment[3]	
Working full-time	1,000 (64.5%)
Working part-time	418 (27.0%)
Not in labour force / unemployed	49 (3.2%)
Other (including 'prefer not to say')	83 (5.4%)
Education level[4]	
Year 10 or below	61 (3.9%)
Year 12	389 (25.1%)
Further education	1,052 (67.9%)
Prefer not to say	48 (3.1%)
Medication supplied	
COC	1,662 (85.4%)
POP	128 (6.6%)
Not supplied	156 (8.0%)
Number of consultations	
1	1,725 (88.6%)
2	182 (9.4%)
3	36 (1.8%)
4	3 (0.2%)

Notes:

1. *Missing BP and BMI data included 564 consultations where patients reported receiving*

the service in the last 12 months, which excluded them from the need to measure vitals.

2. *See Appendix 2.2 for referral criteria.*
3. *Employment status and level of education stats data were only available for the 1,751 people responding to the 7-day follow-up.*
4. *2 participants were referred to the GP on more than 1 occasion (136 referrals made in total).*

Quantitative outcomes

For 79.2% (n=1,751) of consultations, participants completed a follow-up survey at 7 days post-pharmacy consultation. The main difference between responders and non-responders was a higher rate of GP referrals and no resupply of an OCP amongst non-responders (Appendix 3.1 Table 3-1-6).

Primary outcome

For the 1,751 consultations with self-reported follow-up data, the mean composite score (SD) of participants experience measures was 91.6 (17.8) out of a maximum of 100. This suggests a high level of positive participant experience associated with the service. For 76.2% of consultations, the mean composite score was greater than 90.

Secondary outcomes

Participant experience

Figure 3.5 and Appendix 3.1 Table 3-1-7 provide information on each question in the participant experience survey using a 7-point Likert scale to 7 statements (1=strongly disagree with the statement, 7=strongly agree with the statement). Most participants across all 7 statements agreed or strongly agreed, indicating a positive experience with the service. For 57.8% of consultations respondents "strongly agreed" with all participant experience questions; and for 70.9% of consultations, respondents either "agreed" or "strongly agreed" with all questions.

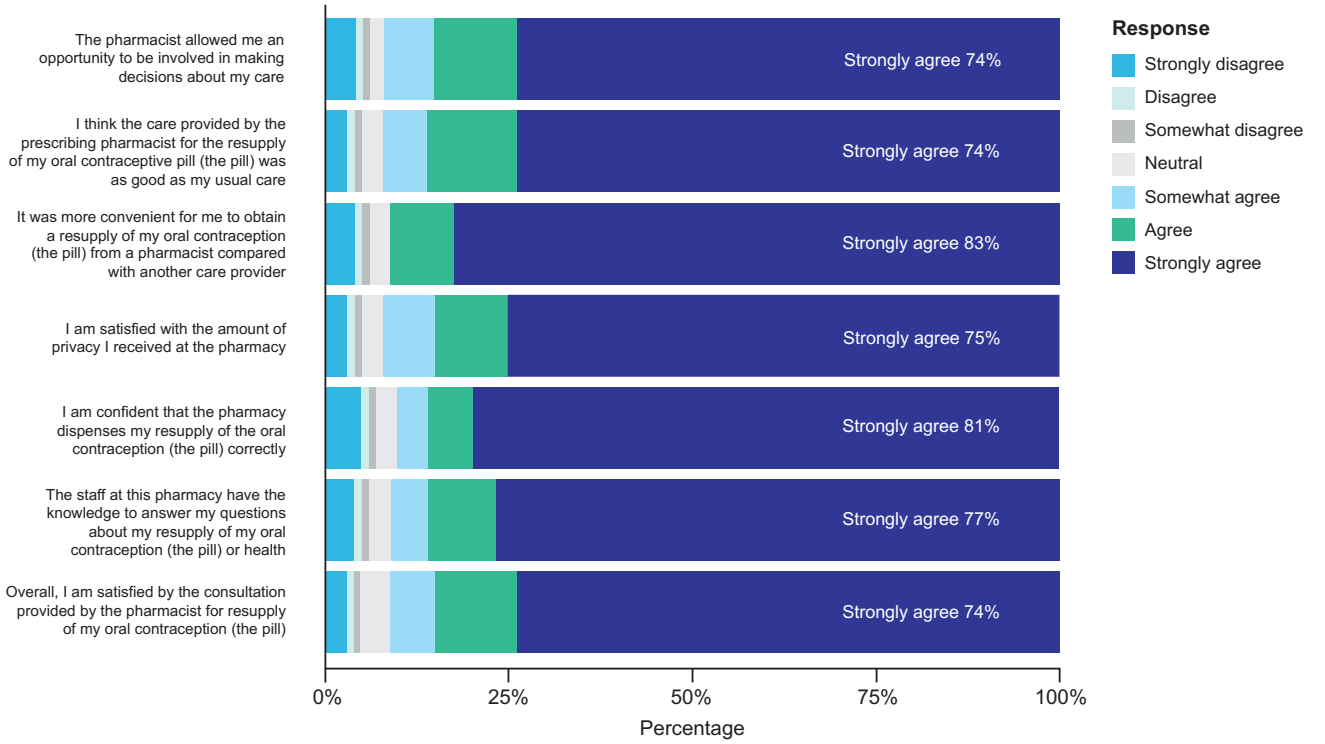


Figure 3.5: Participant experience (n=1,751 consultations)

Implementation outcomes

The proportion of pharmacies that provided consultations and the proportion of participants that received the service are reported above. Most participants received a resupply for 1 of the COC pill formulations (86.2%). Most participants also received general advice related to preventive health activities and/or contraceptive advice. The mean duration of

supply was 5 months, and the majority of resupplies (53.6%) was for 4 months duration (Table 3-2).

Table 3-2: Pharmacy management practices (n=2,209 consultations)

	Total consultations (n=2,209)
Medication supplied	
COC	1,904 (86.2%)
POP	146 (6.6%)
Not supplied	159 (7.2%)
Advice given	
Provided information on contraception, breast-cancer awareness, cervical screening	1,253 (56.7%)
Discussed importance of regular health checks	1,531 (69.3%)
Discussed alternative contraceptive options & encouraged to speak to medical practitioner	1,389 (62.9%)
Duration of supplied treatment	
Mean months (SD)	5 (4)
1 month	66 (3.0%)
2–3 months	251 (11.4%)
4 months	1,184 (53.6%)
5–11 months	136 (6.2%)
12 months	413 (18.7%)
No supply	159 (7.2%)

The mean (SD) self-reported cost for the service (inclusive of medication costs) was $28 (23). Overall, for 77.8% of consultations, participants reported that cost would not be a barrier to using the service again; for 13.7% of consultations, participants considered it may be a barrier and for 8.5% of consultations, participants indicated it would be a barrier (Table 3-3). There were minimal differences in these findings by OCP type (Appendix 3.1 Table 3-1-8).

Table 3-3: Follow-up at day-7 post-pharmacy consultation (n=1,751 consultations)

	Total n=1,751
Resupplied an OCP by the pharmacist	1,667 (95.2%)
Reported taking the pill as recommended	1,584 (90.5%)
Proportion reporting cost as a barrier to using this service again	
Yes	148 (8.5%)
Maybe	240 (13.7%)
No	1,363 (77.8%)
Service fees[1] (mean $ (SD))	28 (23)

Note:

1. *Service fees were related to medication costs only in NSW and consultation plus medication costs in ACT.*

Healthcare utilisation

Based on MBS data (1,725 participants consenting), the proportion of participants seeing another healthcare professional was around 7% per week in the first 4 weeks following the initial pharmacy consultation (Table 3-4). Over the 4-week period post-consult there were 557 GP consultations for 378 people (21.9% of the MBS consenting cohort) – 252 had 1 consultation, 93 had 2 consultations and 33 had more than 2 consultations. There were few pathology tests conducted for STI testing. Hospital utilisation rates were low in the 4 weeks post-pharmacy consultation - with a total of 8 hospitalisations and 19 emergency presentations. Hospitalisations included viral infection, postoperative complications and care, reduced consciousness and pain. Emergency presentations included gastrointestinal symptoms such as nausea and vomiting, convulsive episodes, renal inflammatory conditions as well as mental health related presentations. There were no hospitalisations or emergency department (ED) presentations for OC-related adverse events.

Table 3-4: GP, pathology, and hospital utilisation in the first 4 weeks post consultation

	Week 1	Week 2	Week 3	Week 4
GP consultations[1]	126 (7.3%)	121 (7.0%)	121 (7.0%)	124 (7.2%)
Pathology tests for STIs	8 (0.5%)	6 (0.3%)	8 (0.5%)	10 (0.6%)
Hospital utilisation[2]				
All cause hospitalisations	<5	<5	<5	<5
Hospitalisations for potential OC-related adverse events	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Emergency presentations				
All presentations	<5	8 (0.4%)	<5	<5
Presentations for triage 3–5 conditions	<5	6 (0.3%)	<5	<5
Presentations for potential OC-related adverse events	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Notes:

1. Data available for 1,725 people consenting to MBS linkage.

2. Data available for all 1,946 people participating in the study.

The long-term trends are presented in Table 3-5 pre- and post-pharmacy consultation. All participants consented to link their hospital and emergency data (with data available up to 30 June 2024). Overall, 81.1% had follow-up data for hospital utilisation as they enrolled in the program prior to 30 June 2024. By 6 months post-pharmacy consultation, this number had reduced to 33.2%. By contrast, 94.6% consented to MBS and/or PBS linkage. These data extended to 31 December 2024, with 81.3% having follow-up data at 6 months post-pharmacy consultation (Appendix 3.1 Table 3-1-9).

The mean proportion of days covered with a dispensed OCP medication increased between the 24 months pre-consult and the 6 months post-consult (0.60 vs 0.84). The proportion of people with >80% days covered with an OCP was higher in the post-consultation period compared to the pre-consultation period (65.3% vs 44.1%). There was a small decrease in mean monthly GP consultation rates. STI testing rates were unchanged in the pre- and post-consultation periods. Although there was a statistically significant reduction in hospitalisation and ED utilisation rates in the post-consultation period, the absolute numbers of presentations were very low. Appendix 3.1, Table 3-1-10 provides data on the short- and long-term trends in health GP, medication, ED and hospital utilisation. For those referred to the GP, participants had a lower proportion of days covered >80% and higher GP consultation rates in the first 4 weeks compared with those not referred.

Table 3-5: Long-term trends in OCP prescription coverage, GP, medication, ED and hospital utilisation

	Long-term trends post-consultation[1]		
	Pre-consultation[2]	Post-consultation[2]	p-value
Proportion of days covered with an OCP (mean SD)	0.60 (0.39)	0.84 (0.23)	<0.01
Proportion with OCP days covered >80% (n, %)	8,216 (44.1%)	1,208 (65.3%)	<0.01
GP consultations[3]	35.86 (28.53)	33.96 (40.89)	0.03
STI tests[3]	2.39 (4.14)	2.36 (7.72)	0.84
Hospitalisations[3]	0.64 (2.80)	0.37 (3.89)	<0.01
Potential pill-related hospitalisations[3]	0.02 (0.78)	0.03 (0.84)	0.78
Emergency presentations[3]	1.95 (5.64)	1.11 (6.09)	<0.01
Low acuity emergency presentations[3, 4]	0.01 (0.33)	0.00 (0.00)	0.08
Potential pill-related emergency presentations[3]	1.53 (4.77)	0.81 (4.80)	<0.01

Notes:

1. *The denominator varies depending on dataset used. The utilisation rate per month was calculated by dividing the number of events by the number of months the person was followed up from the date of their pharmacy consultation. See Appendix 3.1 Table 3-1-9 for a breakdown of number of participants with linked data per month of follow-up.*
2. *For MBS and PBS data the pre-intervention period was 36 months. For hospital data the pre-consultation period was 12 months. For all data sources the post-intervention period was up to 6 months post-consultation.*
3. *Mean (SD) per month per 100 people.*
4. *Only NSW data included. Triage data to assess acuity status are not available for ACT.*

Sub-group analyses

Figure 3.6 highlights the pre-specified sub-group analyses for the primary outcome using a multivariate regression model. People aged 26–30 years had greater odds of a high experience score (>90 points) compared to those 18–25 years (adjusted odds ratio (OR_{adj}) 1.78 (95% CI 1.35–2.37)). People residing in medium or small towns also had higher odds of a high experience score than those in metropolitan towns (OR_{adj} 1.88 (95% CI 1.17–3.17)). Conversely, people who were not resupplied an OCP had lower odds of a high experience score than those who received a re-supply (OR_{adj} 0.36 (95% CI 0.16– 0.81)) (Figure 3.6).

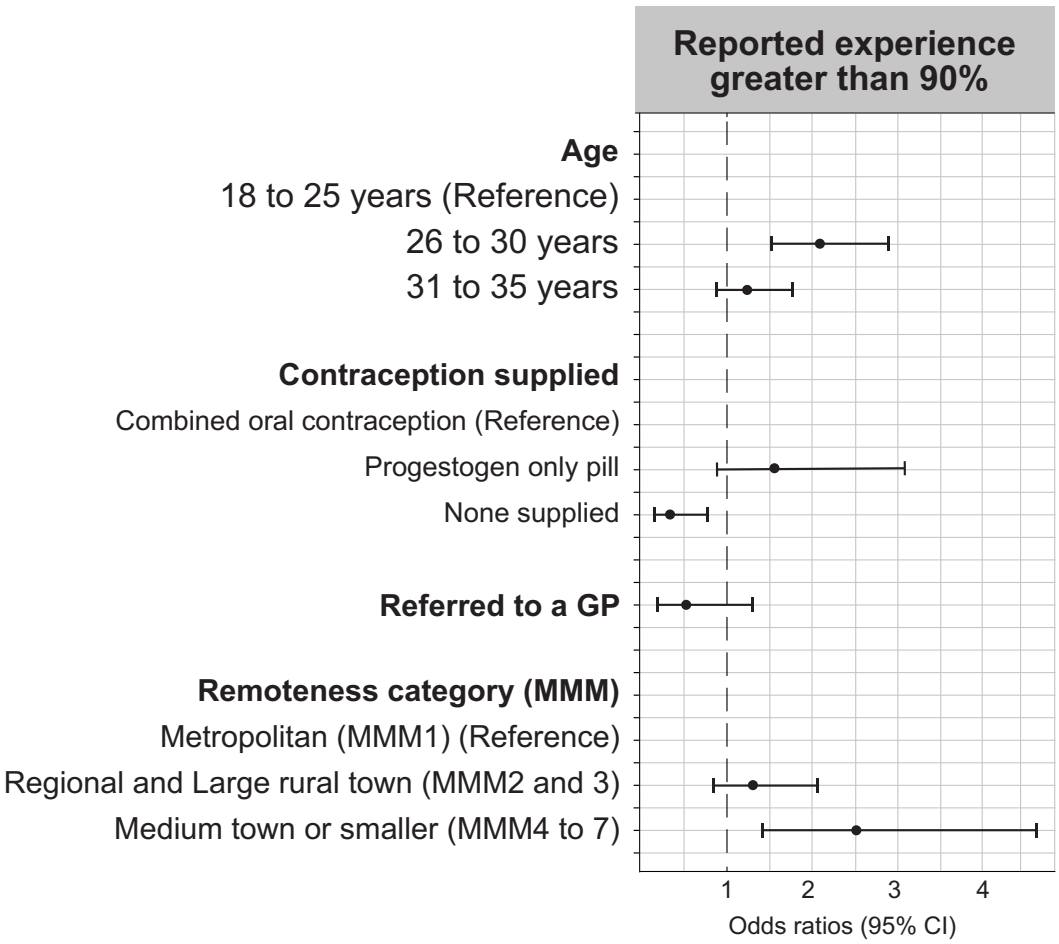


Figure 3.6: Sub-group analyses for participant experience (n=1,751 consultations)[1,2]

1. *Odds ratios are adjusted for all other covariates displayed above.*
2. *There were no participants in remote and very remote locations (MMM 6 and MMM 7).*

Adverse events

At the 7-day follow-up, participants reported side-effects in 6 consultations, possible side effects included prolonged bleeding, increased appetite, more acne than with usual pill, nausea, headache or mood swings.

The numbers of consultations for participants in the red and orange category receiving OCP supply and referred to a GP are reported in Table 3-6 - there were no consultations in which participants assigned to the red category received an OCP resupply and in all 9 consultations, participants assigned to the orange category received an OCP resupply. For 39 of the 48 'red category' consultations (81.2%), participants were referred to a GP.

Table 3-6: Adherence to clinical management protocol by OCP type

		COC n=1,904	POP n=196	Total consultations n=2,209
Red†	Total	47 (2.5%)	1 (0.5%)	48 (2.2%)
	Referred to GP*	38 (2.0%)	1 (0.5%)	39 (1.8%)
	Resupplied OC	0 (0%)	0 (0%)	0 (0%)
Orange	Total	9 (0.5%)	0 (0%)	9 (0.5%)
	Referred to GP†	4 (0.2%)	0 (0%)	4 (0.2%)
	Resupplied OC	9 (0.5%)	0 (0%)	9 (0.5%)

** Please see Chapter 7 Overall Discussion where the free text reasons for not referring are analysed.*
† See Appendix 2.2 for the clinical criteria for each colour category.

In summary, there were no differences in GP utilisation and STI testing rates in the pre-and post-consultation period. For serious adverse events (hospitalisation and ED utilisation rates), there was a slight reduction in hospitalisation and ED presentation rates between the pre-and post-consultation periods. See Appendix 3.1 for a collation of all adverse events.

Interview findings

Pharmacists

Interviews with pharmacists who had resupplied the OCP were completed between January 2024 and October 2024. Thirteen pharmacists were recruited from a sample of purposively selected pharmacies to represent a diverse range of experiences in implementation of the trial, which included both higher and lower recruiting pharmacists from each MMM region where the trial was delivered (Table 3-7). Sampling continued until saturation. Interviews ranged from 30–70 minutes (average 47 minutes).

Table 3-7: Characteristics of pharmacists interviewed (n=13)

Characteristic	Number
Role in pharmacy	7 - proprietors/ business owners
	3 - general pharmacists
	2 - principal pharmacists
	1 - rotational pharmacist
Gender	8 - men
	5 - women
Pharmacy characteristics	4 - retail focus
	9 - offering professional services
	10- extended hours or weekends
	6 - main street
	6 - shopping centre locations
Remoteness category	5 - metropolitan locations (MMM 1)
	2 - regional centres (MMM 2)
	2 - large rural towns (MMM 3)
	2 - medium rural towns (MMM 4)
	2 - small towns (MMM 5)
OCP recruitment	7 - higher recruiting (above median)
	5 - lower recruiting (below median)

The pharmacies were selected to achieve diversity in geographical regions and business models. Participating pharmacies had a variety of business models including extended hours and/or weekend trade and were in the main streets or shopping centres across cities and small regional towns. Pharmacists interviewed held a variety of roles in the pharmacy ranging from pharmacists, proprietors, and those with additional training in the provision of other professional services, such as immunisations and the UTI service.

Service users

Thirteen interviews were conducted between December 2023 and October 2024 with OCP resupply service users; 2 participants had attended pharmacies recruited for interview and the remainder attended another pharmacy not interviewed. Participants were recruited from all MMM regions where the trial was delivered, except for MMM 2.

Interviews ranged from 12–22 minutes (average 16 minutes). Most participants interviewed were in full-time employment and had attended the pharmacy receiving OCP resupply services during business hours on weekdays. All but one person interviewed had received an OCP resupply following consultation (Table 3-8). Service users who did not receive the OCP were approached for interview, but only 1 completed an interview.

Table 3-8: Characteristics of service users participating in interviews (n=13)

	Number
Age	8 - 18–25 years 5 - 26–31 years
Employment status	9 - full time work 4 - part time / casual (4 - also studying)
Education	5 - university / diploma 2 - certificate 6 - high school
Health care concession card eligible	0
Remoteness	5 - metropolitan 0 - regional 3 - large rural town 3 - medium rural town 2 - small rural town
Time seen for initial pharmacy consultation	1 - after business hours 11 - in business hours/ lunch break 1 - not asked
OCP resupplied	12 - yes

Overview of qualitative findings

Six main themes were identified to influence the effective implementation of the OCP resupply service, categorised into 3 domains of access, delivery and integration (Figure 3.7).

1. **Participant incentives to use the service** included limited GP availability, challenges anticipating and managing repeat prescriptions but wanting continuous contraception, and opportunistic promotion direct from pharmacists.
2. **Pharmacist motivation to participate** included alignment with pharmacy business strategies and advancement of professional scope of practice initiatives; and building reputation with patients and community as a trusted and available service.
3. **Participant perceptions of a 'good service'** included immediate access to continued contraception coverage; a quick, convenient service and value for money; and a comprehensive consultation with trusted and knowledgeable providers. Clarity of eligibility earlier in the encounter could avoid dissatisfaction.
4. **Pharmacist perspectives on service quality** included delivering patient centred care for continuous contraceptive coverage alongside existing offerings; and minimisation of adverse events related to disrupted contraceptive coverage. There was an interest to broaden the scope of the service to help more people.
5. **Integration with health system 'infrastructure and information systems'** included initiation of pre-screening for suitability to support patient satisfaction and efficient resource use; and the OCP resupply trial being complementary to existing contraceptive services.
6. **Integration with health system 'values, culture, and relationships'** included perceptions that the requirements of the service were more comprehensive and burdensome than other methods of contraceptive access available to women, and misalignment or inconsistency with other authorised OCP resupply services.

An additional theme was identified which cuts across the 3 domains, related to a common perception that the service eligibility criteria were limiting. This was perceived to have influenced engagement with the service by pharmacies and participants, as well as having an impact on participant and provider satisfaction. While the service prioritised improving access, eligibility limitations meant some interested participants continued to face access issues or needed to rely on other services to ensure access to continuous contraceptive coverage. Themes were mapped to constructs from Weiner's theory of organisational readiness to change, and to the 4 NPT constructs of cognitive participation, coherence, collective action and reflexive monitoring (Figure 3.7).

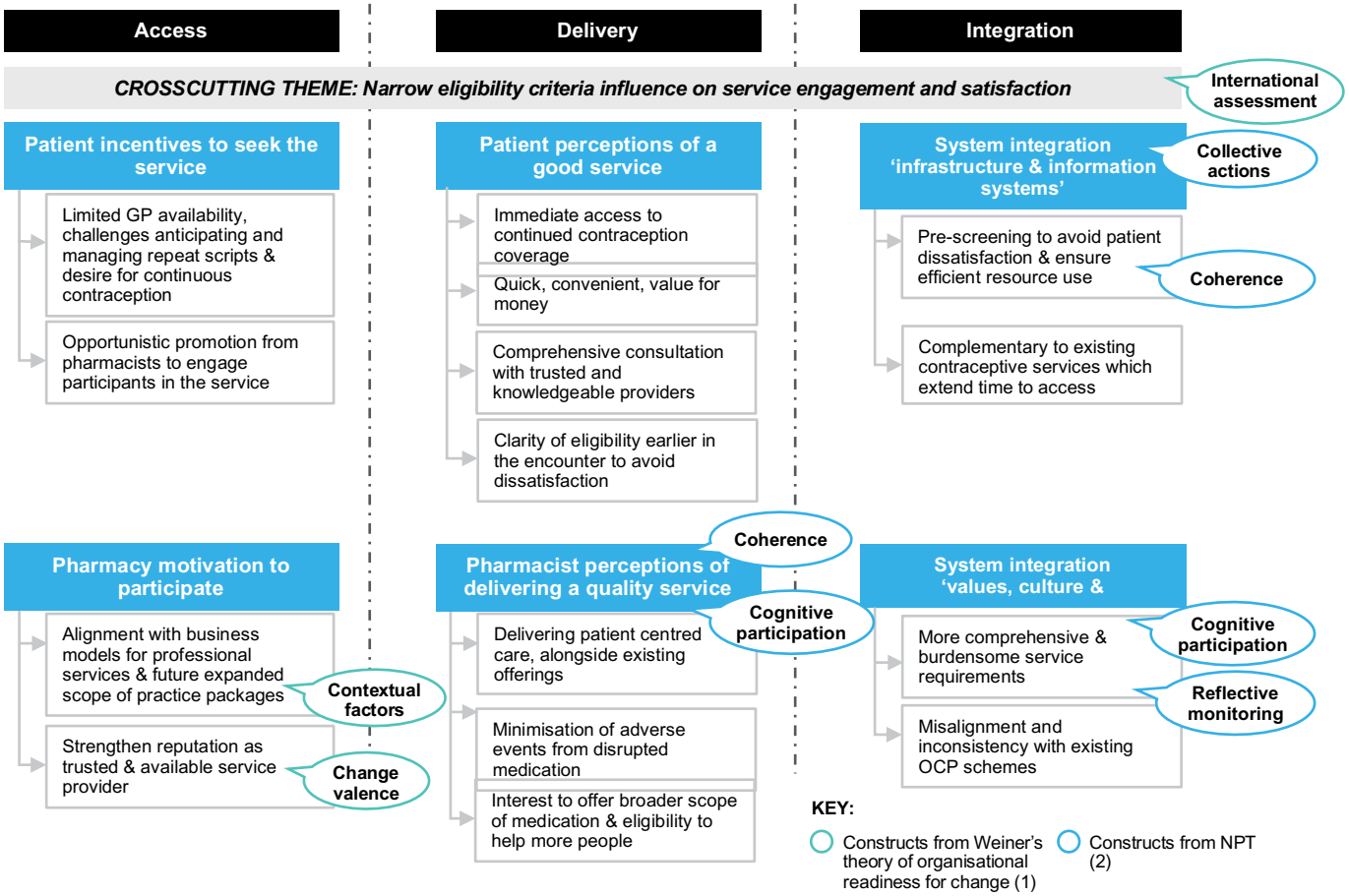


Figure 3.7: Factors influencing effective uptake and sustainability of the OCP resupply service - key themes

Some themes identified in interviews were foundational elements for introduction of new pharmacist-led services for both the UTI and OCP resupply service domains. These themes are described in detail in the UTI trial evaluation report. Motivating pharmacists to participate in new pharmacist-led services that applied to both OCP resupply and UTI services included a sense from pharmacists that service delivery of new professional service offerings was feasible, within their capabilities, that they had adequate support and training. They perceived a quality service to be one that avoided a tick box approach to care, and having quarantined time and workflow adjustments to conduct the consultations. Equity considerations identified in the UTI trial evaluation report are similarly relevant to the OCP resupply service. The findings presented below focus on themes that are specific to the OCP resupply service.

Theme 1: Participant incentives to seek the service

Women who engaged with the pharmacy service tended to be seeking an immediate solution to ensure they had continued contraceptive coverage. Challenges in accessing timely GP services, including for repeat OCP prescriptions, were identified by both participants and providers as a key driver for service uptake. Women were commonly introduced to the service opportunistically while seeking out care options in the pharmacy.

Limited GP availability, challenges anticipating and managing repeat scripts but wanting continuous contraception

Lack of local GP availability for immediate care and the relative ease of access to community pharmacies was a clear driver of participant demand for the OCP resupply service. Interviewees described challenges in obtaining timely local GP appointments needed to secure a repeat OC supply, particularly in rural and regional areas where primary care services were

scarce, books were closed, or there were known long wait times. All interviewees welcomed the trial as addressing an important gap in service provision.

Some participants easily recognised contraception as requiring planned care from GPs and had sought GP appointments well in advance but still faced long wait times (3–4 weeks), while their contraceptive supplies were dwindling. Others were less prepared and had not sought appointments until their supply was almost exhausted. From both participant and provider interviewees there were reports of participants unsuccessfully obtaining a GP appointment close to the time their OCP supply ran out or before going on holidays or out of town. Others were unexpectedly caught out when they presented to the pharmacy with the intention to fill a prescription only to learn they had no remaining repeats or the prescription had expired.

> *I went to the pharmacy for the pharmacy trial to pick up the oral contraceptive script, I was actually leaving for an overseas trip the next day and had run out of the pill. So, it was really great that I was able to access it so quickly rather than having to wait and make phone calls and, you know, and pay for the service as well. It was a big help.*
>
> (Participant–P019, age 24, MMM 1)

The women interviewed expressed a strong desire for continued contraceptive coverage, with several women voicing concerns of the social and economic consequences of an unintended pregnancy should they not be able to gain timely access. While pharmacists also recognised that gaps in contraception may pose a risk for patients, their expressed concerns generally focused on potential health effects of discontinuation, rather than unintentional pregnancy (see section "Minimisation of adverse events from disrupted medication coverage"). Several women stated that in the absence of the trial, they would have needed to go without contraceptive coverage for 'several days' or 'until a GP appointment became available'. Other women shared they would seek out last minute GP appointments, which would likely come with high out-of-pocket costs, or they would need to travel long distances to obtain OCP resupply. Some women had previously used online prescriptions services or telehealth GPs to ensure they achieved continued coverage but were conscious of the additional cost burden of these services.

> *In this instance I wasn't able to get my whole supply, but if I could, it would literally make, you know, not having a child that much easier. Every time I have to do all this background stuff, I just find it so unfair that I'm trying not to be irresponsible and end up, you know, with children that I can't, you know, look after them properly, because I'm not in that stage of my life yet.*
>
> (Participant–P020, age 24, ineligible and given extended supply)

Opportunistic promotion from pharmacists

Most participant interviewees reported that they had heard about the trial from the pharmacy opportunistically when discussing or seeking contraceptive supply at the pharmacy. Many OCP resupply trial participant interviewees had not intentionally sought out the pharmacy OCP resupply trial as they had been unaware of its existence until being told of it at the pharmacy. Those that were aware had learned of the service from informal channels such as friends, radio news segments, or while conducting internet searches when seeking immediate care options; and were often uncertain if it truly existed or if the trial had started. Women who had searched the internet mentioned reputable sources such as NSW Health or ACT Health websites, which gave them confidence in approaching the service and had been pleased to learn of the proximity of participating pharmacies. Pharmacists also perceived that the OCP resupply trial had less marketing and advertising, including in-pharmacy flyers and promotional materials compared to the UTI trial, and postulated that this lack of marketing and publicity may have contributed to the observed lower than expected numbers of women seeking the service. They also observed that few trial enrolments had been initiated by participants intentionally seeking the service.

Despite voicing limited awareness of the OCP resupply trial, participants had intentionally attended the pharmacy to seek advice from pharmacists in relation to options for continuous contraception coverage, with several commenting they commonly sought advice from the pharmacy. The type of advice sought ranged from requesting emergency

prescriptions as learned through past experiences or seeking assistance about how to get an immediate GP appointment or prescription and participants shared these experiences within the context of facing long wait times for local services. Pharmacists commonly reported that direct promotion of the service during these types of encounters, as well as when clients presented with expired or nil repeat scripts, were key entry points to access the service. Some pharmacists promoted the service to regular clients when filling their last script, but due to duration of supply and timing of data collection, they were unable to comment if this strategy had resulted in the return of such clients for the service.

> *I would say mostly it's just been that the occasion, where we've really seen it, is where someone has unexpectedly run out? So, they either can't find their script, they have been traveling, they didn't realise their script was out of date, or their doctors cancelled on them? It's been more opportunistic where they've walked in and said, "I'm without."*
>
> (Pharmacist–PH002, male, higher recruiting pharmacy, MMM 2)

Theme 2: Pharmacist motivation to participate

Pharmacists interviewed believed that the OCP resupply service, similar to the UTI service, is needed and worthwhile and is helping to solve an important community problem relating to health care access. They were motivated to provide the service as one of a suite of professional services, which not only aligned with business strategies, but was believed to benefit their profession and to strengthen their reputation with the community as a trusted service provider.

Alignment with business models and expanded scope of practice packages

Many of the pharmacies participating in interviews offered existing professional services such as vaccinations, and pharmacy owners and pharmacists reported they were motivated to support the advancement of OCP resupply services and other future initiatives since they were seen as a core part of their service brand. Many pharmacies had already invested in the additional staffing and rostering, training, and service fit-outs – such as private consult rooms – needed for other professional services (including the UTI trial) and believed that continued uptake of new initiatives as they arose would be beneficial to increase overall consultation volume to sustain these offerings as a financially viable business model and make it easier to roster.

> *I don't think the remuneration probably provides enough security that you can always run with the extra people. Because you just can't predict how often this is going to happen… at the moment it's just a weird transitional, let's say teething problem.*
>
> (Proprietor pharmacist–PH002, MMM2, higher recruiting pharmacy)

> *My reason for owning a pharmacy and my reason for when I first bought the pharmacy 10 years ago - to extend the trade, so my reason for being here is to serve the community and make a difference to their life. So, it's not just money at the moment. It's been worthwhile.*
>
> (Pharmacy owner–PH011, higher recruiting pharmacy, MMM 1)

Beyond this, pharmacists felt the expanded scope of practice to be of benefit to the future of their profession. Some pharmacists commented on the expansion into new initiatives, seeing OCP resupply services as one of the necessary steps to reach this wider vision. They accepted the need to build evidence cases for each new service and that minimal risk services needed to be adopted to demonstrate capability. Pharmacists were generally satisfied with the OCP resupply service seeing it as an opportunity to expand their skill sets and expertise, however there was some general disappointment with the included scope of practice for OCP resupply (Refer to Theme 2 – Pharmacists were discouraged by limiting trial criteria).

Reputation with the community

Motivation to help address issues of health care access for the local community was evident amongst pharmacists interviewed. Pharmacists had a strong awareness of the local health care context and could easily identify similar access concerns as the participants did in relation to long waits for GP appointments, high out-of-pocket costs, and among pharmacists outside of metropolitan areas, the distances people had to travel to access health care.

Pharmacists recognised their role in the community as providing a convenient and accessible service, where people knew they could seek trusted advice. In rural and regional areas, pharmacists suggested they could offer greater accessibility to the community as a health care provider compared to general practices, which were often further away or had limited workforce availability.

> *Community pharmacists in regional and rural towns, I think, play a bigger role. Like we tend to be public figures, for better or worse… And I think largely because we are accessible... People can walk in and just see you. Walk in and start having a conversation with you.*
> (Pharmacist–PH005, male, MMM 4)

Pharmacists commonly described past experiences when people had sought urgent advice about OCPs due to being unable to reach timely GP services. In these scenarios pharmacists felt they had to offer 'stop gap' methods or recommend online prescription or telehealth services to support their patient but felt they could do more. Thus, the pharmacists expressed satisfaction that they could now help people through the OCP resupply trial by offering another avenue for immediate care.

Theme 3: Participant perceptions of a good service

Women regarded the service highly because it offered immediate access to continued contraceptive coverage. Key factors driving this were perceptions that the service was quick, convenient, and value for money, and involved a comprehensive consultation with a trusted and knowledgeable provider. Dissatisfaction arose when there was a lack of clarity of eligibility until later in the consult.

Immediate access to continued contraception coverage

The women interviewed appreciated that the trial offered them immediate access to contraception where they would have otherwise faced barriers to see a GP, and many believed they would have gaps in contraceptive coverage without access to the pharmacy trial.

> *I just wouldn't have had the pill for a few days, I guess, because I would have had no other option or I would have tried to see if there was an after-hours clinic in the town we were going to.*
> (Participant–P023, age 31, MMM 1)

> *I was only like a couple of days, you know I'm quite busy in my role and it just feels like it's just such an effort to get an appointment, like I almost considered going off it because it's just such an effort. But it was quite easy actually the appointment at the pharmacist, it was much easier than trying to get a doctor's appointment but, yeah, I have reconsidered actually using it because it just feels like such a hassle.*
> (Participant–P021, age 22, MMM 4)

Some women shared experiences of seeking options last minute as they had only discovered they would run out of their OCP supply that same day or were going on holidays out of town. While others were unaware that they had an expired prescription or no more repeats until they reached the pharmacy and then were unexpectedly without supply. In these contexts, these women were aware of the barriers they would face to access a GP appointment and were seeking an immediate solution. Other women who were more prepared had tried in advance to seek GP services but were faced with long waits times for appointments. Several women shared that they would be required to seek more inconvenient and costly options such as GP co-payments, or online prescriptions and telehealth to secure continued coverage.

> *The GP practice I go to, they charge for scripts as well, but it's a bit of a wait time for the GP to actually write the script. So, when I went to the pharmacy for the pharmacy trial to pick up the oral contraceptive script, I was actually leaving for an overseas trip the next day and had run out of the pill. So, it was really great that I was able to access it so quickly rather than having to wait and make phone calls and, you know, and pay for the service as well. It was a big help.*
> (Participant–P019, age 24, MMM 1)

One participant was ineligible to participate in the trial due to not having served the consecutive 2-year period, but instead the pharmacist offered continued access to the pill through the continued dispensing arrangements. Although slightly disappointed by a

shorter supply of contraceptive pill, she appreciated the support of the pharmacist to achieve continued coverage and remained positive of the OCP resupply trial, being eager to participate in future.

Quick, convenient, and value for money service

Overall participants expressed satisfaction with the service and said they would encourage friends and family to use it. Women interviewed greatly appreciated that the service was a 'quick', and easy way to gain access to contraception. Experiences of a quick service were described in relation to the short timeframe required to access the resupply after identifying the need. Participant examples included being able to search the web and locate a pharmacy which was close by, the wait time to speak to a pharmacist or for the consultation to begin, or the consultation itself. Women expected that finding a participating pharmacy and attending for consult would be much quicker than attempting to see their regular GP with wait times of days or weeks to secure an appointment, and lengthy delays sitting in a waiting room. Women reported that the consultation itself took longer at the pharmacy than at the GP due to screening requirements in the trial but did not feel this would dissuade them from using the pharmacy trial again since the overall experience was quicker and more convenient.

Women commonly experienced the OCP resupply service as being 'convenient', and this was described in many ways. Some saw convenience as the ability to walk-in without requiring advance planning or a making a booking. Others appreciated being able to access the service at a time that fit in with life schedules, with examples of longer opening hours allowing them to access their contraceptive supply outside of usual GPs or business hours, or times that aligned with shift work or lunch breaks. Women appreciated accessing care from a location that was close to their home, work, or other amenities such as an education facility or shopping centre. They also recognised there were more pharmacies than GP clinics. For participants coming from rural areas, a pharmacy may be substantially closer to home than their usual GP (for example 45 minutes' drive). Convenience was a strong theme in relation to participant satisfaction with the service, and willingness to use the service again or recommend to friends and family.

> *[The] pharmacy is close to where I live. It's also close to work, so if I needed to go after school. And it didn't take that long, either. I was in and out, like, maximum 25 minutes.*
>
> (Participant–P013, age 28, MMM 3)

> *It was convenient, while I was already in town. Some areas around here are quite rural, so it takes you a little while to get – so you just go into town on certain days and do certain things on certain days, because it just has to fit into that schedule. Because you don't want to travel in just to do another script or go to the doctor. You do want to make sure everything is all in the one day. So, it was very convenient. Because I went in. I hadn't booked any time. He had plenty of time. Walked through everything. So, it was very convenient, is the best way to describe it.*
>
> (Participant–P016, age 27, MMM 3, ineligible but given extended supply)

> *It was closer to where I live. It was cheaper because I didn't have to pay for a doctor's appointment. It was less repetitive because I don't have to get a different doctor to tell me the same thing every time, ask me the same questions. It was just simple, over the counter… a lot more convenient and faster.*
>
> (Participant–P018, age 20, MMM 1)

Overall participants felt the service offered value for money. Cost was not raised as a barrier to using the OCP resupply trial by participants interviewed, and this may be because they were already willing to pay for a prescription and the pharmacy consultation had been subsidised as part of the trial (free in NSW, but minimal cost in ACT). From feedback emails, 1 correspondent was dissatisfied when they were unable to use a health care concession for the prescription itself and another suggested paying for a full 12-month prescription at once may not be affordable.

> *I am aware you can buy up to 12 months' worth however many people will not have the funds to buy multiple prescriptions of the contraceptive pill in one go. It is just not viable to go back through that consultation process every few*

months it is most definitely easier to go to the GP.

(Participant–feedback email 1)

Most participants reported they may have been required to make a co-payment (gap fee) if they had been able to get an appointment with their GP, so comparably the trial service was perceived as a cheaper option. When asked what may have happened without access to the OCP resupply pharmacy trial, interview participants often raised cost as an important consideration when deciding on the alternative care option they could use to get immediate access to resupply. Participants provided examples of services with out-of-pocket costs which they could consider, including co-payments to access GPs with shorter wait times, co-payment to collect a repeat script from a GP practice reception without seeing the GP face-to-face, or payments for online prescription and telehealth services. Some participants had used these options in the past when facing a similar situation. Some participants were happy to accept higher costs of alternate care to ensure continuous coverage, whereas others reported these costs would be a barrier and result in delayed access and gaps in contraceptive coverage.

Based on these cost considerations, participants indicated that they would be willing to pay a service fee in future for pharmacy services if it was less than the cost of attending their regular GP or other services. Some may be willing to pay an equal price due to the fact the service was deemed convenient or offered another option.

Because of my hours of being in hospitality, like I'm a shift worker so it doesn't always line up and I also don't get my rosters until two weeks in advance, so I can't plan too far ahead either, and unfortunately, I can't request a day off just to get the pill every now and again. I think if it was going to be this extra $20 or $30 in cost, I'd probably still go to the GP and travel, it would be nice also to have the option that , you know, $20 or $30 just to go down the road would be good, without a hassle.

(Participant–P020, age 24, MMM 1)

It's still far cheaper than going to the doctor. So yeah, I would still be okay to pay $20 or $30, but I guess if it's going to be the same, even if it was the same price as the doctor, it's still quicker to get in.

(Participant–P024, age 30, MMM 4)

It is important to note that people who did not use the service, or who did not agree to interview, may have had different views on the perceived value for money of the service.

Comprehensive consultation with trusted and knowledgeable providers

Another key component in women's appraisal of a good service was access to a comprehensive consultation with a knowledgeable care provider. For most, the service delivered by the pharmacist was viewed as being equivalent to their experiences with GPs when obtaining a repeat OCP prescription, which they found reassuring. Women trusted that the educational level and expertise of pharmacists was appropriate to resupply OC, particularly if the pharmacy was also their regular medication dispenser and had a record of their medication history.

Some women were impressed by the thorough level of the service and welcomed an opportunity to not feel rushed and to receive additional health information relating to women's health, and medication risks and side effects, which they had not received previously.

Timely notification of eligibility

Across interviewee groups, there was feedback that some women were dissatisfied after learning that they were ineligible for the trial. Some women had only learned that they were ineligible late in the consultation, after enrolment. Ineligibility was only prompted during the MedAdvisor® questionnaires or associated assessments. Pharmacists interviewed relayed how ineligible women expressed disappointment that they had wasted their time with a lengthy consultation since their expectation of receiving the resupply, and now still needed to see a GP which came with added costs and wait times. Others felt that not enough information on the trial eligibility criteria was available publicly and felt they were inconvenienced by having taken time from their day to attend the pharmacy only to learn they were ineligible once they arrived. Many of those women accepted the rationale for ineligibility but felt the criteria should have been clear at the start and that more information should be available to help them

make an informed decision on where to seek care. While we were only able to interview 1 woman who had not received the resupply, feedback emails received expressed similar concerns, and some were dissatisfied with the eligibility criteria being too restrictive (see section Cross-cutting theme: Narrow eligibility criteria influence on service engagement and satisfaction).

> *I was unable to get the pill dispensed by the pharmacy as I had too many risk factors - overweight, higher than normal blood pressure...The pharmacist was very apologetic but explained she was unable to dispense the pill for me, and I would need to go to my GP to discuss these concerns. I understand the impetus behind this policy but I find it to be dangerously unrealistic, especially in consideration of the barriers to primary healthcare that patients face (cost of GP consults with minimal bulk billing, unavailability of good GPs, the high number of Australians who don't have a GP with whom they have a good relationship and regularly see). This negates the utility of the pharmacy pill dispensing scheme for many people who would most stand to benefit from it. In my case, I was already aware of my blood pressure before the pharmacist measured it, and I had already discussed this with my GP. So going back to my GP just to get a prescription added an extra bureaucratic barrier to accessing a contraceptive I've been taking without incident for many years, rather than serving any health purpose.*
>
> (Participant–feedback email 4)

One pharmacist shared their experiences of dissatisfied customers:

> *"You wasted my time," and we just apologise profusely. And then we'd genuinely try and set them up with a GP, but a lot of these women are busy women. So, you imagine a 40-year-old woman who's got a corporate job, who's busy, who's ran out of her pill, and she doesn't meet the criteria because she's too old. It's not a very good thing to say to a woman and so yeah, that was me early on, and that was when I realised, we couldn't do that, or then you tell them that, in layman's terms, they're too fat. They don't meet because of the BMI, and they know exactly what you're saying, that's far from ideal.*
>
> (Pharmacy owner–PH007, male, MMM 3)

Consequently, some pharmacies adopted screening to mitigate the risk of customer disappointment (see section Theme 5: Integration with health system 'infrastructure and information systems).

Theme 4: Pharmacist perspectives on service quality

The OCP resupply trial was seen by pharmacists as contributing to their ability to deliver a patient centred service through addressing community needs. They recognised the OCP resupply service, alongside other authorised contraceptive service offerings supported their community to access timely and continuous contraception and minimised adverse events. Pharmacists expressed an interest to further expand the scope of the service to allow them to help more people.

Delivering patient centred care for continuous contraceptive coverage, alongside existing offerings

Pharmacists perceived the OCP resupply as being an important and necessary service for their patients to achieve timely access to the pill. They cited limitations in availability of timely GP care locally and commonly perceived the resupply service as offering value for their patients by being quick, lower cost, and offering other conveniences compared to general practice or online prescription services. Many pharmacists felt it was important to take into consideration the individual's needs and expectations, to ensure the best care option was provided.

> *An individual being able to control their circumstance under their expectation… like… "I don't necessarily need to go to the GP; it doesn't necessarily need to cost me $120 for the visit. All I'm doing is just getting a resupply of something that I've been using for a while, and I've had no issues with."*
>
> (Pharmacy owner–PH013)

Alongside the trial, pharmacists acknowledged there were several existing authorised pharmacy services, such as continued dispensing and emergency supply, which could also help people achieve

continued coverage while they waited to see a GP. Several pharmacists recalled instances where these other services may be better options for people. Some pharmacists provided information upfront to the participant about the different offerings, allowing them to make their own informed decision about which mechanism to use to obtain contraceptive resupply.

> *They've come in, and they'll try and borrow some tablets before they get to the doctor, or they'll be confused about whether they have got a prescription. And they'll go, "Oh, I've run out, what can you do to help?" … there's four methods to get them across the line, and it's really up to them what they want to do, and we'll go through those things. Obviously, the online script costs money, the emergency supply and get a limited amount, and the continuing supply - we've got to have had a history of them.*
>
> (Pharmacy owner–PH007, male, lower recruiting pharmacy, MMM 3)

Ultimately pharmacists expressed that they wanted to help people walk out with the medication which they wanted and needed, and when presented with 2 options, wanted the best experience for the person rather than one focused on a consultation fee. When people opted for continued dispensing this was perceived to be due to having no consultation fee or being a quicker or easier service, while other patients had existing GP appointments booked and therefore only needed a stop gap. Overall, pharmacists accepted the service as providing people with another option for care (see section Theme 5: Integration with health system 'infrastructure and information systems').

However, some pharmacists felt the trial consultation procedure which was supported through MedAdvisor® forms minimised the ability to offer patient centred care. They preferred to have more organic and natural conversations with patients to elicit their suitability for the resupply rather than working through a tick box form, particularly for existing patients with a long history of dispensing at that pharmacy.

> *the problem with that tick box thing is it really is a tick box. It becomes a little bit perfunctory, and any Tom, Dick and Harry can do that. So that's the argument and patient centred. It's more centred on regulatory environment rather than the patient.*
>
> (Pharmacy owner–PH007, male, lower recruiting pharmacy, MMM 3)

Minimisation of adverse events from disrupted medication coverage

Pharmacists demonstrated concern for minimising poor health outcomes and adverse events associated with disruption in contraception coverage. They saw this as another important aspect of the resupply service for people who could not get timely access to a GP for a repeat prescription.

> *I have had to say to them [GP colleagues], "If your patient came to me because you are literally booked out for the next six weeks and they didn't have their oral contraceptive pill and I did not give it to them, they would have to stop treatment, stop therapy where they could fall pregnant. But then when they see you in six weeks' time, they recommence their oral contraceptive pill and their cardiovascular risk has gone back to where it was at the beginning and their increased risk of heart attack and stroke because they had six weeks of gap. But this trial is to stop that."*
>
> (Pharmacy owner–PH011, higher recruiting pharmacy, MMM 1)

However, many felt these concerns could be mitigated by other authorised services such as continued dispensing or emergency supply.

> *The other person who had higher blood pressure, but they were out of their pill and it's much better to continue their pill because obviously we know that risks of DVT go up if you stop and start again. So, it's just to continue dispensing to get them through to the next lot, if it's just going to be about a patient outcome but they are not to go off it, but they do need to get checked out.*
>
> (Pharmacist–PH003, higher recruiting pharmacy)

Pharmacists also recognised the limitations of the service and had clear understanding of when they

needed to refer people to GPs or other providers to ensure patient safety.

> *It's low risk, and there is a lot of, obviously, criteria that we do have to follow. And anything that we're not sure of or just a little bit wants to double check, we can always give the patient as much information as possible to refer them on.*
>
> (Pharmacist–PH001, higher recruiting pharmacy)

Interest to offer broader scope of medication and to help more people

Many pharmacists felt there was an opportunity for pharmacists to help more people access contraception and this would further enhance the quality of the service. They expressed interest in being able to offer a wider variety of OCP medications and include more people, particularly in the context of the low numbers of women seeking the service, and turning people away who they felt would benefit from the service but who did not meet trial inclusion criteria (see section Cross-cutting theme: Narrow eligibility criteria influence on service engagement and satisfaction). Some pharmacists compared service provision in other jurisdictions and wanted to offer the same to their community.

> *Obviously, there's no initiation. So, if someone's coming in for a new script or they want to change from one to another, that's not possible in this environment. It obviously meets only some of the population's needs. It doesn't meet all of the population.*
>
> (Pharmacy owner–PH013)

Theme 5: Integration with health system 'infrastructure and information systems

When integrating the resupply trial into their service delivery, pharmacists drew on learnings and knowledge of the provision of other services. This included developing procedures and adaptation of workflows and understanding the scope of existing policies and authorisations.

Pre-screening of women for suitability

Similar to findings from the PATH-UTI trial, pharmacists appreciated the integration of the OCP resupply service into the MedAdvisor® platform, a commonly used IT platform used for other categories of professional service delivery such as vaccinations, and the UTI trial. Most pharmacists interviewed found the MedAdvisor® OCP resupply component helpful in guiding the consultation and clinical decisions to ensure eligibility and minimise risks. However, pharmacists had observed that participants were disappointed when they were deemed ineligible part way through the consultation. In a move to manage participant expectations and prevent dissatisfaction, some pharmacies introduced pre-screening procedures prior to initiating trial enrolment (via the QR code) and starting a consultation. Pre-screens were generally informal conversations with interested customers to assess suitability using specific questions about the most common reasons for ineligibility ('red flags'). Some pharmacies had prepared flyers with a list of 'red flags' to present to participants.

> *It's just something that we implemented when the service was initially rolled out; nothing worse than a staff member potentially promising a service to a patient only to then realise, 'oh, sorry, you're not eligible'. So that's why there was active staff training to begin with so that we didn't make those false promises.*
>
> (Pharmacist in charge–PH006, lower recruiting pharmacy)

> *We had a couple of cranky customers, and we thought the whole point of this was to make them happy. So, we thought how can we make it less? and that's to screen them. So, we have staff screening them obviously, because often there's non-pharmacists for that initial port of call.*
>
> (Pharmacy owner–PH007, lower recruiting pharmacy)

Pharmacists and pharmacy owners felt it was necessary to introduce these screening procedures, not only to avoid dissatisfaction for their clients, but to ensure smoother workflows and avoid staff wasting time in lengthy consultations for participants who would ultimately be ineligible. Some pharmacists questioned the appropriateness of charging for consultations if they could not deliver a treatment (from a consumer relationship and trust perspective) but equally recognised (from a business perspective)

that time spent in consultations for ineligible people required staff resources and diverted pharmacists from other duties such as dispensing or other professional services. They reported that the use of pre-screening procedures had also been introduced for the UTI service and are used for other professional services.

> *It's the same thing that we would do for patients coming in for vaccinations. So, we just had to train our staff into screening, like 'Is this patient eligible for these trials? Do they meet the criteria?' because we don't want to waste anyone's time if they're not actually suitable for the trial.*
>
> (Pharmacist in charge–PH012)

Complementary to existing contraceptive services provided by pharmacists, which can extend time to access for ineligible people

There was a clear recognition among pharmacists that the OCP resupply trial added to an existing suite of authorised services that pharmacists could now offer to support people in achieving continued OCP coverage. Most pharmacists offered the OCP resupply service from the trial in the first instance, and if participants were identified as ineligible (either before or during the consultation), pharmacists considered eligibility for continued dispensing arrangements or emergency supply. Many pharmacists perceived the services to be complementary to each other, since people who needed to be referred to a GP had immediate care options available as a fall back, which was perceived as being particularly important to ensure continued coverage, given their patients were experiencing long wait times for GP appointments.

> *We've now got a whole series of things that we can do to help them, that we can do continuing supply, we can do part of this trial - a year's supply, we can do an emergency supply, or we can put in the direction of an online instant script type of thing… And if we can get them across the line, it's hard because the easier option is to do continuing supply if they fit the criteria, whereas the harder and longer is to do the trial."*
>
> (Pharmacy owner–PH007)

However, some pharmacists perceived the resupply trial competed with existing service offerings, such as continued dispensing arrangements (see section Theme 6: Integration with health system 'values, culture, and relationships'). They saw this as a barrier to trial enrolment since they were more inclined to offer other, more practical, services first. They felt they should decide which service to provide based on individual needs, for example if the participant already had a GP appointment booked or a preference to see their GP, or the pharmacist had limited time to provide a consult.

> *One of the factors that I do think for the OCP trial is that pharmacists can do what's called a Continued Dispensing on certain oral contraceptive pills. So, I guess if we've got significant history and we're able to put it through as a Continued Dispensing, that's cheaper and easier for the patient than having them in for the consult, paying for the cost of the medicine and the consultation fee. So, I think that's a big one…*
>
> (Pharmacist–PH001, higher recruiting pharmacy)

Theme 6: Integration with health system 'values, culture, and relationships'

Compared to other ways people can access OCP in the broader health system, there were perceptions that the pharmacy resupply service was comprehensive and, in some ways, more burdensome for both participant and provider. Pharmacists also perceived some inconsistencies with their role in the service compared to other ways that women could access OCP resupply.

Perception of more comprehensive and burdensome service requirements

The OCP resupply trial protocol was perceived by many pharmacists as supporting their delivery of the service by assessing important clinical risks and ensuring nothing was missed. However, there was a perception among the interviewed participants and pharmacists that the requirements of the pharmacist consultation went above what a person might receive in usual care pathways, such as through GPs or online prescription services. There were mixed views on whether or not the comprehensiveness of the service was warranted. Examples included trial requirements that pharmacists take 3 BP

measurements to get an average reading as part of eligibility determination whereas online prescription services used by women do not entail BP measurements, and women claiming their GP had never taken a BP during an OCP consultation. Other examples were women who had no previous history with a GP (for example online prescription services or telehealth) but were still able to get a prescription for OCP quickly. Others commented on the relevance of some of the questions for their personal situation or when they had been using the same medication for many years.

And there was just so many questions. I was like, 'oh, wow. The doctor has never asked me any of this before'.

(Participant–P003, age 30, MMM 3)

.. The first time when I was caught out, I just went to online, to one of those online doctors, to grab a prescription for my pill. And, while it was fine, I just wasn't sure who the doctor was, or where they were located.

(Participant–P013, age 28, MMM 3)

The doctor - did she check my blood pressure and everything? And [pharmacists] explained the risks with the medication as well. The doctor just gave me the script.

(Participant–P024, age 30, MMM 4)

… when I was doing the trial, I've noticed that a lot of patients were like, 'Oh, I should just go in to see the doctor and just get the script. I never really had to measure my blood pressure. They never asked me any of these questions.' There have been situations where people have had migraines, and they were given a pill and no one told them why it was a precaution that they shouldn't be or should be monitored. So, I felt like because we had the trial and we had to be more strict with who we could supply it to, it actually made us be more vigilant and help. Yeah, I think we did a great job.

(Pharmacist in charge–PH012)

While a comprehensive consultation was often raised as being a reassuring quality of the service by participants (see section Theme 3: Participant perceptions of a good service), an overarching concern was the amount of time and steps involved to go through the pharmacy consultation process under the trial and whether this would be perceived as a burden for the participant and pharmacist and may deter participation for return consultations. A comprehensive consultation was not always viewed positively, with suggestions of it wasting time, and having unnecessary checklists that were 'obviously' not relevant for the individual participant. Some participants perceived that the pharmacist needed to be more thorough since they did not have a medical degree, and many understood that the questions needed to be asked. But some expressed that they did not think these should be requirements for ongoing or repeat access to the service.

Pharmacists understood that the trial and these processes were needed to generate evidence to support the capability of the profession and demonstrate patient safety for the resupply service as an ongoing model of care, but some hoped that these requirements would be reduced, and they would be allowed more clinical autonomy once the trial was over.

I think that because it's a trial, people accept that it's a trial and it's a lot more involved. I think if we said this isn't a trial, that maybe they would say, "Hey, why are you asking all these stupid questions?" Whereas if you ask a broad question and say, "What medication are you on?" Then they say, "None," and then, "do you have any diseases," which then you don't have to go through a tick, I don't have this, I don't have this, I don't have this, I don't have this – which of course, there's a much better and simpler way.

(Pharmacy owner–PH007, lower recruiting pharmacy)

Perceived misalignment and inconsistency of some aspects of pharmacist clinical capacity compared to existing OCP schemes

Some pharmacists expressed frustration that under the resupply trial protocol they were unable to resupply the pill to some women who sat outside the eligibility criteria, but whom they felt could have benefited from being included in the resupply service. While pharmacists expressed a desire to help as many women in their community as possible, they felt that the trial restrictions were more limiting than what was allowable in other authorised services, and this hindered them from doing so. Pharmacists perceived

inconsistencies in the clinical autonomy afforded to them across the range of services, since they were allowed to provide a medication to these same women under Continued Dispensing arrangements and Emergency supply. These findings were also voiced in relation to the perception of a restrictive inclusion criteria for the trial (see section Cross-cutting theme: Narrow eligibility criteria influence on service engagement and satisfaction).

The criteria is fairly restrictive, I think, in that you had to have been on therapy, same therapy for the last two years… That rules out a lot of people, particularly if they've been to a few different pharmacies and there's not a consistent history. But, at the same token, the Continued Dispensing option is really simple. You just have to have had it dispensed somewhere in the last six months and you're good to go.

(Pharmacist–PH005, MMM 4)

Yeah, so the crazy thing is, if I've got a woman who's over 35, who's got diabetes and has a high BMI, I can do a continuous supply, but I can't go on the trial.

(Pharmacy owner–PH007, lower recruiting pharmacy)

Cross-cutting theme: Narrow eligibility criteria influence service engagement and satisfaction

From the above 6 themes, there was a consistent theme relating to a perception of the resupply trial eligibility criteria being restrictive which may have been a barrier for engagement with the service and perceived low enrolments. Many pharmacists were discouraged that recruitment to the service was not as high as they would have expected and believed that this could be due to exclusions of some common OCs and other trial requirements being too narrow, such as length of previous scripts history, continuous use of the same type of OC, clinical presentations, and age and 'gender' exclusion which rendered many women who had presented with interest for participation as ineligible. They felt more women with access difficulties would benefit from the service if these criteria were reassessed.

...being on it [the pill] for two years, is very long… They need to open it up a bit more, they have to trust our judgment... and they go to the doctor they just state symptom. What difference does it make? They still have to wait to see the doctor. Meanwhile at least they're getting a treatment… they are the ones who need it

(Pharmacy owner–PH010, MMM 1, higher recruiting pharmacy)

From a professional standpoint, some pharmacists felt that the scope of practice and trial criteria and procedures limited their clinical autonomy, and this may have influenced their intertest and satisfaction with the trial, since they felt they could exercise more autonomy through provision of other services.

...it might be a little bit too restrictive. There's no real engagement with clinical judgment... So, you know, if you enter someone's blood pressure and it's like one point higher, is one point really a huge difference or is it, something that you can make a thing ongoing, "Okay, so what have you done previous to coming to the pharmacy?" And they're like, "I drove in Canberra." So of course, their blood pressure is up… It could be one of those scenarios... like white coat syndrome... Is there a point in that consultation where a clinical judgment could be made in regard to 'it's not exactly what they say, but I do believe that this is still a safe and effective mechanism for us to provide the product or service without the referral'?

(Pharmacy owner–PH010, MMM 1, higher recruiting pharmacy)

Pharmacists shared firsthand experiences of participants who were dissatisfied when being turned away from the trial due to ineligibility. Via feedback emails, some ineligible people shared similar dissatisfaction relating to trial restrictions. Most recognised that risks needed to be minimised, but felt that, at least for some participants, these exclusions would only add additional steps, costs, and risks for gaps in treatment to the person receiving care, who would ultimately end up with the same medication supplied.

Yeah, I think a lot of people are on like Estelle or like Yasmin and Yaz. Those ones because they're not included. And I understand why because there are other benefits, not just for contraceptive reasons that people could have

been on it. So those ones were like, 'Oh, it's a shame that we can't do the trial,' but then they're like, 'Oh, can I just get the other pill then?' And then I'm like, 'No you can't. Unfortunately, it doesn't work like that.' But I think that was the majority of the disappointment, just being not able to supply all of the pills.

(Pharmacist–PH012)

It should also be noted that some women may not be aware they had been ineligible for the trial if they still received supply through emergency supply or continued dispensing arrangements.

Discussion

In this trial of resupply of OCP medicines, 528 of 1,299 consenting pharmacies (40%) enrolled at least 1 participant into the trial with a total of 1,946 participants enrolled, and 2,209 consultations conducted over a 12-month period. The median number of consultations conducted per actively recruiting pharmacy over the trial period was 3 (IQR 1–5). Most participants (79.3%) were from metropolitan areas. The most common age group was 18–25 years (40.3%), and 46.6% were from the least disadvantaged socioeconomic quintile based on residential postcode which suggests that the intervention favoured participation from people residing in more affluent areas. Most participants (86.2%) received a resupply of COCs, 6.6% received the POP, 7.2% were not resupplied with any medication; and the majority received general health advice. The mean duration of resupply was 5 months. A total of 134 participants (6.9%) were referred to a GP by the pharmacist.

Participants completed the 7-day follow-up survey for 1,751 of 2,209 consultations (79.2%) and reported high levels of positive experience with the service with a mean composite score of 91.6 out of 100. In the 4 weeks post consultation, 21.9% of those consenting to MBS linkage had a GP consultation. Data on the reason for consultation are not available and therefore these consultations may not be for contraceptive related health issues. The mean PDC with a dispensed OCP medication increased between the 24 months pre-consult and the 6 months post-consult (0.60 vs 0.84). The proportion of people with >80% days covered with an OCP was higher in the post-consultation period compared to the pre-consultation period (65.3% vs 44.1%) suggesting higher levels of adherence in the relatively short follow-up period.

For the safety outcomes, in 57 of 2209 (2.6%) consultations, participants were assessed to be in the red (48 consultations) or orange categories (9 consultations) (see Appendix 2.2 for details on colour categories). For these consultations, no participants assigned to the red category and all 9 participants assigned to the orange category received an OCP resupply. There were few pathology tests for STI screening conducted in the 4 weeks post consultation and no change in STI pathology testing rates in the 12 months pre- and 6 months post-consultation. Similarly, hospital and ED presentation rates were low overall with a slight reduction in utilisation rates when comparing the 36-month period pre-consultation to the 6-month period post-consultation.

The high participant experience scores observed in this study were also observed in a United Kingdom (UK) study involving 714 consultations at 5 community pharmacies with participants that completed follow-up surveys reporting high levels of acceptability and willingness to pay [82]. In the PATH-OC trial, we used a measure of adherence using the PDC method and found the proportion of participants with over 80% of days covered by a OCP prescription increased from 44.6% in the pre-consultation period to 65.3% in the post-consultation period – although caution is advised in interpreting this finding given the data periods were considerably longer pre-consultation (36 months) compared to post-consultation (6 months). Previous studies have looked at medication continuation rates using a range of methods and follow-up periods and consequently it is difficult to make direct comparisons with previous literature. One United States (US) study involving 26 community pharmacists and 214 participants reported a 12-month continuation rate of 70% in a community pharmacy program [113]. Another US study involving 388 women seeking contraception in 139 pharmacies across 4 states found high rates of self-reported continuation of contraception use in both physician and pharmacist groups (90.4% vs 89.3% respectively) [120]. Another large US study in Oregon used health insurance claims data involving 172,325 contraceptive users, of whom 1,512 (0.9%) received their prescriptions from a pharmacist. The researchers found higher 12-month contraception continuation rates when comparing pharmacist and clinician prescribing (34.3% vs 21.0% respectively) [121].

The qualitative data found similar themes to those observed in the recently completed PATH-UTI trial. Pharmacists who enrolled participants were motivated to participate as it aligned with their business strategies, advanced their professional scope, and built their reputation as a trusted service. However, restrictive eligibility criteria disincentivised them by limiting their clinical decision-making autonomy. They viewed service quality as delivering person-centred care, minimising adverse events, and expressed interest in broadening the service scope. Participants were incentivised to use the service due to limited GP availability, unpreparedness for repeat prescriptions, and a desire for continuous contraception. They appreciated the opportunistic promotion by pharmacists – this contrasts with participants interviewed for the PATH-UTI trial, many of whom had heard about the PATH-UTI trial from news reports or advertising and had googled to find participating pharmacies in their locality. They perceived a "good service" as one that provided immediate access to contraception, was quick and convenient, offered value for money, and included a comprehensive consultation with knowledgeable providers. However, clarity on the eligibility criteria frequently came up as an issue that may promote service dissatisfaction.

Study strengths and limitations

There are 4 main strengths to this study: (1) a large number of pharmacists participated with diverse geographic representation; (2) high follow-up rates (79% participated in the 7-day follow-up survey); (3) linkage of records to NSW and ACT administrative data and federal Medicare data provided information to examine service utilisation in the hospital and primary care sector; and (4) a detailed qualitative evaluation of implementation barriers and enablers. The main study limitation is the lack of a comparison group to assess outcomes relative to usual care and the relatively short follow-up periods to examine long term trends in health service utilisation and medication adherence. The routinely collected data sources precluded the ability to assess unintended pregnancy rates, use of emergency contraception, and reason for GP consultation. An additional study limitation is the relatively small sample of interview participants overall and under-representation from regional areas. We were also unable to determine unmet need as there were no reliable data on numbers of women who wanted the service but did not meet eligibility criteria based on pharmacy pre-screening. The qualitative research provided an in-depth understanding of the implementation model, however the themes generated may be of varying relevance in particular geographic settings.

Conclusion

In this trial of OCP resupply in NSW and ACT, the service was well-received by participants, with high levels of positive experience reported and minimal safety issues identified. The findings are consistent with the literature from other countries, in particular the US and the UK. The trial highlighted the potential benefits of integrating this service delivery model into the broader healthcare system, offering convenient and accessible contraceptive care. There is potential for this service to make a substantive contribution to improving OCP access and continuity of care for women in NSW. However, the modest adoption rate by community pharmacists participating in the trial and low participant numbers recruited per pharmacy suggests that there are opportunities for increasing the scale and spread of the service delivery model. Based on the interviews conducted, focus areas include broadening eligibility criteria and enhancing alignment with existing healthcare services. Attention to these issues could increase pharmacist promotion of the service and service coverage rates. It is noted that NSW Health has since expanded the age criteria to 18–49 years, which may address some of the issues raised around restrictive eligibility. As the service transitions to a non-trial setting, future monitoring and evaluation activities will assist in assessing the impact of these changes.

04

ECONOMIC EVALUATION OF PATH-OC

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-OC
PATHWAY TO ACCESS: ORAL CONTRACEPTION

Chapter 4: Economic Evaluation of PATH-OC

Introduction

Expanding access to oral contraceptives (OCs) through community pharmacies has gained increasing policy attention as a strategy to improve reproductive health outcomes and reduce pressure on primary care services. As potential providers of contraceptive services, community pharmacists can offer a convenient and accessible point-of-care, particularly for populations underserved by traditional healthcare systems [87]. While several studies have explored the clinical and social benefits of community pharmacy provision of contraceptives [122–124], there is limited evidence on the associated economic implications.

The economic evaluation of the PATH-OC trial compared changes in healthcare resource use and associated distribution of costs following the introduction of community pharmacist resupply of oral contraceptive pills (OCPs; PATH-OC) compared to usual care (base-case) prior to implementation. It was conducted from a partial societal perspective, incorporating costs incurred by the Commonwealth government and by patients (out-of-pocket), excluding broader societal costs such as productivity losses. State government costs were not included due to the evaluation focusing on the single presentation and low probability of state funded hospital services being accessed in relation to resupply of OCs. The base-case reflects the pre-PATH-OC setting, in which resupply of OCPs occurred predominately through general practitioners (GPs), either in person or via online GP providers.

Objectives

The aim of this economic evaluation was to assess the change in healthcare resource use associated with the implementation of community pharmacist resupply of OCPs for women in New South Wales (NSW) and the Australian Capital territory (ACT) aged 18–35 years old, inclusive (PATH-OC trial intervention).

Methods

Study design

The trial was conducted in NSW and the ACT, Australia. Both jurisdictions operate under a universal health coverage system that provides publicly funded healthcare services, with hospital care primarily free of charge at the point of use, and primary health care delivered through a nationally subsidised fee-for-service model. Healthcare services and prescription medications can be eligible for government subsidy depending on provider and manner of service delivery. Components of the economic evaluation are summarised in Table 4-1.

Table 4-1: Components of the economic evaluation

Component	Detail
Type of analysis	Cost distribution analysis
Intervention	Model including community pharmacy resupply of OCPs
Comparator	Model including GP and Online GP
Outcome	None
Perspective	Partial societal
Population	Simulated data set of women aged 18–35 years living in NSW
Time horizon	7 days
Method used to generate results	Decision analytic modelling
Software	RStudio [125]

The analysis was conducted from a partial societal perspective consisting of health system costs (government-funded public services such as GP consultations under Medicare) plus patient out-of-pocket costs (hereafter referred to as patient costs) for resupply of OCPs within the trial follow-up period. Other societal costs such as productivity were not included, due to the short timeframe for analysis and limited impact of OCP resupply on productivity within a 7-day period. All costs are reported as 2025 AUD. A time horizon of 7 days was applied to align with the primary outcome of the trial: self-reported 7-day

accessibility and acceptability of the service. The trial follow-up period for all patient self-reported data was 7 days, with no further self-reported data collected. The short time horizon means discounting was not required. The analysis estimated health service use for OCP resupply among the eligible NSW/ACT population over 1 year, assuming only 1 instance of resupply per patient, per year. This was a pragmatic decision aligned with the trial protocol, which required patients to have seen their GP within 12 months, and the trial data which collected only 1 instance of resupply.

Any cleaning of the trial data was conducted as part of the statistical analysis by statisticians from The George Institute of Global Health. Details can be found in the trial Statistical Analysis Plan (SAP) Version: 1.4 (29 May 2025). There is no missing data for the purposes of the economic evaluation.

Population

A simulated dataset was developed to estimate the potential change in service utilisation GP and online only GP services resulting from the introduction of pharmacist-initiated extended supply of OCPs over a 12-month period. Population estimates were sourced from the Australian Bureau of Statistics (ABS) 2025 data [126]. While it is acknowledged that these figures may have increased since their publication, any changes are expected to be marginal. According to these estimates, 2,174,118 individuals representing approximately 25% of the NSW population are aged 18–35 years old inclusive, of whom 1,062,209 are female. Based on existing literature, between 22% [127] and 29.4% of women [124] within this age group are reported to use OCPs. The model used a 22.0% prevalence rate of OCP use [127]. This equates to 233,686 women, which was used as the sample population for this economic analysis.

Decision model

A decision-analytic cost model was developed to compare alternative service pathways for OCP resupply, before and after the introduction of community pharmacy resupply over a 12-month period. Figure 4.1 represents the pre-PATH-OC model, in which patients are assumed to seek resupply through existing pathways only (GP and online GP services). Figure 4.2 shows the PATH-OC model, in which community pharmacy is an additional option for consultation and resupply.

The pre-PATH-OC model in Figure 4.1 captures the consultation regarding OCP resupply, and the resupply itself, through existing pathways only (GP, online GP). It assumes that costs are incurred exclusively during that episode of care, and for obtaining OCP medication, and that no additional healthcare utilisation occurs within the 7-day period. It was possible for no resupply to occur (grey dotted line to the 'no resupply' node). Accordingly, a proportion of patients who had a consultation but did not proceed to resupply was included in the model across all pathways.

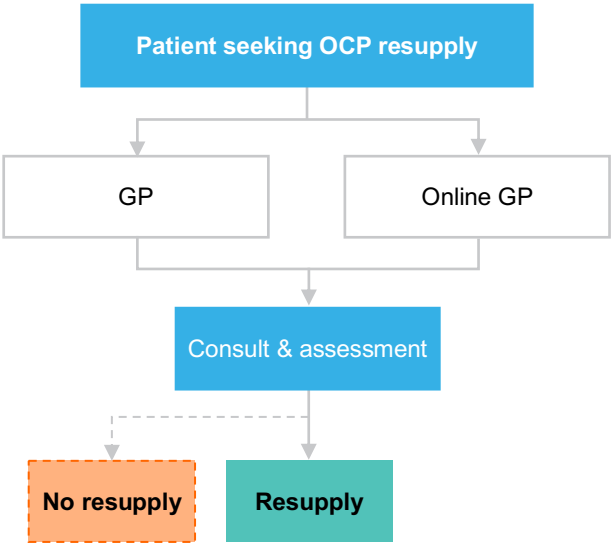


Figure 4.1: Decision-analytic structure for resupply of OCP before the introduction of community pharmacy as a care pathway (Pre-PATH-OC)

Figure 4.2 for PATH-OC retains the same pathways and assumptions but includes community pharmacy as an additional care pathway for direct supply of OCPs in accordance with the Authority [128] and the NSW pharmacist practice standards for the resupply of OCPs [129].

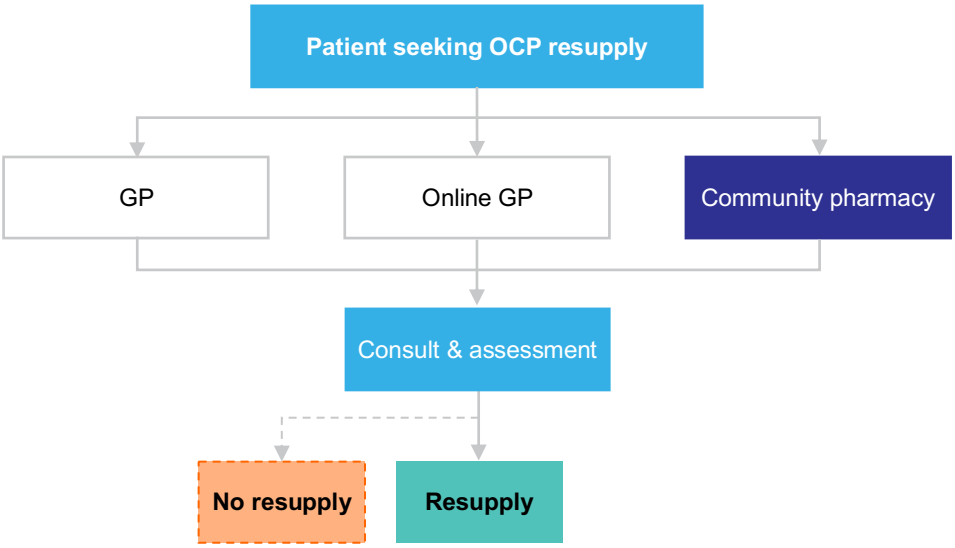


Figure 4.2: Decision-analytic structure for resupply of OCP after the introduction of community pharmacy as a care pathway (PATH-OC)

In both models, costs for consultations and medications are assigned to the different payers (Commonwealth Government and patients) according to Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) rules relevant to each pathway. The resulting models were implemented in RStudio [125]. It is acknowledged that women may seek resupply through healthcare pathways other than those presented in the current analysis (e.g., urgent care, emergency department (ED)). However, the PATH-OC trial did not collect data about the patterns of use of other pathways. Self-management strategies (e.g., non-pharmacological contraceptive methods) are not included.

Model parameters

At each stage of the model, activities were costed by applying the unit costs to the specific item associated with the pathway (Appendix 4.1).

Pathway utilisation

Each pathway was assumed to include 1 consultation and 1 OCP medication supply. Two service configurations were modelled representing pre-PATH-OC and PATH-OC service use (Table 4-2).

Table 4-2: Pathway utilisation proportions used in the model

	Proportion of patients using each pathway	
Pathway	**pre-PATH-OC**	**PATH-OC**
Pharmacy	0%	13%
GP	80%	69.6%
Online GP	20%	17.4%

The PATH-OC trial did not collect information on the proportion of women who would preferentially seek OCP resupply from pharmacies rather than GPs or other providers. In the absence of observed utilisation data for distribution across GP and online GP pathways, pathway probabilities were specified a priori as scenario assumptions, informed by stakeholder consultation and explored in sensitivity analyses. For the pharmacy pathway, the base-case model assumed a pharmacy uptake of 13%, informed by Butler *et al.* [130]. The GP and online GP pathway proportions for PATH-OC were adjusted accordingly. In the absence of other evidence on uptake, this was a pragmatic decision to enable comparison with the economic evaluation of the PATH-UTI trial. We tested this assumption by modelling different levels of uptake in sensitivity analyses.

Identification, measurement, and valuation of resources

All resource use was valued in monetary terms using Australian unit costs of 2025. The cost of prescription medication was sourced from the PBS website [131] and GP services were sourced from the MBS website [123]. The online GP fee schedule was determined by market rates found via an online search of NSW providers. See Appendix 4.1 Tables 4-1-1 and 4-1-2 for cost item details and sources.

Information on the types of resources used in OCP resupply was drawn from the Authority [128] and the NSW pharmacist practice standards for the resupply of OCPs [129]. Details of the approach to valuation are summarised in Appendix 4.1 Tables 4-1-3 and 4-1-4.

The frequency and cost of resource use were estimated using a simulated dataset generated from inputs derived from the statistical analysis undertaken by The George Institute for Global Health.

Consultations

In NSW, during the PATH-OC trial, the cost of the consultation with patients ($20) was paid for by the NSW Government to pharmacies, irrespective of the outcome of the consultation (e.g., resupply of medication or referral to GP). For patients in the ACT, the cost of the consultation was paid for by the patient with no dollar amount specified in the trial protocol. Currently, there is no subsidy or incentive from State or Federal Governments for pharmacists to provide these services. Values used for the cost of pharmacy consultation in the current analysis were sourced from Queensland Community Pharmacy Chronic Conditions Management Pilot Handbook [122].

A proportion of GP consultations was assumed to be bulk billed, resulting in zero out-of-pocket cost to the patient. For non-bulk billed consultations, the patient cost was estimated at $43.00, with minimum ($30.16) and maximum ($60.80) values based on the lowest and highest average patient costs for GP attendances reported by the Australian Institute of Health and Welfare (AIHW) [132].

Consultations provided by online GP service providers were assumed to be not eligible to be bulk billed. Under current MBS arrangements, eligibility for rebated GP telehealth services is generally contingent on the patient having an established clinical relationship with the providing practice, either through a face-to-face attendance within the previous 12 months or registration with that practice under MyMedicare, unless a specific exemption applies [133]. While some online GP service providers advertise MBS-eligible bulk billed appointments, assessment of publicly available booking pathways suggested that these consultations are reserved for out-of-hours, urgent care. Accordingly, consultations delivered through online GP platforms were assumed to attract an out-of-pocket patient fee rather than being MBS-eligible or bulk billed.

Table 4-3: Consultation cost inputs per OCP dispensed, by payer and PBS Eligibility (AUD 2025)

	Commonwealth (min, max)	Patient PBS eligible (min, max)	Patient Not PBS eligible (min, max)
Pharma consult	—	—	36.7 (19.50, 70.50)
GP consult*	53.98 (33.15, 84.90)	—	43.00† (30.16, 60.80)
Online GP consult‡	—	—	56.59 (39.00, 99.95)

** Including MBS subsidy eligible telehealth.*
† Assigned to non-bulk billed consults only.
‡ Consult not eligible for MBS subsidy.

Medication

Medication costs were calculated on a per-pack basis for OCPs, with pack duration varying by product from 28 days to 4 months. Two OCP types were included in the analysis: combined oral contraceptives (COCs), containing synthetic oestrogen and progestogen, and progesterone-only pill (POPs), containing synthetic progestogen alone.

In the PATH-OCP trial, patients reported receiving OCP resupplies ranging from 1–12 months, with a 4-month supply being the most common, reported by over 53% of participants (see Table 3-2). This aligns with the most common pack sizes available for OCPs included in the trial. All trial COCs and the levonorgestrel 30 µg POP are available in 4-month pack sizes. Drospirenone 4 mg POP is available in

28-day, 3-month, and 4-month packs; an average cost for drospirenone was therefore calculated across all available pack sizes. Average costs were calculated separately for COCs and POPs according to payer as shown in Table 4-4, then applied in the model according to the proportions observed in the trial (see Table 3-2).

For PBS-eligible patients, the average patient charge was $24.33 for COC and $25.00 for POP. For patients who were not PBS-eligible and therefore paid the Dispensed Price for Maximum Quantity (DPMQ), the average cost was $21.98 for COC and $60.52 for POP. The difference between DPMQ and the general patient charge was minimal for COC on average ($0.00; range $0.00 to $0.14), but substantially higher for POP on average ($35.52; range $0.00 to $53.96), driven by the cost of drospirenone products (Appendix 4.1). Table 4-4 shows the average and minimum and maximum medication costs applied to the model.

Table 4-4: Medication cost inputs per OCP dispensed, by payer and PBS Eligibility (AUD 2025)

Pill type	Commonwealth (min, max)	Patient PBS eligible (min, max)	Patient Not PBS eligible (min, max)
COC	0.00 (0.00, 0.14)	24.33 (22.47, 25.00)	21.98 (18.20, 25.14)
POP	35.52 (0.00, 53.96)	25	60.52 (21.49, 78.96)

In interpreting Table 4-4, it is important to note that the PBS general patient charge is a standard co-payment cap rather than the actual price of every medicine. Some medicines have a DPMQ that is lower than this co-payment. In these cases, a patient supplied on a private prescription may pay the lower DPMQ instead of the higher PBS general patient charge. This helps explain why, for COCs, the mean patient cost is lower when the medicine is not PBS-eligible than when it is dispensed under PBS. Several levonorgestrel/ethinylestradiol products have DPMQs below the general patient charge, which lowers the average cost of private dispensing in this group. This pattern is also reflected in the negligible mean Commonwealth contribution ($0.00), indicating that there is little or no government subsidy for most combined OCs because their listed prices are already at or below the patient co-payment. In contrast, for POPs, patient costs are markedly higher when the medicine is not PBS-eligible, reflecting higher DPMQs and a greater reliance on PBS subsidy to reduce out-of-pocket expenditure. However, this pattern does not apply uniformly across all brands or products, and any additional brand charge may further reduce or remove any private-cost saving. Itemised values and sources for medication costs can be found in Appendix 4.1.

Concession card holder medication costs were not included as a separate category in the current analysis because concession status was not collected in the trial and could not be reliably estimated for the PATH-OC population. Given that the study population was of reproductive age, the general patient charge was considered the most appropriate base-case assumption for PBS-eligible patients. Including a separate concession category would have required additional, unsupported assumptions about both the prevalence of concession eligibility and its distribution across treatment pathways.

Identification, measurement, and valuation of outcome

The trial outcomes were not considered in the current analysis. This analysis was designed to examine how healthcare costs may be redistributed across care settings and payers following implementation of the intervention, rather than to assess cost-effectiveness or overall value for money. Trial outcomes were not included as drivers of the economic results, as the focus of the analysis was on changes in healthcare utilisation and expenditure rather than on quantifying health benefits. The results should therefore be interpreted as estimates of potential budgetary and payer impacts, rather than as a comprehensive economic evaluation incorporating health outcomes.

Cost-distribution analysis

The cost-distribution analysis assessed changes in patterns of health service utilisation associated with allowing patients to seek resupply of OCPs from community pharmacists. This was undertaken by modelling health service utilisation for OCP resupply among the eligible population in NSW and the ACT over a 12-month period, with each resupply episode assumed to occur over a 7-day horizon. The analysis reports the estimated costs incurred by different

payers under a system without PATH-OC, compared with a system in which community pharmacy management is available.

Mean differences in costs and benefits between PATH-OC and Pre-PATH-OC models were estimated with associated 95% confidence intervals (CIs). Differences in the use of services between the pathways are described but not compared statistically. Descriptive analyses showing the mean, minimum and maximum costs for each pathway are provided.

The analysis modelled estimated health service use for OCP resupply for the eligible population in NSW/ACT in 1 year (12 months). As discussed in the

Population section, a simulated dataset was created to represent the pre-PATH-OC and PATH-OC arms for our models. A sample population of 233,686 women, divided 50/50 between the arms (n=116,843 per arm), was used to model a randomised controlled trial for the scenario evaluated. The scenario modelled (single presentation), includes the costs of 1 instance of care, that is, 1 presentation to a healthcare provider to seek resupply of OCPs.

Patient medicine costs varied by product but were primarily driven by pathway. OCPs supplied through pharmacies were assumed not to attract PBS pricing, resulting in higher out-of-pocket costs for patients in the pharmacy pathway. Consultation costs also differed by pathway and payer. Pharmacy consultations were assumed to generate patient out-of-pocket costs only, whereas GP consultations generated costs for both patients and the Commonwealth. Online GP consultations were assumed to be funded entirely through patient out-of-pocket payments.

GP consultation costs were modelled to account for the probability that some patients would be bulk billed. In the GP pathway, bulk billing status was sampled probabilistically, with a 69% probability of being bulk billed and a 31% probability of not being bulk billed. These proportions were based on the bulk billing rate reported by the Australian Institute of health and Welfare (AIHW) for GP attendances among people aged 16–64 years, which is the age group most closely aligned with the PATH-OC trial population [132]. The specific age group was chosen as it aligns most closely with the patient population of the PATH-OC trial and sits between the latest data on bulk billing rates for NSW and the ACT. While NSW has the highest bulk billing rates in Australia at 82.2%, the ACT has one of the lowest at 53.2% (November 2023 to October 2024 data) [134].

Medication costs to both government and patients were based on PBS-reported values (Appendix 4.1). Patient costs were applied to PBS-eligible prescriptions supplied by GPs and online GP services, and to non-PBS-eligible OCs supplied by community pharmacists. The proportion of consultations resulting in medication resupply was informed by trial data (see Table 3-2). Overall medication use comprised 86.2% COC, 6.6% POP, and 7.2% cases where no medication was supplied.

Sensitivity

Two sensitivity analyses were conducted. Sensitivity analysis 1 varied pharmacy consultation fee distributions (among pharmacy users). In the PATH-OC scenario, pharmacy consultation fees paid by patients were modelled using discrete fee distributions (Table 4-5). These distributions were applied only to individuals using the pharmacy pathway; all other parameters followed the probabilistic sensitivity analysis (PSA) structure. Fee levels and proportions were sourced from the Queensland Community Pharmacy Chronic Conditions Management Pilot Handbook [122] and selected to reflect plausible variation in charging practices (including instances of waived pharmacy consultation fee).

Table 4-5: Model inputs for sensitivity analysis on pharmacy consultation fees

Pharmacy consult fee	Sensitivity Analysis 1	Sensitivity Analysis 2
	% of patients	% of patients
No charge	0	10
$19.50	20	20
$36.70	75	65
$70.50	5	5

Sensitivity analysis 2 assessed pharmacy uptake sensitivity. As shown in Table 4-6, pharmacy utilisation in the PATH-OC scenario was varied to 10%, 13%, 25%, and 50%. The remaining share was allocated between GP and online GP in proportion to their baseline shares (preserving the baseline GP: online GP ratio). Results were compared against the pre-PATH-OC scenario.

Table 4-6: Model inputs for sensitivity analysis on pharmacy uptake

Pharmacy uptake scenario	GP (80% of remaining)	Online GP (20% of remaining)
10%	72.0%	18.0%
13% (base-case)	69.6%	17.4%
25%	60.0%	15.0%
50%	40.0%	10.0%

Uncertainty analysis was undertaken using Monte Carlo simulation (10,000 individuals per iteration; 5,000 iterations). In each iteration, individuals were assigned to a pathway according to scenario-specific utilisation proportions; GP users were assigned bulk billed versus not bulk billed status according to the specified probabilities; and consultation and medication costs were applied by pathway and payer perspective to generate iteration-level per-person and total costs.

Simulation outputs were summarised as the mean and 2.5th and 97.5th percentiles (empirical 95% uncertainty intervals) across iterations. Iteration-level results for the simulated cohort were scaled to the target population (N=116,843) using a constant factor (N/10,000), and scaled means and uncertainty intervals were reported for each payer and scenario.

Model validation

Validity testing (conceptual model, input data, assumptions, model outcomes) was carried out iteratively as part of the development of the model throughout the project, with pharmacy and health economics experts on the research team.

Deviations from Health Economic Analysis Plan (HEAP)

Previously, the primary objective was to estimate the financial resources required to implement and sustain community pharmacy oral contraceptive supply, rather than to assess relative efficiency or value of the initiative. The analysis included initial costs related to regulatory and clinical guideline compliance, such as training, accreditation, and infrastructure, as well as ongoing operational costs, including staff time and consumables.

Following review of the initial work, the focus of the analysis was reframed to understand cost-shifting within the health system and across payers. As a result, the implementation costing as presented was no longer considered relevant to key stakeholders and has been excluded from this report. This re-analysis uses a partial societal perspective, replacing the previous health system perspective.

Results

Cost distribution

The cost-distribution analysis examined changes in health service utilisation resulting from the option for patients to obtain OCP resupply from community pharmacists. Utilisation was modelled for the eligible NSW/ACT population over a 12-month period, assuming a 7-day time horizon for each OCP resupply episode.

Table 4-7 reports total costs using heatmap shading to aid visual interpretation. Blue shading indicates values below zero and red shading indicates values above zero; darker shading indicates values further from zero. Confidence intervals are reported in Appendix 4.1.

As shown in Table 4-7, introducing PATH-OC shifted costs away from GP and online GP services towards pharmacy resupply. Under PATH-OC, the pharmacy pathway generated additional patient costs of $14.7M (95% CI $13.9M to $15.4M). In contrast, patient costs decreased for GP services by $11.8M (95% CI −14.1M to- $0.2M) and for online GP services by $4.1M (95% CI −$15.3M to $6.6M). From the Commonwealth perspective, costs decreased under PATH-OC for both GP and online GP services (−$11.8M and −$0.1M, respectively), for a total Commonwealth cost difference of −$11.98M (95% CI −$49.5M to $26.6M). (Commonwealth costs seen in the online GP pathway are for PBS drugs prescribed to patients.) Overall, patient costs increased by $3.5M (95% CI −$9.9M to $16.2M), reflecting increased pharmacy costs partially offset by reduced GP and online GP costs. Taken together, PATH-OC reduced Commonwealth expenditure while increasing patient out-of-pocket costs, indicating redistribution between payers rather than a uniform increase or decrease in total expenditure.

Table 4-7: Total health care costs for OCP resupply (including consult and pharmaceutical costs) by payer over 12 months (AUD 2025 millions)

	Pre-PATH-OC		PATH-OC		Difference	
	Commonwealth	Patient	Commonwealth	Patient	Commonwealth	Patient
Pharmacy	—	—	—	14.7	—	14.7
GP*	87.9	54.7	76.1	47.6	-11.8	-7.1
Online GP†	0.9	31.5	0.8	27.4	-0.1	-4.1
			Total difference		**-11.90**	**3.50**

** Including MBS subsidy eligible telehealth.*
† Consult not eligible for MBS subsidy.
Note: Totals may not sum exactly due to rounding of individual values.

Sensitivity: pharmacy consultation fees

Sensitivity analysis 1 varied pharmacy consultation fees from $19.50 to $70.50 per consultation, **Table 4-8** are presented using the same heatmap format as Table 4-7. CIs are provided in Appendix 4.1.

The overall pattern of cost redistribution remained consistent with the base-case analysis. Patient costs

consistent with the Queensland Community Pharmacy Chronic Conditions Management Pilot Handbook [122], while holding all other model inputs at base-case values. The results shown in

increased due to the pharmacy pathway adding $14.2M (95% CI -$13.5M to $15M), while patient costs for GP and online GP services decreased. Patient costs increased by $3M (95% CI −$10.4M to $15.7M).

Table 4-8: Total health care costs for resupply of OCP (including consult and pharmaceutical costs) by payer over 12 months: Sensitivity Analysis 1 various pharmacy consultation fees (AUD 2025 millions)

	Pre-PATH-OC		PATH-OC		Difference	
	Commonwealth	Patient	Commonwealth	Patient	Commonwealth	Patient
Pharmacy	—	—	—	14.20	—	14.2
GP*	87.9	54.7	76.1	47.6	-11.8	-7.1
Online GP†	0.9	31.5	0.8	27.4	-0.1	-4.1
			Total difference		**-11.9**	**3.0**

** Including MBS subsidy eligible telehealth.*
† Consult not eligible for MBS subsidy.
Note: Totals may not sum exactly due to rounding of individual values.

Sensitivity analysis 2 assumed that 10% of pharmacy consultations incurred no patient fee, with remaining consultations distributed across low, base-case, and high fees (Table 4-3), while holding other inputs constant. Under this scenario shown in Table 4-9, pharmacy resupply added $13.3M (95% CI $12.6M to $14.0M) in patient costs, while patient costs

decreased for GP services (−$7.1M; 95% CI −$0.2M to $14.1M) and online GP services (−$4.1M; 95% CI −$153M to $6.6M). The net increase in total patient costs was $2.1M (95% CI −$11.4M to $14.9M). Including a zero-fee subgroup reduced the magnitude of the increase in patient out-of-pocket costs.

Table 4-9: Total health care costs for OCP resupply (including consult and pharmaceutical costs) by payer over 12 months: Sensitivity Analysis 2 various pharmacy consultation fees including $0 no fee (AUD 2025 millions)

	Pre-PATH-OC		PATH-OC		Difference	
	Commonwealth	**Patient**	**Commonwealth**	**Patient**	**Commonwealth**	**Patient**
Pharmacy	—	—	—	13.3	—	13.3
GP*	87.90	54.7	76.1	47.6	-11.8	-7.1
Online GP†	0.90	31.5	0.8	27.4	-0.1	-4.1
			Total difference		**-11.9**	**2.1**

** Including MBS subsidy eligible telehealth.*
† Consult not eligible for MBS subsidy.
Note: Totals may not sum exactly due to rounding of individual values.

Across pharmacy consultation fee scenarios, PATH-OC was consistently associated with lower Commonwealth costs and higher patient expenditure. The magnitude of the increase in patient costs was sensitive to the assumed distribution of pharmacy consultation fees.

Sensitivity: pharmacy uptake sensitivity

Table 4-10 presents cost shifting across payers under increasing pharmacy uptake (10%, 25%, and 50%), comparing pre-PATH-OC with PATH-OC. Total costs are displayed using heatmap shading for visual interpretation (Appendix 4.1 provides CIs).

At 10% uptake, PATH-OC generated additional patient pharmacy costs of $11.8M, partially offset by reductions in patient GP and online GP costs (−$5.5M and −$3.1M, respectively). Commonwealth costs decreased for GP and online GP services, resulting in a net increase in patient costs of $3.3M and a reduction in Commonwealth expenditure of $8.9M.

At 25% uptake, patient pharmacy costs increased to $29.5M, with larger reductions in patient GP and online GP costs (−$13.7M and −$7.8M). Commonwealth GP and online GP expenditure decreased by $21.9M and $0.2M, respectively. Overall, Commonwealth costs decreased by $22.1M and patient costs increased by $8M.

At 50% uptake, patient pharmacy costs increased to $59M, corresponding to reductions in patient GP and online GP costs (−$27.3M and −$15.7M). Commonwealth GP and online GP expenditure decreased by $44.1M and $0.4M, respectively. Overall, patient costs increased by $16M and Commonwealth expenditure decreased by $44.5M.

Table 4-10: Cost-shifting for resupply of OCP (including consult and pharmaceutical costs) by payer: various rates of pharmacy utilisation (AUD 2025 millions)

	Pharmacy utilisation rate					
	10%		**25%**		**50%**	
	Commonwealth	**Patient**	**Commonwealth**	**Patient**	**Commonwealth**	**Patient**
Pharmacy	—	11.8	—	29.5	—	59
GP*	-8.8	-5.5	-21.9	-13.7	-44.1	-27.3
Online GP†	-0.1	-3.1	-0.2	-7.8	-0.4	-15.7
Total difference	**-8.9**	**3.3**	**-22.1**	**8.0**	**-44.5**	**16.0**

** Including MBS subsidy eligible telehealth.*
† Consult not eligible for MBS subsidy.
Note: Totals may not sum exactly due to rounding of individual values.

Across all uptake scenarios, higher pharmacy uptake produced progressively larger increases in patient costs (driven by pharmacy consultation costs), only partially offset by reduced patient payments for GP and online GP services. Commonwealth savings increased with uptake, driven primarily by reduced GP and online GP expenditure. Uncertainty intervals widened at higher uptake levels (shown in Appendix 4.1).

Discussion

Community pharmacy management for common ailments has been shown to be clinically effective compared with usual practice in Australia [135], with growing evidence of cost-effectiveness [136]. However, many evaluations have assessed multiple conditions together, making it difficult to isolate the economic value of pharmacy management for a specific condition. This evaluation focused on a single service: community pharmacy resupply of OCPs, with the primary aim of estimating the potential for cost shifting between payers following introduction of PATH-OC.

Overall, introducing community pharmacy as an option for OCP resupply was associated with lower Commonwealth expenditure and higher patient out-of-pocket costs. Compared with the pre-PATH-OC scenario, the model estimated annual Commonwealth savings of $11.9M, largely driven by a shift in consultations from GP and online GP services to community pharmacies. This was accompanied by an estimated increase in patient costs of $3.5M, reflecting that pharmacy consultations were assumed to be funded entirely by patients in the base-case. These findings suggest PATH-OC may reduce publicly funded service use but can redistribute costs towards patients rather than reduce total expenditure uniformly.

Sensitivity analyses varying pharmacy consultation fees demonstrated that the magnitude of increased patient costs depended on the fee structure. When pharmacy consultation fees were varied within plausible ranges (including a subgroup with zero consultation fees), the estimated increase in patient costs ranged from $2M to $3M. Because these analyses held pharmacy uptake constant, estimated Commonwealth savings were unchanged. In practice, consultation fees may influence both affordability and uptake and therefore may materially affect the overall distribution of service use and costs. At present, pharmacies have discretion in setting consultation fees, and there are limited publicly available data on real-world fees for these services in NSW or the ACT. Evaluating consultation fees and their relationship with utilisation should be a priority as implementation data become available.

There are several limitations to the current evaluation. The model relied on a synthetic dataset that assumed a single resupply episode per woman per year, with medicine costs corresponding to supplies of up to 4 months. In practice, some women may seek more frequent resupply or obtain supplies exceeding 4 months from pharmacies, particularly over longer time horizons. This was a pragmatic decision that allowed us to estimate annual costs, and aligned with the trial protocol, which required patients to have seen their GP within 12 months, and the trial data which collected only 1 instance of resupply. This assumption is therefore likely to underestimate the frequency of pharmacy resupply episodes and, consequently, to underestimate overall patient out-of-pocket costs and potential Commonwealth savings associated with substitution away from GP-funded consultations

Because evidence on patient preferences for OCP resupply settings is limited, pharmacy uptake in the base-case (13%) was informed by Butler *et al.* [130]. Uptake could plausibly be higher for OCP resupply, as suggested by international evaluations, including Canadian analyses that assumed uptake of 38% [137] to 50% [138] and reported substantial system-level savings. Consistent with this, our uptake sensitivity analysis indicated that if 50% of eligible women used the pharmacy pathway, estimated Commonwealth savings would be $44.5M, alongside an increase in patient costs of $16M. This reinforces that the budgetary impact of PATH-OC is highly sensitive to real-world uptake patterns.

This evaluation adopted a partial societal perspective. Available data supported inclusion of out-of-pocket medicine costs, but not broader societal impacts such as productivity changes associated with reduced waiting time, fewer GP appointments, or improved convenience. In addition, the short analytic timeframe meant longer-term outcomes, such as unintended pregnancies and downstream healthcare costs, were not captured. If improved and timely access to contraception reduces

unintended pregnancy risk, the longer-term societal benefits of PATH-OC could be greater than estimated here. Accordingly, the societal impact of pharmacy resupply is likely underestimated.

Concession card holder medication costs were not modelled as a separate category as concession status was not collected in the trial and its prevalence within the PATH-OC population could not be estimated reliably. This may have led to an overestimation of out-of-pocket costs for participants who would have been eligible for concessional PBS pricing and underestimation of related Commonwealth government costs. However, in the absence of reliable patient-level data, this approach was considered preferable to introducing unsupported assumptions into the model.

Finally, implementation and provider-incurred costs (e.g., training, workflow redesign, consultation room requirements, and other costs borne by pharmacies to deliver the service), were not included in the current evaluation. These costs are important for understanding the full economic implications of scale-up and should be incorporated into future evaluations, alongside analysis of service capacity, quality assurance requirements, and any impacts on equity of access.

Equity considerations

Introducing pharmacy consultation fees for OCP resupply raises equity considerations. Because these fees are paid wholly by the patient, they may create a financial barrier for women with lower incomes, including younger women, students, and those in insecure work who are more likely to be price sensitive and less able to absorb unexpected health expenses. Even modest fees can deter timely access to contraception, particularly when women require repeated resupply episodes across a year [139–141]. If pharmacy fees are higher than (or less predictable than) patient costs in subsidised GP pathways, the policy may unintentionally shift the burden of contraceptive access towards those least able to pay, widening existing disparities in access to primary care and reproductive health services. Equity impacts may also vary geographically: in settings with limited bulk billing, long GP wait times, or poor access to sexual and reproductive health services, pharmacy resupply could reduce non-financial barriers (e.g., appointment availability and travel time), but if fees are unaffordable the pathway may primarily benefit those with greater financial means, creating a two-tier system where convenience is purchased out-of-pocket. Monitoring uptake and out-of-pocket costs by age, socioeconomic status, and remoteness, alongside real-world fee data, would help assess whether access improves equitably, and mitigation options such as fee caps, concession pricing, targeted subsidies, and transparent fee disclosure could reduce the risk of disproportionate impacts on disadvantaged groups.

Conclusion

Evidence on community pharmacy resupply of OCPs remains limited. This economic evaluation suggests that PATH-OC has the potential to generate substantial savings for the Commonwealth by shifting resupply consultations from GP and online GP services to community pharmacies, while increasing patient out-of-pocket costs under current fee assumptions. If supported and implemented at scale, pharmacist resupply of OCPs may reduce pressure on GP services and improve access to OC for women. These findings provide policy-relevant evidence on the likely direction and magnitude of cost redistribution between payers and highlight key data needs for future evaluations, including real-world consultation fees, uptake, implementation costs, and longer-term outcomes.

05

AN EVALUATION OF IMPLEMENTATION FIDELITY AND EFFECTIVENESS

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-OC
PATHWAY TO ACCESS: ORAL CONTRACEPTION

Chapter 5: An Evaluation of Implementation Fidelity and Effectiveness

Introduction

Implementation science plays a vital role in bridging the gap between research evidence and everyday practice. An important challenge in healthcare is the delay between the generation of such research evidence and its integration into routine practice. A literature review estimated that, on average, it takes 17 years for evidence-based practices to be widely adopted in clinical care, with only about half of the programs achieving successful implementation [142]. This translation gap is an outcome persistently observed across healthcare settings, disciplines, and countries [143]. To maximise the public health benefits of evidence-based healthcare innovations, investment in the design and application of structured implementation programs are essential. Implementation programs and evaluations should incorporate the assessment of implementation determinants and strategies to address different challenges that occur at various levels: healthcare practitioners, mid-level and high-level leaders, organisations and external settings outside the organisation [144, 145]. In healthcare settings such as community pharmacies, as the profession shifts from a product-focused model to the delivery of complex mixed models including patient-centred services, it becomes crucial to support and evaluate how these services are implemented to ensure their effectiveness and long-term sustainability. Moullin *et al.* [146] underscored the importance of systematically evaluating implementation programs over time and proposed a systematic and structured approach.

The Consolidated Framework for Implementation Research (CFIR) [147] is widely and frequently used to identify, categorise and assess the contextual determinants that influence implementation efforts. These determinants fall into 5 domains: characteristics of the innovation (e.g., the pharmacy service itself), the individuals involved (e.g., pharmacists, patients or managers), the inner setting (e.g., pharmacy infrastructure and culture), the outer setting (e.g., relationships with general practitioners or regulatory context), and the implementation process. Determinants can act as either barriers or facilitators, depending on whether they hinder or support implementation. Most implementation determinants identified in the literature on pharmacist-led services have been barriers [148–152]. These include challenges in the outer setting, such as negative perceptions of pharmacist-led services by general medical practitioners; within the inner setting, such as time constraints faced by pharmacists; and innovation-level issues, including lack of financial reimbursement [148, 149, 151, 152]. A scoping review [153] identified insufficient training in diagnostic skills as a key barrier. Some studies have noted important facilitators, including an expanded clearly defined legislative authority, a supportive organisational culture [150], pharmacist competence and self-confidence, and the perceived benefit to patient care [154].

Once implementation determinants are identified, it is essential to apply implementation strategies to address them. These strategies are defined as the methods or techniques used to enhance the adoption, execution, and sustainability of clinical practices [155]. The Expert Recommendations for Implementing Change (ERIC) framework [155] offers a taxonomy of 73 discrete strategies grouped into categories such as training and educating stakeholders, modifying infrastructure, supporting clinicians, and engaging consumers. Some of those specific 73 strategies include continuous performance feedback, promoting network interaction or adaptability of the intervention to the local context. Another important key strategy is the facilitation of the implementation process, which is defined as “a process of interactive problem solving and support that occurs in a context of a recognised need for improvement and a supportive interpersonal relationship” [155]. Practice Change Facilitators (PCFs) are used to action facilitation. These are individuals with subject-matter and implementation expertise who mentor, coach, and assist with implementation [156]. They assist community pharmacies and pharmacists adopt new services, such as pharmacist-led resupply of oral contraceptive (OC) treatments.

To complete implementation programs and evaluations, it is important to assess implementation

outcomes or the direct effects of efforts to implement new services or practices, which are distinct from clinical or patient outcomes (16). Proctor *et al.* [157] outlined 8 key implementation outcomes: acceptability, adoption, appropriateness, feasibility, fidelity, cost, penetration, and sustainability. These outcomes can be assessed at various levels, including service-level metrics (e.g., reach, fidelity) and provider-level measures (e.g., feasibility) [146].

NSW Government-sponsored research

The research contract with NSW Health involved 3 trials: PATH-UTI (pharmacist-led management of uncomplicated urinary tract infections (UTIs)), PATH-OC (pharmacist-led resupply of oral contraceptives (OCs)) and PATH-DERM (pharmacist-led management of 4 common skin conditions in community pharmacy). Due to the contractual arrangements and time sensitivity of these trials, there were periods where active services were concurrently being delivered in the community pharmacies (Figure 5.1). The PATH-OC study was carried out for 12 months overlapping with the PATH-UTI and PATH-DERM trials. The PATH-OC and PATH-UTI overlapped during the first 8 months of the PATH-OC. This was followed by 2 months where only the provision of the resupply of oral contraceptive pills (OCP; PATH-OC) was being delivered. In the last 2 months of the PATH-OC, it overlapped with the PATH-DERM trial.

Figure 5.1: Timeline for New South Wales (NSW) pharmacy trials

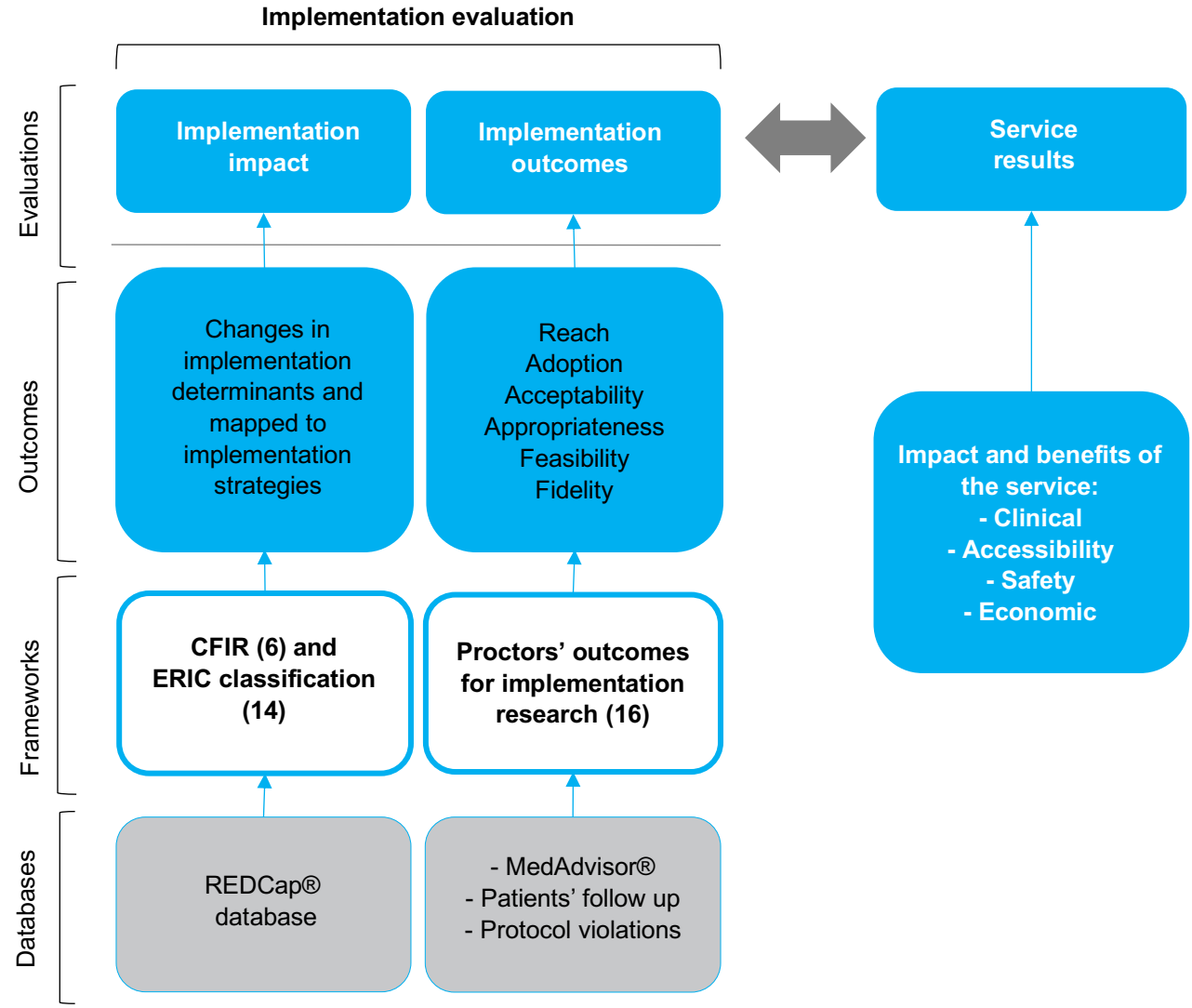
Aim

The overall aim for the implementation evaluation was to:

- assess contextual implementation determinants;
- evaluate the implementation facilitation process and the implementation strategies used by PCFs; and
- evaluate the implementation outcomes in community pharmacies.

Methods

As with the PATH-UTI trial, this study took a comprehensive approach to evaluating the implementation of the pharmacist-led service for the resupply of oral contraceptive pills (OCPs). The evaluation considered both the facilitation processes and the outcomes of the service. An overview of the evaluation strategy, including study outcomes, theoretical frameworks, and data sources, is presented in Figure 5.2.



CFIR [147]
ERIC [155]

Figure 5.2: Implementation evaluation aligned with study outcomes, theoretical frameworks and databases

Facilitation process, implementation determinants and strategies

The key components of the facilitation process in this study are described in Figure 5.3.

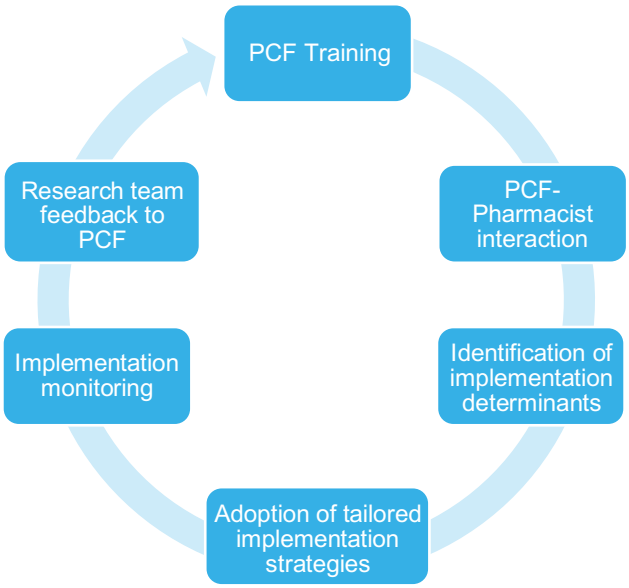


Figure 5.3. PCF-pharmacist intervention process

Training for PCFs

At the start of the trials, the research team provided training to 4 PCFs. This training was reinforced fortnightly throughout the study. These PFCs were the same individuals across the 3 trials. The training covered:

- the pharmacist OCP resupply service, with PCFs also completing the clinical online training required for participating pharmacists;
- classification of implementation determinants using the CFIR framework [147];
- classification of implementation strategies using the ERIC framework [155];
- data collection systems used in the trial, including the PCF implementation database in a pre-designed REDCap form, a secure web application for building and managing online databases [158]. PCFs used this database to record every pharmacist encounter, including discussion topics and strategies provided;
- key priorities for supporting pharmacists and triaging requests; and
- performance feedback reports for both PCFs and pharmacies.

PCF-pharmacist interaction

Practice Change Facilitators supported pharmacists through face-to-face visits in community pharmacies, video calls, phone calls, and emails, responding to queries and ensuring the quality of patient data. The frequency of these interactions was influenced by:

- the trial start date for each pharmacy and the overlap of the service delivery of the trials;
- pharmacist-initiated requests regarding service delivery (e.g., MedAdvisor® use, OCP resupply protocol, training requirements, materials);
- research team analysis of pharmacist–patient consultations, classifying pharmacies as low (0 consultations), medium (1–5), or high performers (>5); and
- strategic decisions by the research team based on study progress and needs.

Identification of implementation determinants

During in-situ visits and other contacts, PCFs identified barriers and facilitators to implementation using a checklist developed by the research team (Appendix 5.1). Determinants were classified using the CFIR framework [147].

Tailored implementation strategies and monitoring

Following the identification and prioritisation of determinants, PCFs selected and applied tailored strategies, matching to barriers or facilitators based on feasibility and anticipated impact. Strategies were classified using the ERIC framework [155]. Follow-up and prioritisation of contacts were guided by pharmacy performance, considering the number of consultations, adherence to clinical protocols, and use of the MedAdvisor® platform. Low-performing pharmacies were prioritised for face-to-face support. Ongoing monitoring assessed both the strategies implemented and pharmacist engagement with the service.

PCFs audit and feedback

Pharmacy performance was tracked through daily consultation data from the MedAdvisor® platform.

The research team provided continuous feedback to PCFs via weekly meetings and 3 types of formal reports:

1. Weekly activity report: tracking pharmacy contacts (in-situ visits, calls, emails).
2. Weekly implementation report: summarising determinants and strategies recorded in REDCap, including Sankey diagrams (study-level and PCF-specific) to visually link determinants with strategies and assess their effectiveness (Appendix 5.2).
3. Monthly clinical-implementation report: detailing pharmacy performance.

Implementation outcomes

Outcomes were derived from PCF-generated data and MedAdvisor® consult data.

Accessibility

Geographical accessibility was examined using a heatmap of registered NSW pharmacies (as of June 2023) compared with trial pharmacies participants. Locations were categorised using the Modified Monash Model (MMM) from 2023 [159].

Adoption and reach

Adoption is defined as the intention, decision, or action to initiate the service [157]. It was measured by the number and proportion of pharmacies and pharmacists commencing service delivery. Reach is the representativeness of individuals participating in the program [160]. It was assessed through:

- consultations per pharmacy (MedAdvisor® data); and
- number of participating pharmacies and pharmacists (University of Newcastle training and consent database).

Fidelity

Fidelity is the "degree to which the service is implemented as it was outlined in the protocol or as it was intended by the program developers" [157]. It was assessed through pharmacists' compliance to the clinical protocols. All consultations and follow-up surveys underwent 48-hour reviews covering pharmacist recommendations, patient outcomes, and responses. The process for data validation, and for identifying and classifying any potential adverse events arising from lack of fidelity (protocol violations) were sent to and approved by the committees in charge of monitoring the trial safety, including University of Newcastle Human Ethics Committee, an external Data Safety Monitoring Board (DSMB) and an internal Safety and Stewardship Working Group (SSWG) as well as the Leadership Group for the trials (see governance structure Appendix 1.2). Nonadherence to the clinical management protocol and/or to the research protocol were identified as protocol violations, which were defined as "any departure from the requirements of Good Clinical Practice, the approved 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 and the study outcomes".

Additionally, other implementation outcomes have been measured (acceptability, appropriateness and feasibility) through qualitative analysis by The George Institute for Global Health during patient follow-ups on the consultation, interviews with patients and pharmacists. For further information see Chapter 3.

Databases

The following databases were used:

- PCF data (REDCap® IT platform) [158]: contained PCF checklists, documented implementation determinants, and tailored implementation strategies; and
- Clinical consultation data (IT platform): participating pharmacists entered patient consultation records directly into the application.

Data analysis

A mixed-methods analytical approach was employed. Descriptive statistics were generated for quantitative implementation outcomes (adoption and reach, and fidelity) as well as for implementation determinants (classified using the CFIR framework) and strategies (classified using the ERIC framework). Sub-analyses examined differences in determinants and strategies based on their association with the services provided: PATH-OC with PATH-UTI, PATH-OC only, and PATH-OC with PATH-DERM. These sub-analyses were relevant as most pharmacists participating in the PATH-OC trial were concurrently delivering 1 or 2 additional community pharmacy services, with PCFs providing support for all services during their visits and contacts.

Results

A total of 1,299 pharmacies consented to the PATH-OC trial. Most had previously participated in PATH-UTI (99.8%). 39% of PATH-OC pharmacies continued delivering PATH-DERM (Table 5-1).

Table 5-1: Overview of the 1,299 OCP consented pharmacies per trial participation

Trial Pharmacies	Enrolled in PATH-UTI and PATH-OC		Enrolled in PATH-OC only		Enrolled in PATH-OC and PATH-DERM		Enrolled in PATH-UTI, PATH-OC and PATH-DERM*	
	n	%	n	%	n	%	n	%
Number (%) of pharmacies (activated† and withdrawn‡)	1,297	99.8	1	0.1	1	0.1	511	39.3
Number (%) of pharmacies (withdrawn from PATH-OC)	206	15.9	1	0.1	0	0.0	12	0.9

** Only pharmacies who that had been participating in PATH-UTI and/or PATH-OC were invited to participate in PATH-DERM.*
† Activated: pharmacies who had the MedAdvisor® program installed.
‡ Withdrawn: pharmacies were withdrawn voluntarily or involuntarily from the study by the research group for various reasons.

The mean and median duration of consultations was 16.3 minutes (standard deviation (SD) 6.7) and 15 minutes [10,20], respectively.

More than three quarters of the participant pharmacies (78.1%, n=1,015) in the PATH OC trial were visited in situ at least once by PCFs and most (99.2%, n=1,289) have had some form of contact (additional contacts were made through emails, phone calls, video calls or messaging). Those contacts may have been related to the resupply of OCP only and/or in relation to other services.

Implementation determinants

PCFs identified implementation barriers in 800 pharmacies (61.6%) out of 1,299 participating pharmacies, with a mean of 2.6 barriers per pharmacy (Table 5-2). A mean of 4.11 facilitators was identified per pharmacy in 76.7% (n=996/1,299) of the pharmacies. Regardless of the number of services (1 or 2 at a time) that pharmacies were providing, determinants were analysed based on their relationship to the services. Most determinants, both barriers and facilitators, were associated with 2 of the services, namely PATH-UTI and PATH-OC.

Table 5-2: Implementation determinants and their relationship with services

Implementation determinants	Barriers		Facilitators	
	n	%	n	%
Total number of determinants	2,078	100.0	4,093	100.0
Number and percentage related to PATH-UTI and PATH-OC services	1,265	60.9	3,300	80.6
Number and percentage related to PATH-OC service only	754	36.3	457	11.2
Number and percentage related to PATH-OC and PATH-DERM services	59	2.8	336	8.2
Mean per pharmacy* ± SD	2.60	± 1.68	4.11	± 2.54

** Mean number of barriers/facilitators in pharmacies where implementation determinants were identified by PCFs (800 pharmacies with barriers and 996 pharmacies with facilitators).*

Over 12 months, 2,087 barriers were reported for the PATH-OC trial. The 7 most common barriers accounted for 89.3% of all barriers for the trial (Table 5-3). These barriers were attributed to the pharmacists' capability, the promotion of the services, the pharmacy equipment to provide the service, the pharmacy workflow, the consultation room or limited patients' eligibility to the service (see Table 5-3). Barriers related to both UTI management and OCP resupply services accounted for 60.9% of the total implementation determinants during the first eight months, while 36.3% were related to the OCP resupply service only. Those barriers identified for the OCP resupply and skin conditions management service, only accounted for 2.8% of the total amount (Table 5-3).

Table 5-3: Common implementation barriers according to the CFIR framework [147] identified through any type of contacts with pharmacists/pharmacies

Barriers	Overall study		In relation to PATH-OC & PATH-UTI services		In relation to PATH-OC service only		In relation to PATH-OC & PATH-DERM services		Common examples*
	n	%	N	%	n	%	n	%	
Pharmacists' capability	484	23.3	246	19.5	234	31.0	4	6.8	Some pharmacists have not completed the training
									Pharmacists had issues with the consent forms for their own or patients' participation in the trial
Engaging patients	348	16.7	210	16.6	131	17.4	7	11.9	Lack of coverage for service provision at all opening hours
									Lack of service promotion
Available resources (equipment)	340	16.4	202	16.0	123	16.3	15	25.4	QR code unavailable in the pharmacy
									Lack of availability of computers in the consultation room
Work infrastructure	202	9.7	152	12.0	39	5.2	11	18.6	Solo pharmacist working in the pharmacy or other staffing issues
Physical infrastructure	150	7.2	128	10.1	11	1.5	11	18.6	Consultation room did not meet all the NSW requirements
Patients' knowledge and availability for the service	114	5.5	70	5.5	44	5.8	0	0	Patients not complying with the inclusion criteria due to age, medication, treatment duration
									Lack of patients' awareness about the service
IT infrastructure	89	4.3	54	4.3	30	4.0	5	8.5	Software issues associated with the MedAdvisor® IT program
Others†	351	16.9	203	16.0	142	18.8	6	10.2	†
Total	**2078**	**100**	**1265**	**100**	**754**	**100**	**59**	**100**	

** Common examples of each barrier are cited and were the "open ended" descriptions provided by PCFs, e.g., training, computer, consultation room.*

† Others are described in Appendix 5.3.

A total of 208 pharmacies withdrew from the PATH-OC study for various reasons (Table 5-1), of which 80.3% (n=167) were also withdrawn from PATH-UTI. PCFs identified implementation determinants for 151 of the withdrawn pharmacies (72.6%). In total, 203 barriers were identified (Table 5-4), the majority of these related to pharmacies that were concurrently participating in the PATH-OC and PATH-UTI services (66.5%, n=135) (Table 5-4). The most reasons for withdrawals (55.7%, n=113) were linked to lacking trained pharmacists or having incomplete training, limited pharmacy resources, or low patient engagement. None of these pharmacies continued to the PATH-DERM trial.

There were 39 remaining pharmacies that consented to PATH-UTI but were withdrawn from PATH-OC (18.8%). Among these pharmacies, 17 of the 56 barriers identified were related to pharmacists' capabilities, with 13 of these specifically attributed to training issues.

Table 5-4: Common implementation barriers according to the CFIR framework [147] for the pharmacies withdrawn from the study

Barriers	Overall study		In relation to PATH-OC & PATH-UTI services		In relation to PATH-OC service only	
	n	%	n	%	n	%
Pharmacists' capability	46	22.7	29	21.5	17	25.0
Available resources (equipment)	37	18.2	23	17.0	14	20.6
Engaging patients	30	14.8	21	15.6	9	13.2
Work infrastructure	18	8.9	15	11.1	3	4.4
Physical infrastructure	15	7.4	13	9.6	2	2.9
Others	57	28.0	34	25.2	23	33.9
Total	**203**	**100**	**135**	**100**	**68**	**100**

The 6 most common facilitators accounted for 96.6% (n=3,954) of all facilitators (n=4,093) (Table 5-5). Most facilitators were attributed to pharmacists' capability, the consultation room or other available resources to provide the service and adequate staffing. Facilitators accounted for 80.6% (n=3,300) of the total implementation determinants in relation to both UTI management and OCP resupply services, 11.2% (n=457) related to the OCP resupply service only and 8.2% (n=336) of the total implementation facilitators for the OCP resupply and skin conditions management service. Examples of the most common facilitators are included in Table 5-5.

Table 5-5: Most common implementation facilitators coded to the CFIR framework [147] identified through any type of contacts with pharmacists/pharmacies

Facilitators	Overall study		In relation to PATH-OC & PATH-UTI services		In relation to PATH-OC service only		In relation to PATH-OC & PATH-DERM services		Common examples*
	n	%	n	%	n	%	n	%	
Pharmacists' capability	1,251	30.6	1,044	31.6	155	33.9	52	15.5	Pharmacists' knowledge or skills
Physical infrastructure	716	17.5	579	17.5	81	17.7	56	16.7	Consultation room met all the NSW requirements
Available resources (equipment)	704	17.2	508	15.4	62	13.6	134	39.9	Availability of QR code
									Availability of computer in the consultation room
IT infrastructure	636	15.5	533	16.2	70	15.3	33	9.8	MedAdvisor® IT program was active in all computers in the pharmacy
Engaging patients	455	11.1	389	11.8	41	9.0	25	7.4	Service delivered at all opening hours
Work infrastructure	158	3.9	108	3.3	19	4.2	31	9.2	More than 1 pharmacist on duty and/or delivering the service
Others†	173	4.2	139	4.2	29	6.3	5	1.5	†
Total	**4,093**	**100**	**3,300**	**100**	**457**	**100**	**336**	**100**	

** To find common examples of each facilitator key terms were used in their "open ended" descriptions, e.g., training, computer, consultation room.*
† Others described in Appendix 5.3.

Implementation strategies

After PCFs identified implementation determinants (barriers and facilitators), targeted strategies were designed and enacted to mitigate barriers and reinforce facilitators. Overall, 671 pharmacies (51.7%) implemented at least 1 strategy, with a mean of 1.86 ± 1.11 strategies per pharmacy. Among identified barriers, 55.6% (n=1,155) had a planned strategy; by study end, 67.1% (n = 775) of these were completed, and 65.6% (n=508) of the completed actions successfully addressed the barrier (Figure 5.4). Appendix 5.2 presents a Sankey diagram mapping implementation barriers to corresponding strategies across the 12 months of the study.

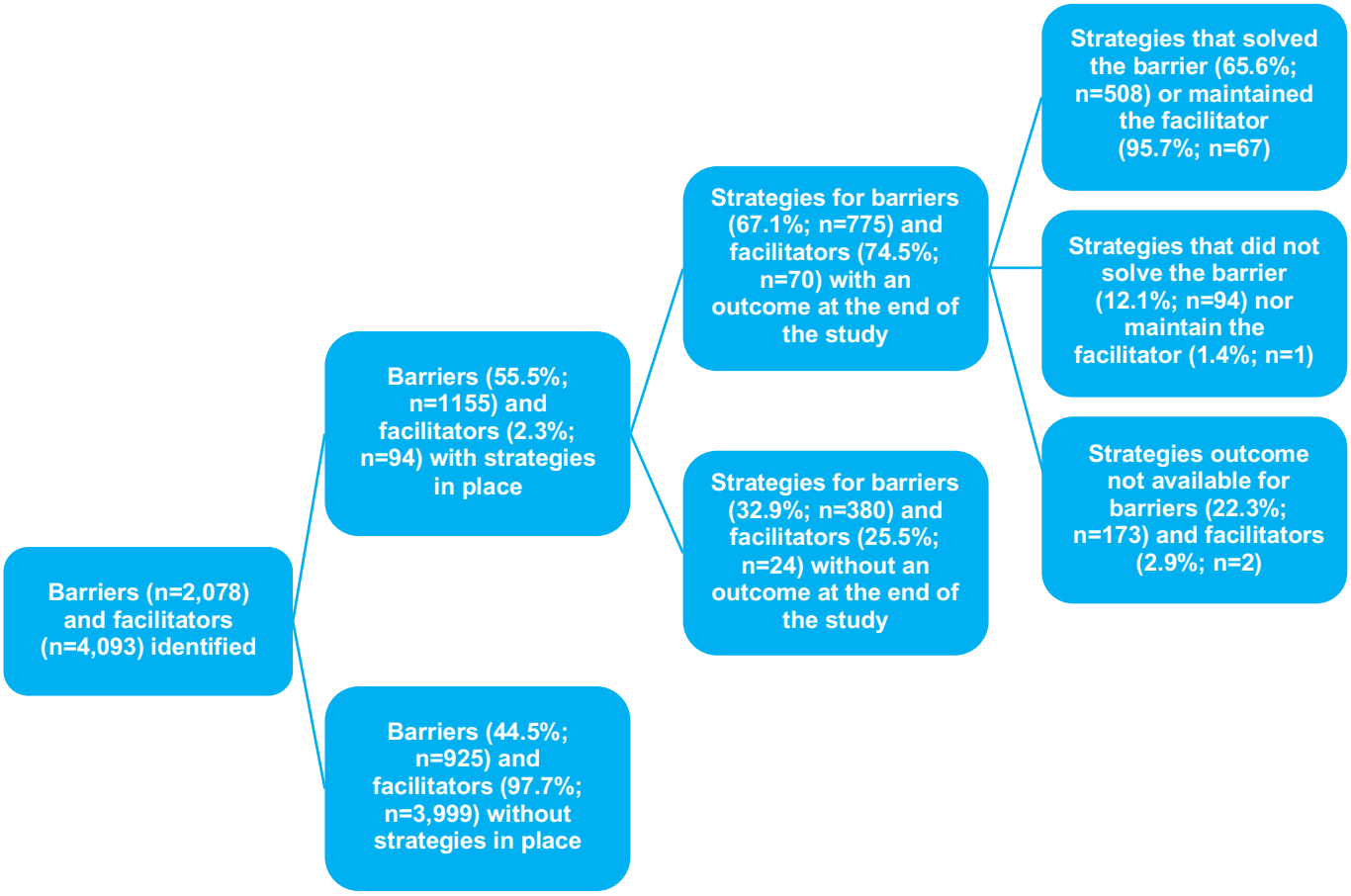


Figure 5.4. Planning and progress of the implementation strategies to solve identified barriers or to maintain facilitators during the trial

The majority of implemented strategies centred on facilitation, development of an implementation blueprint, audit and feedback, distribution of educational materials, and local needs assessments across participating pharmacies and pharmacists (Table 5-6).

Table 5-6: Strategies used during the study for either solved the barrier or maintained the facilitator

Strategies	Overall study		Strategies that solved barriers or maintained facilitators		In relation to PATH-OC & PATH-UTI services		In relation to PATH-OC service only		In relation to PATH-OC & PATH-DERM services	
	n	%	n	%	n	%	n	%	n	%
Facilitation, defined as “a process of interactive problem solving and support that occurs in a context of a recognised need for improvement and a supportive interpersonal relationship”	369	29.5	202	35.1	128	30.5	15	39.5	226	28.7
Develop a formal implementation blueprint,	229	18.3	51	8.9	95	22.6	7	18.4	127	16.1

Strategies	Overall study		Strategies that solved barriers or maintained facilitators		In relation to PATH-OC & PATH-UTI services		In relation to PATH-OC service only		In relation to PATH-OC & PATH-DERM services	
	n	%	n	%	n	%	n	%	n	%
defined as "use and update an implementation plan to guide the implementation effort over time. The blueprint should include the aim/purpose of the implementation; scope of the change; timeframe and milestones; and appropriate performance/progress measures"										
Audit and provide feedback, defined as "collect and summarised clinical performance data over a specified time period and give it to pharmacists to monitor, evaluate, and modify behaviours"	117	9.4	86	15.0	40	9.5	9	23.7	68	8.6
Distribute materials, defined as "distribute educational materials (including guidelines, manuals, and toolkits) in person, by mail, and/or electronically"	108	8.6	72	12.5	29	6.9	1	2.6	78	9.9
Conduct local needs assessments, defined as "collect and analyses data related to the need for the service"	94	7.5	15	2.6	27	6.4	0	0.0	67	8.5
Other strategies (n=25)*	332	26.7	149	25.9	101	24.0	6	15.8	221	28.1
Total	**1,249**	**100.0**	**575**	**100.0**	**420**	**100.0**	**38**	**100.0**	**787**	**100.0**

** Others described in Appendix 5.3.*

Implementation outcomes

Accessibility

The heatmap in Figure 5.5 depicts statewide patterns of potential patient access to the service. Access was defined within 1 kilometre radius from a consented pharmacy.

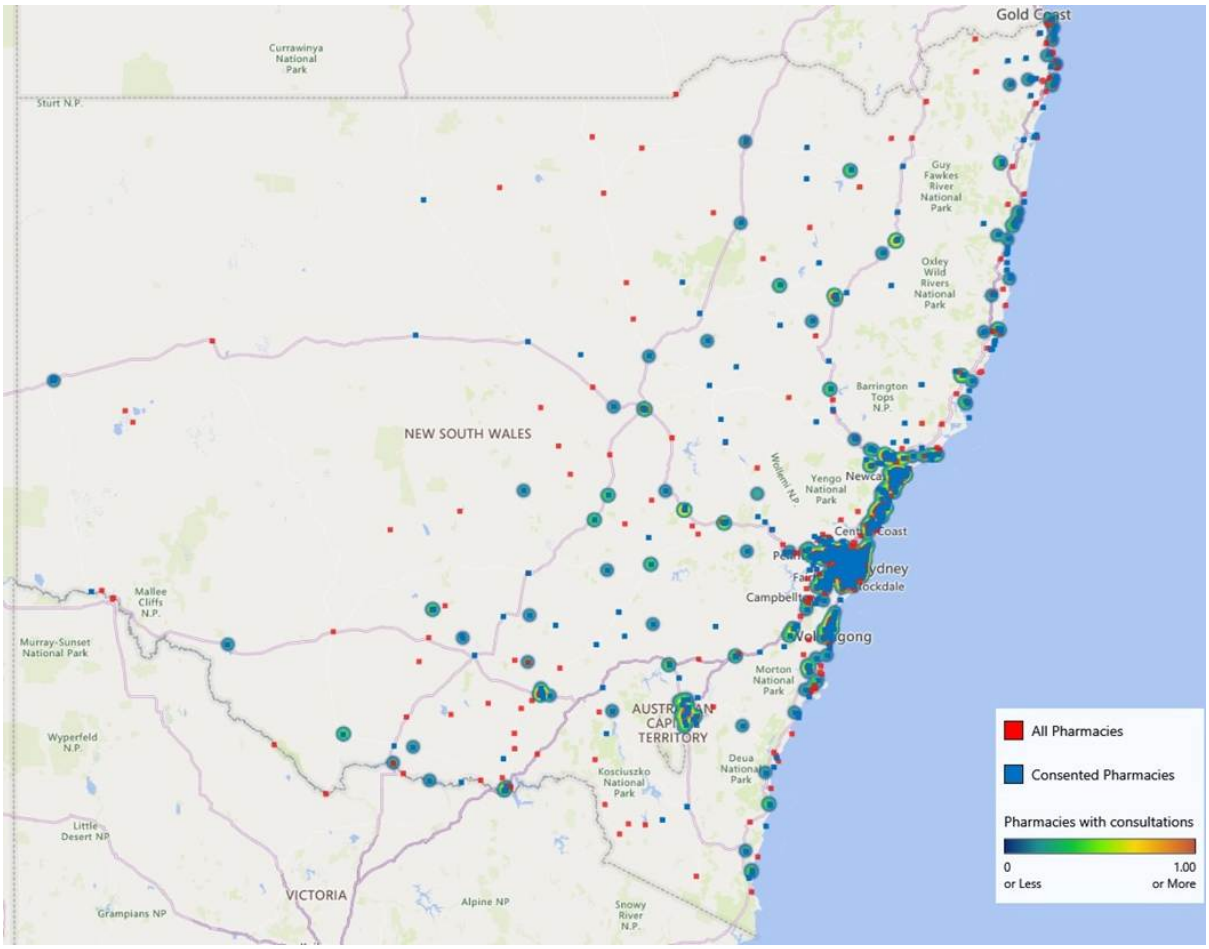


Figure 5.5: Heatmap for the accessibility of the service by total pharmacies in NSW versus consented pharmacies (excluding withdrawals)

Additionally, Table 5-7 shows that most participating pharmacies in the trial and pharmacies with consultations provided were in MMM 1.

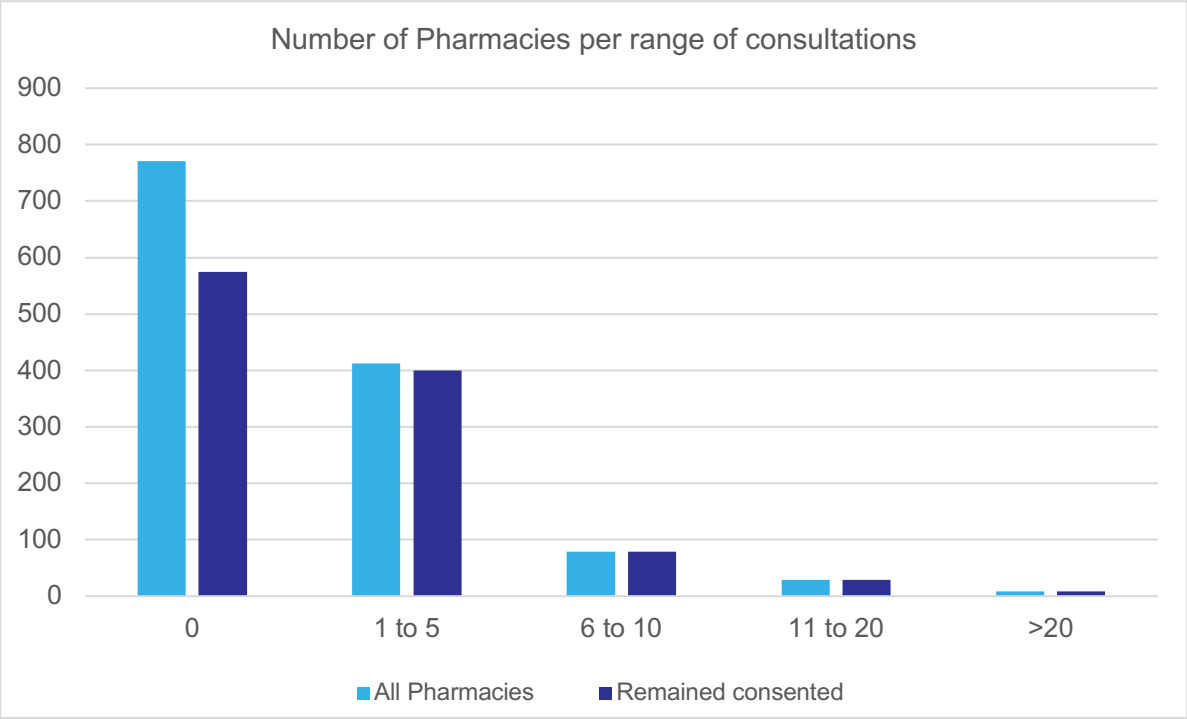
Table 5-7: Type of NSW participant pharmacies participating in PATH-OC according to MMM 2023 [159]

MMM	Number of Pharmacies per MMM in NSW	% Pharmacies per MMM in NSW	Participant pharmacies in PATH-OC	% Pharmacies from all NSW pharmacies	Participant pharmacies with consults	% Pharmacies with consults MMM NSW Pharmacies
1	**1,450**	72.1	885	61	373	42
2	**47**	2.3	37	79	8	22
3	**215**	10.7	164	76	68	41
4	**118**	5.9	91	77	36	40
5	**165**	8.2	102	62	28	27
6	**11**	0.5	4	36	0	0
7	**6**	0.3	1	17	0	0
Total	**2,012**	**100.0**	**1,284***	**63.8**	**513**	**25.5**

** 1,284 consented pharmacies (including withdrawn pharmacies at the end of the trial) in NSW (1,299 includes the Australian Captital Territory (ACT pharmacies).*

Adoption and reach

Nearly one-third (31.7%) of pharmacies provided 1–5 consultations (Figure 5.6); the average was 1.7 per pharmacy (SD=3.93).



** Remained consented pharmacies are those that finalised the study (represented in orange).*

Figure 5.6: Distribution of consented* pharmacies by the number of consultations

There were 1299 pharmacies, and 3040 pharmacists consented to the trial. 528 (40%) pharmacies and 915 (30.1%) pharmacists provided at least 1 consultation (Figure 5.7).

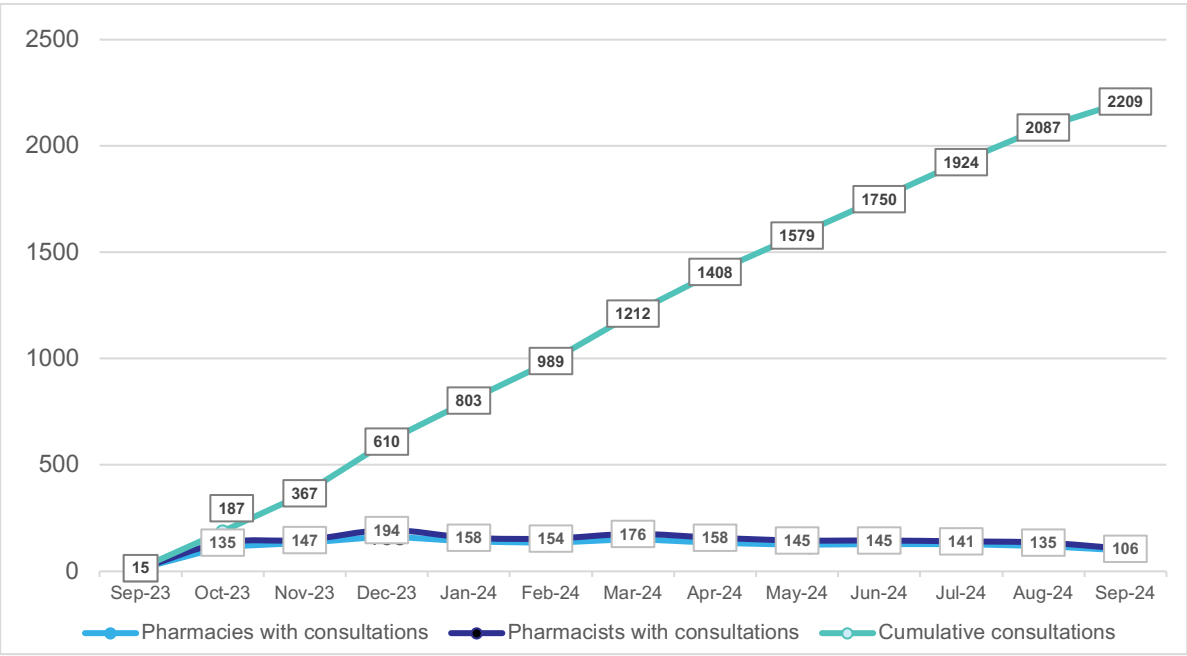


Figure 5.7. Number of consultations and consented pharmacies

Fidelity

In 99.7% of total consultations (n=2,136/2,143), pharmacists appropriately followed the clinical management protocols, referring patients to a general practitioner (GP) or the emergency department (ED) when complications or risk factors were identified. A single protocol violation was a 23-year-old patient who presented with blood pressure (BP) readings exceeding 210/110 mmHg in all 3 measurements but was not referred to a GP by the pharmacist, despite the severity of the condition. However, when the pharmacist was contacted, they noted that the patient had been referred to the GP, but the recommendation had not been recorded in the software. There were 6 protocol deviations identified (0.2% of 2,145 consultations; 0.46% of 1,299 pharmacies involved), all of which occurred in different pharmacies and were related to moderate risk factors such as treatment and referral timelines and supply.

Discussion

The implementation program for the resupply of OCPs in community pharmacies for the 12-month period resulted in 2,200 consultations. Mirroring the outcomes of the pharmacist-led management of uncomplicated UTIs (PATH-UTI), the program was delivered mostly to populations in high-density urban areas. Most pharmacies in the study were classified as MMM 1 (72.1%), representing almost two-thirds of all MMM 1 pharmacies in NSW. Across MMM 1–5 locations, participation ranged from 61% (MMM 1) to 79% (MMM 3). In MMM 1, MMM 3 and MMM 4, 40–42% of pharmacies delivered consultations, whereas MMM 2 and MMM 5 recorded roughly half that rate. No pharmacies from MMM 6–7 participated; the most cited reasons were limited on-site pharmacist availability and low patient demand. The coverage was particularly valuable in areas with high healthcare demand, where timely access to contraception supports women's autonomy in making reproductive choices, including the decision to avoid pregnancy.

In contrast, there was no participation by pharmacies in remote areas, while in rural areas uptake was similar to metropolitan areas. Addressing this gap will require future research to investigate implementation barriers in these settings and develop targeted strategies to improve adoption, an essential step toward advancing health equity.

Facilitation and support for pharmacists

Practice Change Facilitators played a key role in supporting pharmacists throughout the implementation process. As the program matured, the proportion of pharmacies visited in-situ by PCFs increased from 69.3% in PATH-UTI to 78.1% at the end of PATH-OC trial, indicating enhanced outreach and engagement during the OCP resupply phase.

Most determinants, both barriers and facilitators, were similar for the 2 services associated PATH-UTI and PATH-OC trials. This may be explained, firstly, by the overlap between the studies, as these services were delivered at the same time for 8 of the 12 months of the PATH-OC trial, and secondly, by the fact that many determinants were common across the different services.

The number of pharmacies reporting barriers slightly decreased (from 854 in PATH-UTI to 800 in PATH-OC); nevertheless, the average number of barriers per pharmacy increased from 2.2 to 2.6. This suggests that the complexity associated with the provision of more than 1 service generates a greater average number of barriers in some pharmacies.

A greater proportion of participating pharmacies reported more facilitators (76.7%) than barriers (61.6%), although fewer facilitators were identified in PATH-OC compared to PATH-UTI, with total numbers decreasing from 4,648 in PATH-UTI to 4,093 in PATH-OC. The mean number of facilitators per pharmacy also declined from 5.22 to 4.11. This reduction may be partly attributed to changes in how PCFs used the implementation checklist during visits. For practical reasons, PCFs were instructed to use the checklist only during initial in-situ visits to pharmacies for an overall assessment. Therefore, subsequent visits and contacts focused mainly on barriers and the strategies in place to solve them. This decline in the number of identified facilitators for the provision of the service could also be due to service-specific differences. An analysis of the most commonly reported facilitators revealed some variation over the study period. Pharmacist training consistently emerged (similarly to PATH-UTI) as the top facilitator, cited by approximately 30–35% of pharmacists, highlighting the necessity and challenges in equipping pharmacists with the necessary knowledge and confidence to deliver the service effectively. Additionally, and likely due to their experience in PATH-UTI, increased awareness of

operational needs such workflow integration, and staffing arrangements became more salient.

Throughout the 12-month period, the top 5 implementation strategies used by PCFs to support pharmacists remained consistent to those used in the previous study PATH-UTI. Over half of the participating pharmacies had 1 or more strategies in place during the program. As anticipated, PCFs primarily directed their efforts toward overcoming identified barriers rather than reinforcing existing facilitators. This focus is consistent with the goal of enabling service uptake and addressing points of resistance. Notably, and similarly to PATH-UTI, 65% of the strategies employed were successful in resolving the specific barriers they targeted, indicating a high level of effectiveness in the tailored support provided. The proportion of resolved issues per strategy also suggests that these approaches were appropriately matched to the challenges encountered. These findings highlight the practical value of ongoing, needs-based facilitation in ensuring timely problem-solving and promoting sustained service delivery. As outcomes of the facilitation support and processes, certain challenges became less frequent. For instance, issues related to consultation room availability dropped from 10.1% in PATH-UTI to just 1.5% in PATH-OC only sites. Similarly, work infrastructure concerns were reported less frequently in PATH-OC only pharmacies (5.2%) compared to those providing both services (12%), uncomplicated UTI management and resupply of OC, suggesting improved alignment of the environments with service needs.

Little variation was found in the types of strategies employed. Among these strategies, facilitation and creating a plan to guide the implementation effort were the most commonly applied. These strategies played a key role in addressing service-specific challenges, such as clinical decision-making, consultation workflow, and adherence to protocols. Their targeted nature underscores the importance of tailoring implementation efforts not only to practice change, but also to the particular characteristics of the clinical service being introduced.

Pharmacies completing PATH-OC consultations

Nearly all pharmacies that participated in PATH-UTI also provided the OCP resupply service indicating a willingness to incorporate expanded scope of practice. This high degree of overlap may reflect pharmacists' motivation to expand their professional scope or could be due to the confidence gained through the successful implementation of previous services. Interestingly most pharmacies that were withdrawn from the study were also withdrawn from both services (80.3%, n=167), due to shared requirements such as the availability of a consultation room.

While pharmacists completed more than 18,000 PATH-UTI consultations, they provided only about 2,200 consultations for OC resupply. Although initially a similar number of pharmacies consented to participate there was a higher percentage and number of pharmacies without any consultation in the PATH-OC trial. There were a number of complex factors and implementation determinants which affected this outcome:

Service promotion and patient demand

Service promotion emerged as a salient barrier in PATH-OC, rising from 9.6% in PATH-UTI to 16.7%. Gaps were evident at both the pharmacy and organisational levels, with pharmacists frequently requesting stronger public information and advertising from the Ministry of Health and pharmacy organisations to raise patient awareness.

Service inclusion criteria

The eligibility parameters set by the NSW Authority and ACT licence likely constrained patient uptake of the OCP resupply service. Key constraints included: (i) age limits (women >35 years were ineligible); (ii) product restrictions (narrow formularies e.g., specified combined oral drospirenone products, and exclusion of non-oral formulations such as vaginal rings or transdermal patches); and (iii) treatment history requirements (continuous 2-year OCP use initially prescribed by a medical practitioner). These findings highlight differences between local and international models of care, where frameworks in the UK, US, and Canada often permit initiation as well as continuation and include a broader range of contraceptive options [111].

Alternative pathway to supply OCs

The availability of an alternative pathway (continued dispensing of contraceptive treatments) that allowed patients to obtain the treatment with a different type of consultation could have contributed to a smaller number of consultations for the resupply of contraceptives. This alternative pathway was introduced in 2020 to enable pharmacists to resupply

OCs without a prescription from a GP or nurse practitioner. This pathway was established by the Australian Government to give patients access to continuing medications in emergency situations when their usual healthcare provider was unavailable. The continuing dispensing arrangements permit pharmacists to supply up to 3 packs of OCs to meet an immediate need. The patient must have previously been supplied the same OCP via a Pharmaceutical Benefits Scheme (PBS) prescription from a GP or a nurse practitioner. For an individual patient, the continued dispensing arrangements can be invoked only once within a 12-month period.

Pharmacist training

Pharmacist training remained the most frequently reported barrier in both the PATH-UTI and PATH-OCP trials, accounting for approximately 23% of reported barriers overall. However, this was significantly more pronounced among OC-only pharmacies (31%) compared to those delivering multiple services concurrently (either with management of uncomplicated UTI in PATH-UTI or dermatological conditions in PATH-DERM) ranging 7–19%. It is interesting to note that training approved through the NSW Health Authority was provided free of charge for all pharmacists in NSW by the professional organisations, whilst for PATH-OC non-members of these organisations were charged.

Together, these findings reflect the dynamic nature of implementation across service types, highlighting both the continued role of PCFs in addressing barriers and the similarities in the need and required support for each protocol-based pharmacy-led service.

Conclusion

Implementation of pharmacist-led prescribing services was characterised by effective facilitation at the point-of-care. Practice Change Facilitators consistently identified and helped resolve local barriers, and the pattern of determinants, barriers as well as facilitators, remained broadly stable over time. Differences between PATH-OC and PATH-UTI (notably training costs and the need for more active service promotion) emerged as salient contextual factors shaping day-to-day uptake and delivery.

Across settings, the need for task-specific and ongoing training was evident, particularly where new digital tools were introduced (e.g., software for extended OC resupply). In PATH□OC, promotion surfaced more prominently as a barrier than in PATH□UTI, with gaps reported at both pharmacy and organisational levels. As services became embedded into routine practice, physical and digital infrastructure (private consultation spaces; reliable, integrated IT with access to clinical records and forms) increasingly influenced the smoothness of clinical workflows and the consistency of service quality.

At the policy and program level, the service's progression into a business-as-usual phase coincided with broader patient inclusion criteria, including an expanded eligible age range (from 35–49 years). International comparators indicate that community pharmacy contraception pathways in other jurisdictions commonly encompass both initiation and continuation and span a wider mix of contraceptive products and routes of administration; this context frames how local protocols were perceived by stakeholders during the study period.

Finally, access and equity considerations persisted. Participation and delivery were strongest in metropolitan areas, with limited activity in rural and remote locations. In the contraceptive pathway, model overlap (e.g., with continued dispensing) was observed to shape patient flow and provider workload. Extended resupply consultations entailed greater clinical input and consultation time but provided longer treatment coverage, a pattern consistent with potential system-level efficiencies and continuity of care.

06

A MIXED METHODS REVIEW OF PERSPECTIVES AND ACCESS TO RESUPPLY OF ORAL CONTRACEPTIVES FOR ABORIGINAL AND TORRES STRAIT ISLANDER COMMUNITIES

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-OC
PATHWAY TO ACCESS: ORAL CONTRACEPTION

Chapter 6: A Mixed Methods Review of Perspectives and Access to Resupply of Oral Contraceptives for Aboriginal and Torres Strait Islander Communities

Introduction

This chapter outlines the methods and rationale for exploring the perspectives of Indigenous peoples, the Aboriginal Community Controlled Health Organisation (ACCHO) staff and community pharmacists in relation to pharmacist-led services. This research was conducted by the Co-Design Health Research and Innovation team at the University of New South Wales (UNSW).

Reproductive autonomy is fundamental to health equity. In Australia, oral contraceptives (OCs) represent one of the most used forms of contraception [161]. Despite publicly funded programs such as the Pharmaceutical Benefits Scheme (PBS), Close the Gap (CTG), and Medicare, barriers to timely and culturally appropriate contraceptive services remain [162]. Across Australia there are several trials expanding the scope of practice for community pharmacists resupply medications [62, 163–165]. The New South Wales (NSW) Pharmacy Trial includes 6 areas of clinical practice including management of uncomplicated urinary tract infections (uUTIs), 4 common skin conditions and the resupply of OCs. Patients in NSW were eligible for resupply of OCs if they: (i) were between 18–35 years of age (inclusive); (ii) were taking a low-risk pill for contraceptive reasons; and (iii) had taken the pill continuously for 2 years, as prescribed by a medical practitioner or nurse practitioner [163].

International models demonstrate that pharmacist-led supply of OCs can be both safe and effective. In countries such as New Zealand (NZ) and the United Kingdom (UK), pharmacists have long been integrated into reproductive health care, including supply of OCs. Evaluation data from these systems suggests improvements in health equity, faster access to medicines, and enhanced patient satisfaction particularly among priority populations [42, 166, 167].

Workforce shortages in general practice, particularly in regional and remote Australia, further compound barriers to accessing medications [168, 169]. With increasing general practitioner (GP) wait times and limited bulk-billing options, there is growing momentum to expand the roles of pharmacists in primary care. Pharmacists are highly accessible and well-positioned to provide low-barrier, quick access to contraception, including resupply of OCs. Pharmacist-led resupply of OCs has emerged as a strategy to improve access and timeliness, with some studies reporting high patient satisfaction [153, 170].

Conversely, concerns have been raised in some research about the risks associated with pharmacist-led supply, including lack of clinical skills and training, limitations with patient record keeping and integrated care coordination, privacy concerns, and risks involved in the management of patients with complex and chronic conditions [153, 170]. It is noted that these issues should be addressed in any expansion of practice scope for pharmacists.

Aboriginal and Torres Strait Islander peoples face additional challenges in accessing culturally responsive and timely healthcare, including geographic isolation, racism, lack of continuity of care, and contextualised health communication [171, 172]. Although overall rates of contraceptive use may not differ dramatically from non-Indigenous populations, the types of contraception used, and the contexts in which they are accessed by Aboriginal and Torres Strait Islander people, vary significantly. The use of OCs among Aboriginal and Torres Strait Islander people is shaped by a range of cultural, social, and systemic influences [173, 174]. For example, studies show a high uptake of long-acting reversible contraceptives (LARCs) in some remote Aboriginal communities when services are provided by trusted health workers through community-led clinics [175]. While not examined here, LARCs minimise ongoing prescription requirements and avoid adherence issues associated with daily OCs. There is a clear demand by Aboriginal and Torres Strait Islander people for contraception, and it is

reasonable to expect services to be accessible, respectful, and culturally safe [174, 175].

Conversely, shame and mistrust of mainstream health systems, and negative past experiences continue to impede access [174, 176]. Many Aboriginal and Torres Strait Islander people report hesitancy in discussing reproductive health with non-Indigenous clinicians or in clinical settings perceived as judgemental or paternalistic [174, 176]. This is particularly acute in small communities, where concerns around confidentiality, judgement, and cultural misunderstanding act as barriers to care. Community-led research and health initiatives have consistently shown that when healthcare is customised to context and culture, particularly those led by or co-designed with Aboriginal and Torres Strait Islander peoples and organisations, health outcomes and service engagement markedly improve [177, 178].

Recognising that Aboriginal and Torres Strait Islander people experience significantly higher rates of avoidable morbidity and mortality, this trial represents a timely opportunity to assess whether pharmacist-led care can be culturally responsive, clinically effective, and community-endorsed.

Aim

The aims of this project were to:

- explore the perspectives of Aboriginal and Torres Strait Islander community members, health workers, and community pharmacists in remote, regional, rural and urban communities regarding community pharmacy resupply of oral contraceptive pills (OCPs) [179]; and
- analyse data extracted from the trial about access and experience of Aboriginal and Torres Strait Islander people who accessed OCs under the trial.

Methods

A mixed methods sub-study was co-designed and implemented across four sites representing a spectrum of urban, regional, rural, and very remote Modified Monash Model (MMM) classifications [180]. Conducted in partnership with 3 ACCHOs and governed by a Consumer User Panel (CUP), the study applied culturally responsive methodologies including co-design and yarning and was guided by Aboriginal and Torres Strait Islander people from inception through to analysis and reporting.

Co-design

To ensure local context and culture were prioritised in this study, a co-design model validated for health research involving Aboriginal and Torres Strait Islander people, including oral health [181, 182], vocational health education [183] and atrial fibrillation [184], was applied. The Co-design Health Research and Innovation model of co-design [185] (Figure 6.1) is measurable and structured and requires the sharing of power and resources. It centres the collective over the individual, elevates the voices of those most impacted by the research, and values community contributions in ways that are meaningful to them, such as through co-authorship on publications and appropriate compensation for their time. The model aligns with the National Health and Medical Research Council guidelines for conducting ethical research with Aboriginal and Torres Strait Islander people [186]. The study protocol for the qualitative component of this project is provided in the Appendix 6.1.

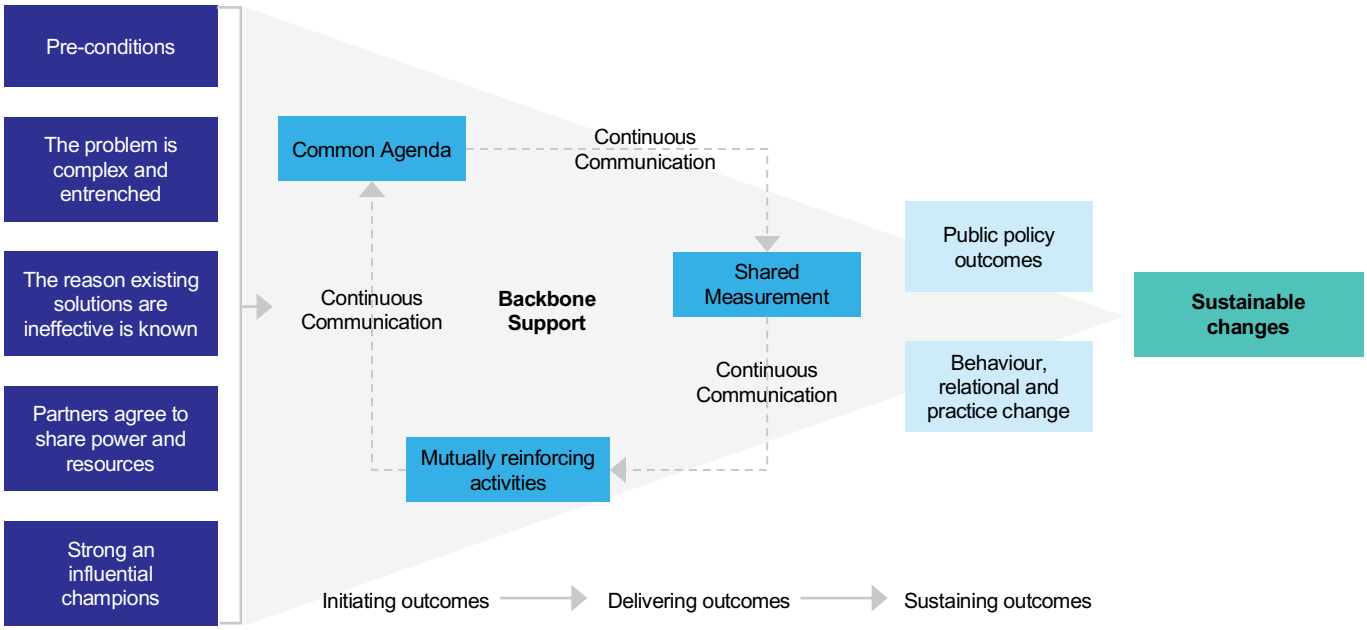


Figure 6.1: Model of co-design [185, 187]

Recruitment of communities and consent

Three ACCHOs and 4 sites (1 ACCHO provided a rural site and a regional site; 1 ACCHO provided a remote site and 1 ACCHO provided an urban site) in NSW were invited to collaborate as partners, with their participation and leadership pivotal to the success of the project. The research team had longstanding partnerships with the ACCHOs involved in this study. To classify the study locations, the MMM 2019 was applied (31). The research sites included 1 very remote with an MMM category of MMM 7 (2019), a second rural site (MMM 4 – 2019), a third regional site (MMM 3 – 2019), and the fourth site was urban (MMM 2).

Ethics

In addition to approval of the University of Newcastle Human Research Ethics Committee (HREC) under protocol number H-2023-0119, this research was also approved by the Aboriginal Health and Medical Research Council of NSW (AHMRC 2096/23). This research is part of a registered clinical trial (ACTRN12623001124628). The AHMRC ethics was amended to allow analysis of up to 2 months of quantitative data from the main trial.

Qualitative methods

Following the establishment of research partnerships for this project with ACCHOs, support was sought in recruiting Aboriginal and Torres Strait Islander clinicians and other staff working with Aboriginal and Torres Strait Islander peoples, and community members including Elders. Recruitment was guided by the ACCHOs, with an estimated range of 3–12 participants per yarning circle and between 15–30 participants per community. The study was fully explained to those expressing interest in participation, with a detailed participant information sheet and consent form provided. Participants received a A$50 voucher of each hour or part thereof of participation in recognition of their time and contributions.

Yarning

Yarning is an Aboriginal and Torres Strait Islander research tool and a key technique to co-create knowledge, including collecting, analysing, and interpreting research data. It is an Aboriginal and Torres Strait Islander communication style that ensures participants feel safe, comfortable, and confident enough to participate by providing their opinions and perspectives [188, 189]. A yarning circle comprises group discussion, whereby facilitators pose open questions and invite participants to use the questions as a catalyst for discussion. Similarly, individual yarns are semi-structured and begin with questions to stimulate thinking and discussion on a particular topic of interest. In the individual and group-based yarns, participants are encouraged to reframe and reinterpret the questions, and the format

includes ample time for nonstructured discussion [188, 189].

Data collection

Six investigators, in pairs, conducted yarns. The yarning groups were homogeneous regarding cohort; for example, no ACCHO staff or pharmacists were included in yarns with Aboriginal and Torres Strait Islander community members. The yarns began by briefly describing the aims of the sub-study and a knowledge check regarding potential changes in pharmacists' resupply of certain medicines. Investigators commenced the yarns by asking the group to discuss their perspectives on the potentially changed scope of practice for pharmacists. Participants were prompted to describe the positives (benefits) and the negatives (risks) they envisioned for Aboriginal and Torres Strait Islander people. Participants were also asked to discuss any recommendations to make the practice safe and acceptable for Aboriginal and Torres Strait Islander people. In keeping with the yarning methodology, participants were free to take the discussion in any direction that suited them, thus ensuring issues not anticipated by the research team but that were important to the participants, were also included in the data collection (see Figure 6.2 Yarning Prompts). Data collection continued until saturation was reached.

There were 4 prompts to facilitate discussion in all the yarns.

What positives/benefits do you see for Aboriginal and Torres Strait Islander people related to this change in practice?

What negatives/risks do you see for Aboriginal and Torres Strait Islander people related to this change in practice?

Do you have any recommendations to make the service safer or more accessible for Aboriginal and Torres Strait Islander people?

If there was a significant difference in prices of medications via this scheme, would this influence whether you used the service?

Figure 6.2: Yarning Prompts

Yarns were audio recorded and transcribed. Qualitative data were intuitively, thematically analysed, creating composite descriptions of participants' experiences and perspectives related to each area of interest: positive perceptions, including potential benefits; negative perceptions, including risks and recommendations to improve equity or access for Aboriginal and Torres Strait Islander people.

Data-checking sessions were conducted to ensure findings and conclusions resonated with participants. These data-checking sessions were conducted in pairs of investigators. Findings were described regarding the 4 areas of interest and asked participants if these resonated with their experiences. The data-checking sessions were conducted online and in person for participants and included Aboriginal and Torres Strait Islander community members who had not participated but expressed an interest in learning about the findings.

Quantitative methods

Deidentified data were made available for the current OC study from participants who commenced the OC arm of the NSW Pharmacy trial between 17 July and 17 September 2024. The protocol for the trial is available (ANZCTR - Registration). Participant data came from the structured consultation (reported by the participating pharmacist through MedAdvisor®) and follow-up. Follow-up was carried out 7 days after the consultation for the resupply of OC trial arm. Participants were asked during follow-up about their health outcomes and levels of satisfaction with the service. Satisfaction levels were assessed by asking participants to rate different aspects of the service using a Likert scale, ranging from 1 (least satisfied) to 7 (most satisfied). Satisfaction ratings related to: (i) pharmacist; (ii) pharmacist's level of knowledge; (iii) if the pharmacist dispensed medication correctly; (iv) if privacy was received; (v) if it was convenient to obtain care from the pharmacist; (6) if the pharmacist providing the service was good; and (7) if pharmacist allowed the patient to be involved.

Using deidentified records, we analysed data for participants who identified as Aboriginal and/or Torres Strait Islander, covering: (i) demographics (age, sex and/or gender, geographic remoteness); (ii) service characteristics (presenting request and, where available, consultation length); (iii) health outcomes (whether resupply was provided; referrals to other services; whether a regular GP was recorded when a referral occurred; symptom change where relevant; and any adverse reactions); and (iv) service satisfaction (rating levels).The satisfaction levels were calculated by reviewing: (i) the mean of the 7

ratings provided by each participant; and (ii) the mean of all participants' ratings for each aspect of the service. Due to the small number of participants who identified as Aboriginal or Torres Strait Islander, findings were reported descriptively.

Results

Qualitative

A total of 64 adults participated in the yarning sessions (Table 6.1). ACCHO staff included both Aboriginal and Torres Strait Islander and non-Indigenous employees. Pharmacists were registered professionals practising within the communities identified through ACCHO staff or Aboriginal and Torres Strait Islander investigators as likely service providers for Aboriginal and Torres Strait Islander people. Community members were residents and self-identified as Aboriginal and Torres Strait Islander. To ensure privacy of people living in these small communities, no demographic data was collected, and only high-level descriptors of cohort sizes are reported.

Table 6-1: Participants in the yarning groups

Location/ Participant	Community member	ACCHO staff	Pharmacist
Remote*	17	6	0
Rural/Regional	7	3	1
Urban	17	9	4
Total	41	18	5

** Remote can be classified as MMM 6 and 7, rural/regional MMM 3–5, and urban MMM 1 and 2.*

This study benefited from a strong community engagement with highly engaged ACCHO staff. Participants provided thoughtful and considered responses and engaged in respectful discussions, with key themes and risk mitigation suggestions, uniformly endorsed in the data-checking sessions.

Scope of qualitative data

The qualitative data presented here were collected concurrently for the urinary tract infection (UTI), dermatology and OCP resupply sub-studies using the same yarning and co-design framework. While this section focuses primarily on findings related to UTI management, the data also capture issues relevant to dermatology and OCP resupply. Separate reports will provide detailed findings specific to OCP resupply and dermatology sub-studies.

Key findings from qualitative data

Participants highlighted convenience and rapid access to medications as the main benefits of this pharmacist-led service (Appendix 6.2). These included easier access to resupply, reduced waiting times, greater flexibility for older adults and working parents, and strong rapport between pharmacists and clients in smaller communities. Prompt relief from UTIs and other conditions outside clinic hours was also highly valued. Participants raised concerns about quality and continuity of care, including potential loss of incidental checks at clinics, misdiagnosis risks, and the importance of double-checking supply and dispensing roles. Privacy concerns were noted, particularly for sensitive issues such as UTIs, contraceptives, and skin conditions.

To ensure equitable and safe access, participants emphasised aligning the service with the CTG program and providing pharmacists with cultural competence training. Additional recommendations included public education about the scheme, clear continuity-of-care protocols, and longer opening hours for pharmacists in smaller communities.

Quantitative Results

Across the entire study period, 47 of the 1,751 total survey respondents identified as Aboriginal and/or Torres Strait Islander (2.7%); however, these participants could not be included in the present analysis because ethics approval restricted the analysis to the 2-month dataset. During the 2-month period, 300 people requested resupply of OCs. Of those, 227 completed this question in the follow-up survey: 3.5% (n=8) replied "Yes, Aboriginal"; 95.6% (n=217) replied "No"; and 0.9% (n=2) replied "Prefer not to say" (Figure 6.3). Accordingly, the demographic analysis reported here is based on the 8 Aboriginal and/or Torres Strait Islander participants identified within this subset, all 8 were female (both gender and biological sex), with an average age of 24 years and an age range of 19–31 years. These participants were 2 years younger (on average) than participants in the full dataset, which had an average age of 26 years and a range of 18–36 years. Four Aboriginal and/or Torres Strait Islander participants accessed the service in a metropolitan area (MMM 1), 3 in a large rural town (MMM 3), and 1 in a small rural town (MMM 5), as classified according to the MMM [180].

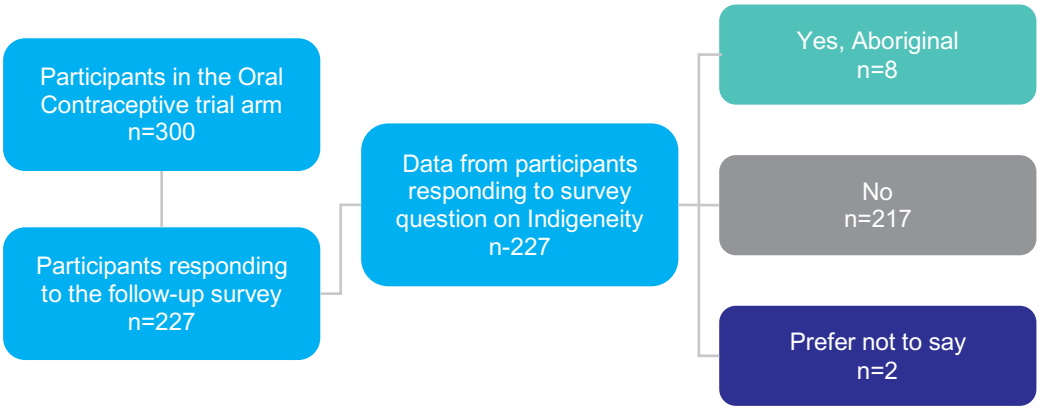


Figure 6.3: Participants included in the sub-study (2-month) analysis

All 8 Aboriginal and/or Torres Strait Islander participants requested resupply of combined OCs (150 µg levonorgestrel / 30 µg ethinylestradiol, n=6; 100 µg levonorgestrel / 20 µg ethinylestradiol, n=2). Six Aboriginal and/or Torres Strait Islander participants were resupplied with 3-4 months of OCs. All 6 participants stated during follow-up that they took the OC supplied and had no side-effects or other complications. The remaining 2 participants (aged 20 and 22 years) were declined resupply and referred to their GP for follow-up. GP referrals were made based on "clinical measurements", with no other information available regarding the clinical rationale for referral. Four Aboriginal and/or Torres Strait Islander participants stated that they had a regular GP while the other 4 (including 1 participant who was declined resupply) did not.

The average consultation duration was 13.6 minutes (n=7, excluding 1 consultation where duration was not reported), compared to 15.3 minutes for all participants (n=300). Satisfaction ratings from the 8 known Aboriginal and Torres Strait Islander participants were lower than the ratings from the full OC dataset. The average satisfaction rating across all 7 aspects of the service was 4.4 for Aboriginal and Torres Strait Islander participants, compared to 6.3 for all participants (1 being the lowest and 7 being the highest rating). Satisfaction ratings were lowest for: (i) convenience in obtaining care from the pharmacist (4.0 for Aboriginal and Torres Strait Islander participants versus 6.3 for all participants); and (ii) pharmacy dispensing medication correctly (4.1 for Aboriginal and Torres Strait Islander participants versus 6.3 for all participants).

Satisfaction ratings differed between participants, being 4.9 for Aboriginal and Torres Strait Islander participants versus 6.3 for all participants. The 4 Aboriginal and/or Torres Strait Islander participants in the 15–24 year age range gave markedly lower satisfaction ratings compared to non-indigenous participants in the same age range. The 2 participants who were declined resupply and referred gave low scores for convenience; 1 of these participants gave satisfaction ratings of 1–2 across all aspects of the service. No further information is available to explain why these participants were dissatisfied with the service, and there was no opportunity for participants to provide unstructured feedback in this arm of the trial.

Discussion

Early findings highlight that Aboriginal and Torres Strait Islander community members are supportive of the principle of resupply of OCs particularly where pharmacists are known, trusted, and embedded within, or partnered with, ACCHOs. Participants noted the potential benefits of easier, faster access to contraceptive resupply, particularly in communities with limited GP access, to reduce wait times, avoid travel burdens, and improve continuity of medication. Pharmacies are often more geographically accessible, with extended hours and walk-in access. For people with established contraceptive routines, a straightforward resupply option could support autonomy and reduce the risk of unintended pregnancy. Pharmacist-led services may increase healthcare engagement among patients who use the service when pharmacists are culturally competent and embedded within the community.

Concerns were raised by some participants about cultural safety, privacy, and trust. For many, the key

determinant of acceptability was not the model of care but the manner in which it was delivered. Aboriginal and Torres Strait Islander participants emphasised the need for pharmacists to undergo cultural responsiveness training, for services to be confidential and discreet, and for partnerships between pharmacies and ACCHOs to be formalised. Despite the small sample size, this is reinforced in the follow-up survey where Aboriginal and Torres Strait Islander people reported lower satisfaction with the service than non-Indigenous people.

The study also reinforced the need for pharmacist services to be integrated, rather than fragmented. Participants were concerned about losing continuity of care or creating parallel systems that do not connect with existing health records and care teams. Ensuring data integration and referral pathways between pharmacists and ACCHOs was seen as critical to success.

Limitations and next steps

The ethical approval for analysis of the Aboriginal and Torres Strait Islander quantitative data was limited and therefore the number of participants in this aspect of the study are low. The quantitative findings should be interpreted with caution. Larger studies are recommended. Future studies would benefit from cultural respect training for pharmacists, instructing pharmacists to ask patients if they are Aboriginal and/or Torres Strait Islander during the consultation, and consulting with Aboriginal and Torres Strait Islander peoples about the best wording to use for any questions about culture and experience. Further work is also needed to engage community pharmacies in remote and very remote communities where timely access to medicines can be especially challenging.

Interpretation of Aboriginal and Torres Strait Islander participation in PATH-OC is limited by scope and coverage. Long-acting reversible contraceptives were outside the study scope, coverage across MMM areas was uneven (with participation concentrated in metropolitan and inner regional sites and none from MMM 6–7), and uptake in rural and remote settings was low. As a result, subgroup estimates are imprecise and may not be generalisable to all communities; the quantitative findings should therefore be interpreted with caution.

Conclusion

Expanding the scope of community pharmacists to include OC resupply offers a promising strategy to improve timely access to contraception, however, this approach needs to be informed by Aboriginal and Torres Strait perspectives and governance and embedded in culturally safe practice. Expanding access to OCs through community pharmacy resupply has potential to improve reproductive autonomy for Aboriginal and Torres Strait Islander people, especially in regions with poor GP access. However, effectiveness depends on cultural responsiveness, trust, and integration with ACCHO services. Pharmacist resupply should be delivered in ways that do not present cultural or structural barriers patients could encounter in other services. Through co-design, workforce development, and strong partnerships with ACCHOs, pharmacy-led care can be a tool for equity and self-determination for reproductive health.

07

OVERALL DISCUSSION AND CONCLUSION

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PATH-OC
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Chapter 7: Overall Discussion and Conclusion

The key measures of success from the NSW Government were to:

- provide timely access to care for patients;
- ensure patient safety by appropriately referring those who do not meet criteria for pharmacy-only resupply to a general practitioner (GP) or hospital;
- foster stronger relationships between pharmacists and GPs, particularly in regional and rural areas; and
- ensure the model does not negatively impact lower socio-economic patients in terms of out-of-pocket costs.

This chapter will integrate and discuss the results from the all the sub-studies addressing key measures of success under 5 main pillars: access and equity, economic sustainability, safety and efficacy, and implementation.

The PATH-OC trial specifically involved pharmacist resupplying or continuing specific oral contraceptives (OCs) for women in the age range from 18–35 years old. Eligibility criteria were made based on an international review, co-designed protocol with relevant stakeholders, and guidance from NSW Health. In this study, the NSW Health Authority functioned as the legal instrument that allowed the trials to commence. The trial content and scope were shaped by the co-design process by the chief investigators and the broader trial team. The criteria defined through the co-design process were more conservative compared to international literature, and initiation was not considered. The decision to focus on continuation only may have reflected a balance between expansion of access and patient safety concerns voiced by stakeholders including medical practitioners and health regulators. Criteria were added for the New South Wales (NSW) trial, including the requirement of having been prescribed an oral contraceptive pill (OCP) by a medical or nurse practitioner and used it for the last 24 months, patients having a recent (within 12 months) appointment with their medical practitioner, and specific referral criteria related to moderate and high risks factors. Patients that did not meet these requirements were not eligible for the service. These decisions were made based on stakeholder engagement.

Several practical issues were also resolved during the co-design workshop, including how to manage missed dosages, referral criteria, pharmacist training requirements, and integration of clinical measurements. The medical practitioners present also made the point of the need for a holistic approach, with the consultation providing an opportunity for educating patients in matters like sexual health and checking for sexually transmitted infections (STIs). Recommendations were made that referring to and using the United Kingdom Medical Eligibility Criteria for Contraceptive Use (UKMEC) provided a robust, standardised framework to navigate these clinical complexities. The suggestion was made that the UKMEC could form the basis for the future education of pharmacists. Importantly, discussion during the workshop presented concerns about risk exposure if protocols were not properly adhered to, highlighting the need for high-quality training and audit mechanisms. Similarly, it was suggested that pharmacists needed support in the form of clear guidelines, clinical decision aids, escalation pathways, and integration with digital health records. The 2-phased process used for developing the NSW trial clinical management protocol for pharmacist-led OC treatment continuation incorporated evidence-based safety mechanisms, clearly defined scope, and attempted to ensure appropriate referral mechanisms for complex cases.

The development of the co-design protocol marked the first step of the service implementation for both NSW and the Australian Capital Territory (ACT). It is important to note that outside the trial, there was the availability of an alternative pathway for resupply through continued dispensing of contraceptive treatments. This pathway was established by the Australian Government to give patients access to continuing medications in emergency situations when their usual healthcare provider was unavailable. The continuing dispensing arrangements permit pharmacists to supply up to three packs of OCPs to meet an immediate need. The patient must have previously been supplied the same OCP via a Pharmaceutical Benefits Scheme (PBS) prescription from a GP or a nurse practitioner. For an individual patient, the continued dispensing arrangements can be invoked only once within a 12-month period. This alternative pathway, which is less clinically rigorous

and easier to implement, may have affected the number of consultations delivered in this trial.

Access and Equity

Most pharmacies and pharmacist participating in the PATH-UTI trial choose to consent in participating in the PATH-OC trial. During the trial, 2,209 consultations were delivered. A total of 1,284 pharmacies consented to the PATH-OC trial, representing 63.8% of all NSW pharmacies. From these, 513 (40.0%) performed at least 1 consultation during the 12-month period. Additionally, 15 pharmacies delivered consultations in the ACT. A total of 3,054 pharmacists consented to the trial, while 915 (30.1%) delivered at least 1 consultation. Most pharmacies that performed consultations belonged to the MMM 1, 3 and 4, with approximately 40% of all consented pharmacies providing at least 1 consult. For MMMs 2 and 5, these proportions decreased to 20–25%. Like PATH-UTI, no MMM 6 and MMM 7 pharmacies delivered consultations. Further research is needed to clarify the barriers to uptake in remote (MMM 6) and very remote pharmacies (MMM 7). Among actively recruiting pharmacies, the number of consultations per site had a median of 3 (Interquartile range (IQR) 2–8) across the trial period. The mean duration of resupply was 5 months.

Overall, 77.8% of the trial participants in the OCP resupply trial reported that cost would not be a barrier to using the service again. However, 13.7% of consultations, participants considered it may be a barrier and for 8.5% of consultations, participants indicated it would be a barrier. Interestingly, the distribution of participants based on postcodes showed 20.7% of patients belonging to the 1st and 2nd quintiles, and a total of 46.6% were from the two least disadvantaged socioeconomic quintile. When conducting qualitative interviews, most participants reported they may have been required to make a co-payment (gap fee) if they had been able to get an appointment with their GP, so comparably the trial service was perceived as a cheaper option.

Most participants (79.3%) were from metropolitan areas with the most common age group between 18–25 years (40.3%). Interestingly 46.6% were from the two-least disadvantaged socioeconomic quintile based on residential postcode. About 80% completed the 7-day follow-up and reported high levels of positive experience with the service, the primary outcome for the study, with a mean composite score of 91.6 out of 100. 1,946 unique women received an OC from the pharmacists during the trial. Based on the 2021 Australian Longitudinal Study on Women's Health (ALSWH), approximately 29.4% of women between 18–35 were using OCs in Australia. [125] Applying this to NSW population, approximately 307,000 women would be using OCs annually, with the proportion being larger for the groups closer to 18. A broad assumption may indicate that 0.63% (1,946/307,000) women in NSW accessed the OCP resupply service through community pharmacy.

The study reinforced the need for pharmacist services to be integrated with, rather than fragmented from primary care. Interviews, as part of the Aboriginal and Torres Strait Islander sub-study, indicated concerns about losing continuity of care or creating parallel systems that do not connect with existing health records and care teams. Ensuring data integration and referral pathways between pharmacists and ACCHOs was seen as critical to success. Early findings highlight that Aboriginal and Torres Strait Islander community members are supportive of the principle of resupply of OCs particularly where pharmacists are known, trusted, and embedded within, or partnered with, ACCHOs having slight lower enthusiasm and support. Participants noted the potential benefits of easier, faster access to contraceptive resupply, particularly in communities with limited GP access, to reduce wait times, avoid travel burdens, and improve continuity of medication. Pharmacies are often more geographically accessible, with extended hours and walk-in access. However, concerns were raised about cultural safety, privacy, and trust. For many, the key determinant of acceptability was not the model of care but the way it was delivered. Aboriginal and Torres Strait Islander participants emphasised the need for pharmacists to undergo cultural responsiveness training, for services to be confidential and discreet, and for partnerships between pharmacies and ACCHOs to be formalised. The participation rate for Aboriginal and Torres Strait Islander was 2.7%, similar to the proportion of people identified as such in the general population in NSW (3.4% by 2021). In this sub-study additional ethics, although delayed provided the opportunity of quantitative data. Despite the small sample size (8), Aboriginal and Torres Strait Islander people reported a trend to lower satisfaction (not statistically significant) with the service than non-Indigenous people.

Economic Sustainability

Based on the evidence and usage generated, the cost-shifting evaluation isolated the economics of a single pharmacy service i.e., community pharmacy resupply of OCP. Modelled as a payer impact analysis, the base-case indicates that introducing PATH-OC shifts some resupply consultations from GP and online GP services to community pharmacies, producing lower Commonwealth expenditure alongside higher patient out-of-pocket costs. In dollar terms, estimated annual Commonwealth savings were $11.9 million, while patient out-of-pocket costs increased by $3.5 million, reflecting the assumption that pharmacy consultations are fully patient-funded in the base-case. Thus, the fiscal effects differ by payer rather than moving uniformly across the system.

Sensitivity testing varied the pharmacy consultation fee, showing that out-of-pocket increases depended on fee levels (approximately $2.1–$3 million across plausible ranges) while Commonwealth savings were unchanged because pharmacy uptake was held constant. In real settings, fees can influence affordability and utilisation, which would, in turn, alter service mix and payer impacts. At present, publicly available data on real-world fees in NSW and the ACT are limited; as implementation matures, empirical tracking of fees and utilisation will be important for interpreting distributional effects and equity.

Several modelling constraints qualify the estimates. The synthetic dataset assumed 1 resupply episode per woman per year, and medicine costs reflected supplies of up to 4 months; both features likely underestimate repeated pharmacy episodes and, consequently, underestimate total patient out-of-pocket and Commonwealth savings from additional substitutions away from GP-funded visits. Base-case pharmacy uptake (13%) was informed by PATH-UTI; higher uptake is plausible and, when set to 50%, increased estimated Commonwealth savings to $44.5 million with patient out-of-pocket rising to $16 million, underscoring the sensitivity of budgetary impacts to real-world uptake.

The perspective was partial societal: productivity effects (e.g., time saved, fewer GP visits) and long-term outcomes (e.g., unintended pregnancies) were not captured, and implementation/provider costs (training, workflow redesign, consultation rooms) were excluded. Equity also warrants attention: patient-funded fees can be more burdensome for younger or lower-income women and may interact with local GP access and wait times. Overall, PATH-OC appears capable of reducing Commonwealth costs via substitution to pharmacy, while the distribution of costs to patients will depend on actual fees, uptake, implementation costs, and longer-term outcomes not captured here.

Safety and Efficacy

Most participants received a re-supply for 1 of the combined OCP formulations with associated general advice related to preventive health activities and/or contraceptive advice. The mean duration of supply was 5 months, and most resupplies (53.6%) was for 4 months duration. At the 7-day follow-up, most respondents reported taking the OCP as recommended. Using linkage data, the mean proportion of days covered with a dispensed OCP medication increased between the 24 months pre-consult and the 6 months post-consult (0.60 vs 0.84). The proportion of people with >80% days covered with an OCP was higher in the post-consultation period compared to the pre-consultation period rose from 65.3% vs 44.1%. The data indicated that high adherence was achieved through pharmacist-led resupply process potentially avoiding unwanted pregnancies. For those referred to a GP, participants had a lower proportion of days covered >80% and higher GP consultation rates in the first 4 weeks compared with those not referred. Caution is advised in interpreting this finding given the data periods were considerably longer pre-consultation (36 months) compared to post-consultation.

Adverse events

At 7-day follow-up, participants reported side-effects in 6 consultations, all of which were potentially attributable to OCP use. There is a need to consider that the protocol only allowed resupply to women who had previously prescribed an OCP for at least 2 years, and therefore one would have expected most issues associated with OCP to have been dealt with prior to the pharmacist resupply.

Overall, 81.2% of the trial participants had follow-up data for hospital utilisation at 6 months post pharmacy consultation. The proportion with follow-up data beyond 6 months reduced substantially. Hospital utilisation rates were low in the four weeks post-pharmacy consultation with a total of 8 hospitalisations and 19 emergency presentations.

There were no deaths, hospitalisations or emergency department (ED) presentations for OC-related adverse events. The linkage data for patients suggested there were no differences in GP utilisation and STI testing rates in the pre-and post-consultation period for patients that had the resupply from the pharmacy versus the doctor.

Referral rate to general practice or emergency departments

There was high adherence by pharmacists to the protocols. Pharmacist followed the protocol in consultations for participants in the red (need for referral without supply) and orange categories (referral but resupply). Patients in the green category could receive an OCP resupply without requiring a referral. In 57 of 2209 (2.6%) consultations, participants were assessed to be in the red (48 consultations) or orange categories (nine consultations). Seven patients (0.33%, 7/2,143) who should have been referred did not have records of referrals in the system.

A total of 134 (6.9%) unique participants were referred to a GP based on the referral criteria, mostly related to screening questions at the initial pharmacy assessment. The screening systems were effective, and consideration should be given to include screening tools as part of protocols and guidelines.

A total of 26 cases were identified where 2 IT-related process inconsistencies influenced protocol application. The first related to 13 patients whose blood pressure (BP) readings sat exactly at the protocol thresholds (systolic 145 mmHg and/or diastolic 90 mmHg). The clinical protocol contained minor wording inconsistencies – 1 section referred to values *equal to or above* the thresholds, while another referenced values *above* them. The system applied the latter interpretation, meaning no referral alert was generated for readings at the exact threshold, and resupply proceeded. The second issue involved data entry formats used for calculating body mass index (BMI). The system accepted height and weight in mixed units (for example, height in centimetres or metres, or weight entered as 5.0 kg instead of 50 kg). On review, 13 participants were found to have a BMI > 35 who, under the protocol, would have required referral.

Both issues were identified during post closure data validation undertaken as part of a detailed sub-analysis. A review of the complete database did not identify any additional concerns. These cases were not classified as protocol violations or deviations, as the contributing factors could not reasonably be attributed to pharmacist actions. However, they were noted in the analysis as instances where participants would have met referral criteria under the protocol.

Based on Medicare Benefits Schedule (MBS) data (1,725 participants consenting), the proportion of participants seeing another healthcare professional was around 7% per week in the first 4 weeks following the initial pharmacy consultation. Over the 4-week period post consult there were 557 GP consultations for 378 people (21.9% of the MBS consenting cohort) – 252 had 1 consultation, 93 two consultations, 33 had more than two consultations.

Implementation

Practice Change Facilitators (PCFs) were central to supporting pharmacists during implementation. In-situ pharmacy visits by PCFs rose from 69.3% in PATH-UTI to 78.1% by the end of PATH-OC.

Determinants influencing implementation, both barriers and facilitators, were largely shared across PATH-UTI and PATH-OC. This overlap is unsurprising as the services ran concurrently for 8 of the 12 months of PATH-OC, and many challenges were common to both. Although it would have been valuable to examine barriers separately for each service, the contractual timelines meant that both had to be delivered simultaneously.

Interestingly, while the overall number of pharmacies reporting barriers fell slightly from PATH-UTI to PATH-OC, the average number of barriers per site increased. Some of the identified implementation barriers were related to service promotion and patient demand, eligibility criteria for patients, alternative pathways (continued dispensing scheme), or pharmacists' training costs. Some of these barriers such as the service promotion emerged as a bigger challenge in PATH-OC (16.7%) than in PATH-UTI (9.6%). Pharmacists frequently noted the need for stronger advertising both at the pharmacy and system level.

On the other hand, some facilitators remained consistent with those identified in PATH-UTI. Pharmacist training stood out again as the most frequently cited enabler, mentioned by around 30–35% of pharmacists. This underscores the challenges of preparing pharmacists with the

necessary skills. With experience from PATH-UTI, pharmacists also became more aware of operational requirements, such as workflow integration and staffing, once services moved from early implementation into routine delivery.

Across the 12 months, the top 5 implementation strategies used by PCFs mirrored those of PATH-UTI. More than half of pharmacies adopted 1 or more of these strategies, with PCFs focusing mainly on removing barriers rather than reinforcing existing strengths. Importantly, around 65% of strategies were successful in resolving the barriers they targeted, showing the effectiveness of tailored, needs-based facilitation. As a result, some challenges diminished substantially, for example, issues with consultation room availability dropped from 10.1% (PATH-UTI) to 1.5% (PATH-OC-only sites). Likewise, infrastructure-related concerns were less frequent in OC-only pharmacies (5.2%) compared to those delivering multiple services (12%).

Two strategic approaches consistently proved valuable: a. structured facilitation and b. creating clear implementation plans. These were particularly useful for addressing service-specific issues such as clinical decision-making, workflow, and adherence to protocols, highlighting the need to tailor support to both practice change and the unique characteristics of each new service.

Therefore, to ensure long-term sustainability and broader reach of pharmacy services, it would be valuable for an implementation program to be embedded with PCFs. By institutionalising these positions, PCFs could continue to provide customised, ongoing assistance to pharmacists, with impact during the critical early phases of service rollout and integration.

Strengths and Limitations

During PATH-OC, almost 2,000 women received a resupply of their usual contraceptives. The follow-up rate was over 80%, and more than 90% of participants expressed being highly satisfied with the service provision by pharmacists. PATH-OC is one of the most important trials to date in relation to pharmacists led resupply of OCs. Almost 80% of the participants expressed than cost would not be a barrier to access the pharmacist consultation.

To further evaluate the service's efficacy and safety, data linkage was conducted using data from both NSW and ACT Health, together with MBS and PBS data, all these variables presenting more than 80% of information for the trial participants. This allowed for a deeper understanding of the service clinical implications. The results were highly positive, with most patients receiving a safe and effective resupply of their usual contraceptive, without increased in hospital admissions nor emergency presentations.

In addition, Aboriginal and Torres Strait Islander's voices and experiences were captured and explored, with similar positive views and findings than the ones for the general populations and previously encountered in PATH-UTI. Increased service accessibility for Aboriginal women was seen as the biggest advantage.

The findings also highlighted additional barriers to pharmacist-led resupply of OCP, including restrictions related to eligibility criteria, prior OC use, and the range of products available for resupply. Moreover, differences in training requirements compared with the PATH-UTI program were evident, particularly in terms of associated costs and the skills needed to conduct consultations.

At the same time, several limitations for the trial were encountered. As for PATH-UTI, in PATH-OC the main limitation continues to be the lack of control group for the intervention. However, there is limited data available in both Australia and internationally in relation to the resupply of OCs in other pharmacist-led OCP resupply services, or for GP prescribing. Some studies show OCP resupply rates between 80 and 90% of GP and/or pharmacists-led encounters, which is similar to the rates found in PATH-OC, suggesting that the service was effective for providing these medications.

There were several mechanisms implemented to enhance the trial and to take account of limitations.:

1. PATH-OC was prospectively registered on the Australian New Zealand Clinical Trials Registry (ANZCTR), providing transparency regarding the clinical management protocol, consultation process, and evaluation of outcomes. Statistical analyses were conducted independently from the University of Newcastle research team.
2. A co-design process was used to develop the clinical management protocol, enabling appropriate local adaptation of the intervention

and incorporating perspectives from GPs and health authorities on the pharmacist consultation pathway. The protocol remained unchanged throughout the trial. Data collection processes included multiple validation checks to identify potential data errors and minimise the risk of data loss or incomplete follow-up.

3. Several interim reports were provided throughout data collection and validation to the trial sponsor (NSW Health), the University of Newcastle Human Research Ethics Committee, the external Data Safety Monitoring Board, and the internal Safety and Stewardship Working Group. These reports included data on accessibility, efficacy, and safety outcomes, as well as updates on trial implementation, enabling ongoing monitoring of any potential patient safety risks.

These mechanisms to reduce the risks associated with the trial design and limitations seem to have accounted for most of the bias, specifically when considering the independent analysis and data interpretation.

Conclusion

The PATH-OC trial generated empirical data on accessibility, safety, acceptability and economic impact for pharmacist-led resupply of OCs, providing a basis for evidence informed policy consideration. Within NSW and the ACT, the service was well received by participants, with high reported satisfaction and limited safety concerns, and the implementation was characterised by effective facilitation in pharmacies. PCFs routinely identified and helped resolve local barriers, while the pattern of determinants (barriers and facilitators) remained broadly stable. Observed contrasts with PATH-UTI, especially training costs and the greater salience of service promotion, shaped uptake and day-to-day delivery; in parallel, task specific and ongoing training needs were apparent where new digital tools were introduced, and the quality of physical and digital infrastructure increasingly influenced workflow and consistency of care.

Participation was concentrated in metropolitan and rural areas, with minimal uptake in remote settings. Patient flow was also shaped by overlap with existing pathways such as continued dispensing. Resupply consultations generally required more clinical input than this alternative pathway, but resupply offer longer coverage intervals, supporting potential efficiency gains and improved continuity of care. Economic modelling indicated reduced Commonwealth expenditure accompanied by higher patient out-of-pocket costs under prevailing fee assumptions, highlighting redistribution rather than uniform reduction of total costs. Taken together, the findings indicate that pharmacist-led OCP resupply can function as a safe and acceptable primary care option through community pharmacy, with impacts contingent on real-world fees, uptake, implementation context and longer-term outcomes beyond the study horizon.

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APPENDICES

UNIVERSITY OF NEWCASTLE AUSTRALIA

PATH-OC
PATHWAY TO ACCESS: ORAL CONTRACEPTION

Appendices

Chapter 1

Appendix 1.1: Research team and consortium

The Chief Investigators included:

- Dr Sarah Dineen-Griffen (Lead Investigator and Chair).
- Emeritus Prof Charlie (Shalom) Benrimoj (Independent Consultant).
- Professor David Peiris (The George Institute for Global Health).
- Dr Belinda Ford (The George Institute for Global Health).
- Dr Gill Schierhout (The George Institute for Global Health).
- Dr Anna Campain (The Geroge Institute for Global Health).
- Associate Professor Kris Rogers (University of Technology Sydney/ The George Institute for Global Health).
- Associate Professor Penny Reeves (University of Newcastle/ Hunter Medical Research Institute).
- Emeritus Professor Julie Byles AO (University of Newcastle/ Hunter Medical Research Institute).
- Dr Therese Foran, Sexual Health Physician,
- Dr Indy Sandaradura (Centre for Infectious Diseases and Microbiology, Westmead Hospital).
- Professor Leanne Holt (The University of NSW).
- Associate Professor Kylie Gwynne (The University of NSW).
- Professor Kylie Williams (University of Technology, Sydney).
- Dr Helen Benson (University of Technology, Sydney).
- Associate Professor John Rae (Charles Sturt University, Bathurst).
- Ms Anna Barwick (University of New England)
- Dr Joanna Moulin (Curtin University, WA).
- Ms Jan Donovan (Consumer Health Forum).

Research team members included:

- Dr Francisco Martinez Mardones (Senior Lecturer, University of Technology Sydney).
- Simone Diamandis (University of Newcastle, Research Project Manager and PhD student).
- Kristin Xenos (University of Newcastle, Education Lead and PhD Student).
- Mitchell Budden (University of Newcastle, PhD Student).
- Victoria Chisari (University of Technology Sydney, PhD Student).
- Dr Joy Bowles (University of New England, Research Assistant).
- Abeer Ellabaan (University of New England, Research Assistant).
- Bradley Rockliff (University of Newcastle, PhD student).
- Dr Valerie Looi (The George Institute for Global Health, Project Manager).
- Dr Noelia Amador Fernandez (University of Technology Sydney).
- Dr Victoria McCreanor (Hunter Medical Research Institute, Head of Health Economics).
- Dr Xenia Dolja-Gore (Hunter Medical Research Institute, Senior Biostatistician).
- Dr Olivia Wynne (Hunter Medical Research Institute, Health Economist).

A total of 13 project partners were part of the research consortium led by the University of Newcastle in collaboration with NSW Health. The partners were divided into three groups across each research phase were.

4. The Pharmacy Guild of Australia.
5. Royal Australian College of General Practitioners.
6. Pharmaceutical Society of Australia.
7. The George Institute for Global Health.
8. Hunter Medical Research Institute.
9. University of Technology Sydney.
10. University of New England.
11. Charles Sturt University.
12. Co-Design Health Research and Innovation team at UNSW.
13. Consumer Health Forum.
14. Deloitte Australia.
15. Rural Doctors Network New South Wales
16. MedAdvisor.

Appendix 1.2: Program governance

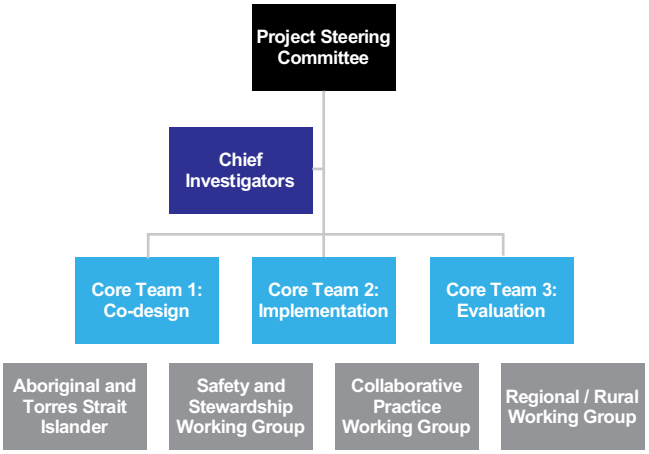

Figure 1.2.1: NSW Pharmacy OC Trial governance structure, May 2023

The Project Steering Committee (PSC) was established and approved the governance structure. The first meeting of the PSC was held in March 2023.

The Safety and Stewardship Working Group (SSWG), Collaborative Practice Working Group and the Regional and Rural Working Group (RRWG) had their first meetings in Q4 2023. The Aboriginal and Torres Strait Islander Working Group held its first meeting in Q4 2024.

Weekly, fortnightly or monthly meetings have occurred over the course of the project with the following key stakeholder groups:

- Royal Australian College of General Practitioners (RACGP) (fortnightly)
- Pharmacy Guild of Australia (NSW Branch) (weekly)
- Pharmaceutical Society of Australia (PSA) (fortnightly)
- MedAdvisor® (weekly)
- Ministry of Health (fortnightly and ad hoc – re: scope of practice contracts, general advice, communications, IT)

Further to Ethics requirements, an independent Data Safety Monitoring Board (DSMB) was also established to assess, review and provide recommendations to the research team on safety aspects of the trial, including all adverse events reported in patient interviews or through any other reporting channel. Operating as an independent and external body, the first DSMB meeting was convened in August 2023. Following a review in late 2023, the governance structure was amended and approved by the Project Steering Committee. The revised structure saw amalgamation of the 3 Core Teams into the Chief Investigators group. The 4 Working Groups were retained.

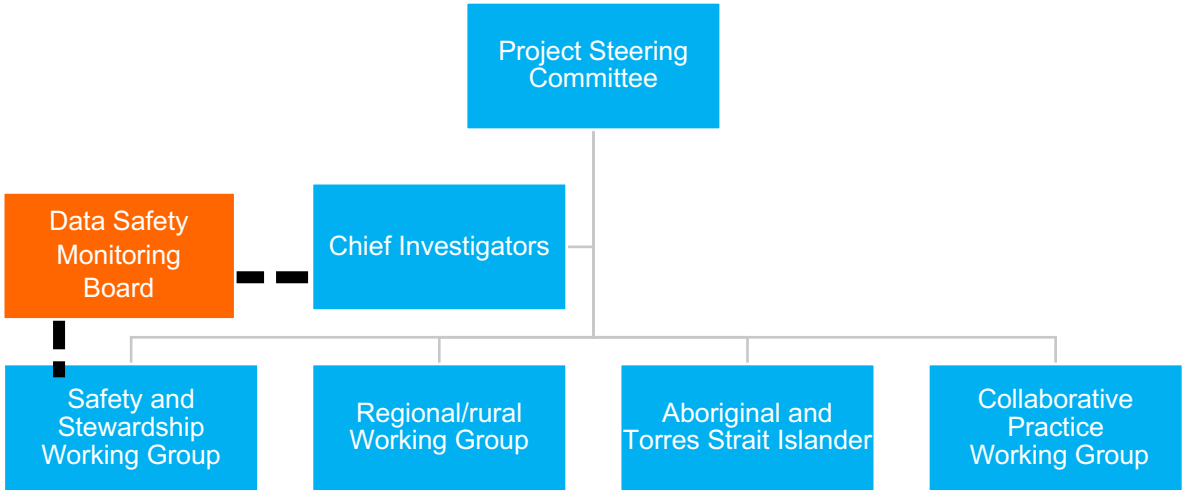

Figure 1.2.2: Revised NSW Pharmacy Trial governance structure, November 2023

Information exchanged between groups to monitor patient safety, participants interest, data validity and trial credibility

Membership within the Committees and Working Groups changed over the course of the Project, with representatives from the research team, state-wide partners and key stakeholders present across all Committees and Groups. Each Committee and Working Group had a Terms of Reference (ToR). An overview of the key role of each Committee and Working Group is provided below.

The **PSC** provided strategic advice and feedback for the project and facilitated productive working relationship with the external environment and all stakeholders. The main role of the PSC was to engage stakeholders, ensure ongoing advice and information on primary healthcare industry developments, and to provide feedback on all matters relating to the trial.

Membership of the PSC

- Jan Donovan, Chair, Board Director, Finance Audit, Risk Committee Chair, Consumers Health Forum of Australia.
- Emeritus Prof Shalom (Charlie) Benrimoj, Member, Co-Investigator, NSW Pharmacy Trials, University of Newcastle.
- Associate Professor Sarah Dineen-Griffin, Member, Chief Investigator, NSW Pharmacy Trials, University of Newcastle.
- Professor Charlotte Hespe, Member, Head of General Practice and Primary Care Research, Sydney School of Medicines, University of Notre Dame, Australia.
- Chris Campbell, Member, General Manager, Policy and Program Delivery, Pharmaceutical Society of Australia.
- Catherine Bronger, Member, Vice President, Pharmacy Guild of Australia, NSW Branch, General Manager, Chemistworks Group.
- Dr Yann Guisard, Member, Director, Knowledge Mobilisation, Rural Doctors Network.
- Richard Samimi, Member, Co-Founder & Managing Director, Macquarie Health Hub Pharmacy Group, President & Pharmacist, Pharmacy Council of NSW.
- Jess Hadley, Member, Professional Officer NSW/ACT, Pharmaceutical Defence Limited.
- A/Prof Kylie Gwynne, Member, Associate Professor Indigenous Studies, University of NSW.
- Daniel Gilbertson, Member, Director, Health Consulting Team, Deloitte Australia.
- Professor David Peiris, Member, Chief Scientist, The George Institute for Global Health, Professor, Faulty of Medicine, University of NSW.
- Dr Caitlin Swift, Observer, Medical Advisor, Public Health Physician, Office of the Deputy Secretary, Population and Public Health & Chief Health Officer, NSW Health.
- Jo Root, Observer, Director, Policy and Research, Consumers Health Forum of Australia.
- Sarah Taylor, Secretariat, Operations Manager, NSW Pharmacy Trial, University of Newcastle.

Importantly the structure **included the DSMB,** an independent board was established to review, at regular intervals, the trial data to identify and advise on safety issues and make recommendations to safeguard the interests of study participants.

The primary role of the DSMB was to:

- review and frequently monitor the trial safety data to identify any emerging safety concerns as rapidly as possible to mitigate the risk of harm;
- provide recommendations to the Chief Investigators based on an assessment of the data and balance of risks and benefits;
- maintain confidentiality of unblinded interim results and provide an objective and unbiased assessment of those results; and
- refer matters that arise beyond its expertise to external experts to provide the necessary insight to better respond to issue(s) of concern.

Membership of the DSMB

- Emeritus Professor Arthur Conigrave, Chair, Endocrinologist, Royal Prince Alfred Hospital, Biology Domain Group Leader, School of Life and Environmental Sciences, University of Sydney.
- Dr Margot Woods, Member, General Practitioner, Rozelle Total Health, Discipline Lead, General Practice, Department of General Practice, School of Medicine, University of Notre Dame, Australia.
- Ms Genevieve Adamo, Member, Senior Pharmacist, Poisons Information, NSW Poisons Information Centre.
- Professor Micheal Frommer, External Public Health Expert, Senior Advisor, The Sax Institute.
- Simone Diamandis, Secretariat, Research Manager, University of Newcastle.

Four working groups were established to look at specific patient groups and practice issues related to

UTI service delivery and were continued for the OC trial including the Aboriginal and Torres Strait Islander Working Group, SSWG, Regional and Rural Working Group and the Collaborative Practice Working Group.

The Aboriginal and Torres Strait Islander Working Group worked collaboratively to:

- provide guidance and feedback on Aboriginal and Torres Strait Islander specific issues relating to the project;
- facilitate communication with key stakeholders that engage with the Aboriginal and Torres Strait Islander community to support project implementation;
- provide advice and feedback on external communication and resources for the project to the Aboriginal and Torres Strait Islander community;
- provide advice on the progress and final reports to NSW Health relating to the Aboriginal and Torres Strait Islander community;
- identify potential risks that may impact service provision to Aboriginal and Torres Strait Islander peoples and provide advice to the project team to mitigate these risks;
- report recommendations and actions to the Chief Investigators; and
- provided advice on specific issues, where appropriate, that arose relating to Aboriginal and Torres Strait Islander care in relation to the project.

Membership of the Aboriginal and Torres Strait Islander Working Group

- Professor Leanne Holt, Chair, Deputy Vice-Chancellor Indigenous, University of NSW.
- Associate Professor Kylie Gwynne, Member, Associate Professor Indigenous Studies, University of NSW.
- Associate Professor Cara Cross, Member, Executive Officer of the DVC Indigenous Division, University of NSW.
- Dr Vita Christie, Member, Postdoctoral Research Fellow, University of NSW.
- Dr Uncle Joe Perry, Member, Senior Research Fellow, Heart Research Institute.
- Associate Professor Sarah Dineen Griffin, Member,
  Chief Investigator, NSW Pharmacy Trials, University of Newcastle.
- Emeritus Professor Shalom (Charlie) Benrimoj, Member, Co-Investigator, NSW Pharmacy Trials, University of Newcastle.
- Sarah Taylor, Secretariat, Operations Manager, NSW Pharmacy Trial, University of Newcastle.

The SSWG worked collaboratively to:

- provide guidance and feedback on issues relating to safety and stewardship throughout the project;
- provide advice on communication to optimise safety and stewardship throughout the project;
- identify potential risks that relate to safety and stewardship that may impact service provision or patient outcomes and provide advice to the project team to mitigate these risks;
- report recommendations and actions to the Chief Investigators; and
- provide advice on specific issues, where appropriate, that arose relating to safety and stewardship in relation to the project.

Membership of the SSWG

- Dr Indy Sandaradura, Chair, Centre for Infectious Diseases and Microbiology, Westmead Hospital.
- Dr Therese Foran, Member (Advisor Oral Contraceptives), Sexual Health Physician; Conjoint Senior Lecturer, School of Women's and Children's Health, University of NSW.
- Dr Titi Chen, Member, Nephrologist and Transplant Physician, Westmead Hospital.
- Associate Professor Deshan Sebaratnam, Member (Advisor Dermatology), University of NSW, Staff Specialist Liverpool Hospital.
- Bradley Rockliff, Member, Antimicrobial Stewardship Pharmacist, Randwick Children's Hospital and University of Newcastle.
- Dr Anna Campain, Senior Biostatistician, The George Institute for Global Health, Conjoint Lecturer, Faculty of Medicine, University of NSW.
- Professor Kylie Williams, Head of Discipline, Pharmacy, Graduate School of Health, University of Technology Sydney.
- Emeritus Professor Shalom (Charlie) Benrimoj, Member, Co-Investigator, NSW Pharmacy Trials, University of Newcastle.

- Dr Francisco Martinez Mardones, Data Manager, NSW Pharmacy Trial, University of Newcastle.
- Simone Diamandis, Secretariat, Research Manager, University of Newcastle.

The Collaborative Practice Working Group worked collaboratively to:

- Recognise facilitators of collaboration that should be considered in the project.
- Provide guidance and feedback on how to optimise collaboration between pharmacists and medical practitioners and other key stakeholders throughout the course of the project.
- Provide advice on external communication and updates in relation to the project to key stakeholders.
- Identify potential risks to collaborative practice that may impact service provision and provide advice to the project team to mitigate these risks.
- Report recommendations and actions to the Chief Investigators.
- Provided advice on specific issues, where appropriate, that arose relating to collaborative practice in relation to the project.

Membership of the Collaborative Practice Working Group

- Dr Helen Benson, Chair, Senior Lecturer Pharmacy, University of Technology Sydney.
- Catherine Bronger, Member, Vice President, Pharmacy Guild of Australia, NSW Branch, General Manager, Chemistworks Group.
- Karen Carter, Member, Partner, Carter's Pharmacy Gunnedah, Owner, Narrabri Pharmacy, NSW Branch Committee Member, Pharmaceutical Society of Australia.
- Dr Rebekah Hoffman, Member, RACGP NSW/ACT Faculty Chair, General Practitioner, Kirrawee Family Medical Practice.
- Professor Charlotte Hespe, Member, Head of General Practice and Primary Care Research, Sydney School of Medicines, University of Notre Dame, Australia.
- Dr Yann Guisard, Member, Director, Knowledge Mobilisation, Rural Doctors Network.
- Associate Professor Sarah Dineen-Griffin, Member, Chief Investigator, NSW Pharmacy Trials, University of Newcastle.

The RRWG worked collaboratively to:

- recognise aspects of regional and rural care that should be considered in the project;
- provide guidance and feedback on regional and rural specific issues relating to the project;
- facilitate communication with key regional and rural stakeholders;
- provide advice on external communication for the project to the regional and rural community;
- identify potential risks that may impact service provision in regional and rural communities and provide advice to the project team to mitigate these risks;
- report recommendations and actions to the Chief Investigators; and
- provide advice on specific issues, where appropriate, that arose relating to regional and rural care in relation to the project.

Membership of the RRWG Group

- Anna Barwick, Chair, Pharmacy Lecturer, University of New England, Founder and Director, PharmOnline Telehealth Service.
- Associate Professor John Rae, Member, Head of School, School of Dentistry and Medical Sciences, Charles Sturt University.
- Dr Yann Guisard, Member, Director, Knowledge Mobilisation, Rural Doctors Network.
- Abeer Ellabaan, Member, Practice Change Facilitator, University of New England.
- Hamish Nott, Member, Community Pharmacist, Director, Phil Davies Pharmacy.
- Dr Rebekah Hoffman, Member, RACGP NSW/ACT Faculty Chair, General Practitioner, Kirrawee Family Medical Practice.
- Associate Professor Kylie Gwynne, Member, Associate Professor Indigenous Studies, UNSW.
- Emeritus Professor Shalom (Charlie) Benrimoj, Member, Co-Investigator, NSW Pharmacy Trials, University of Newcastle.
- Associate Professor Sarah Dineen-Griffin, Member, Chief Investigator, NSW Pharmacy Trials, University of Newcastle.

Chapter 2

Appendix 2.1: Literature review conducted during codesign

Contraception 149 (2025) 110979

Contents lists available at ScienceDirect

Contraception

journal homepage: www.elsevier.com/locate/contraception

Pharmacist-prescribed contraception using clinical protocols: A review of the gray literature☆,☆☆

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ARTICLE INFO

Article history:
Received 12 February 2025
Received in revised form 13 May 2025
Accepted 26 May 2025

Keywords:
Clinical protocols
Contraceptive agents
Female
Hormonal contraception
Nonmedical prescribing
Pharmacists

ABSTRACT

Background: Many women face barriers to starting and continuing contraception due to difficulties in accessing primary care. Pharmacist-prescribed contraceptives have emerged as a strategy to improve access. This approach offers an additional pathway for women to access contraceptive care, with benefits such as lower costs, shorter wait times, and extended hours.
Objectives: This review aims to analyze clinical protocols used by community pharmacists to prescribe and continue hormonal contraceptives and evaluate their quality.
Study design: This review utilized gray literature since protocols are often not formally published. The search involved four processes: searching a gray literature database, using Google, reviewing health agency websites, and consulting international experts. Records were included if they met the definition of a clinical protocol, were for community pharmacist prescribing or continuation of hormonal contraception, and were written in English. Grounded Theory was used for analysis. Quality appraisal was performed using the Appraisal of Guidelines for Research and Evaluation II tool.
Results: Thirty clinical protocols were identified from the USA (n = 23), Canada (n = 2), the UK (n = 2), New Zealand (n = 1), and Australia (n = 2). Pharmacists were authorized to prescribe and continue contraceptives in 27 protocols and continue contraceptives only in three. Key requirements included age restrictions, measurement of blood pressure and body mass index, review by a health professional, patient self-completed screening tools, and use of best-practice guidelines. The lowest-scoring domains in the quality assessment were "Editorial Independence," "Applicability," and "Rigor of Development."
Conclusions: The review provides insights into the current international landscape of pharmacist-prescribed contraception and highlights key components of clinical protocols. It offers valuable information for policymakers to support the development of frameworks for pharmacist-prescribed contraception globally.

1. Introduction

Contraception is important for promoting the health and well-being of women by providing control over reproductive choices, including the choice not to become pregnant [1,2]. From a public health perspective, prevention of unintended pregnancies lowers maternal morbidity and mortality, improves birth outcomes [1,2], improves socioeconomic status [1], slows population growth, and improves educational and employment opportunities for women [2]. The number of women seeking to use contraceptives, such as oral contraceptive pills, implants, injectables, [3] patches, vaginal rings, and intrauterine devices, has significantly increased in the past two decades, from 900 million in 2000 to nearly 1.1 billion in 2021 worldwide [4]. Demand for contraception is expected to increase by a further 70 million by 2030 [5]. Multiple barriers have been identified that can prevent women from initiating and/or continuing contraception [6,7]. Obtaining a prescription from an appropriate prescribing professional, such as medical practitioner, has been identified as a barrier to access [3,8,9].

One strategy to improve contraceptive access is increasing the scope of allied health professionals to include prescribing of contraceptives [2,10,11]. Among these, community pharmacists have

☆ Conflicts of interest: None declared.
☆☆ Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.
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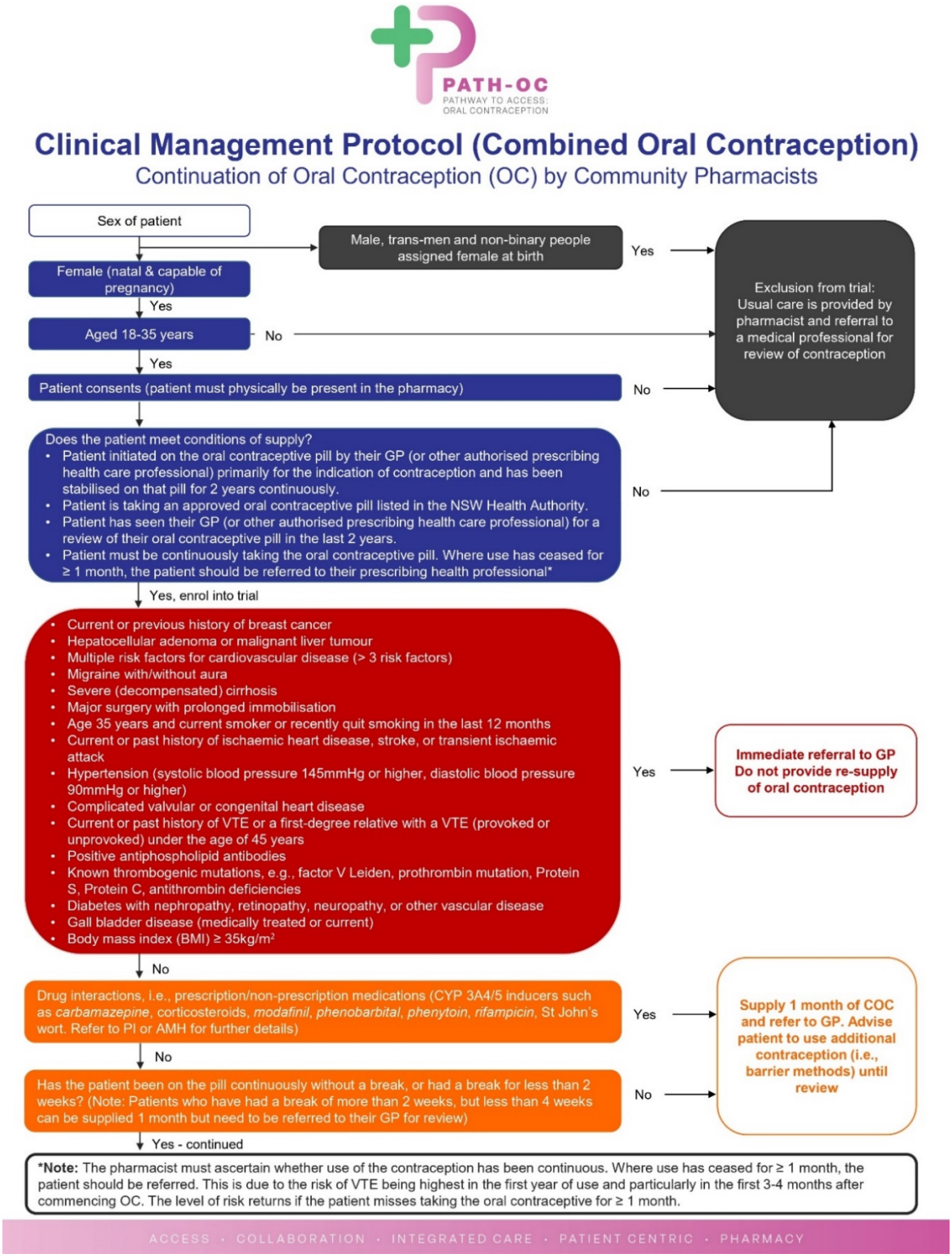
https://doi.org/10.1016/j.contraception.2025.110979

Appendix 2.2: Clinical Management Protocols for PATH-OC



PATH-OC
PATHWAY TO ACCESS: ORAL CONTRACEPTION

Clinical Management Protocol (Combined Oral Contraception)

Continuation of Oral Contraception (OC) by Community Pharmacists

Yes - continued

Before re-supply, pharmacists should discuss contraceptive options such as the use of long-acting reversible contraception (LARCs) with women seeking contraception as per the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) recommendations.

Yes

If this is the first time the OC service has been provided to the patient, the following clinical measurements MUST be recorded:
Blood pressure: If BP exceeds **145mmHg** systolic **or 90mmHg** diastolic, **do not supply** OC and refer to GP
BMI: Weight and height should be recorded. If BMI ≥ **35kg/m²** **do not supply** OC and refer to GP

Proceed with re-supply

Yes

Pharmacists can re-supply up to 12-months of the patient's current pill for the continuation of contraception provided that the patient has been reviewed by their treating medical practitioner for the purposes of contraception within the last 2 years (i.e., **pharmacists are not permitted to initiate or change therapy**)

Note → **Patients taking oral contraception not listed must be referred to their treating medical practitioner**

Provide patient with a resupply of their existing oral contraception (Note: Pharmacists are only permitted to supply oral contraceptives listed in the NSW Health Authority)

Note → **Dispense any medications (if supplied) via pharmacy dispensing software and label according to the legislative requirements outlined in the Poisons and Therapeutic Goods Regulation 2008**

Provide non-pharmacological and self-care advice
Consumer Medicines Information and/or a Self-Care Fact Card
Appropriate counselling on the OC supplied, (i.e., how to take, side effects to expect/how to manage side effects, when the OC is less effective, what to do in the event of a missed pill, reiterate the importance of adherence and avoiding starting/stopping the pill)

Provide follow up advice and expectations around duration of symptoms
- Educate patients on the importance of getting regular women's health and sexual/reproductive health checks, (i.e., Cervical screening is available for women from the age of 25 and is recommended every 5 years, Breast checks for women who have a personal or family history of breast cancer should be advised to see their medical practitioner for advice regarding frequency and type of screening, Sexually transmitted infection (STI) screening is recommended for anyone who is sexually active and engaging in unprotected sex)
- If patients have a concern with the type of contraception they are using, encourage them to speak with their medical professional.

Note → **Document the consultation in MedAdvisor and share a record of the consult with the patient's usual treating medical practitioner or medical practice**

Note: If no GP or hospital service is available for the patient, referral should be made for the patient to **HealthDirect** via 1800 022 222

* Protocol developed and agreed as part of co-design with Project Partners

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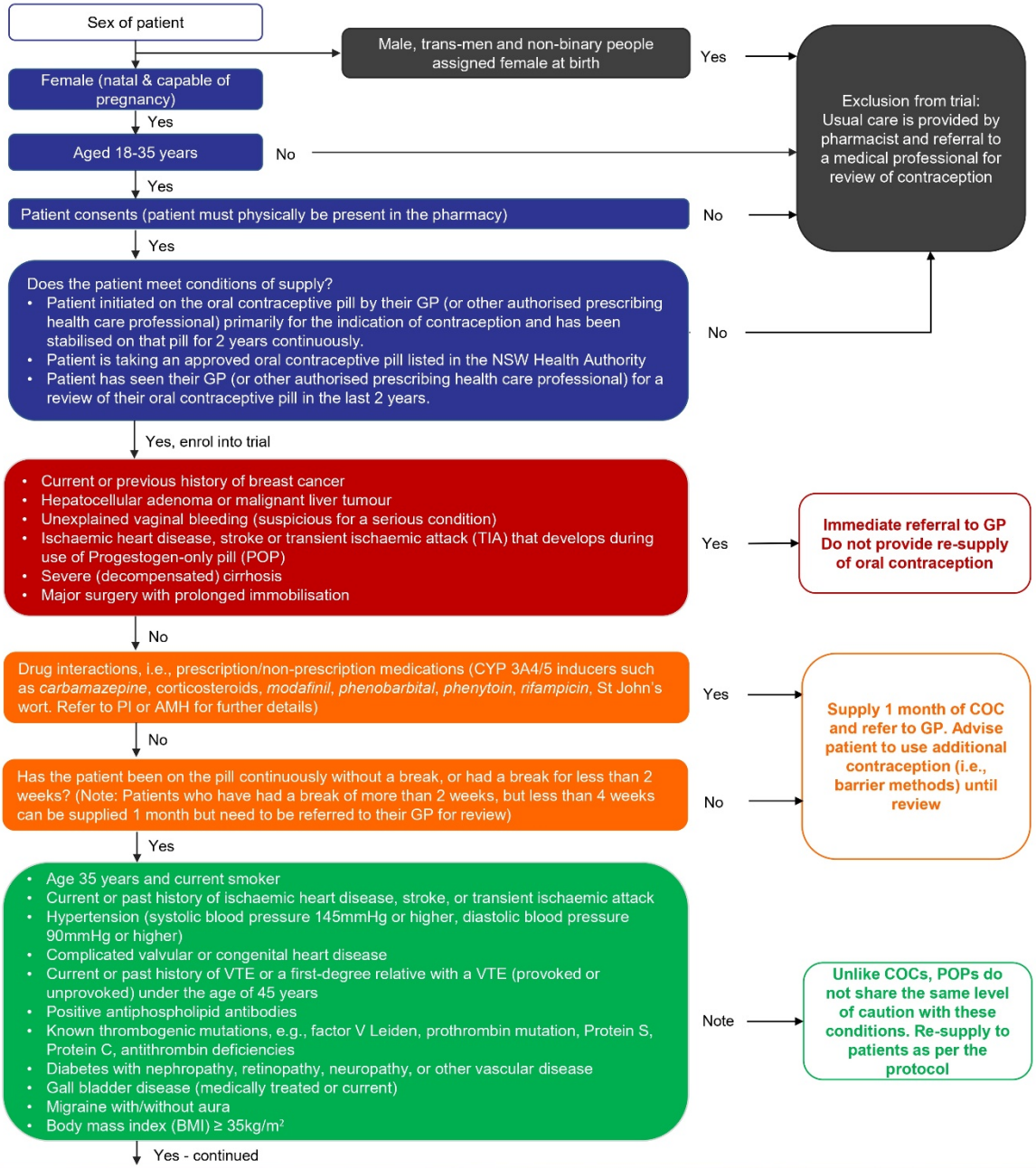
PATH-OC
PATHWAY TO ACCESS: ORAL CONTRACEPTION

Clinical Management Protocol (Progestogen-Only Contraception)

Continuation of Oral Contraception (OC) by Community Pharmacists



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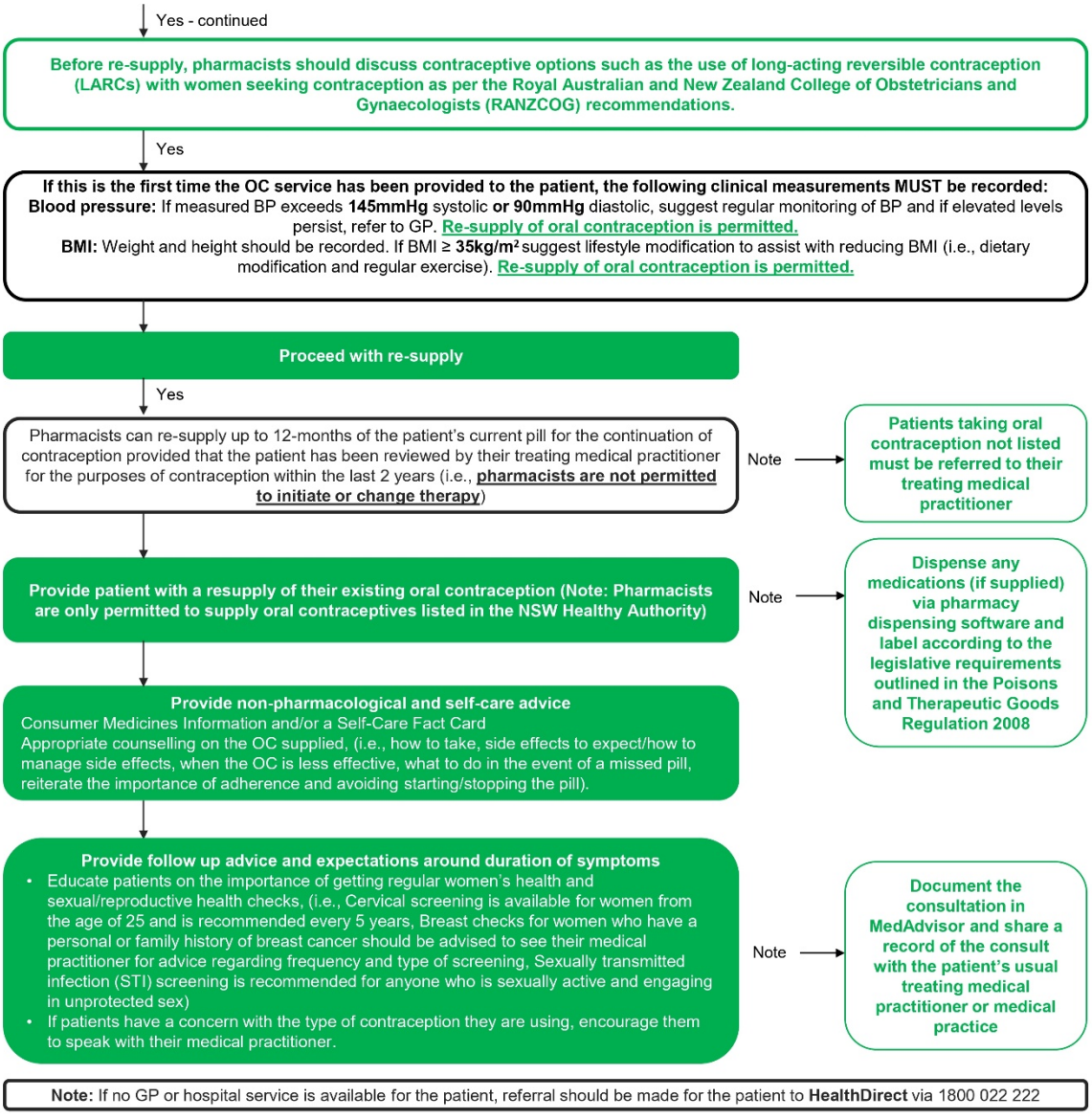
PATH-OC
PATHWAY TO ACCESS: ORAL CONTRACEPTION

Clinical Management Protocol (Progestogen-Only Contraception)

Continuation of Oral Contraception (OC) by Community Pharmacists



* Protocol developed and agreed as part of co-design with Project Partners

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Appendix 2.3: NSW Health Authority for PATH-OC

NSW GOVERNMENT | Health

POISONS AND THERAPEUTIC GOODS ACT 1966

Section 10 Poisons and Therapeutic Goods Act 1966

Clauses 170 and 171 of the Poisons and Therapeutic Goods Regulation 2008

AUTHORITY

I, Dr Kerry Chant, Chief Health Officer, a duly appointed delegate of the Secretary, NSW Health, pursuant to clauses 53, 170, and 171 of the Poisons and Therapeutic Goods Regulation 2008 for the purpose of section 10 of the Poisons and Therapeutic Goods Act 1966, hereby make this instrument.

Dr Kerry Chant

Chief Health Officer

Dated: 5/9/23

Authority – Supply of specified restricted substances by pharmacists

---

1) Authorisation

This instrument authorises an 'approved pharmacist' to supply to an 'applicable patient' a restricted substance listed in clause 2 otherwise than on prescription subject to the conditions in clause 3 of this instrument for the purposes of the 'clinical trial'.

2) Restricted substance to which this instrument applies

This instrument applies to single or combined oral forms of:

a. ethinyloestradiol (40µg or less)
b. levonorgestrel
c. norethisterone
d. drospirenone (single ingredient preparations only)

3) Conditions — Limitation on supply

An approved pharmacist may supply the restricted substance listed in clause 2, subject to the conditions that:

a. The supply to the applicable patient must be primarily for the purpose of oral contraception.

Page 1 of 3

b. The patient must have been treated with the restricted substance referred to in clause 2 by a medical practitioner or nurse practitioner for the past 24 months and the use has been continuous.

c. The pharmacist must ensure that the applicable patient has not been supplied a restricted substance listed in clause 2 by the pharmacist or has, to the pharmacist's knowledge, been supplied by any other pharmacist acting under this authority for a period exceeding 12 months.

d. The pharmacist complies with the 'Management Protocols', including the requirement that the pharmacist makes a record in MedAdvisor pharmacy software, or an approved system by the Ministry of Health, regarding the supply.

e. The pharmacist must make and keep a clinical record of the consultation for 7 years (at the pharmacy where the patient consultation occurred) that contains:

- sufficient information to identify the patient
- the date of the treatment
- the name of the pharmacist who undertook the consultation
- any information known to the pharmacist that is relevant to the patient's diagnosis or treatment (for example, information concerning the patient's medical history)
- any clinical opinion reached by the pharmacist
- actions taken by the pharmacist
- particulars of any medication supplied for the patient (such as form, strength and amount)
- notes as to information or advice given to the patient in relation to any treatment proposed by the pharmacist who is treating the patient
- any consent given by a patient to the treatment proposed.

f. The pharmacist shares a record of the supply with the patient's usual treating medical practitioner or medical practice, where the patient has one, following consent by the patient.

g. The pharmacist must consent to participate in the clinical trial and its evaluation, including by sharing records of applicable patients with the University of Newcastle.

h. The pharmacist must comply with the AHPRA & National Boards Code of Conduct; and the expected standards of ethical behaviour of pharmacists towards individuals, the community and society.

4) Publication

This instrument will be published on the NSW Health website.

5) Definitions

In this instrument:

- An 'applicable patient' means a female patient 18 years of age or over and up to and including aged 35 years who has been supplied or prescribed the oral

contraceptive pill by a medical practitioner or nurse practitioner for the previous 24 months and use has been continuous.

- An 'approved pharmacist' means a pharmacist holding general registration with the Australian Health Practitioner Regulation Agency (AHPRA) and who is employed or engaged in an 'approved pharmacy' who has successfully completed:
    - Australasian College of Pharmacy Continuation of Oral Contraception Course; or
    - Pharmaceutical Society of Australia NSW - Contraception Essentials; and
    - Training module(s) that have been approved by the Chief Health Officer for the purposes of the clinical trial.
- An 'approved pharmacy' means a pharmacy or class of pharmacies approved in writing by the Chief Health Officer which:
    - offers applicable patients the services specified in this authorisation at all opening hours of the pharmacy; and
    - has a service room, consulting room, or area consistent with the following:
        - the room or area is not to be used as a dispensary, storeroom, staff room or retail area,
        - is 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.
- 'Management protocols' means the protocols established for use by pharmacists in the clinical trial.
- The 'clinical trial' means the trial put in place by the University of Newcastle on behalf of the Ministry of Health regarding the supply of specified contraceptive medication by community pharmacists without a prescription.
- A 'pharmacy' has the same meaning as in the Health Practitioner Regulation National Law.

6) Commencement

This authority commences on publication.

7) Cancellation

This authority is cancelled on 30 September 2024, unless earlier cancelled.

Chapter 3

Appendix 3.1 - Supplementary tables

Appendix Table 3-1-1: Medicare Benefits Schedule (MBS) item numbers – general practitioner (GP) consultations

Type	MBS item number
General practitioner consultations	3, 4, 23, 24, 36, 37, 44, 47, 123, 124, 5000, 5003, 5010, 5020, 5023, 5028, 5040, 5043, 5049, 5060, 5063, 5067, 5071, 5076, 5077, 90020, 90035, 90043, 90051, 90054, 91790, 91800, 91801, 91802, 91890, 91891, 91900, 91910, 91920
Medical practitioner consultations	52, 53, 54, 57, 58, 59, 60, 65, 151, 165, 179, 181, 185, 187, 189, 191, 203, 206, 301, 303, 733, 737, 741, 745, 761, 763, 766, 769, 772, 776, 788, 789, 2197, 2198, 2200, 5200, 5203, 5207, 5208, 5209, 5220, 5223, 5227, 5228, 5260, 5261, 5262, 5263, 5265, 5267, 90092, 90093, 90095, 90096, 90098, 90183, 90188, 90202, 90212, 90215, 91792, 91794, 91803, 91804, 91805, 91806, 91807, 91808, 91892, 91893, 91903, 91906, 91913, 91916, 91923, 91926
Sexually transmitted infection testing	Chlamydia trachomatis (69316, 73813, 73825) Gonorrhoea (69317, 73813, 73825) HIV serology (69384, 69387, 69390, 69393, 69396, 69405, 69408, 69411, 69413, 69415) or RNA or genotype testing (69378, 69380, 69381, 69382) Syphilis serology (69387) Hepatitis B serology or DNA testing (69405, 69408, 69411, 69413, 69415, 69475, 69482, 69483, 69484)

Appendix Table 3-1-2: Pharmaceutical Benefits Scheme (PBS) ATC Codes for oral contraceptives (OC)

Combined oral contraceptive pills resupplied			
Formulation	Estrogen dose (micrograms)	Progestogen dose (micrograms)	ATC code
Monophasic (Low-dose Estrogen)	Ethinylestradiol 20 mcg	Levonorgestrel 100 mcg	G03AA07
Monophasic (Standard-dose Estrogen)	Ethinylestradiol 30 mcg	Levonorgestrel 150 mcg	G03AA07
	Ethinylestradiol 35 mcg	Norethisterone 500 mcg	G03AA05
	Ethinylestradiol 35 mcg	Norethisterone 1000 mcg	G03AA05
Monophasic (Extended Regimen)	Ethinylestradiol 30 mcg Ethinylestradiol 10 mcg	Levonorgestrel 150 mcg	G03AA07
Triphasic (low- or standard-dose Estrogen)	Phase 1: (6 pills): Ethinylestradiol 30 mcg + levonorgestrel 50 mcg Phase 2: (5 pills): Ethinylestradiol 30 mcg + levonorgestrel 75 mcg Phase 3: (10 pills): Ethinylestradiol 40 mcg + levonorgestrel 125 mcg		G03AB04
Progestogen-only contraceptive pills resupplied			
Levonorgestrel 30 mcg			G03AC03
Norethisterone 350 mcg			G03AC01
Drospirenone 4mg			G03AC10

Appendix Table 3-1-3: International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED) codes for oral contraceptive pills (OCP) related conditions

Condition	ICD-10 code	SNOMED codes
Cerebral infarction	I63, I63.4	422504002, 432504007, 71444005, 195190007
Stroke	I64	230690007, 422504002
Sequelae of cerebrovascular disease	I69	195239002, 230690007
Other paralytic syndrome following cerebral infarction	I69.36	116288000
Diseases of veins, lymphatic vessels and lymph nodes, not elsewhere classified	I80-I89	362971004, 61599003, 64156001, 40283005, 2477008, 404223003, 128054009, 38739001
Adverse effect of oral contraceptives, initial encounter	T38	866260004
Migraine	G43	37796009, 193030005
Adverse effect of a drug	T88.6-7, T78	62014003, 401207004, 309298003

Appendix Table 3-1-4: Baseline characteristics by Australian Capital Territory (ACT) vs new South Wales (NSW) for 2,209 consultations)

Characteristic	ACT n=176[1]	NSW n=2,033[1]
Age (Years)		
Mean (SD)	26 (4)	27 (5)
Age group		
18–25 years	81 (48.2%)	779 (39.9%)
26–30 years	66 (39.3%)	702 (35.9%)
31–35 years	21 (12.5%)	472 (24.2%)
Socioeconomic index for advantage and disadvantage (quintile)		
1 (most disadvantaged)	<5	159 (7.8%)
2	<5	294 (14.5%)
3	0 (0%)	369 (18.2%)
4	27 (15.3%)	292 (14.4%)
5 (most advantaged)	136 (77.3%)	891 (43.8%)
Unknown	8 (4.5%)	28 (1.4%)
Remoteness category (MMM)		
Metropolitan (MMM 1)	176 (100.0%)	1,587 (78.1%)
Regional centres (MMM 2)	0 (0%)	30 (1.5%)
Large rural town (MMM 3)	0 (0%)	212 (10.4%)
Medium rural town (MMM 4)	0 (0%)	104 (5.1%)

Characteristic	ACT n=176[1]	NSW n=2,033[1]
Small rural town (MMM 5)	0 (0%)	100 (4.9%)
Remote communities (MMM 6)	0 (0%)	0 (0%)
Very remote communities (MMM 7)	0 (0%)	0 (0%)
Employment[1]		
Working full-time	88 (58.3%)	1,054 (65.9%)
Working part-time	46 (30.5%)	419 (26.2%)
Not in labour force / unemployed	10 (6.6%)	42 (2.6%)
Other	7 (4.6%)	84 (5.3%)
Level of education[1]		
Year 10 equivalent or below	<5	67 (4.2%)
Year 12 equivalent	43 (28.5%)	395 (24.7%)
Further education	104 (68.9%)	1,089 (68.1%)
Prefer not to say	<5	48 (3.0%)
Blood pressure		
Mean systolic blood pressure (mmHg) mean (SD)	120 (11)	118 (11)
Mean diastolic blood pressure (mmHg) mean (SD)	79 (9)	78 (9)
BMI		
Underweight: < 18.5	11 (6.25%)	50 (2.5%)
Normal Weight: 18.5–24.9	130 (58.5%)	893 (43.9%)
Overweight: 25.0–29.9	30 (17.0%)	304 (15.0%)
Obese: >= 30	6 (3.4%)	162 (8.0%)
Missing	29 (14.8%)	624 (30.7%)
Referred to GP		
Total consultations resulting in GP referral	6 (3.4%)	130 (6.4%)
Based on screening questions	<5	68 (3.3%)
Based on clinical measurements	<5	36 (1.8%)
Other referral criteria[2]	0 (0%)	26 (1.3%)
Medication supplied		
COC	158 (89.8%)	1,746 (85.9%)
POP	11 (6.3%)	135 (6.6%)
Not supplied	7 (4.0%)	152 (7.5%)

SD=standard deviation

[1] *n (%) data available for survey responders only.*
[2] *See Appendix 1 for referral criteria.*

Appendix Table 3-1-5: Baseline characteristics by remoteness category (Monash Modified Model, MMM)

	Metropolitan n=1,543	Regional Centre n=29	Large rural town n=192	Medium rural town n=98	Small rural town n=84
Mean age (SD)	26 (5)	25 (5)	25 (5)	26 (5)	25 (5)
Agre group					
18–25 years	718 (46.5%)	16 (55.2%)	104 (54.2%)	45 (45.9%)	51 (60.7%)
26–30 years	526 (34.1%)	10 (34.5%)	51 (26.6%)	30 (30.6%)	19 (22.6%)
31–35 years	299 (19.4%)	<5	37 (19.3%)	23 (23.5%)	14 (16.7%)
Employment[1]					
Working full-time	819 (65.8%)	9 (47.4%)	95 (62.5%)	41 (56.2%)	36 (59.0%)
Working part-time	324 (26.0%)	7 (36.8%)	41 (27.0%)	25 (34.2%)	21 (34.4%)
Not in labour force / unemployed	40 (3.2%)	<5	<5	<5	<5
Other	62 (5.0%)	2 (10.5%)	12 (7.9%)	5 (6.8%)	<5
Level of education[1]					
Year 10 equivalent or below	37 (3.0%)	<5	6 (3.9%)	8 (11.0%)	8 (13.1%)
Year 12 equivalent	266 (21.4%)	8 (42.1%)	55 (36.2%)	34 (46.6%)	26 (42.6%)
Further education	907 (72.9%)	7 (36.8%)	85 (55.9%)	28 (38.4%)	25 (41.0%)
Prefer not to say	35 (2.8%)	<5	6 (3.9%)	<5	<5
Blood pressure					
Mean systolic blood pressure (mmHg) (SD)	118 (11)	118 (6)	119 (11)	121 (12)	119 (10)
Mean diastolic blood pressure (mmHg) (SD)	78 (9)	79 (5)	79 (9)	79 (9)	78 (7)
BMI					
Underweight: < 18.5	48 (3.1%)	<5	6 (3.1%)	<5	<5
Normal Weight: 18.5–24.9	816 (52.9%)	16 (55.2%)	73 (38.0%)	32 (32.7%)	25 (29.8%)
Overweight: 25.0–29.9	245 (15.9%)	<5	42 (21.9%)	22 (22.4%)	17 (20.2%)
Obese: >= 30	117 (7.6%)	<5	26 (13.5%)	14 (14.3%)	6 (7.1%)
Missing	317 (20.5%)	7 (24.1%)	45 (23.4%)	28 (28.6%)	33 (39.3%)
Referred to GP					
Total participants referred to GP	96 (6.2%)	<5	20 (10.4%)	10 (10.2%)	6 (7.1%)
Based on screening questions	52 (3.4%)	<5	11 (5.7%)	<5	<5
Based on clinical measurements	28 (1.8%)	0 (0%)	6 (3.1%)	<5	<5
Based on referral criteria[2]	16 (1.0%)	<5	<5	<5	<5
Medication supplied					

	Metropolitan n=1,543	Regional Centre n=29	Large rural town n=192	Medium rural town n=98	Small rural town n=84
COC	1,319 (85.5%)	26 (89.7%)	158 (82.3%)	85 (86.7%)	74 (88.1%)
POP	103 (6.7%)	0 (0%)	15 (7.8%)	6 (6.1%)	<5
Not supplied	121 (7.8%)	<5	19 (9.9%)	7 (7.1%)	6 (7.1%)
Number of consultations					
1	1,360 (88.1%)	28 (96.6%)	174 (90.6%)	92 (93.9%)	71 (84.5%)
2	150 (9.7%)	<5	16 (8.3%)	6 (6.1%)	9 (10.7%)
3	30 (1.9%)	0 (0%)	<5	0 (0%)	<5
4	<5	0 (0%)	0 (0%)	0 (0%)	0 (0%)

[1] *n (%) data available for survey responders only.*
[2] *See Appendix 1 for referral criteria.*

Appendix Table 3-1-6: Baseline characteristics by follow-up response status

Characteristic	Non-Responder n=396[1]	Responder n=1,550[1]
Mean age (years (SD))	26 (5)	26 (5)
Age group		
18–25 years	199 (50.3%)	735 (47.4%)
26–30 years	118 (29.8%)	518 (33.4%)
31– 35 years	79 (19.9%)	297 (19.2%)
Remoteness category (MMM)		
Metropolitan (MMM 1)	298 (75.3%)	1,245 (80.3%)
Regional centres (MMM 2)	10 (2.5%)	19 (1.2%)
Large rural town (MMM 3)	40 (10.1%)	152 (9.8%)
Medium rural town (MMM 4)	25 (6.3%)	73 (4.7%)
Small rural town (MMM 5)	23 (5.8%)	61 (3.9%)
Remote communities (MMM 6)	0 (0%)	0 (0%)
Very remote communities (MMM 7)	0 (0%)	0 (0%)
Employment[1]		
Working full-time	--	1,000 (64.5%)
Working part-time	--	418 (27.0%)
Not in labour force / unemployed	--	49 (3.2%)
Other	--	83 (5.4%)
Level of education[1]		
Year 10 equivalent or below	--	61 (3.9%)
Year 12 equivalent	--	389 (25.1%)
Further education	--	1,052 (67.9%)

Characteristic	Non-Responder n=396[1]	Responder n=1,550[1]
Prefer not to say	--	48 (3.1%)
Blood pressure		
Mean systolic blood pressure (mmHg) mean (SD)	118 (11)	120 (12)
Mean diastolic blood pressure (mmHg) mean (SD)	78 (8)	79 (10)
BMI		
Underweight: < 18.5	12 (3.0%)	48 (3.1%)
Normal Weight: 18.5–24.9	159 (40.2%)	803 (51.8%)
Overweight: 25.0–29.9	63 (15.9%)	266 (17.2%)
Obese: >= 30	41 (10.4%)	124 (8.0%)
Missing	121 (30.6%)	309 (19.9%)
Referred to GP		
Total participants referred to GP	62 (15.7%)	72 (4.6%)
Participant referred to GP based on screening questions	33 (8.3%)	37 (2.4%)
Participant referred to GP based on clinical measurements	19 (4.8%)	20 (1.3%)
Participant referred to GP based on referral criteria[2]	10 (2.5%)	15 (1.0%)
Medication supplied		
COC	302 (76.2%)	1,360 (87.7%)
POP	24 (6.1%)	104 (6.7%)
Not supplied	70 (17.7%)	86 (5.5%)
Number of consultations		
1	369 (93.2%)	1,356 (87.5%)
2	24 (6.1%)	158 (10.2%)
3	<5	33 (2.1%)
4	0 (0%)	<5

[1] *n (%) data available for survey responders only.*
[2] *See Appendix 1 for referral criteria.*

Appendix Table 3-1-7: Participant experience responses

Overall, I am satisfied by the consultation provided by the pharmacist for resupply of my oral contraception (the pill)						
Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
69 (4%)	15 (1%)	23 (1%)	39 (2%)	116 (7%)	191 (11%)	1,297 (74%)
The staff at this pharmacy have the knowledge to answer my questions about my resupply of my oral contraception (the pill) or health						
Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
59 (3%)	10 (1%)	16 (1%)	56 (3%)	110 (6%)	204 (12%)	1,295 (74%)
I am confident that the pharmacy dispenses my resupply of the oral contraception (the pill) correctly						
Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
64 (4%)	6 (0%)	9 (1%)	20 (1%)	53 (3%)	143 (8%)	1,455 (83%)
I am satisfied with the amount of privacy I received at the pharmacy						
Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
58 (3%)	14 (1%)	25 (1%)	52 (3%)	117 (7%)	177 (10%)	1,307 (75%)
It was more convenient for me to obtain a resupply of my oral contraception (the pill) from a pharmacist compared with another care provider						
Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
84 (5%)	13 (1%)	17 (1%)	52 (3%)	65 (4%)	104 (6%)	1,415 (81%)
I think the care provided by the prescribing pharmacist for resupply of my oral contraceptive (the pill) was as good as my usual care						
Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
64 (4%)	14 (1%)	19 (1%)	59 (3%)	90 (5%)	163 (9%)	1,341 (77%)
The pharmacists allowed me an opportunity to be involved in making decisions about my care						
Strongly Disagree	Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Agree	Strongly Agree
58 (3%)	11 (1%)	19 (1%)	74 (4%)	98 (6%)	192 (11%)	1,298 (74%)

Appendix Table 3-1-8: Follow-up at day 7 post-pharmacy consultation by OCP type (n=1,751 consultations)

	Supplied COC n=1,544	Supplied POP n=119	Not supplied n=88
OCP re-supply type	1,519 (98.4%)	118 (99.2%)	29 (33.0%)
Reported taking the pill as recommended	1,443 (93.5%)	112 (94.2%)	28 (31.8%)
Proportion reporting cost as a barrier to using this service again			
Yes	126 (8.2%)	12 (10.1%)	10 (11.4%)
Maybe	212 (13.7%)	17 (14.3%)	11 (12.5%)
No	1,206 (78.1%)	90 (75.6%)	67 (76.1%)
Service fees (mean (SD))[1]	27 (20)	47 (37)	13 (23)

Note: Service fees were related to medication costs only in NSW and consultation plus medication costs in ACT.

Appendix Table 3-1-9: Number of participants with administrative data and the number of months observed

Length of time (minimum follow-up)	Hospital and emergency data	PBS and MBS data (approx.)
Latest available date	30 June 2024	31 December 2024
Total consenting	1946 (100%)	1841 (94.6%)
No administrative data	368	-
Less than 1 month	1578	1841
1 month	1447	1841
2 months	1316	1841
3 months	1166	1841
4 months	974	1746
5 months	817	1632
6 months	645	1497
7 months	422	1367
8 months	258	1239
9 months	99	1084

Appendix Table 3-1-10: Short- and long-term trends in GP, ED and hospital utilisation by referred status

	Not referred (n=1812)[1]						Referred (n=134)[1]					
	Pre intervention[2]	**Post intervention[2]**	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Pre intervention**	**Post intervention**	**Week 1**	**Week 2**	**Week 3**	**Week 4**
Proportion of days covered with an OC[3]	0.63 (0.41)	0.88 (0.25)					0.40 (0.45)	0.34 (0.45)				
Proportion with OCP days covered >80% (n, %)	786 (45.68%)	1,177 (68.42%)					38 (29.89%)	31 (24.32%)				
GP Consultations[3]	35.69 (32.61)	33.21 (44.79)	7.29 (34.32)	7.97 (34.47)	7.41 (31.74)	7.79 (31.87)	38.39 (36.98)	44.36 (48.35)	21.90 (46.89)	10.11 (35.19)	15.16 (41.04)	10.11 (35.19)
STI tests[3]	2.41 (4.53)	2.32 (8.07)	0.31 (5.92)	0.37 (6.49)	0.62 (9.90)	0.44 (7.00)	2.20 (3.81)	2.95 (10.28)	2.53 (16.76)	0.00 (0.00)	0.00 (0.00)	3.37 (23.73)
Hospitalisations[3]	0.62 (2.77)	0.35 (3.90)	0.11 (3.32)	0.17 (4.07)	0.06 (2.35)	0.06 (2.35)	0.93 (3.18)	0.62 (3.77)	0.75 (8.64)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Potential pill related hospitalisations[3]	0.02 (0.81)	0.03 (0.88)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Emergency presentations[3]	1.87 (5.51)	1.01 (5.67)	0.28 (6.21)	0.44 (6.63)	0.17 (4.07)	0.11 (3.32)	3.05 (7.05)	2.49 (10.12)	0.75 (8.64)	0.00 (0.00)	0.00 (0.00)	0.75 (8.64)
Low acuity emergency presentations[3,4]	0.01 (0.28)	0.00 (0.00)	0.22 (5.75)	0.33 (5.75)	0.11 (3.32)	0.17 (5.25)	0.06 (0.72)	0.00 (0.00)	0.75 (8.64)	0.00 (0.00)	0.00 (0.00)	0.75 (8.64)
Potential pill related emergency presentations[3]	1.43 (4.57)	0.69 (4.14)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	2.80 (6.85)	2.36 (10.04)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00)

1. *Denominator varies depending on dataset used.*
2. *For MBS and PBS data the pre-intervention period was 36 months. For hospital data the pre-consultation period was 12 months. For all data sources the post-intervention period was up to 6 months post-consultation.*
3. *Mean (SD) per month per 100 people.*
4. *Only NSW data included. Triage data to assess acuity status are not available for ACT.*

Adverse Events Summary

Appendix Table 3-1-11: Adherence to clinical management protocol

		COC n= 1,904	POP n= 196	Total consultations n= 2,209
Red*	Total	47 (2.5%)	1 (0.5%)	48 (2.2%)
	Referred to GP*	38 (2.0%)	1 (0.5%)	39 (1.8%)
	Resupplied OC	0 (0%)	0 (0%)	0 (0%)
Orange	Total	9 (0.5%)	0 (0%)	9 (0.5%)
	Referred to GP†	4 (0.2%)	0 (0%)	4 (0.2%)
	Resupplied OC	9 (0.5%)	0 (0%)	9 (0.5%)

** Please see Chapter 7 Overall Discussion where the free text reasons for not referring are analysed.*
† See Appendix 2.2 for the clinical criteria for each colour category.

Self-reported adverse events

At the 7-day follow-up, participants reported side-effects in 6 consultations, possible side effects included prolonged bleeding, increased appetite, more acne than with usual pill, nausea, headache or mood swings.

Appendix Table 3-1-12: Hospital admissions, Emergency department presentations, MBS pathology services for STIs

	Pre-consultation[1,2]	Post-consultation[1,2]	p-value
GP consultations[3]	35.86 (28.53)	33.96 (40.89)	0.03
STI tests[3]	2.39 (4.14)	2.36 (7.72)	0.84
Hospitalisations[3]	0.64 (2.80)	0.37 (3.89)	<0.01
Potential pill related hospitalisations[3]	0.02 (0.78)	0.03 (0.84)	0.78
Emergency presentations[3]	1.95 (5.64)	1.11 (6.09)	<0.01
Low acuity emergency presentations[3, 4]	0.01 (0.33)	0.00 (0.00)	0.08
Potential pill related emergency presentations[3]	1.53 (4.77)	0.81 (4.80)	<0.01

Notes:

1. *Denominator varies depending on dataset used.*
2. *For MBS and PBS data the pre-intervention period was 36 months. For hospital data the pre-consultation period was 12 months. For all data sources the post-intervention period was up to 6 months post-consultation.*
3. *Mean (SD) per month per 100 people.*
4. *Only NSW data included. Triage data to assess acuity status are not available for ACT.*

Serious adverse events

A serious adverse event was defined as any potential pill-related adverse event that involves either an emergency presentation or a hospitalisation. These are reported in the table above.

Chapter 4

Appendix 4.1: Supplementary tables

Appendix Table 4-1-1: Approach to valuation - Consultation costs

Pathway	Patient Costs	Government	Source Patient Costs	Source Government
Pharmacy	Costs specified in guidance for community pharmacists in Queensland (14) will be used to determine the likely range of fees patients may be charged.	Current business as usual (BAU) has no government subsidy	Chronic Conditions Pilot Handbook. Queensland Health [122]	Expanded scope pharmacy services – Information for pharmacists [190]
GP	Values reported in the Australian Institute of Health and Welfare (AIHW) report. We will report average, minimum, and maximum values. Minimum and maximum costs determined by value reported for the highest and lowest average costs for local government authorities (LGAs). A proportion will be assigned a patient cost of $0 to account for bulk billed General Practitioner (GP) appointments.	Medicare Benefit Schedule (MBS) items for GP appointment accounting for appointment type. Costs assigned to the Commonwealth Government.	AIHW report [132] and RACGP report [191] on costs of GP attendance	MBS website (e.g., Items 23[1], 24[2], and 36[3]). AIHW report [132] and RACGP report [191] on costs of GP attendance.
GP online	Market price, calculated as the average of listed costs from a sample of GP online websites. We will report average, minimum, and maximum values.	As MBS rebates/bulk billing are unlikely, due to eligibility requirements, government cost will be considered $0.	See Table 4.1.3	Services Australia [133]

[1] *https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=23*
[2] *https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=24&qt=ItemID*
[3] *https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=36&qt=ItemID*

Appendix Table 4-1-2: Approach to valuation – Medication costs

Pathway	Patient Costs	Government	Source Patient Costs	Source Government
Pharmacy	Base cost for each prescription medication will be the general patient charge plus the Max safety net value listed on the MBS. Range will be estimated by market price for private prescriptions with reference to listed costs from a sample of pharmacy websites.	Pharmacists are private prescribers, as such the medication is not eligible for a PBS subsidy. Government cost will be considered $0.	MBS website for medications listed in the protocol, and pharmacy websites.	MBS website for medications listed in the protocol.
GP	The mean value will be calculated from the general patient charge listed on PBS for the relevant medications. Range will be determined by lowest and highest values listed on the PBS for the same.	The average of relevant PBS items, applying 100% of the listed benefit. If relevant, the average, minimum, and maximum will be reported. Costs assigned to the Commonwealth Government.	MBS website for medications listed in the protocol.	MBS website for medications listed in the protocol.
GP online	Base cost for each prescription medication will be the general patient charge plus the Max Safety Net value listed on the MBS. Range will be estimated by market price for private prescriptions calculated as the average of listed costs from a sample of pharmacy websites.	Pharmacists are private prescribers, as such the medication is not eligible for a Pharmaceutical Benefits scheme (PBS) subsidy. Government cost will be considered $0.	MBS website, pharmacy websites for medications listed in the trial protocol.	MBS website for medications listed in the protocol.

Appendix Table 4-1-3: Sources used to value patient costs for online GP service consult

Business name	Appointment type	Cost ($)	Website
Instant scripts		49.00	instantscripts.com.au/gp-online
Updoc	Standard	49.95	updoc.com.au
	Priority	99.95	
Hola Health	Standard	39.00	hola.health
	Long	49.00	
Doctors on demand	Standard	62.95	doctorsondemand.com.au/
	After hours	92.95	
My telehealth clinic		39.95	https://mytelehealthclinic.com.au
Teledoc Australia		45.00	https://teledocaustralia.com.au/
Qoctor.com.au		49.99	https://www.qoctor.com.au/online-gp-telehealth/
Medmate		39.90	https://medmate.com.au/frequently-asked-questions/
Teldoc	Standard	49.00	https://teldoc.com.au/price/
	Weekend/ public holiday	69.00	
	Mean	**56.59**	
	Minimum	**39.00**	
	Maximum	**99.95**	

Appendix Table 4-1-4: Costs and sources for combined oral contraceptives (COC)

Medication	DPMQ	Max safety net	General patient charge	Additional brand charge	Diff b/t DMPQ & general charge	Patient PBS eligible (General Patient Charge)	Patient Not PBS eligible (DMPQ)	Link
Levonorgestrel 100 µg + ethinylestradiol 20 µg	19.9	21.38	24.17	—	-4.27	24.17	19.9	https://www.pbs.gov.au/medicine/item/2416E
Levonorgestrel 150 µg + ethinylestradiol 30 µg	18.2	19.68	22.47	5.66	-4.27	22.47	18.2	https://www.pbs.gov.au/medicine/item/1394J
Levonorgestrel 50 µg + ethinylestradiol 30 µg	21.51	22.99	25	13.56	-3.49	25	21.51	https://www.pbs.gov.au/medicine/item/1392G
Levonorgestrel 75 µg + ethinylestradiol 40 µg								
Levonorgestrel 125 µg + ethinylestradiol µg								
Norethisterone 1 mg + ethinylestradiol 35 µg	25.14	25	25	—	0.14	25	25.14	https://www.pbs.gov.au/medicine/item/2775C
Norethisterone 500 µg + ethinylestradiol 35 µg	25.14	25	25	—	0.14	25	25.14	https://www.pbs.gov.au/medicine/item/2774B
			Average (min, max)		0.00 (0.00, 0.14)	24.33 (22.47, 25.00)	21.98 (18.20, 25.14)	

DMPQ=Dispensed Price for Maximum Quantity.

Appendix Table 4-1-5: Costs and sources for progestogen-only pill (POP)

Medication	DPMQ	Max safety net	General patient charge	Additional brand charge	Diff b/t DMPQ & general charge	Patient PBS eligible (General Patient Charge)	Patient Not PBS eligible (DMPQ)	Link
Levonorgestrel 30 µg	21.49	22.97	25	—	-3.51	25	21.49	https://www.pbs.gov.au/medicine/item/2913H
Drospirenone 4 mg x 28	78.96	25	25	—	53.96	25	78.96	https://www.pbs.gov.au/medicine/item/14875X
Drospirenone 4 mg 3 x 28	62.66	25	25	—	37.66	25	62.66	https://www.pbs.gov.au/medicine/item/14931W
Drospirenone 4 mg 4 x 28	78.95	25	25	—	53.95	25	78.95	https://www.pbs.gov.au/medicine/item/14791L
			Average (min, max)		35.52 (0.00, 53.96)	25	60.52 (21.49, 78.96)	

Appendix Table 4-1-6: Detailed total health care costs for oral contraceptive pills (OCP) resupply (AUD 2025 millions)

	Pre-PATH-OC		PATH-OC		Difference	
	Commonwealth	**Patient**	**Commonwealth**	**Patient**	**Commonwealth**	**Patient**
Pharmacy	—	—	—	14.7 [13.9, 15.4]	—	14.7 [15.4, 13.9]
GP*	87.9 [62.0, 115.8]	54.7 [49.9, 60.1]	76.1 [54.1, 101.8]	47.6 [43.4, 52.3]	-11.8 [-49.6, 26.8]	-7.1 [-14.1, 0.2]
Online GP†	0.9 [0.7, 1.0]	31.5 [24.6, 40.6]	0.8 [0.6, 0.9]	27.4 [21.5, 35.2]	-0.1 [-0.3, 0.1]	-4.1 [-15.3, 6.6]
			Total difference		**-11.9 [-49.5, 26.6]**	**3.5 [-16.2, 9.9]**

** Including MBS subsidy eligible telehealth.*
† Consult not eligible for MBS subsidy.

Appendix Table 4-1-7: Detailed total health care costs for resupply of OCP: Sensitivity Analysis 1 various pharmacy consult fees (AUD 2025 millions)

	Pre-PATH-OC		PATH-OC		Difference	
	Commonwealth	**Patient**	**Commonwealth**	**Patient**	**Commonwealth**	**Patient**
Pharmacy	—	—	—	14.2 [13.5, 15.0]	—	14.2 [13.5, 15.0]
GP*	87.9 [62.0, 115.8]	54.7 [49.9, 60.1]	76.1 [54.1, 101.8]	47.6 [43.4, 52.3]	-11.8 [-49.6, 26.8]	-7.1 [-14.1, 0.2]
Online GP†	0.9 [0.7, 1.0]	31.5 [24.6, 40.6]	0.8 [0.6, 0.9]	27.4 [21.5, 35.2]	-0.1 [-0.3, 0.1]	-4.1 [-15.3, 6.6]
			Total difference		**-11.9 [-49.5, 26.6]**	**3.0 [-10.4, 15.7]**

** Including MBS subsidy eligible telehealth.*
† Consult not eligible for MBS subsidy.

Appendix Table 4-1-8: Detailed total health care costs for resupply of OCP: Sensitivity Analysis 2 various pharmacy consult fees incl. $0 (AUD 2025 millions)

	Pre-PATH-OC		PATH-OC		Difference	
	Commonwealth	**Patient**	**Commonwealth**	**Patient**	**Commonwealth**	**Patient**
Pharmacy	—	—	—	13.3 [12.6, 14.0]	—	13.3 [12.6, 14.0]
GP*	87.9 [62.0, 115.8]	54.7 [49.9, 60.1]	76.1 [54.1, 101.8]	47.6 [43.4, 52.3]	-11.8 [-49.6, 26.8]	-7.1 [-14.1, 0.2]
Online GP†	0.9 [0.7, 1.0]	31.5 [24.6, 40.6]	0.8 [0.6, 0.9]	27.4 [21.5, 35.2]	-0.1 [-0.3, 0.1]	-4.1 [-15.3, 6.6]
			Total difference		**-11.9** **[-49.5, 26.6]**	**2.1** **[-14.9, 11.4]**

** Including MBS subsidy eligible telehealth.*
† Consult not eligible for MBS subsidy.

Appendix Table 4-1-9: Detailed total health care costs for resupply of OCP: 10% pharmacy uptake (AUD 2025 millions)

	Pre-PATH-OC		PATH-OC		Difference	
	Commonwealth	**Patient**	**Commonwealth**	**Patient**	**Commonwealth**	**Patient**
Pharmacy	—	—	—	11.8 [8.8, 15.5]	—	11.8 [15.5, 8.8]
GP*	87.9 [62.0, 115.8]	54.7 [49.9, 60.1]	79.1 [56.1, 105.3]	49.3 [44.8, 54.3]	-8.8 [-45.9, 29.7]	-5.5 [-12.6, 1.4]
Online GP†	0.9 [0.7, 1.0]	31.5 [24.6, 40.6]	0.8 [0.7, 0.9]	28.4 [22.2, 36.4]	-0.1 [-0.3, 0.1]	-3.1 [-14.6, 7.7]
			Total difference		**- 8.9** **[-46.0, 29.6]**	**3.3** **[-10.7, 16.4]**

** Including MBS subsidy eligible telehealth.*
† Consult not eligible for MBS subsidy.

Appendix Table 4-1-10: Detailed total health care costs for resupply of OCP: 25% pharmacy uptake (AUD 2025 millions)

	Pre-PATH-OC		PATH-OC		Difference	
	Commonwealth	**Patient**	**Commonwealth**	**Patient**	**Commonwealth**	**Patient**
Pharmacy	—	—	—	29.5 [21.9, 38.8]	—	29.5 [21.9, 38.8]
GP*	87.9 [62.0, 115.8]	54.7 [49.9, 60.1]	66.0 [46.5, 87.2]	41.0 [37.4, 45.2]	-21.9 [-57.5, 13.8]	-13.7 [-7.1, -20.5]
Online GP†	0.9 [0.7, 1.0]	31.5 [24.6, 40.6]	0.7 [0.5, 0.8]	23.7 [18.6, 30.4]	-0.2 [-0.4, 0.0]	-7.8 [-18.5, 2.1]
			Total difference		**-22.1 [-57.7, 13.6]**	**8.0 [7.4, 23.1]**

** Including MBS subsidy eligible telehealth.*
† Consult not eligible for MBS subsidy.

Appendix Table 4-1-11: Detailed total health care costs for resupply of OCP: 50% pharmacy uptake (AUD 2025 millions)

	Pre-PATH-OC		PATH-OC		Difference	
	Commonwealth	**Patient**	**Commonwealth**	**Patient**	**Commonwealth**	**Patient**
Pharmacy	—	—	—	59.0 [44.2, 77.4]	—	59.0 [44.2, 77.4]
GP*	87.9 [62.0, 115.8]	54.7 [49.9, 60.1]	43.8 [31.0, 58.5]	27.4 [24.9, 30.2]	-44.1 [-76.1, -14.2]	-27.3 [-33.3, -21.7]
Online GP†	0.9 [0.7, 1.0]	31.5 [24.6, 40.6]	0.4 [0.3, 0.6]	15.8 [12.4, 20.3]	-0.4 [-0.6, 0.3]	-15.7 [-25.4, -7.3]
			Total difference		**-44.5 [-76.5, -14.5]**	**6.0 [-3.7, 37.1]**

** Including MBS subsidy eligible telehealth.*
† Consult not eligible for MBS subsidy.

Chapter 5

Appendix 5.1: PCFs' checklist for the identification and evaluation of implementation determinants

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UTI, OC and DERM Main Study PCF Checklist

Pharmacy Name	
Pharmacy Category	☐0-1 ☐2-5 ☐6-12 ☐12+
Consultation Rate and Response	Does this pharmacy have >5 consultations with 0% response rate? ☐ Yes ☐ No
Date of Visit	

Consultation room checklist- NSW UTI, OC and Skin Trials

Consult room	Met *(Yes/No)*	Additional Measures that need to be taken prior to service commencement *(N/A or stipulate change required)*
Mandatory requirements		
Must not be used as a dispensary, storeroom, staff room or retail area		
Must provide adequate privacy		
Must have adequate lighting		
Must be maintained at a comfortable ambient temperature		
Must have a hand sanitisation facility		
Must have ready access to a hand washing facility		
Must have sufficient floor area		
Must ensure the area is clear of equipment and furniture to accommodate the person receiving the consultation and an accompanying person		
Must ensure area allows the pharmacist adequate space to manoeuvre		

Background information:

		Answer	CFIR Factor[1]
1	**Does the consultation room comply with the NSW Health Authority for the UTI, OC and Skin Trial?** *if no, please take photos of different aspects (position in pharmacy and consult area) and attach to form.*	☐Yes ☐No	Inner Setting -> Structural Characteristics -> Physical infrastructure
2	**Confirm the pharmacy has MedAdvisor operating for both UTI, OC and Skin**	☐Yes ☐No	Inner Setting -> Structural Characteristics -> IT Infrastructure
3	**Does the pharmacist have any issues operating MedAdvisor?** – *If yes, please specify.*	☐Yes ☐No	Individuals -> Innovation Deliverers -> Capability
4	**Has the old QR Code been replaced with the new QR code and is it visible?**	☐Yes ☐No	Inner Setting -> Available resources -> Materials & Equipment
5	**Have you confirmed the pharmacist understands the e-consent process? (Patient scans QR Code, consents and is sent a verification code that must be entered in MedAdvisor)**	☐Yes ☐No	Individuals -> Innovation Deliverers -> Capability
6	**Is the pharmacy offering the services during all operating hours?** *If no, why is this?*	☐Yes ☐No	Implementation Process -> Engaging -> Innovation Recipients
7	**Have all pharmacists participating in the UTI, OC and DERM trial at the pharmacy completed the required training modules? (UTI/OC/DERM Module PSA or ACP AND UoN education modules required)** - UTI Module – PSA OR ACP - UoN education modules (UTI)	☐Yes ☐No ☐Yes ☐No	Individuals -> Innovation Deliverers -> Capability

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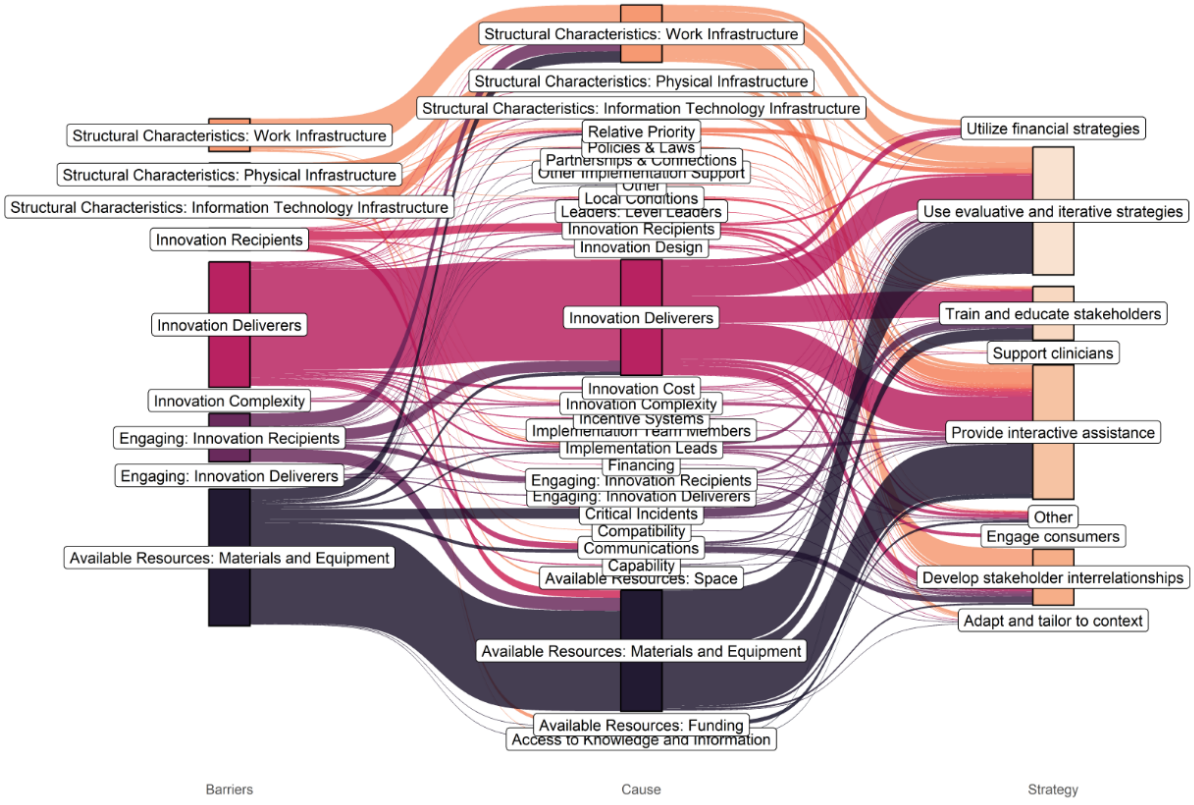
	- OC Module – PSA OR ACP - UoN education modules (OC) - DERM Module- PSA OR ACP - UoN education modules (DERM) *If no, please inform that pharmacist immediately that they are not permitted to deliver the service until they have completed the required training.*		☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No	
	Please record the name of the pharmacist(s) who have completed the required training (certificates cited):	Name of Pharmacist(s)	Certificate cited: UTI / OC / DERM	
8	**Service Delivery Fidelity** Internal info only. DO NOT share any trial data on consultations or response rates. ☐ UTI ☐ OC ☐ DERM **Review consultation process** Does the pharmacist use appropriate counselling techniques to determine patient eligibility (e.g., open ended questions)?		☐Yes ☐No	
	Application of the Clinical Management Protocol Does the pharmacist follow the clinical management protocol? Checking for allergies to antimicrobials? Discussing symptom improvement within 48hr and referral/follow-up?		☐Yes ☐No ☐Yes ☐No ☐Yes ☐No	
	Patient instructions and counselling Does the pharmacist communicate the consultation with the patients GP? *If yes, please select option.* Does the pharmacist remind the patient of the 7 day follow up survey?		☐Yes ☐No ☐ Letter printed (patient) ☐Email ☐Fax ☐Other ☐Yes ☐No	
9	**General observations/other notes have you made, i.e., *Have you identified any other barriers/facilitators?*** *If yes, please specify and record in REDCAP Implementation database.*		☐Yes ☐No	

Appendix 5.2: Sankey diagrams to link implementation barriers and strategies during the 12 months of the study



Appendix 5.3: Other implementation determinants (CFIR classification) and implementation strategies (ERIC classification) identified

List of other implementation barriers identified (n=351, 16.9%)

- Access to Knowledge and Information.
- Assessing Needs: Innovation Recipients.
- Available Resources: Funding.
- Available Resources: Space.
- Communications.
- Doing.
- Engaging: Innovation Deliverers.
- Financing.
- Implementation Facilitators.
- Implementation Leads.
- Implementation Team Members.
- Innovation Trialability.
- Incentive Systems.
- Innovation Adaptability.
- Innovation Complexity.
- Innovation Cost.
- Innovation Design.
- Innovation Relative Advantage.
- Leaders: High Level Leaders.
- Local Attitudes.
- Local Conditions.
- Mission Alignment.
- Other Implementation Support.
- Partnerships & Connections.
- Planning.
- Policies & Laws.
- Reflecting & evaluating: Implementation.
- Relational Connections.
- Relative Priority.

List of other implementation facilitators identified (n=173, 4.2%)

- Access to Knowledge and Information.
- Assessing Needs: Innovation Deliverers.
- Assessing Needs: Innovation Recipients.
- Available Resources: Funding.
- Communications.
- Compatibility.
- Critical Incidents.
- Culture: Recipient Centeredness.
- Doing.
- Engaging: Innovation Deliverers.
- Implementation Leads.
- Implementation Team Members.

- Incentive Systems.
- Innovation Complexity.
- Innovation Design.
- Innovation Recipients.
- Local Conditions.
- Mission Alignment.
- Other Implementation Support .
- Partnerships & Connections.
- Relational Connections.

List of other implementation strategies identified (n=332, 26.7%)

- Assess for readiness and identify barriers and facilitators.
- Build a coalition.
- Change physical structure and equipment.
- Capture and share local knowledge.
- Centralize technical assistance.
- Conduct local consensus discussions.
- Conduct ongoing training.
- Create a learning collaborative.
- Create new clinical teams.
- Develop educational materials.
- Fund and contract for the clinical innovation.
- Identify and prepare champions.
- Increase demand.
- Model and simulate change.
- Obtain formal commitments.
- Organize clinician implementation team meetings.
- Promote network weaving.
- Provide clinical supervision.
- Provide local technical assistance.
- Provide ongoing consultation.
- Purposefully reexamine the implementation.
- Recruit, designate, and train for leadership.
- Revise professional roles.
- Stage implementation scale up.
- Tailor strategies.

Chapter 6

Appendix 6.1: Study protocol for the qualitative component

CSIRO PUBLISHING

ARTICLE
https://doi.org/10.1071/AH24110

Australian Health Review

ahha

Aboriginal and Torres Strait Islander peoples' perspectives on community pharmacists prescribing: a co-designed study protocol

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Received: 15 November 2023
Accepted: 3 June 2024
Published: 25 June 2024

Cite this: Cross C *et al.* (2025) Aboriginal and Torres Strait Islander peoples' perspectives on community pharmacists prescribing: a co-designed study protocol. *Australian Health Review* **49**, AH24110. doi:10.1071/AH24110

ABSTRACT

Background. In Australia, medications can be prescribed by medical practitioners, dentists, nurses, and dispensed by pharmacists. Until recently, pharmacists have been limited to prescribing Schedule 2 and 3 medications, and optometrists, podiatrists, and nurse practitioners can prescribe medications under their scope of practice in some areas of Australia. Recently, the New South Wales (NSW) Government initiated a trial where approved pharmacists in NSW and Australian Capital Territory have an expanded scope of practice to prescribe further medications for urinary tract infections, dermatology conditions (mild to moderate atopic dermatitis, herpes zoster (shingles), impetigo, and mild plaque psoriasis), and resupply of contraceptives. This protocol is for a sub-study of the larger research trial and will explore the perspectives of Aboriginal and Torres Strait Islander peoples and communities including clinicians, healthcare services, and community members about the expanded scope of pharmacists' practice. **Methods and analysis.** Yarning circles (group) and individual yarns (semi-structured interviews) will be conducted with leaders, clinicians working with Aboriginal and Torres Strait Islander peoples (general practitioners, nurses, Aboriginal health workers, community pharmacists), Aboriginal Elders, and community members to understand perspectives of the risks, benefits, opportunities, and issues associated with pharmacists prescribing for these specific conditions. Ethics approval was obtained through the Aboriginal Health and Medical Research Council of NSW. **Conclusion.** The findings of this sub-study will clarify Aboriginal and Torres Strait Islander peoples' unique perspectives, including perception of risks and opportunities.

Keywords: Aboriginal and Torres Strait Islander, Indigenous health, pharmacy prescribing.

Introduction

International and national context for pharmacist prescribing

In Australia, various non-medical professions have been granted expanded prescribing rights to enhance the accessibility of medicines and promote equity. This includes nurse practitioners, midwives, dentists, optometrists, and podiatrists, and each profession (excluding podiatrists) are able to prescribe medicines subsidised under the Pharmaceutical Benefits Scheme (PBS) within their scope of practice.[1] Medications for most conditions are subsidised by the Australian Government under the PBS, providing a cost-effective way for Australians to access a wide range of medicines (Pharmaceutical Benefits Scheme (PBS) | Home). Currently, Australia's healthcare system is facing a crisis due to a workforce shortage of general practitioners (GPs), nurses, and pharmacists, which is contributing to an increase in the time and resource demands on both primary and secondary health services.[2] The workforce shortage, and subsequent long wait times to see a GP, has made it difficult for many Australians to access diagnoses and prescriptions in a timely manner.[3]

Until recently, Australian pharmacists have been limited to prescribing Schedule 2 and 3 medications. This differs to other countries, where prescribing by pharmacists of certain medications and antibiotics has become routine practice, and there has been an overall positive impact in terms of improving patient outcomes, improving access to care, decreasing the workload of primary care physicians, and reducing the likelihood of antibiotic resistance. We did not find any peer-reviewed evidence of patient safety issues as a result of the expanded scope of practice for pharmacists.[4]

The New South Wales (NSW) Government recently initiated a trial to examine the statewide implementation, and the clinical and economic impact, of pharmacists to manage and prescribe medications for urinary tract infections, dermatological conditions (mild to moderate atopic dermatitis, herpes zoster (shingles), impetigo, and mild plaque psoriasis), and resupply of contraceptives.[5] In May 2023, the first stage of the trial was rolled out via a feasibility study in 100 community pharmacies across NSW. In July 2023, the trial was expanded to include over 1100 community pharmacies.[6] Concerns about the risks associated with an expanded scope of practice for pharmacists include: a potential conflict of interest for diagnosis and prescribing; pharmacists' knowledge and experience as a diagnostician;[7] and concerns that the push for the expanded scope of pharmacists may be motivated by commercial interests rather than patient wellbeing.[8] The evaluation of the trial being undertaken in NSW will examine these specific issues, including patient safety.[9]

Aboriginal and Torres Strait Islander peoples and access to medications

The PBS has been comparatively underused by Aboriginal and Torres Strait Islander peoples in Australia despite having higher mortality and morbidity rates than non-Indigenous Australians.[10] From July 2010, Aboriginal and Torres Strait Islander peoples were provided access to subsidised medications under the Close The Gap (CTG) PBS co-payment program which was designed to improve access for Aboriginal and Torres Strait Islander peoples to affordable medicines.[11] This has significantly improved access to medicines for Aboriginal and Torres Strait Islander peoples.[12] Aboriginal Community Controlled Health Organisations (ACCHOs) and other healthcare providers help facilitate access to CTG PBS medicines for Aboriginal and Torres Strait Islander patients and research shows the obvious health benefits of improving access generally.[13] The pharmacist direct prescribing pilot in NSW did not take any CTG into consideration; a substantial difference to getting a script from the doctor and having the medication discounted through CTG. It is not clear whether this is factored into the longer-term plan.

There will likely be specific benefits and risks that need to be considered and mitigated for Aboriginal and Torres Strait Islander peoples due to expanded scope of practice for pharmacists. Aboriginal and Torres Strait Islander peoples may face barriers accessing medicines including geographic and financial constraints, with many having complex chronic conditions and associated medication requirements that need to be monitored and managed.[14–16] While pharmacist prescribing has the potential benefits of improving patient access to medication and patient care, and more equitable access to healthcare,[17] consideration needs to be placed on ensuring mechanisms are in place to best ensure that pharmacies offering expanded scope of practice services are culturally safe spaces.

This study will explore the perceptions of Aboriginal and Torres Strait Islander community members, ACCHOs, and clinicians working with Aboriginal and Torres Strait Islander peoples about the risks and opportunities for Aboriginal and Torres Strait Islander peoples of expanded scope of practice for pharmacists. Specifically, it will examine the issues unique to Aboriginal and Torres Strait Islander peoples and explore how these could be managed and mitigated to increase safety and continuity of care. The primary aim of this research is to understand the perspectives of Aboriginal and Torres Strait Islander peoples and organisations in NSW regarding the expanded scope of pharmacists and including better understanding the risks, issues, and opportunities for Aboriginal and Torres Strait Islander peoples accessing medications through a community pharmacy and ways to optimise care. This study is a sub-study of a larger, separate study, the 'Expansion of the NSW Government-Sponsored Clinical Trial: Management of Urinary Tract Infections by Community Pharmacists to include oral contraception and management of minor skin conditions' (the Trial). This sub-study will operate independently from the Trial. The specific objectives of this sub-study are:

1. To understand the perspectives of Aboriginal and Torres Strait Islander peoples and organisations regarding pharmacists prescribing, as being trialled in NSW; and
2. To reflect and amplify these perspectives to researchers and policymakers.

Methods

Project design

Data collection will be conducted with leaders, clinicians working with Aboriginal and Torres Strait Islander peoples (GPs, nurses, Aboriginal health workers), Elders, and community members to understand the risks, benefits, opportunities, and issues associated with an increased scope for pharmacists prescribing for Aboriginal and Torres Strait Islander peoples and organisations. These yarns will be conducted until data saturation is reached. There is negligible risk for any individual, community, or Aboriginal-controlled health organisation, and the benefits are

potentially significant for informing the Trial to increase the likelihood that pharmacist practices are culturally safe and acceptable for Aboriginal and Torres Strait Islander peoples if implemented in policy.

Recruitment of communities and consent

Three ACCHOs in New South Wales will be invited to collaborate as partners, with their participation and leadership being pivotal to the success of the project. The research team has established longstanding partnerships with the ACCHOs involved in this study. The Modified Monash Model (MMM) is used to define whether a location is a city, rural, remote, or very remote. There are seven categories: Modified Monash (MM) category MM 1 through MM 7, with MM 1 being a major city and MM 7 being very remote.[18] One of the research sites will be very remote with an MM category of MM 7 (2019), a second site will be a rural community (MM 4 – 2019) and a third site will be regional (MM 3 – 2019).

After establishing partnerships with ACCHOs, we will seek their support in recruiting Aboriginal and Torres Strait Islander adults from the clinic, clinicians who work with Aboriginal and Torres Strait Islander peoples, and participants from the communities served by the ACCHOs, including Elders and other community members. We would be guided by the ACHHO as to participant numbers but would anticipate there being three to 12 people in each group, and between 15 and 30 participants per community. The yarning circles of the different groups will be separate, so as to avoid influence within feedback. The study will be described to those who express interest in participating, and a detailed participant information sheet and consent form will be provided to potential participants. Participants may withdraw their consent for the study without consequence to their treatment (if a community member/patient) or employment (if staff). Participants will be offered a A$25 voucher as an honorarium to thank them for their time.

Rambaldini Model of Collective Impact: our framework for co-design

The Rambaldini Model of Collective Impact (a co-design methodology with five stages) will be applied (Figs 1 and 2). The model is measurable and structured and requires sharing of power and resources.

The features of the model align with the National Health and Medical Research Council guidelines for conducting ethical research with Indigenous communities.[19] This model emphasises the collective, rather than individuals and hierarchies, aligns well with respectful engagement and decision making, and has enabled significant and measurable improvement to seemingly intractable problems.[20] The Rambaldini Model of Collective Impact[21] has been authenticated for health research with Indigenous communities and aligns with Indigenous ways of knowing, being, and doing. This model has been successfully used in translational research to improve Indigenous oral health,[22] Indigenous health workforce development,[23] and to detect and treat atrial fibrillation.[24]

Yarning circles

Yarning (group yarning circles and one-on-one yarns) will be applied as a key technique to collect, analyse, and interpret data. Yarning is a recognised and validated Indigenous research method for qualitative research which encourages respectful and honest interactions in a safe place to be heard

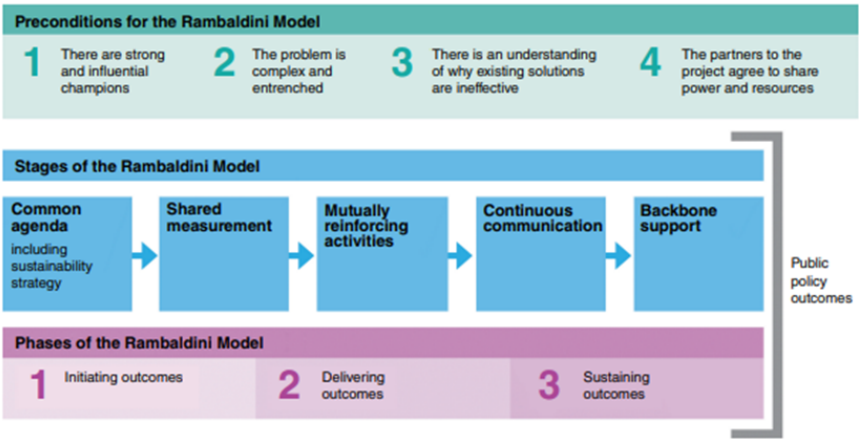

Fig. 1. The Rambaldini Model of Collective Impact.

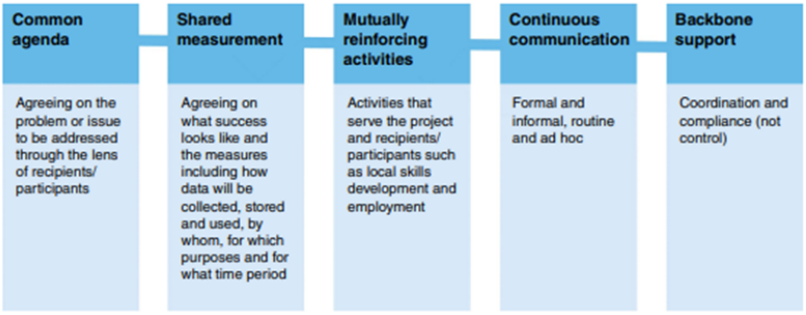

Fig. 2. Details regarding the stages of the Rambaldini Model of Collective Impact.

and to respond (Box A1, Appendix 1).[25] The yarning will be facilitated by Aboriginal and Torres Strait Islander investigators who will prompt the conversation with open-ended questions to stimulate discussion (Box A2, Appendix 1). Each yarning session will begin with a quick summary of the sub-study and knowledge check regarding the practice of pharmacists providing scripts directly to clients. However, the direction and contents of the discussions will be ultimately determined by the participants.

Once the initial yarning sessions with participants have been completed, the research team will consolidate and summarise the themes and generate draft findings based on these themes. The team will then present the themes and the draft findings to participants in a second round of yarns to check our analysis and provide the opportunity for further development of themes and findings. Respectful adherence to cultural protocols, obligations, and understanding the Indigenous ways of being, doing, and knowing, including knowledge sharing, mean that this process is often not a linear progression of data collection, analysis followed by the documentation of outcomes. See Box A3, Appendix 1 for sample prompts used for data and interpretation checking.

Dissemination

Once themes and recommendations are finalised, the findings will be amplified to the investigators on the Trial and to policymakers. In addition to publishing the findings in peer-reviewed journals, a checklist or other communication tool will be created to convey the findings to researchers and policymakers. The findings will also be shared through social media and other mechanisms recommended by participants.

Research governance

The Djurali Centre for Aboriginal and Torres Strait Islander Health Research and Education Research Advisory Panel provides governance, advice, and support to Djurali researchers. The Research Advisory Panel members ensure cultural oversight to each specific project.

Ethics

Ethics approval was obtained through the Aboriginal Health and Medical Research Council of NSW, Reference 2096/23: KG00193.

Discussion

This is a pragmatic study, interested in mitigating risk and creating safer and more timely access to treatment and medications through community pharmacy with the expanding scope of pharmacist practice. This subset of the study will operate independently from the broader study. It is not to intended to establish separate systems or requirements for Aboriginal and Torres Strait Islander peoples, but to better understand the opportunities and risks and how to better support pharmacists to provide culturally safe care, in the context of other primary healthcare services supporting Aboriginal and Torres Strait Islander peoples.

Fragmentation of primary healthcare is a major issue which disproportionately impacts Aboriginal and Torres Strait Islander peoples.[16] Careful attention will need to be paid to patient record management, collaboration between health providers, and ensuring all health providers have access to sufficient information to appropriately manage and refer a patient. Further compounding this is ensuring the affordability of care and medications.[26] However, the risks of fragmented care need to be weighed against the risks inherent to limited, delayed, or no access to timely primary healthcare. This study will inform the weighting of these risks and provide insights to balancing these risks in the interests of Aboriginal and Torres Strait Islander peoples and timely and safe access to care and medicines.

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Data availability. Data sharing is not applicable as no new data were generated or analysed during this study.

Conflicts of interest. There are no conflicts of interest to declare. Views expressed in this article are the views of the authors and are not necessarily the views of any other organisation they may be affiliated with at the time of publication.

Declaration of funding. This work was supported by the NSW Government.

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Appendix 1

Box A1. Yarning

Indigenous researchers use yarning circles and individual yarns to co-create knowledge. Research data are collected, analysed, and interpreted as part of this form of knowledge co-creation. Yarning will be an important co-design tool in this research. Using yarning circles for qualitative research is a recognised and validated Indigenous method.[27] In yarning circles, culturally safe facilitators provide discussion prompts and/or pose questions, inviting participants to respond to the prompts and/or questions. It is also possible for participants to reinterpret the prompts and/or questions in their own words. Participants in the yarning circle have ample time for non-structured discussion. As in the individual yarns, participants are invited to express their individual perspectives and reflect on their own experiences during one-to-one discussions.

Box A2. Sample prompts for initial yarns

The yarning circles and individual yarns initially explore the risks, opportunities, and issues Aboriginal and Torres Strait Islander peoples perceive to be associated with the Trial for Aboriginal and Torres Strait Islander peoples and organisations. Each yarning session will begin with a summary of the trial and a knowledge check of the participant/s regarding community pharmacists providing prescriptions directly to customers.

Prompts for the initial yarns may include:

What risks do you see for Aboriginal and Torres Strait Islander peoples if the pharmacists prescribed the following medications (xxxx) directly to customers?

Do you see any way to get around those risks? And if so, what needs to happen to keep Aboriginal and Torres Strait Islander peoples safe?

What opportunities do you see for Aboriginal and Torres Strait Islander peoples if this became normal practice?

What conditions or factors would ensure Aboriginal and Torres Strait Islander peoples benefited if this becomes normal practice?

If there was a significant difference in prices of medications via this scheme, would this influence whether you used the service?

What other concerns do you have about this?

Box A3. Themes and recommendations

The themes we gathered from the initial yarning are:

- What do you think about that finding?
- How do you think these findings apply in your community?
- What questions does that finding raise for you?
- What characteristics or conditions in this community must be considered when understanding these findings?

These are the recommendations we developed based on our initial yarning:

- What do you think about this recommendation?
- How could we improve it?

Appendix 6.2: Key Findings from Qualitative Data: Benefits, Concerns, and Conditions for Equity

Theme	Specific concerns	Quotes from participants
Benefits – Convenience	Obtaining supply easier and faster than waiting for a doctor; access at the last minute while travelling; flexibility for older people reliant on transport; easier for working parents; strong rapport with pharmacists in smaller communities; no appointment needed.	"I think it saves the stress of running out of meds, people going without, you know, blood pressure meds." – *Community member, Rural* "My daughter has bad skin conditions … there's been times we've gone days waiting for the doctor to get a script. Even if it was $20 … she could have gone to school the next day if it was treated." – *Community member, Urban*
Benefits – Rapid access to medications	Prompt relief from the discomfort of urinary tract infections (UTIs) and skin conditions, especially outside clinic hours.	"As a support worker, we're always trying to get clients in to see GPs … but a lot of times they're not available. By doing this here … that'll save a lot of time too, because with an appointment it could take up to two weeks." – *ACCHO staff, Rural*
Concerns – Quality and continuity of care	Loss of incidental care and health checks at clinics; Aboriginal Community Controlled Health Organisation (ACCHO) knowledge of family history not replicated in pharmacy; concerns about UTI diagnosis standards; value of double-checking supply/dispensing roles	"People wouldn't be actually getting their health checks … you're missing opportunistic education and interventions." – *ACCHO staff, Remote* "On a philosophical level, I don't think there should be the same people prescribing and dispensing … the pharmacist provides such an important second pair of eyes." – *ACCHO staff, Rural*
Concerns – Privacy	Sensitive issues (UTI, contraceptives, skin conditions)	-
Conditions – Align with CTG scheme	Costs of consultations and medicines risk inequity; some elders unable to pay.	"A lot of our elders can't afford to pay extra money for their medication … that will become a barrier." – *Community member, Rural*
Conditions – Cultural competence	Importance of trusting relationships; hesitancy of Aboriginal women with male pharmacists; pharmacists recognised need for further training.	"When people come in … the doctor's fully aware and can treat them very culturally appropriately … especially with the younger girls." – *ACCHO staff, Remote* "We are taught a little about Aboriginal health, but … understanding that their barriers to health is different." – *Pharmacist, Rural*
Conditions – Public education	Awareness of how the scheme works, including medicines included and costs.	–
Conditions – Continuity-of-care protocols	Clear communication between pharmacists and primary health providers to maintain patient care.	–
Conditions – Extended pharmacy hours	Longer opening hours in smaller communities to improve access.	–

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ISBN 978-0-7259-0847-8 (print)
ISBN 978-0-7259-0846-1 (electronic/online)