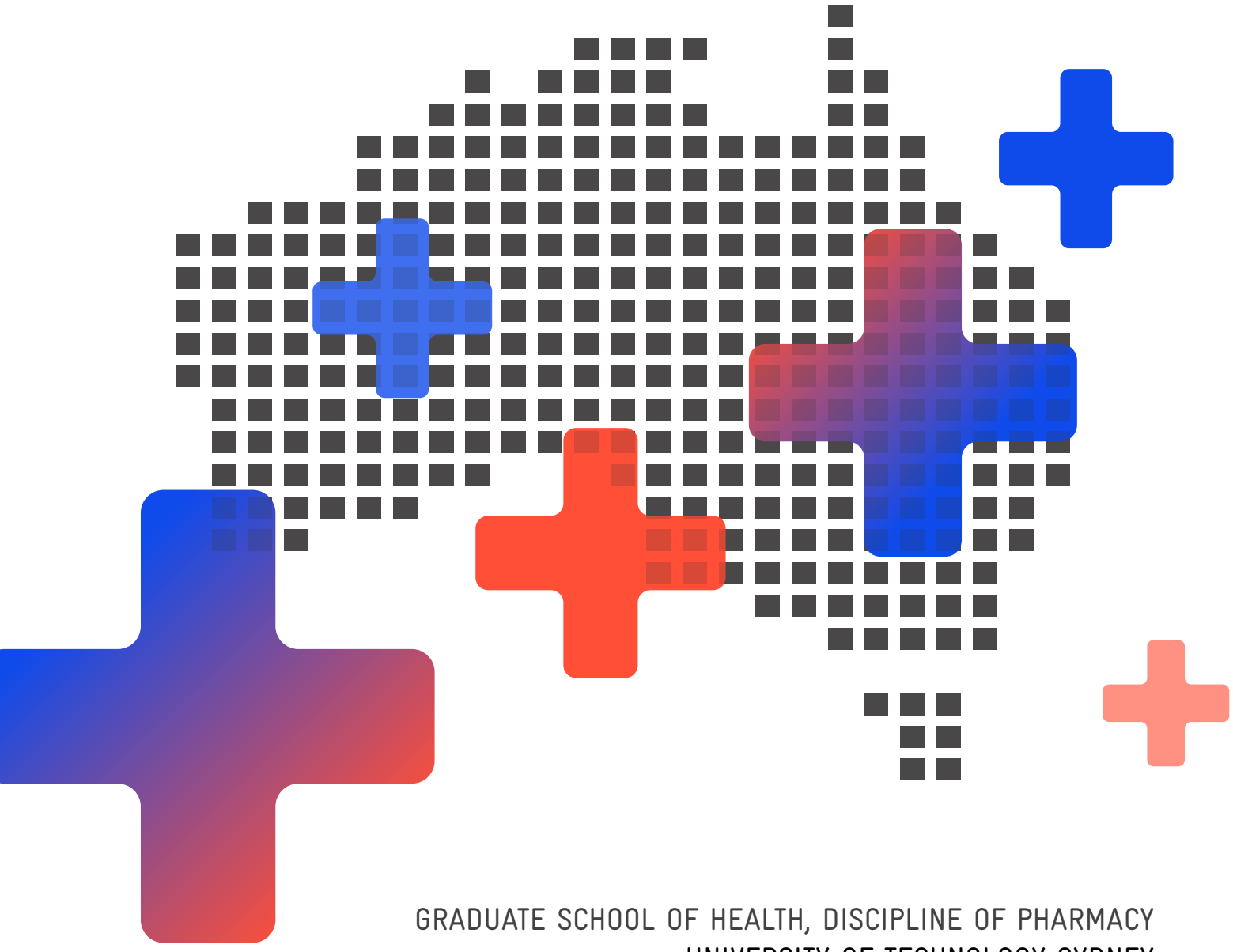
AN AUSTRALIAN MINOR AILMENTS SCHEME

EVALUATION OF AN INTEGRATED APPROACH BY COMMUNITY PHARMACISTS AND GENERAL MEDICAL PRACTITIONERS

REPORT OCTOBER 2019



GRADUATE SCHOOL OF HEALTH, DISCIPLINE OF PHARMACY
UNIVERSITY OF TECHNOLOGY SYDNEY

ISBN 9780646808833 Ebook

AUTHORS

SARAH DINEEN-GRIFFIN

CHIEF RESEARCH INVESTIGATOR

BBioMedSci MPharm (Distinct) GradCertPharmPrac

Graduate School of Health, University of Technology Sydney, Australia

DR VICTORIA GARCIA-CARDENAS

CO-INVESTIGATOR

PhD BPharm

Graduate School of Health, University of Technology Sydney, Australia

ASSOC PROF KRIS ROGERS

BIOSTATISTICIAN

PhD MBiostatistics Biostatistics

Graduate School of Health, University of Technology Sydney, Australia

CONSTANZA VARGAS PARADA

RESEARCH FELLOW

MSci MHEcon

The Centre for Health Economics Research and Evaluation (CHERE), University of Technology Sydney, Australia

PROF KYLIE WILLIAMS

CO-INVESTIGATOR

PhD BPharm

Graduate School of Health, University of Technology Sydney, Australia

EMERITUS PROF SHALOM I BENRIMOJ

CHIEF RESEARCH INVESTIGATOR

PhD BPharm (Hons)

Emeritus Professor, University of Sydney, Australia

CORRESPONDING AUTHOR

Email: sarah.dineen-griffin@uts.edu.au

Phone: +61-2-9514-1448

Current Address: Graduate School of Health

100 Broadway, Ultimo, NSW, Australia 2007

ACKNOWLEDGEMENTS

We would like to thank and acknowledge the contributions to the project made by the following:

- Pharmacy owners and pharmacists who agreed to participate in this study. This report would not have been possible without their valued cooperation and effort in providing their time and commitment to the trial;
- General medical practices who took part in the trial;
- Stakeholders involved in the co-design focus group (general practitioners, community pharmacists, consumers and representatives from the Pharmaceutical Society of Australia and Western Sydney Primary Health Network (WSPHN);
- WSPHN for their advice on project matters, assistance with the funding and development of HealthPathways, engagement of general practitioners, registration of providers to IT systems and assistance with organisation of training educational sessions and resources;
- Consumer Healthcare Products Australia (formerly the Australian Self-Medication Industry) and the University of Technology Sydney (UTS) for funding to undertake this research. We also thank the Pharmaceutical Society of Australia (PSA) for funding the pilot study;
- Dr Emma Green (WSPHN, former HealthPathways GP clinical editor), Associate Professor Walter Kmet (WSPHN, former CEO), Ian Corless (WSPHN, Director Integrated Care and Commissioning) and Diana Dous (WSPHN, former Health Programs Manager) for their valuable contribution to the project;
- Stephan Kovacic, Sylvia Hanna, and Lara Martin from the Graduate School of Health, UTS, who helped to facilitate this research in their roles as Practice Change Facilitators.

AUTHORS CONTRIBUTIONS

SDG was study chief investigator involved in intervention co-design, study methods, led the delivery of the cRCT including design of data collection tools and oversight of data collection, contributed to the analysis of the cRCT data, data analysis interpretation, assisted in the design and conduct of the economic analysis, led drafting of the report, review and the editorial process. SB was study chief investigator involved in intervention co-design, study methods, design of data collection tools and oversight of data collection, data analysis interpretation, review of the economic analysis for practice face validity and extensively involved in review of drafts and the editorial process. VGC was study co-investigator involved in intervention co-design, study methods, assisted with the design of data collection tools and oversight of data collection, assisted with the design of the economic analysis and review of the final report. KW was study co-investigator involved in intervention co-design, study methods, oversight of data collection and review of the final report. KR led the statistical design, carried out the sample size calculation and statistical analysis and assisted with data analysis interpretation. CVP designed and built the economic model, including collection of input data on transition probabilities, utilities and costs and carried out the economic analysis (including method and estimation of overall cost effectiveness). All authors have read and approved the final report. The study funders did not have any influence with study design, data collection, management, analysis, interpretation, the writing of the report or decision to submit for publication.

CONFLICTS OF INTEREST

None declared.

EXECUTIVE SUMMARY

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BACKGROUND

Integrated care is part of the solution to the rising demand for health care services. Evidence indicates that health systems with strong integrated primary health care are effective in improving patient outcomes and are efficient at delivering high-quality appropriate services (1, 2). Many countries have undergone major health reforms in order to deliver effective and efficient primary health care, moving toward sustainable health systems that are resilient to withstand impending and ongoing challenges (3-6).

The Australian federal and state/ territory governments have made substantial policy progress to deliver integrated care (7). Multiple strategies have been employed including structural health reform, implementation of new integrated service delivery models and specific targeted community-based programs (8-13). A substantial investment in integration was made in 2015 with the introduction of Primary Health Networks (PHNs) (14, 15). PHNs were established to lead improvements in the quality and delivery of primary health care that align with local hospital networks to drive efficiencies and better direct health funding to the delivery of frontline health care services (16). Their focus includes strengthening and redesigning health care by bringing together a range of health care professionals to work together more effectively. The principles that underpin PHNs are universally relevant and fundamental to strong primary care; care that is patient-centred, comprehensive, coordinated and committed to the highest level of quality and safety (17).

Major questions exist however surrounding how health care systems can address self-care and minor ailments more efficiently by delivering care at the appropriate level in an integrated capacity (18, 19). The World Health Organisation (WHO) concluded in 2009 that self-care should be a fundamental component to achieve health goals, being important not only to reduce costs but also to improve access to the health system (20). Self-care and self-medication are usually the primary methods for the management of minor ailments. Many countries are increasing or "switching" prescription medication to nonprescription status. Health professionals have a fundamental role ensuring that this is undertaken safely and appropriately. Among these health professionals is the community pharmacist, who has had and continues to have a significant role particularly through the availability of nonprescription medications which are used to treat minor ailments. The first port of call for many consumers to present with symptoms perceived to be minor ailments has been the community pharmacy. There is an international and national trend with the community pharmacist's role evolving as medicine experts to deliver individualised care to patients through a combination of medicines supply, self-care, and working in collaboration with other health professionals. In Australia, community pharmacists are increasingly being integrated into the healthcare system (21) and also are increasingly collaborating with other health professionals to ensure that medicines-related management is part of a more collaborative approach to patient care.

Minor ailments have been defined as ***"conditions that are self-limiting, with symptoms easily recognised and described by the patient and falling within the scope of pharmacist's knowledge and training to treat" (22).*** It is already known that patients self-manage their conditions to a large extent (23), and encouraging people to exercise greater levels of self-care, either for acute or chronic problems, has significant potential to

directly affect positive health outcomes, and shift costs from more costly health care settings. Pharmacists are positioned to facilitate self-care and appropriate self-medication processes (24). Undoubtedly, developments in university clinical pharmacy education and the expansion of nonprescription medicines has given patients greater choice and access to treatments, providing community pharmacy with an opportunity to demonstrate real and tangible benefits (24).

Internationally, governments have been investing in supporting pharmacists to facilitate self-care for health system efficiency. In Scotland, Northern Ireland, Wales, England and Canada as part of national health policy there is strategy to encourage patient self-care of minor symptoms at the community pharmacy through Minor Ailment Schemes (MASs) (UK) and Minor Ailment Prescribing Services (Canada). These international initiatives were introduced with various objectives as part of their general health policy and include (12, 25):

- **Contributing to the sustainability of health systems and optimising healthcare costs, through treating patients with common minor ailments at an appropriate leve with nonprescription medicines indicated for these health problems;**
- **Improving accessibility by providing timely treatment for patients with common minor ailments through the community pharmacy network in both urban and rural areas;**
- **Increasing the primary care capacity and availability of general practice for medical provision in chronic and complex patients, through the transfer of common minor ailment consultations from general practice to community pharmacy;**
- **Relieving pressure on existing emergency and urgent care services;**
- **Improving collaboration and communication among health professionals through consensus of standardised protocols of work, particularly the referral of patients;**
- **Empowering consumers to self-care for conditions which can be self-treated, and increasing patients' skills to responsibly self-medicate through community pharmacy.**

International schemes have demonstrated positive clinical, humanistic and economic impact (12, 25).

RATIONALE FOR AN AUSTRALIAN MINOR AILMENTS SCHEME

The potential for community pharmacists to meet patients' needs for the management of minor ailments and alleviate health system pressure in Australia has been widely recognised (26).

There is considerable scope for policy development and system efficiency gains in Australia as:

- There is no self-care policy within Australian health care policy;
- Patients are seeking care for minor ailments at an inappropriate level of care (ie. general practice and emergency departments with resource implications);
- Accessibility to primary care is limited in rural and remote regions of Australia;
- Some patients may be self-medicating inappropriately with nonprescription medicines leading to safety and efficacy issues;
- Health providers may be unaware of self-medication, and continued or inappropriate use of nonprescription medicines may go undetected;
- Although national standards exist, pharmacist-led care for minor ailments is not standardised which invariably results in unstructured patient-pharmacist exchanges;
- No agreed clinical care pathways exist to facilitate appropriate referral and escalation when necessary for timely care from pharmacy to the rest of the health system;
- There is no requirement for patient follow up or documentation for direct-product requests or symptom-based presentations in community pharmacy;
- GP-pharmacist communication can be challenging and is inconsistent. Lack of effective communication surrounding referral and use of nonprescription medicines is of concern regarding the quality and safety of primary care currently being provided;
- There are no substantial local, state or national campaigns directing patients to the appropriate level of entry into the health care system.

These issues contribute to a lack of integration, collaboration and cost inefficiency in the Australian health care system.

RESEARCH METHODS FOR THE DESIGN AND EVALUATION OF AN AUSTRALIAN MAS MODEL

It is evident that pharmacists could contribute to the Australian healthcare system in a way that is optimally cost-efficient and clinically effective through an integrated approach to self-care. Building on this concept, there should be systems to support seamless triage from community pharmacy, responsible self-care and self-medication and referral on through local or national care pathways. There appear to be good prospects for system efficiency gains within current institutional and funding arrangements for pharmacists to provide a national minor ailments scheme in Australia.

National implementation of a minor ailment scheme in Australian primary care, underpinned with national and state self-care policy, could have many benefits including:

- **Coordination of services** (increased collaboration between pharmacists and medical practitioners, use of health technologies, improved flow of patients and information between pharmacy, general practice and emergency departments, to ensure health outcomes for patients at the best cost).
- **Efficiencies** (greater accessibility, cost-effective treatment of self-treatable conditions, increased capacity of primary care by transferring consultations from general practice and emergency department settings safely to the community pharmacy, optimisation of costs through use of less expensive settings).
- **Effectiveness** (best clinical outcome for patients at the appropriate accessible point of entry into the health care system).

A MAS model applicable to the Australian health care system and context was co-designed with patients, GPs, community pharmacists, PHNs, and professional organisations. In addition to focusing on stakeholders' needs and the contextualisation to Australia, the international literature pertaining to minor ailment schemes, including typical features, elements and differences in structural characteristics, was considered.

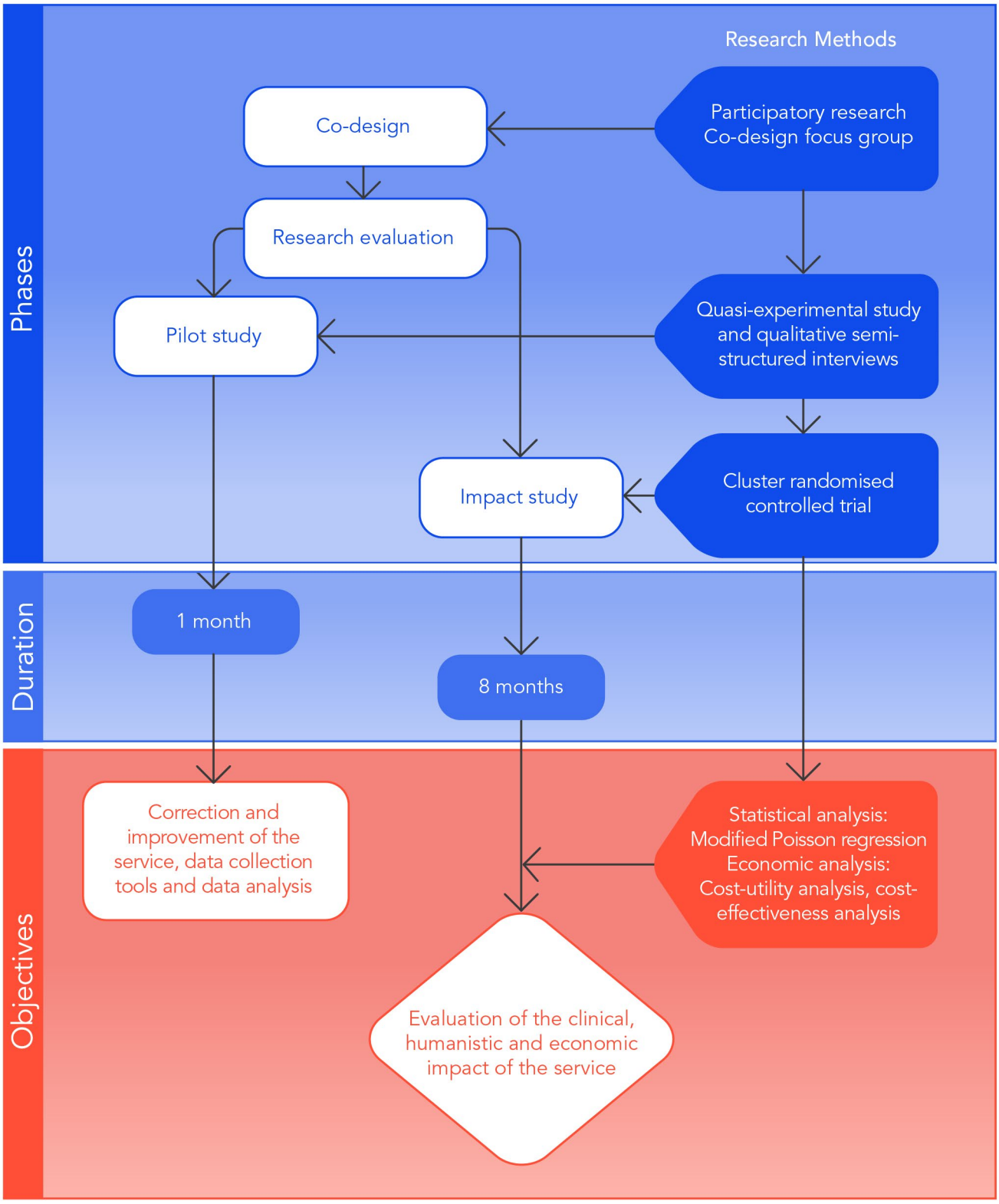
The guiding principles were integration of community pharmacy practice into the health care system, collaboration with general medical practitioners and patients, high quality and safe use of nonprescription medicines and appropriate treatment of minor ailments. The research was divided into three phases (Figure 1) using a mix methods approach.

The aims of each phase of the research included:

1. Co-design:
   - To investigate stakeholder perspectives for the co-design and collaborative agreement on service elements and operational characteristics of a MAS in Australia to ensure future seamless implementation and facilitate integration into practice;
2. Pilot study:
   - To assess the feasibility of the MAS and research methods for the impact study in Australia;
   - To explore preliminary data trends on clinical, humanistic and economic outcomes of the MAS, compared with usual pharmacist care;
3. Impact study:
   - To evaluate the clinical, humanistic and economic impact of the MAS in Australia, compared with usual pharmacist care.

The specific objectives to meet these aims can be found within Chapter 2 (Co-design and Pilot study), Chapter 3 (Clinical impact evaluation) and 4 (Economic impact evaluation).

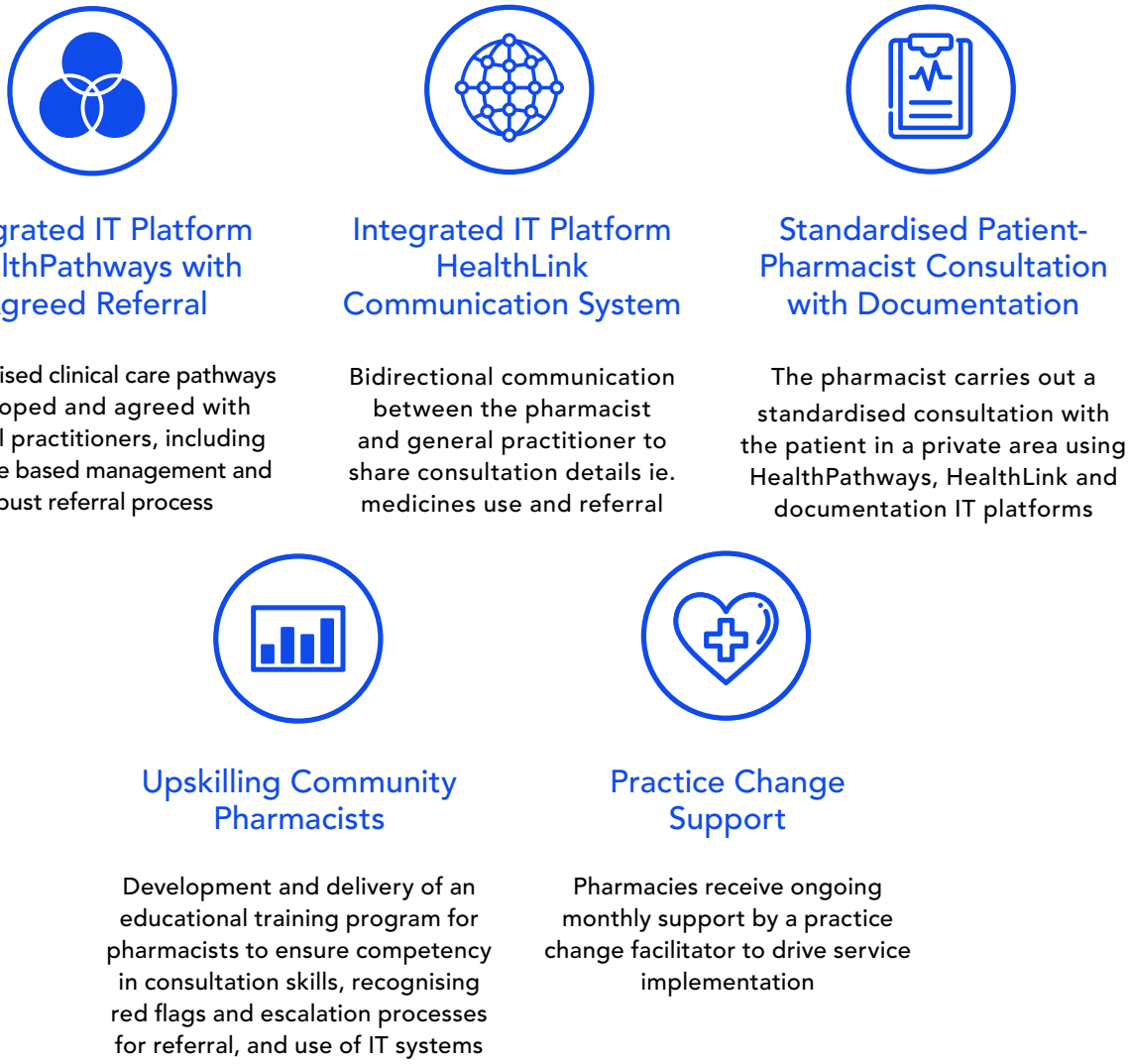
Figure 1 Flow chart of study phases and methods



CO-DESIGN

Focus group discussions and ongoing stakeholder engagement during the co-design process enabled the development of the Australian minor ailments scheme (AMAS) that is cognisant of the need to build the 'foundations' of (i) integration, (ii) collaboration, (iii) quality and safe use of medicines, and (iv) appropriate treatment of minor ailments. These core values provide the foundation of the five key elements of the AMAS model. The conceptualised components of AMAS have been developed in consultation with key stakeholders including PHN leaders and, importantly, leading general medical professionals involved in PHN governance in Australia. Stakeholder engagement with GPs and WSPHN played a role in ensuring these core values were upheld and shaped each service feature (Figure 2). The AMAS is a practice model with key elements including clinical treatment pathways *(HealthPathways)* with agreed referral points, integrated secure communication systems *(HealthLink)* between pharmacists and GPs, consultation between pharmacist and patients using standardised IT systems, upskilling of community pharmacists, and an implementation strategy using practice change support. The model uses existing IT systems. Each element is described below.

Figure 2 AMAS Model



Abbreviations: *AMAS: Australian minor ailments scheme; IT: Information technology.*

INTEGRATED AND COLLABORATIVE TREATMENT PATHWAYS FOR MINOR AILMENTS (HEALTHPATHWAYS)

As part of the co-design process, the *HealthPathways* (care pathways for action and criteria for referral to the GP for primary health complaints) were developed. *HealthPathways* is a proprietary system of clinical pathways developed in New Zealand in 2007, and currently in 2019 used in many PHNs in Australia (27). Information in the portal is peer reviewed and region specific. Each PHN tailors the content of *HealthPathways* to reflect local arrangements and opinion, and deploys their own instance of *HealthPathways* to their clinical community. It is primarily being used as a resource for general practitioners in Australia. These "care pathways" (1) provide a structured process to management and referral for specific clinical conditions; (2) translate national evidence-based clinical guidelines into local structures, and (3) provide a time frame or criterion-based progression through the health system (28). Care pathways localise and operationalise clinical guidelines, and are likely to optimise resource allocation (29).

Importantly, for a collaborative approach for referral and care, it made sense for pharmacists to utilise *HealthPathways* at the point of care through pre-agreed protocols. The collaborative approach ensures information for the treatment of minor ailments and recommendation of nonprescription medicines is agreed. Furthermore, patients are receiving care at the appropriate level, with sequencing of care by pharmacists through referral for health system efficacy and optimal quality and safety (30-35). The development of agreed *HealthPathways* for minor ailments followed a literature review undertaken by UTS of international and national clinical guidelines, and the Therapeutic Goods Administration (TGA) approved indications for nonprescription medicines. This process followed WSPHN processes and was undertaken with the GP clinical lead, the *HealthPathways* planning group and the GP clinical editor at WSPHN. Through consultation with pharmacy, these pathways were endorsed via WSPHN governance processes. The development, localisation and review of each pathway were carried out for seven conditions through a series of working meetings.

Conditions included:

- **Respiratory:** Common cold, cough;
- **Gastrointestinal:** Heartburn/reflux;
- **Pain:** Headache (tension and migraine), menstrual pain or primary dysmenorrhea, and acute low back pain.

Pathways specific to each ailment include questioning, assessment and management. The appropriate course of action includes self-care, nonprescription medicines for symptomatic relief and/ or referral. A robust framework for agreed referral was also built-in, outlining red flag criteria to trigger escalation processes, and an appropriate time frame within which a patient was recommended to seek care from a particular health care provider.

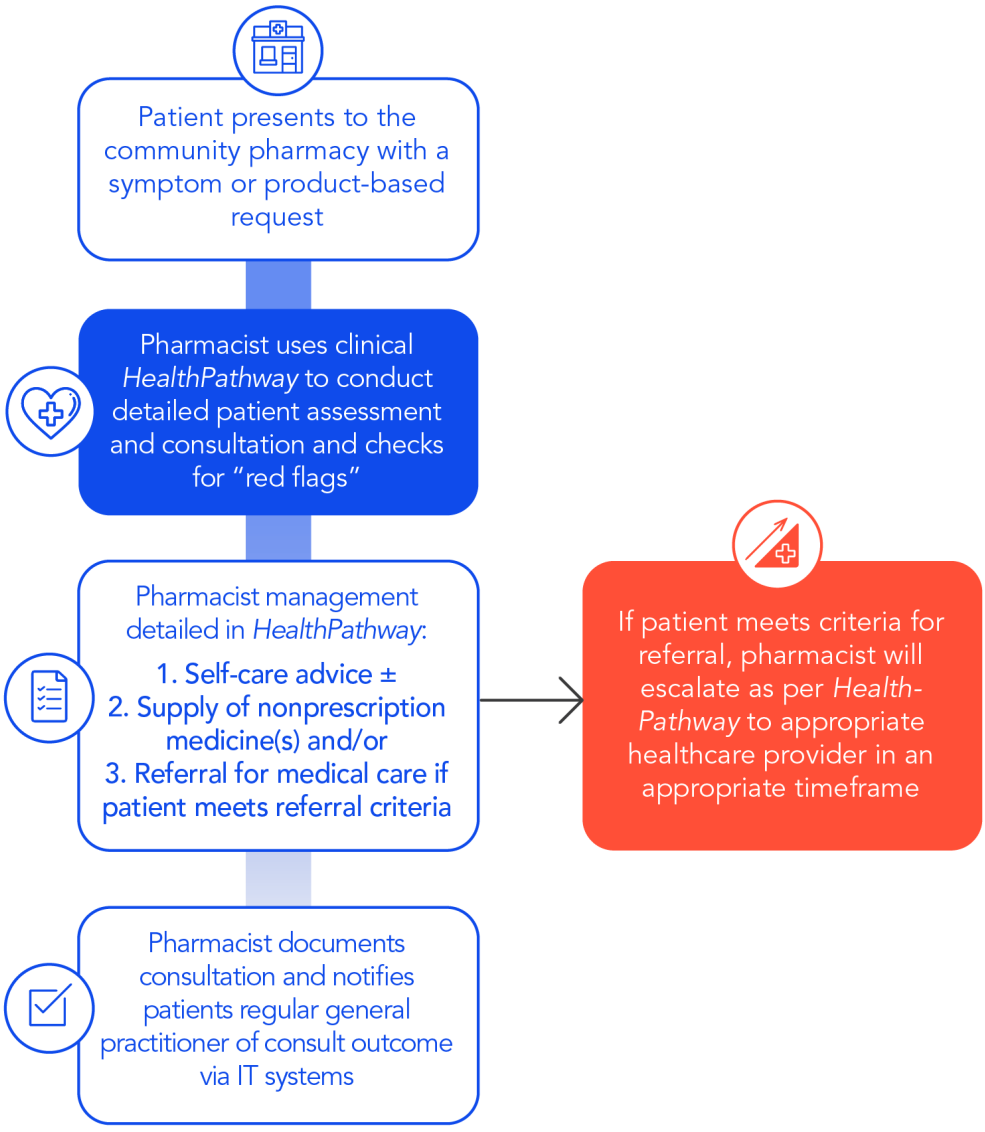
INTEGRATED HEALTH PLATFORM: HEALTH LINK

The stakeholder engagement process identified existing GP IT systems to share data and work together through a single platform. *HealthLink* secure messaging, offers access to the largest GP messaging network in Australia (36). *HealthLink* is already used by clinicians in Australia for the exchange of pathology and radiology reports, referrals, and discharge summaries. This system was pre-agreed during the co-design process for bidirectional communication of clinical and referral information between pharmacists and GPs within WSPHN. It was logical to use existing platforms as GPs are already familiar and accustomed to use this system for further integration of minor ailments into current processes and systems. The bidirectional nature of the platform encourages collaborative care and supports a quality referral process from local community pharmacies to general practitioners. Importantly and with the consent of patients, nonprescription medicine use, treatment and referral information can be shared with general medical practitioners.

STANDARDISED IT BASED PATIENT–PHARMACIST CONSULTATION

As agreed during co-design, the community pharmacist would undertake a standardised consultation with patients presenting to the pharmacy for one of the seven agreed conditions (directly requesting a product to self-treat or with a symptom-based request) (Figure 3). On consent, the pharmacist conducted a face-to-face consultation in a private area of the pharmacy (eg. the pharmacy consultation room). The pharmacist assessed the patient's symptoms using a structured approach provided in *HealthPathways*. The pharmacist identified any concurrent medications or medical conditions, considered past medical history and current medications and assessed the appropriateness of medicines requested by the patient to purchase. The pharmacist used *HealthPathways* during consultation to ensure that 'red flags' or other referral criteria were recognised and responded to appropriately.

Figure 3 Service flow



Abbreviations: *IT: Information technology.*

Patients who accessed the service were provided with verbal self-care advice, and printed or electronic information resources relevant to their condition. The information included PSA's self-care cards (in *HealthPathways*), expected duration of symptoms, red flag symptoms, when and where to go for further advice or treatment. Furthermore, the standardised consultation allowed for structured data collection as part of the pharmacists' practice. The AMAS IT documentation system (REDCap) was used to document relevant clinical assessment (37), observations and outcomes of the consultation in a secure central database (via an iPad or desktop computer). The pharmacy maintained a consultation record including advice, referral or nonprescription medicines supplied as a result of the service. In the need to refer the patient to another setting or healthcare professional for medical care, the pharmacist provided referral details to the patient, advising them to attend within a set time period. Higher acuity care locations requiring same day referral included emergency departments, and immediate in-hours or after-hours GP appointments. A GP notification was made for all consultations to ensure the patient's primary care record held by their GP was updated. An electronic secure message (on consent) was forwarded to the GP via the *HealthLink* IT system.

PHARMACIST TRAINING

Pharmacists were trained for 7.25 hours at WSPHN. Training aimed to provide pharmacists with the confidence and skills for an effective consultation using IT systems. The 2016 National Competency Standards Framework for Pharmacists in Australia (38) and the PSA's Professional Practice Standards (v5) (39), and PSA's self-care cards informed the development of content emphasising competencies to enhance the pharmacist's role in service provision. This included the:

- ability to assess the clinical needs of patients including relevant physical assessment where appropriate;
- ability to appropriately refer to other health professionals through the identification of 'Red Flags' and other symptoms warranting referral (using *HealthPathways*) and escalate patients appropriately;
- ability to collaborate effectively and appropriately with general medical practitioners (using *HealthLink*);
- ability to adequately document consultations (using the AMAS IT documentation systems).

The workshops included a combination of lecture presentations, interactive workshops including role-play scenarios, supplemented by pre-reading materials. Workshops were delivered by the research team and general medical practitioners.

PRACTICE CHANGE SUPPORT

Pharmacies were supported by a Practice Change Facilitator (PCF) to incorporate the delivery of the AMAS into their practice work flow. The PCF performed onsite monthly facilitation visits and telephone support to pharmacies. The PCF was involved in a range of change facilitation processes and activities during visits to overcome barriers, build readiness and drive the implementation process ensuring quality of service provision, quality of documentation and adherence to the service protocol.

PILOT STUDY

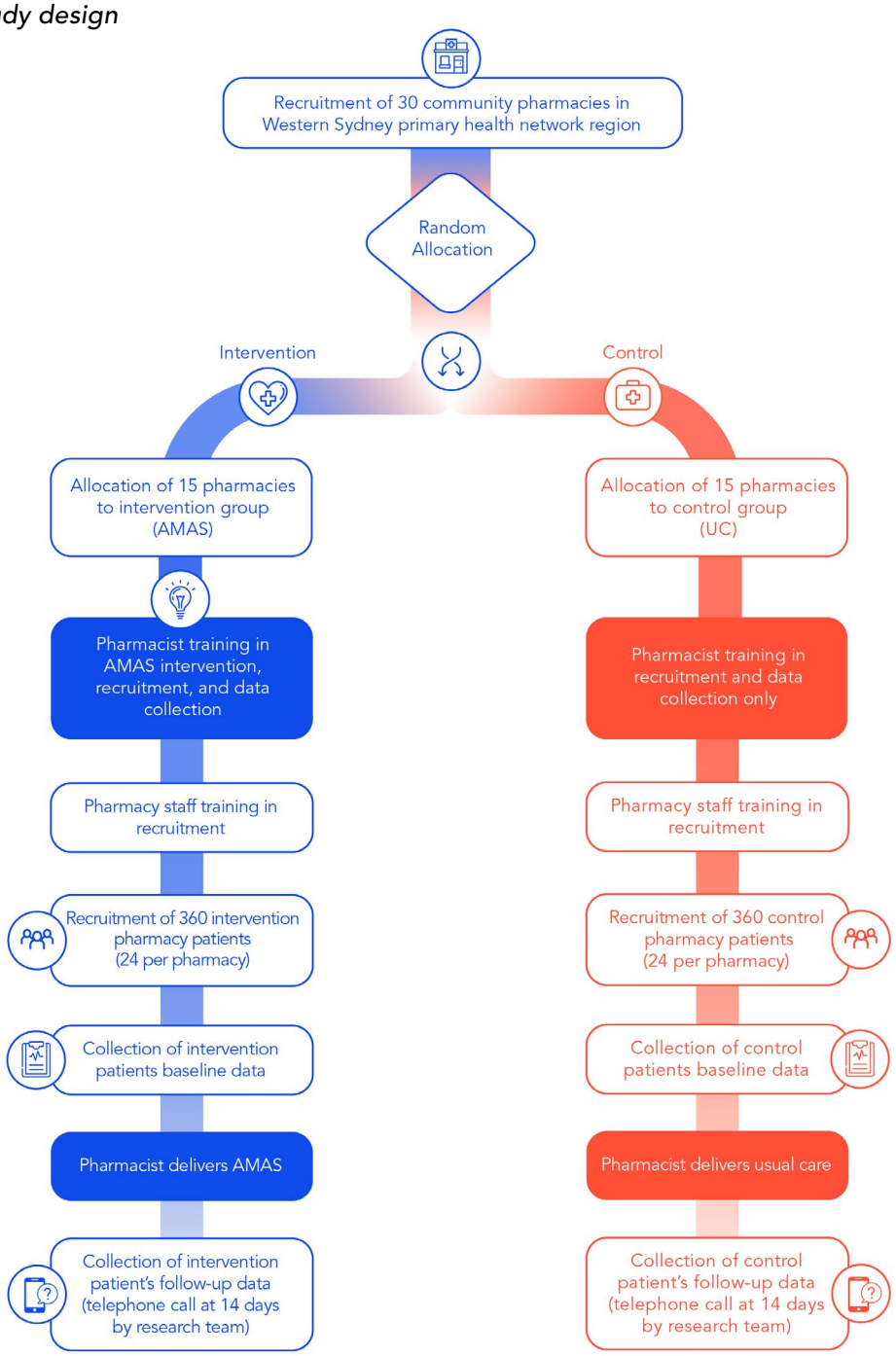
The AMAS was tested for feasibility in a two group quasi-experimental study (usual care and the AMAS) between October and December 2017 using a convenience sample of seven community pharmacies in WSPHN. Adult patients were included in the study presenting to the pharmacy with a symptom or product-based request for one of seven ailments: reflux, cough, cold, headache/migraine, period pain or low back pain. Eighty patient consultations were documented during the four-week recruitment period. Overall, the pilot phase demonstrated the clinical effectiveness and feasibility of an AMAS. Primary and secondary outcomes were considered appropriate. Further detail on methodology and clinical results are published in the UTS:WSPHN pilot study report (40).

IMPACT STUDY

Following the pilot study, the impact study used a cluster randomised controlled trial (c-RCT) design, comparing individuals receiving a structured intervention (AMAS) with those receiving usual care (UC) for specific health ailments (Figure 4). Participants were community pharmacies, general practices, and patients located in WSPHN region. The study was performed over 8

months from July 2018 to March 2019. The research was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR): ACTRN12618000286246. The detailed study protocol is published in *JMIR Research Protocols* (41). Ethics approval was granted by the UTS Human Research Ethics Committee (HREC) (UTS HREC approval number: ETH17-1350). Participating community pharmacies were reimbursed the estimated cost of pharmacists' time to deliver the consultation and recording data. Control (UC) pharmacies were reimbursed AUD5 and intervention (AMAS) pharmacies reimbursed AUD10 per consultation. We offered two iPads to the highest recruiting pharmacist in each study arm. This was submitted as a variation to the original approved protocol and ethics approval was subsequently granted.

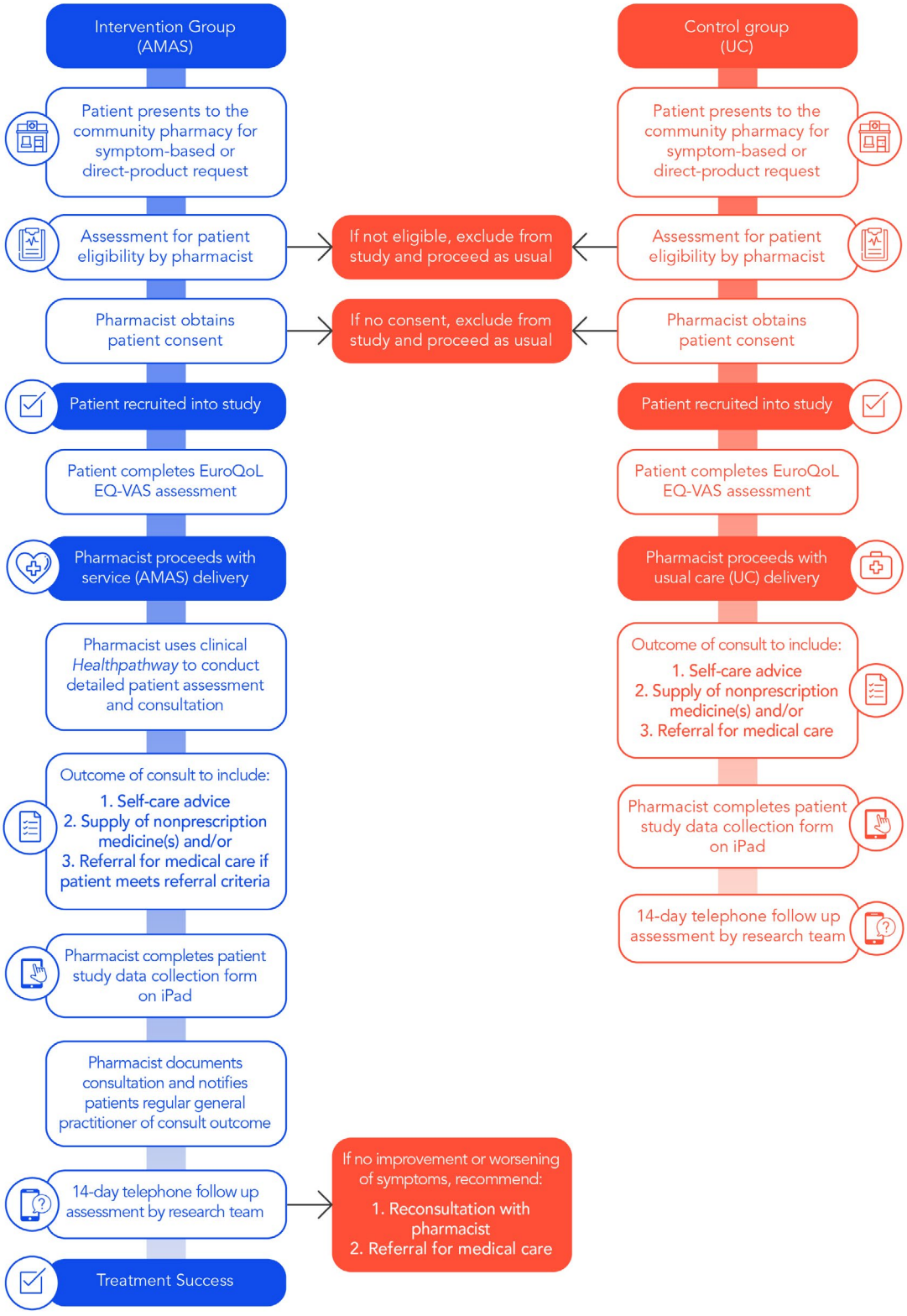
Figure 4 cRCT study design



Abbreviations: *AMAS: Australian minor ailments scheme*

During the protocolised face-to-face patient consultation, pharmacists followed a number of steps (Figure 5).

Figure 5 Usual care versus intervention: clinical management algorithm



Abbreviations: *AMAS: Australian minor ailments scheme; UC: Usual care*

DATA COLLECTION METHODS

Data were collected at two time points in intervention and control arms—baseline and 14 days after the consultation. Pharmacists completed a baseline questionnaire in the pharmacy, including demographic characteristics, and EuroQoL Visual Analogue Scale (EQ-VAS) for all patients recruited. Data about a patient's ailment history, their contact details, and pharmacist intervention was collected by pharmacists on iPads. The time taken per patient to deliver the intervention or usual care was recorded to inform the economic analysis. Follow-up with patients through telephone questionnaires was conducted by research assistants.

STUDY OUTCOMES

Clinical, humanistic and economic outcome variables included:

- Appropriate medical referral rate meeting agreed protocols
- Adherence to pharmacists referral advice rate
- Appropriate recommendation of nonprescription medicine rate
- Pharmacist intervention rate (or clinical intervention rate) for direct product requests
- Patient self-reported symptom resolution or relief rate
- Reconsultation rate
- Change in self-reported health related quality of life
- Time and resources of service delivery
- Health services resource utilisation within 14 days

Details of study outcomes, definitions and methods of assessment can be found in Chapter 2.

SAMPLE SIZE

The primary outcome measures of the study were appropriate medical referral rate and appropriate recommendation of nonprescription medicines rate. Sample size calculations were based on an assumed baseline appropriate medical referral rate of 85% and assumed baseline appropriate recommendation of nonprescription medicine rate of 82% (42, 43). To test for a 10% absolute increase in primary outcomes (appropriate medical referral rate: 85%-95% and appropriate recommendation of nonprescription medicine rate: 82%-92%) with ≥0.9 power, alpha of .05, equal allocation ratio, and assuming intra-cluster correlation is 0.01, 30 pharmacies (15 in each arm), an overall sample of 720 patients was required (allowing for 10% dropout).

STATISTICAL ANALYSIS

Data were analysed using Stata 16 for Windows (44). A modified Poisson regression approach was used for the analysis to estimate relative rates (RRs) (45, 46). As a secondary analysis, we adjusted for key baseline covariates at both the pharmacy level (eg. pharmacy type) and the patient level (eg. age and sex). An exploratory subgroup analysis by treatment classification (respiratory, pain, and gastrointestinal) and type of inquiry (symptom presentation, direct product request, and both) was also considered. Multiple imputation (MI) by chained equations was performed to account for missing patient outcomes (47).

ECONOMIC EVALUATION AND THRESHOLD ANALYSIS

A cost-utility analysis (CUA) and cost-effectiveness analysis (CEA) were performed through examining the resource use of adult patients in the context of the randomised controlled study. A societal perspective was applied for the analysis (Table 1).

Table 1 Key components of the economic evaluation

Types of analysis	CUA, CEA
Patient population	Adults that present at the pharmacy with any of the following minor ailments: common cold, cough, low back pain, tension headache, migraine, primary dysmenorrhoea and reflux.
Intervention	AMAS
Comparator	UC
Outcomes	Cost per QALY, cost per appropriate PH care, cost per SR
Time horizon	14 days
Method used to generate results	Decision tree
Quality of life	Utility values reported from the literature for SR and non-SR of minor ailments which used EuroQoL EQ-5D-3L
Resource utilisation sources	Trial based, MBS, AIHW, Pharmacy Industry Award
Software	Microsoft Excel For Mac Version 16.16.10, TreeAge Pro Healthcare 2019 R1.1

Abbreviations: *AIHW: Australian Institute of Health and Welfare; AMAS: Australian minor ailments scheme; CEA: cost-effectiveness analysis; CUA: cost-utility analysis; MBS: Medicare Benefits Schedule; PH: pharmacy; QALY: quality adjusted life years; SR: symptom resolution; UC: Usual care*

Costs during the 2-week follow-up period were analysed for all patients included in the cRCT and grouped into four main categories: (1) pharmacist time, (2) medications, (3) referrals and reconsultation, and (4) training, facilitation and IT setup costs. The average time of an AMAS consultation was 10.9 minutes (including documentation of the consultation in an iPad). The average time to deliver UC was 3.3 minutes. An additional three minutes was estimated for UC documentation of data for research purposes. Pharmacists wage was based on unit prices sourced from the Pharmacy Industry Award Australia (June 2018) (48). Out-of-pocket patient nonprescription medicine costs were determined by averaging the list price of nonprescription medicines from three pharmacy banner groups (Priceline, Amcal, Chemist Warehouse).

Referral and reconsultation costs consisted of costs of contacts with the general practitioner (in and out of hours) and other primary healthcare providers such as emergency departments, allied health, and medical specialists. Costs were included for patients who (i) adhered to referral advice (adherence was established at 14 day follow up by confirming whether the patient had reported visiting their healthcare provider), or (ii) reconsulted with a medical provider (reconsultation was established at 14 day follow up for patients not-referred by the pharmacist but had reported seeking care from a healthcare provider). Costs were calculated by considering the average cost per consult and patient out-of-pocket costs for all medicines (including nonprescription and prescription) as a result of referral adherence or reconsultation. Prescription prices were determined using PBS and non-PBS prices. Nonprescription medicine costs were calculated using the average price reported across three Australian pharmacy banner groups (Priceline, Amcal, Chemist Warehouse 2019). A cost related to training, information technology and monthly facilitation were included for the AMAS patients only.

The trial-based outcome measures used for the economic evaluation were QALYs, symptom resolution rates and appropriateness of pharmacist care (as a proxy of health gain). A decision analytic modelling technique

was employed for the economic evaluation consisting of a decision tree. The model inputs were informed by data from the trial and supplemented with published literature. The output in the economic evaluation was expressed as the incremental cost-effectiveness ratio (ICER), a summary measure that represents the economic value of AMAS compared with the alternative of usual care. A number of sensitivity analyses were undertaken to assess the robustness of the CUA results.

Furthermore, using the output from the economic evaluation, the average modelled cost per AMAS consultation was used to estimate the cost reduction potential for minor ailment consultations transferrable from GP and ED services. National and international literature estimates were used to determine the proportion of GP and ED services potentially transferrable to AMAS at the WSPHN, NSW state and national level. Different scenarios were assumed of patients being transferred from ED or GP settings to receive AMAS. Furthermore, various thresholds were applied for actual patient transfer. The most optimistic scenario assumes 100 percent of eligible patients are transferred to receive pharmacy based AMAS, to the most conservative assuming only 1 percent patient transferability.

RESULTS

Clinical and humanistic evaluation

A total of 33 community pharmacies in WSPHN participated in the impact study. Surrounding general practices consented to receive referral information and details of the pharmacy consultation (150 GPs from 27 practices) for their patients. In total, 894 patient consultations were documented during the study period. Of these, 524 (59%) and 370 (41%) patients were recruited into AMAS and UC arms, respectively. Of the 894 patients who participated in the study, 82% (n=732) were successfully followed up by telephone. See CONSORT 2010 Flow Diagram of the progress through the cluster randomised controlled trial (cRCT) phases for the two groups (that is, intervention allocation, follow-up, and data analysis) (Figure 6).

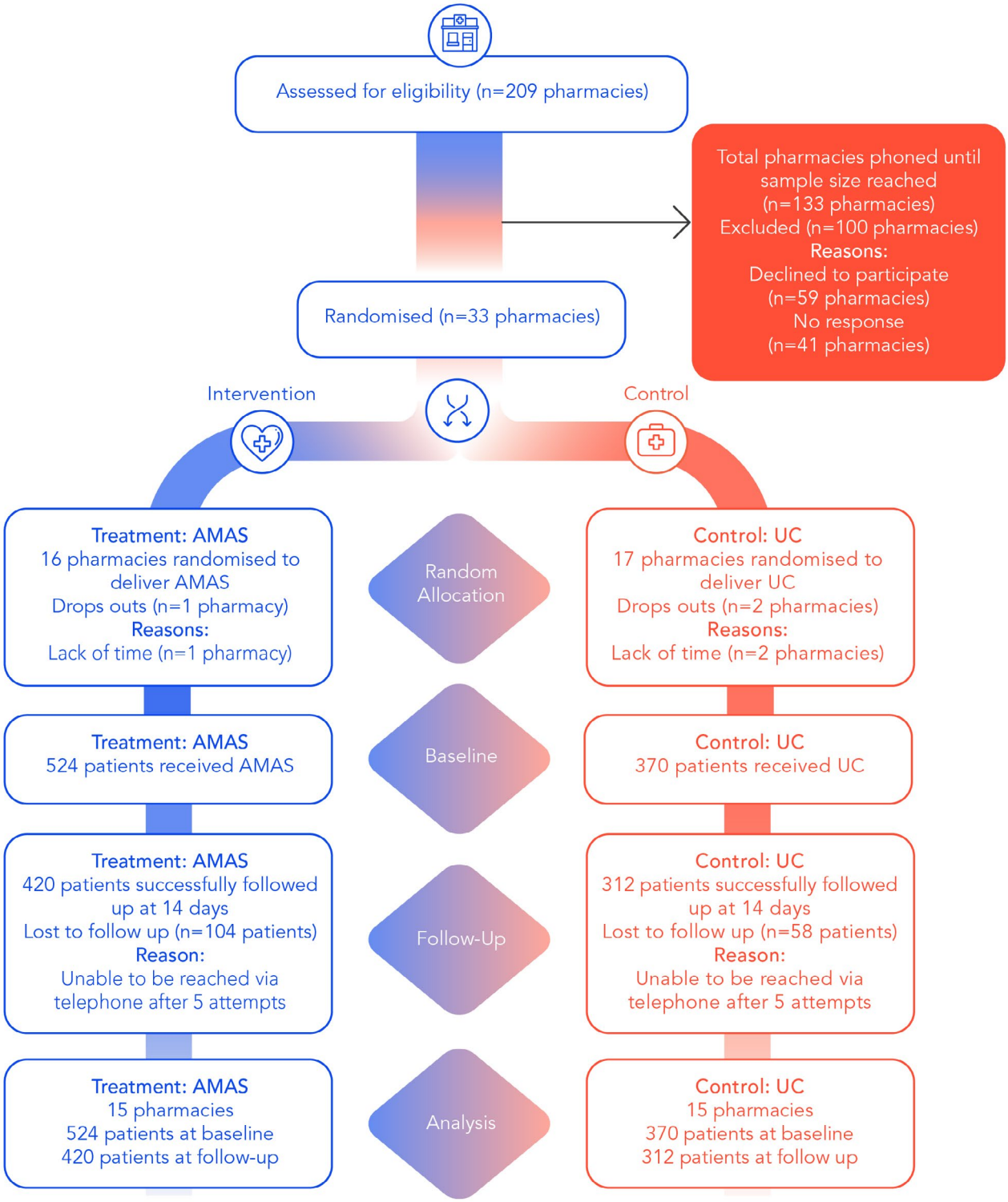
Patients presented to the pharmacy in one of three ways (i) symptom-based presentation; (ii) direct product request to self-medicate; or (iii) a combination of both. Overall, the majority of patients were documented with a symptom-based presentation in both study arms (Table 2).

Table 2 Presentation type: both study arms (n=894 patients)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL	894	100%	524	100%	370	100%
Direct product request	245	27.4%	114	21.8%	131	35.4%
Symptom presentation	598	66.9%	386	73.7%	212	57.3%
Both symptom presentation and direct product request	51	5.7%	24	4.5%	27	7.3%

Abbreviations: *AMAS: Australian minor ailments scheme; UC: usual care.*

Figure 6 Consort 2010 Flow Diagram



Abbreviations: *AMAS: Australian minor ailments scheme; UC: Usual care*

Primarily, AMAS patients presented with symptoms or directly requested medicines to self-treat symptoms of common cold (38%), cough (26%) and reflux (14%) (Table 3). Half of patients were self-medicating for their current symptoms prior to seeking advice at AMAS pharmacies. Around 27% had experienced their current symptoms beyond seven days before seeking advice at the pharmacy while 10% had experienced symptoms beyond four weeks.

Table 3 Conditions presented: both study arms (n=894 patients)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL	894	100%	524	100%	370	100%
Common cold	340	38.0%	197	37.6%	143	38.6%
Cough	223	24.9%	136	25.9%	87	23.6%
Gastroesophageal reflux	106	11.8%	74	14.1%	32	8.6%
Non-specific low back pain	98	11.0%	64	12.2%	34	9.2%
Tension headache	55	6.2%	15	2.9%	40	10.8%
Migraine	42	4.7%	24	4.6%	18	4.9%
Primary dysmenorrhoea	30	3.4%	14	2.7%	16	4.3%

Abbreviations: *AMAS: Australian minor ailments scheme; UC: usual care.*

** Includes symptom presenters and those directly requesting a medicine to treat one of the ailments.*

SUMMARY OF KEY STUDY FINDINGS: PRIMARY AND SECONDARY OUTCOMES

An incidence rate ratio (RR) is a relative difference measure to compare the incidence rates of outcomes between study arms. That is, the incidence of each clinical or humanistic outcome occurring for those receiving AMAS, compared with those receiving UC. Our results consider baseline differences in the sample and we have provided adjusted results. Confidence intervals (CI) and p-values are provided for significance ($p<0.05$). The 95% CI around the RR assesses the impact and precision of the change in RR for each outcome. Table 4 provides a summary of primary and secondary outcome results.

Table 4 Comparison of outcome measures between AMAS and UC groups (n=894 patients)

OUTCOME	Effect of AMAS	Adjusted Rate Ratio estimate (CI)	Adjusted p-value
Objective 1			
Appropriate medical referral rate	Rate Ratio (AMAS/ UC)	1.51 (1.07 - 2.11)	0.0175*
Adherence to referral advice rate	Rate Ratio (AMAS/ UC)	5.08 (2.02 - 12.79)	0.0006*
Appropriate recommendation of nonprescription medicine rate	Rate Ratio (AMAS/ UC)	1.20 (1.1 - 1.3)	<0.0001*
Pharmacist intervention rate (or clinical intervention rate) for direct product requests	Rate Ratio (AMAS/ UC)	2.62 (1.28 - 5.38)	0.0087*
Self-reported symptom resolution or improvement rate	Rate Ratio (AMAS/ UC)	1.06 (1 - 1.13)	0.0353*
Reconsultation rate to all health providers	Rate Ratio (AMAS/ UC)	0.98 (0.73 - 1.33)	0.91
Objective 2			
Change in self-reported health related quality of life	Mean Difference (AMAS/ UC)	4.08 (1.27 - 6.89)	0.0044*

Abbreviations: *AMAS: Australian minor ailments scheme; CI: confidence interval; EQ-VAS: EuroQoL-visual analogue scale; UC: usual care.*
**indicates AMAS shows a statistically significant improvement in outcome, compared with UC.*

In summation, patients receiving AMAS were 1.5 times more likely to receive an appropriate referral by their pharmacist, for medical care meeting the agreed protocols than UC patients (adjusted RR 1.51; 95% CI 1.07 to 2.11; p=0.0175). There was strong evidence that patients receiving AMAS were 5 times more likely to adhere to the pharmacist's referral and seek medical care within an appropriate timeframe (adjusted RR 5.08; 95% CI 2.02 to 12.79; p=0.0006).

Pharmacists were 1.2 times more likely to recommend an appropriate nonprescription medicine meeting agreed protocols as a result of the AMAS consultation (adjusted RR 1.2; 95% CI 1.1 to 1.3; p<0.0001). Pharmacists were 2.6 times more likely perform a clinical intervention and recommended an alternative medicine that was safer or more appropriate than that requested on presentation by the patient (adjusted RR 2.62, 95% CI 1.28 to 5.38; p=0.0087), compared with UC. At follow up, patients were 1.06 times more likely to achieve symptom resolution or relief as result of AMAS (adjusted RR 1.06; 95% CI 1 to 1.13; p=0.0353). No change was observed in reconsultation rate between groups. Humanistic results revealed improved health related quality of life for AMAS patients, compared with UC (mean difference 4.08; 95% CI 1.23 to 6.87; p=0.0049). Outcomes are further explored as follows:

REFERRAL RATE

Referral to another healthcare professional was provided for 20% of patients in the AMAS arm, compared to 5% in the UC arm. AMAS patients were referred to a number of settings and providers including ED, general practice (in- and after-hours), to allied health (ie. physiotherapist), or specialist settings. Interestingly, 60 of the 104 AMAS referrals (58%) had previously seen a GP for previous episodes of the same symptoms, yet the pharmacist re-referred the patient back to the GP for medical assessment knowing this information. Of the 104 referrals in AMAS notably, 16% of patients (n=83) received self-care advice and/or referral for medical assessment, without the supply of a nonprescription medicine. Most commonly in the AMAS group patients were referred back to their GP within 1-3 days, whereas in the UC group the most common referral was made to the GP at their next scheduled appointment.

RED FLAG REFERRALS

Importantly, AMAS pharmacists identified patients with clinical features or 'red flags'[1] in 2% of all AMAS patients (n=11). No patients with red flag symptoms were identified in the UC arm. The eleven patients were referred immediately (to GP or ED) for the following reasons:

- Severely unwell eg. marked lethargy, shortness of breath (n=2)
- Trouble breathing or feeling faint (n=1)
- Severe or disabling pain (n=3)
- Fever or neck stiffness (n=2)
- Thunderclap headache – sudden onset (n=2)
- Monocular pain, red eye, visual disturbance (n=1)

LESS URGENT REFERRALS

Prolonged duration, persistent and frequent symptoms were identified as the main reasons for referral in 38% of all referral cases with AMAS. Prolonged duration and frequency of symptoms were criteria for referral which required medical assessment to eliminate conditions more chronic and/or to be recommended other treatment. Examples of this type of referral were for persistent low back pain progressively worsening beyond four weeks (n=3), cough greater than two weeks or recurrent cough (especially smokers) (n=11), or reflux symptoms persisting or relapsing frequently (n=13).

ADHERENCE TO PHARMACISTS REFERRAL ADVICE

Patients referred by the pharmacist during the consultation were followed at fourteen days to determine if they adhered to referral advice and sought medical care. Over half of patients (52%) who were referred by their pharmacist in AMAS followed through with referral, compared with 16% of patients receiving UC. As a result, AMAS patients were five times more likely to adhere to referral advice and seek medical care, compared with UC.

[1] A red flag is a symptom that is recognised as likely to be of a more serious nature and requires immediate referral.

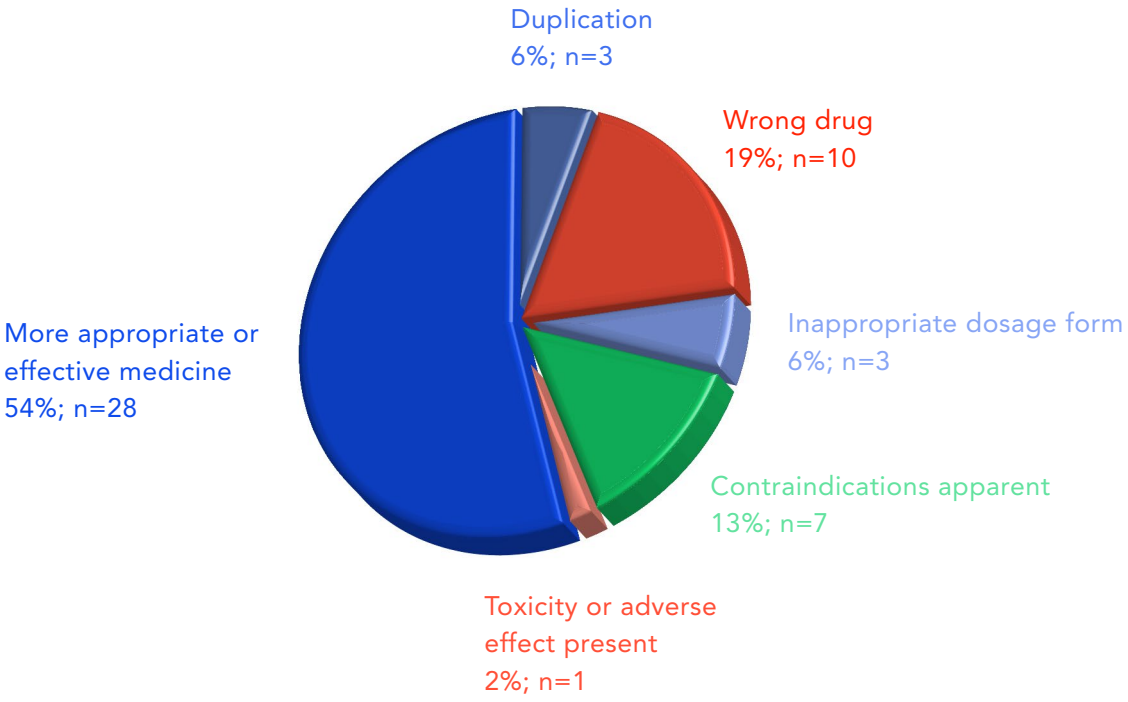
APPROPRIATE RATE OF NONPRESCRIPTION MEDICINE RECOMMENDATION

The AMAS showed 91% of all nonprescription medicine recommendations were considered appropriate meeting the agreed protocols, compared to 79% in UC. Findings demonstrate patients were 1.2 times more likely to receive an appropriate medicine recommendation by their pharmacist as defined by the agreed protocol with AMAS, compared with UC. The most common medicines supplied were for symptomatic relief of upper respiratory tract infections (URTIs), including cold or cough preparations, accounting for 63% of all medicines supplied (across both study arms). Oral analgesics, including NSAIDs, non-opioid analgesics alone or in combination (22%) were also commonly supplied for the symptomatic relief of pain. Gastrointestinal nonprescription medicines for reflux accounted for 10% of medicines supplied and included combination antacids, histamine-2 receptor antagonists and proton pump inhibitors (PPIs).

PHARMACIST INTERVENTION RATE (OR CLINICAL INTERVENTION RATE) FOR DIRECT PRODUCT REQUESTS

Pharmacists performed a clinical intervention in 21% of direct product request presentations with AMAS, compared to 11% in UC. Findings reveal AMAS pharmacists were 2.6 times more likely to perform a clinical intervention for direct product request presentations (for example, provide an alternative medicine deemed more effective or more appropriate for the patient in 21% of patient cases), than UC. The reasons for recommending a change are outlined in Figure 7.

Figure 7 Reasons for recommending a change in direct product requests: both study arms (n=47 clinical interventions made, with 52 reasons for recommending the change)



SYMPTOM RESOLUTION RATES

Most patients in the AMAS arm achieved complete symptom resolution or relief (94%) while this was reported 6% less in the UC arm (88%) at two weeks. As a result, AMAS patients were 1.06 times more likely to achieve complete symptom resolution or relief at follow up, than UC patients.

RECONSULTATION RATES

Patients not referred by the pharmacist self-reported if they had reconsulted with another healthcare professional at follow-up within the two weeks following consultation with the pharmacist. Our study found no difference in reconsultation rates, with GP reconsultation rates to be 15% with AMAS, and 16% in UC, and to all health providers was 22% for both arms.

CHANGE IN SELF-REPORTED HEALTH RELATED QUALITY OF LIFE

The results show an improved quality of life in both arms at follow up. Patients who received AMAS however had a greater increase in EQ-VAS from baseline, four points greater at follow up than that seen in UC. This may coincide with the greater likelihood of patients receiving self-care advice during the consultation with AMAS (98%), compared to patients in UC (62%). A summary of descriptive statistics for clinical findings are provided (Table 5).

Table 5 Descriptive statistics summary of clinical findings

OUTCOME	AMAS group (%)	UC group (%)
Appropriate medical referral meeting agreed protocols	94.2%	73.7%
Identification of red flag referrals	2.1%	0%
Referral rate	19.8%	5.1%
Adherence to pharmacist's referral advice rate	51.6%	15.8%
Pharmacist clinical intervention rate	21.0%	11.4%
Appropriate recommendation of nonprescription medicine rate meeting agreed protocols	90.7%	79.1%
Provision of self-care advice as part of consultation	97.5%	61.9%
Symptom resolution or relief rate	93.6%	87.5%

Abbreviations: *AMAS: Australian minor ailments scheme; UC: usual care.*

ECONOMIC EVALUATION

A cost-utility analysis (CUA) and cost-effectiveness analyses' (CEA) were performed through examining the resource use of adult patients in the context of the randomised controlled study designed to investigate the effectiveness of AMAS compared with UC. Our CUA was undertaken from a societal perspective (includes patient out-of-pocket costs for all medicines as a result of consultation, reconsultation and referral adherence within the 14-day period following consultation for the same ailment).

Costs

Costs were identified, measured and valued using trial-based data and Australian sources. Costs were grouped into four major categories: (1) pharmacists time; (2) nonprescription medicines; (3) referrals and reconsultation, and (4) training, facilitation and IT costs. The average hourly pharmacist wage of AUD29.37 was multiplied by total training time. Thirty-five AMAS pharmacists completed 7.25 hours of face-to-face training. The cost of workshop facilitators, materials, venue hire and food for workshop attendees were incorporated. AMAS pharmacies received 60-minute monthly visits for the duration of the study and fortnightly 10-minute telephone calls from the practice change facilitator. The hourly wage of AUD46.28 for the practice change facilitator was applied to calculate total facilitation costs. An iPad cost for documentation of AUD457 per pharmacy and an annual HealthLink license cost of AUD180 per pharmacist's license was included. The average cost of a GP consultation of AUD44.07 was determined through examination of MBS report for annual GP services in WSPHN.

The mean cost per AMAS consultation was found to be AUD29.56, compared with AUD22.28 per UC patient (Table 6). Please note this cost includes patient out-of-pocket medicine(s) costs.

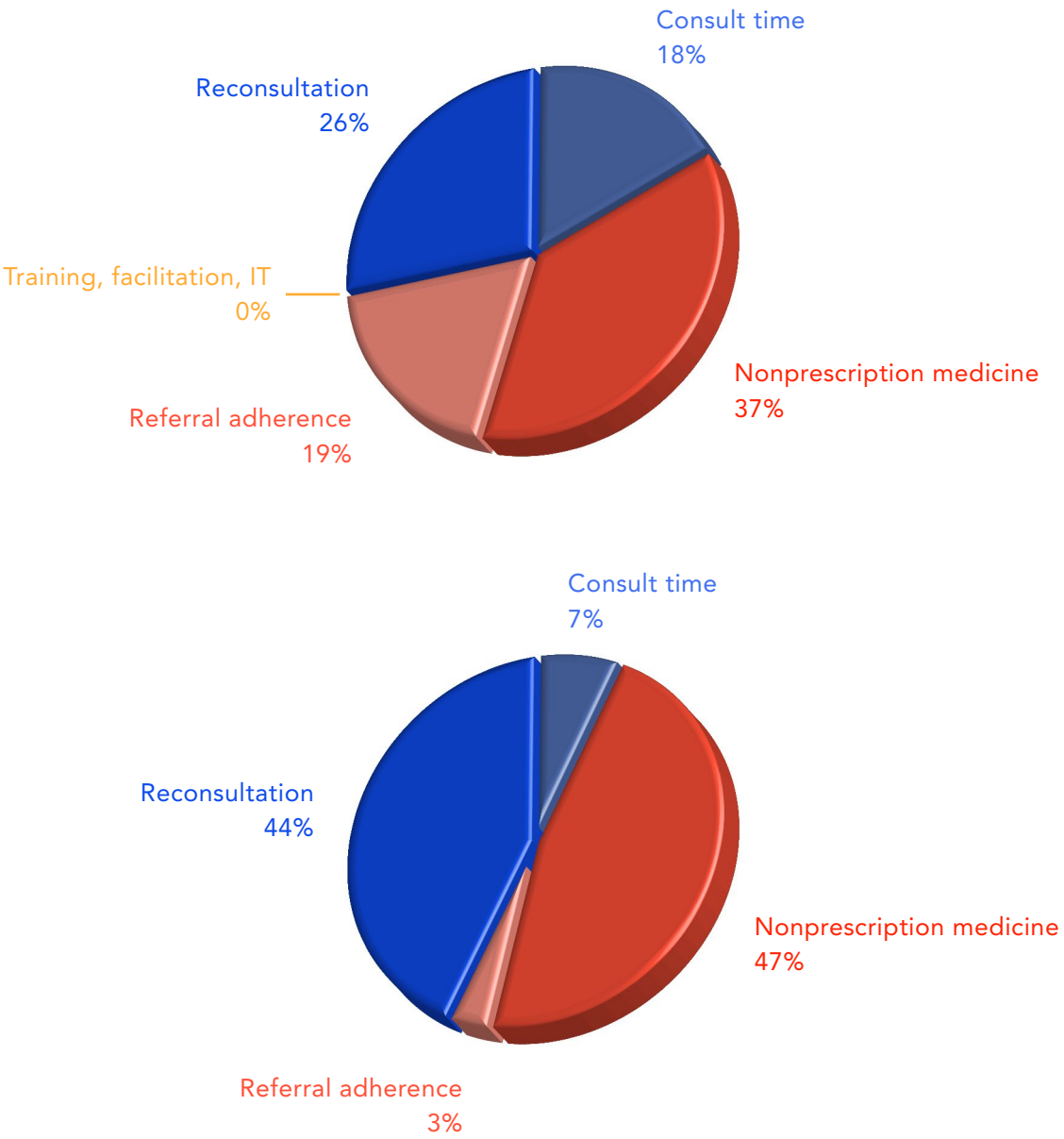
Table 6 Results of cost analysis

	AMAS average cost per patient (AUD $)	UC average cost per patient (AUD $)
Consultation time	$5.33	$1.61
Nonprescription medicines	$10.85	$10.36
Referral adherence (incl. medicines)	$5.59	$0.61
Reconsultation (incl. medicines)	$7.73	$9.70
Training, facilitation, IT set-up	$0.07	-
TOTAL	AUD29.56*	AUD22.28*

Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; IT: information technology; UC: usual care*
** Note that the costs used in the cost-utility and cost-effectiveness evaluations were different as a result of a decision tree modelled analysis that considers the proportion of patients in each arm.*

The largest cost was attributed to the nonprescription medicine in both study arms (AUD10.85, compared with AUD10.36 in UC). The second largest cost of AUD5.33 was attributed to the pharmacist's time to deliver the AMAS consultation. In comparison, the pharmacist's time to deliver UC was AUD1.61 per patient. A referral adherence cost of AUD5.59 per AMAS patient was determined compared to AUD0.61 per UC patient. This is due to the high referral rate and higher adherence to the advice. The cost of reconsultation per patient (patients who were not referred by the pharmacist but sought medical care within two weeks) was greater for UC at AUD9.70, in comparison to AUD7.73 per patient receiving AMAS. Despite reconsultation rates being similar between groups, the cost and number of prescribed medicines following reconsultation was higher in UC than AMAS and accounts for the difference in reconsultation cost. Figure 8 provides a comparative breakdown of cost distribution for AMAS and UC.

Figure 8 Distribution of costs for AMAS and UC, respectively



COST-UTILITY ANALYSIS

The total QALYs accrued during the 14-day time horizon were 0.0293 (AMAS) and 0.0261 (UC). The AMAS resulted in an incremental QALY score of 0.003 relative to UC. The total expected mean cost of AMAS per patient was AUD26.88 and AUD19.75 per UC patient, resulting in a mean incremental cost of AUD7.13 per patient. The base case ICER was estimated at AUD2,277 per QALY gained.

The results of the CUA show higher costs but also higher QALYs in the AMAS group, compared with UC.

The AMAS dominates UC in clinical effectiveness (see Chapter 3 for clinical effectiveness) and lies in the north-east quadrant of the cost effectiveness plane. Australia does not work with an explicit cost-effectiveness threshold. However, a base-case reference ICER of AUD28,033 per QALY gained is recommended to inform value-based decision making in Australia (49). Based on this reference threshold, national implementation of the AMAS is a highly cost-effective option. Table 7 presents the results of the CUA.

Table 7 Cost-utility results (outcome= QALYs)

	Average cost per patient*	Total QALY	Inc. cost	Inc. QALY	ICER ($AUD/ QALY)
UC	AUD19.75	0.0264			
AMAS	AUD26.88	0.0296	AUD7.14	0.003	AUD2,277

Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; QALY: Quality adjusted life year; UC: usual care*

**Total cost includes out-of-pocket costs of all medicine(s) as a result of AMAS (ie. medicines paid by patient).*

Note: The costs used in the cost-utility and cost-effectiveness evaluations for AMAS is AUD26.88 rather than AUD29.56 as a result of a decision tree modelled analysis that considers the proportion of patients in each arm receiving an outcome instead of the mean costs stated above. Similarly, UC is AUD19.75 instead of AUD22.28.

Two cost effectiveness analyses (CEAs) were conducted using the clinical effect measures of (i) an additional episode of appropriate pharmacist care meeting the agreed protocols and (ii) an additional patient achieving symptom resolution for their minor ailment. The CEA results are expressed in terms of extra cost per additional episode of appropriate pharmacist care and extra cost per additional patient achieving symptom resolution. The results of the CEA revealed an ICER of AUD37.42 per additional patient receiving appropriate pharmacist care with AMAS, compared with UC (Table 8).

Table 8 Cost-effectiveness results (outcome = appropriate pharmacist care meeting the agreed HealthPathway protocols)

	Average cost per patient*	Total app. PH care	Inc. cost	Inc. app. PH care	ICER ($AUD/ app. PH care)
UC	AUD19.75	0.676			
AMAS	AUD26.88	0.866	AUD7.14	0.191	AUD37.42

Abbreviations: *AMAS: Australian minor ailments scheme; App. PH care: Appropriate pharmacist care; AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; UC: usual care*
**Total cost includes out-of-pocket costs of all medicine(s) (ie. medicines paid by patient).*

The results of the second CEA revealed an ICER of AUD586.88 per additional patient achieving symptom resolution with AMAS, compared with UC (Table 9).

Table 9 Cost-effectiveness results (outcome = symptom resolution)

	Average cost per patient*	Total SR	Inc. cost	Inc. SR	ICER ($AUD/SR)
UC	AUD19.75	0.738			
AMAS	AUD26.88	0.750	AUD7.14	0.012	AUD586.88

Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; SR: symptom resolution; UC: usual care*
**Total cost includes out-of-pocket costs of all medicine(s) (ie. medicines paid by patient).*

Similarly, in both CEAs, the AMAS dominates UC in clinical effectiveness and lies in the north-east quadrant of the cost effectiveness plane. Based on the reference threshold of AUD28,033 per QALY, national implementation of the AMAS is a highly cost-effective option.

THRESHOLD ANALYSIS: TRANSFER OF ED AND GP MINOR AILMENT SERVICES TO AMAS

Using national and international literature estimates, it was estimated that 2.9 to 11.5 percent of ED services and 7 to 21.2 percent of GP services can be safely transferred to pharmacy in Australia. This represents between 232,507 and 922,012 visits to ED for self-treatable conditions at a cost of AUD124.5 to AUD493.8 million and between 8.8 and 26.6 million GP appointments each year for self-treatable conditions at an annual cost of AUD397 million to AUD1.2 billion to the Australian health system.

Combining these national estimates, between 9 million and 27.5 million GP and ED services are for minor illnesses, representing a cost to the Australian health system between AUD511 million to AUD1.67 billion per annum. At the NSW state level, this equates between 3 million and 9.2 million services resulting in an annual cost of AUD175 to AUD572 million. At the WSPHN level, the transfer of 422,742 and 1.3 million services could result in costs savings between AUD20 to AUD62 million (Table 10).

Table 10 Annual overall cost reduction potential

		Estimated annual community pharmacy manageable services			Cost reductions	
		GP services (n)	ED services (n)	Combined services (n)	Overall cost reduction potential with shift of services to pharmacy	Overall cost reduction potential if AMAS is paid for
National	Maximum	26,586,994	922,012	27,509,006	-$1,665,411,901	-$1,266,806,407
	Minimum	8,778,725	232,507	9,011,232	-$511,373,307	-$380,800,559
NSW	Maximum	8,831,535	331,233	9,162,768	-$572,069,660	-$439,301,145
	Minimum	2,916,073	83,528	2,999,601	-$174,621,799	-$131,157,576
WSPHN	Maximum	1,271,558	11,454	1,283,012	-$62,356,841	-$43,765,997
	Minimum	419,854	2,888	422,742	-$20,096,087	-$13,970,549

Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; ED: emergency department; GP: general practitioner; NSW: New South Wales; WSPHN: Western Sydney primary health network*

Under this scenario, if AMAS was paid through a consultation fee structure of AUD14.49 per consultation and if the patient paid for their nonprescription medications, the Australian federal government would save between AUD380 million and AUD1.3 billion per annum. Similarly, in NSW, the transfer of these services to pharmacy would results in cost savings between AUD131 million and AUD439 million per annum. At the WSPHN level, the transfer of these services could result in cost savings of AUD14 to AUD44 million. Alternate scenarios can be found in Chapter 4.

DISCUSSION OF POTENTIAL FUNDING MODELS FOR AMAS

National funding mechanisms include federal, state or territory governments and local PHNs who have a shared responsibility for health governance in Australia. The federal government may fund AMAS through inclusion in the 7th Community Pharmacy Agreement or as an MBS item (50). For example, a pharmacist consultation payment similar to GP MBS Item 3 would be a suitable fit which provides a fee of AUD17.45 per GP consultation for patients presenting with 'an obvious problem characterised by a short patient history and limited examination and management if required' (51). Pharmacists and their services could be embedded within the delivery models commissioned and funded by PHNs which have the objectives of increasing the efficiency and effectiveness of services for patients at the local level. Alternatively, state and territory governments, who are primarily responsible for public hospitals, may fund AMAS with the specific objective of alleviating ED and hospital presentations for certain low-acuity conditions.

FUNDING MODELS

Internationally, there are a number of funding models available for policy makers to consider and a range of systems are offered to deliver reimbursement to pharmacies for consultations involving triage, referral and management of minor ailments. Remuneration for MASs differ across nationally and locally funded programs. Funding options include a fee for consultation with or without reimbursement for the cost of the product for the patient, banded capitation fees, one off payments, and retainer fees (25). Importantly, there is a need to consider the patient types that could have access to the service through pharmacy (available to all Australians, within certain PHNs, special demographic or population groups (disadvantaged, elderly, children, and so forth). The following remuneration models could be evaluated to meet needs of stakeholders in Australia:

FUNDING MODEL 1: FEE FOR CONSULTATION

In Australia, flexible funding pools to support pharmacist activity as a service provider may be established within the Community Pharmacy Agreement or MBS to support fee-for-service for minor ailment consultations allowing pharmacists to triage and support patient-level activities for certain minor ailments. Payment could be irrespective of the outcome of assessment (ie. product supply, self-care advice or referral). Medicine costs could be paid for by individuals as an out-of-pocket expense or the health care system for specific patient classes.

Internationally, pharmacies are paid a consultation fee in England for the delivery of MASs. Payment ranges from GBP2 to GBP10 per consultation and in some localities pharmacies are reimbursed for the cost of medicines supplied under a given formulary for certain minor ailments (22). Pharmacies may also receive a small annual retainer of GBP50 to assist with set-up costs (22). Foremost amongst the new services in England is the new national NHS Community Pharmacist Consultation Service (CPCS), connecting patients who have a minor illness with a community pharmacy which should rightly be their first port of call. The CPCS includes a GBP14 fee per completed consultation (and does not include reimbursement for product sold), following referral from NHS111 initially, with a rise in scale with referrals

from other parts of the NHS to follow. The CPCS seeks to alleviate the system pressures of all patient groups visiting GP or ED for conditions which can be managed by a pharmacist.

Under the current MAS agreement in Scotland, which is only available to some patients (children, people aged over 60, people on certain benefits), pharmacists are paid a fee for registering the patient (capitation model) and are reimbursed if a medicine is dispensed from a formulary. However, Community Pharmacy Scotland (CPS) are currently in negotiations with the Scottish government for pharmacists to receive funding for each consultation they undertake with the roll out of the new national MAS (available to all patient groups) in April 2020. The payment model being negotiated seeks to recognise the advice and care pharmacists provide, rather than dispensing a medicine as part of the consultation.

FUNDING MODEL 2: BANDED CAPITATION FEE MODEL

An alternative to a consultation fee, is the banded capitation fee model. This model is used in Scotland, Wales & Northern Ireland (22). The payment to pharmacies is banded according to the number of patients enrolled in the scheme, paid monthly in arrears. Capitation payments are calculated on the number of patients registered with the MAS provider on the last day of each month. With this, a patient may access the service as needed. Medicines supplied during the consult from a defined formulary are also reimbursed. A registered patient who has not sought pharmacist care within a fixed time period (eg. 12 months), is not included in the number of registered patients for which the capitation payment is calculated. As an example, a fee is paid for the first 250 patients who have registered with MAS pharmacies in Scotland (irrespective of whether they use the service or not), then 251 – 500 patients, and so forth, increasing depending on the number of patients enrolled in the service (22).

FUNDING MODEL 3: HYBRID CAPITATION WITH FEE FOR CONSULTATION MODEL

Remuneration for the provision of AMAS may incorporate a combination of the funding models above.

CONCLUSIONS AND RECOMMENDATIONS FOR PRACTITIONERS, POLICY AND FUNDING

Community pharmacy is an integral part of the Australian primary health system and with the appropriate supporting systems, a sustainable funding framework and pre-agreement with physicians has the potential to facilitate an improved flow of patients and information transfer within the health system. We have provided clinical and economic evidence that a national scheme would be successful in Australia, and have demonstrated improved patient health outcomes as a result of deeper consultations and a structured approach to management. National implementation of AMAS as part of a portfolio of services offered in Australia offers a solution for policy decision makers to increase the efficiency of the health system through improved service navigation to guide the patient towards the most appropriate care destination. It is imperative that closer relationships are built by community pharmacy and pharmacists with other parts of the health and care system. Integration, collaboration, communication and teamwork will be vital to provide effective healthcare in the future. Implementing a scheme which is integrated and collaborative will set the foundation for service sustainability in practice.

The present research evaluated the clinical, economic and humanistic impact of a structured approach to the management of minor ailments in Australian community pharmacy (AMAS). Three phases of research (co-design, pilot and impact study) were undertaken in WSPHN. The AMAS model was codesigned with key stakeholders to the service including general medical practitioners involved in WSPHN clinical governance, community pharmacists, management leaders from WSPHN, patients and the representatives from the PSA.

The model was collaboratively designed applying our guiding principles of integration of community pharmacy practice into the health care system, collaboration with general medical practitioners and patients, ensuring high quality and safe use of nonprescription medicines and, appropriate treatment of minor ailments. These core values provided the foundations for the five key service elements within the AMAS model. Stakeholder engagement with GPs and WSPHN played a critical role in ensuring these core values were upheld and shaped each service feature. *HealthPathways*, and IT systems were agreed with general medical practitioners as a result of co-design.

The research demonstrated the efficacy of the AMAS for a number of clinical, humanistic and economic indicators in WSPHN. The clinical effectiveness evaluation revealed an improved appropriateness in consultation outcomes compared with usual care, including the pharmacist's treatment recommendation or decision to refer a patient for medical care. The AMAS service offered pharmacists a framework to operate, through the pre-agreed *HealthPathways* to differentially diagnose and manage a patient which is consistent. Pharmacists were trained in *HealthPathways* and referral process. The referral pathways together with use of existing IT systems provides structure to consultation and documentation processes. The systematisation of clinical decision making and referrals was achieved through development of relatively easy-to-update protocols and collaboratively agreement with other service providers.

The study results showed improved identification of patients presenting with red flag clinical features

with AMAS. Pharmacists responded appropriately to potentially serious symptoms whereby timely and appropriate referral was recommended at the appropriate level (ie. general practice or emergency department). The structured consultation resulted in increased identification of medication related problems for direct product presentation types and pharmacists' appropriately responding through clinical intervention. This supports the notion that community pharmacists facilitate safe self-medication processes for patients and have an important role in identifying inappropriate self-treatment with nonprescription medicines. Further to this, the AMAS resulted in increased lower-urgency referral for patients for medical assessment, compared with usual care. Pharmacists were referring patients whose symptoms were meeting pre-agreed referral criteria when patients' symptoms were persistent, frequent, worsening and because of this were no longer considered self-limiting in nature. Pharmacists also identified instances where patients were continuing to self-medicate for persistent symptoms without seeking medical assessment by a GP. Not only did AMAS demonstrate clinical effectiveness, the economic evaluation revealed AMAS as cost-effective. Our analysis estimated the proportion of patients seeking care for minor ailments in GP and ED settings allowing for the overall cost reduction potential to be calculated and the total cost savings if these consultations were transferred to pharmacy. As such, national AMAS implementation would contribute to greater efficiency of health care resources and encourage care to be delivered at an appropriate level, patients triaged effectively and referred on by the pharmacist when medical assessment is required.

RECOMMENDATIONS

While AMAS can be implemented with current legislation and within the scope of practice for pharmacists, consideration should be given for the policy and legislative changes required to further promote and develop self-care. A number of recommendations are presented for consideration by federal and state policy makers, primary care organisations such as PHNs, professional organisations, the pharmaceutical industry and practitioners. These recommendations detail the broader opportunities for patients to access cost-effective and the appropriate level of care for their minor ailment conditions while encouraging the safe and quality use of nonprescription medicines.

RECOMMENDATION 1. IMPLEMENT A NATIONAL AMAS SYSTEM IN AUSTRALIA

An important consideration for the Australian Government is how to enhance community pharmacy's role in supporting self-care for minor ailments and self-management for long-term conditions, as part of a more integrated care model. Many of the improvements envisioned with AMAS can be achieved by better use of health care resources through patients accessing the appropriate level of care with quality, safety and accessibility. Protocols agreed collaboratively between ED physicians, GPs and pharmacists can determine what level of care is required, and treat or escalate appropriately. There is good evidence that the clinical advice provided by community pharmacists regarding symptoms of minor illness will result in the same health outcomes as if the patient went to see their GP or attended the emergency department (52). Patients seeking care and delivery of care from ED for conditions such as headaches, coughs, colds, and earaches are obviously an inefficient use of resources. Building upon the accessibility of community pharmacies in primary health care, it could be promoted that instead of going to ED, patients can visit their community pharmacist. Similarly, increased healthcare spending in Australia is also a result of the gradual increase in GP services. It is estimated that 7 to 21.2 percent of all GP consultations and 2.9 to 11.5 percent of all ED services in Australia could be safely transferred to a community pharmacy as part of a national scheme (53-60).

The findings from this research reveal AMAS as a cost effective alternative and demonstrate the potential clinical and economic impact of national implementation. It is evident that pharmacists could contribute to the Australian healthcare system in a way that is optimally cost-efficient and clinically effective through an integrative approach to facilitate self-care. With national implementation there is huge potential for system efficiency gains, demonstrated through systematically delivering care for minor ailments at the appropriate level, and working collaboratively within an integrated health system. Conceptually, the AMAS model provides a solid framework for roll out. Training, IT infrastructure, and agreed protocols have already been established and provide a conduit for pharmacists, GPs and other health professionals to operate in a collaborative professional capacity to best meet the healthcare needs of patients. Ultimately, for community pharmacists, delivering AMAS would require a shift in clinical behaviour from 'advice and supply', to a consultative approach with formalised triage, referral, documentation and provision of self-care.

National implementation of a minor ailment scheme in Australian primary care, underpinned with national and state self-care policy, could have many benefits including:

- **Coordination of services** (increased collaboration between pharmacists and medical practitioners, use of health technologies, improved flow of patients and information between pharmacy, general practice and emergency departments, to ensure health outcomes for patients at the best cost).
- **Efficiencies** (greater accessibility, cost-effective treatment of self-treatable conditions, increased capacity of primary care by transferring consultations from general practice and emergency department settings safely to the community pharmacy, optimisation of costs through use of less expensive settings).
- **Effectiveness** (best clinical outcome for patients at the appropriate accessible point of entry into the health care system).

Recommendation 1: It is recommended that due consideration be given for an AMAS for community pharmacies nationwide to adopt and implement.

RECOMMENDATION 2. IMPLEMENT A NATIONAL SELF-CARE STRATEGY IN AUSTRALIA

Increased self-care brings many benefits, for the individual, health care professionals, the Australian health system, government and society as a whole. However, development and implementation of a national self-care policy in Australia is needed to effectively support self-care for self-treatable conditions, either by patients themselves and/or with the support of a cost-effective delivery system such as community pharmacy. There are between 232,507 and 922,012 visits to ED for self-treatable conditions at a cost of AUD124.5 to AUD493.8 million to the Australian health system. At the same time, there are between 8.8 and 26.6 million GP appointments each year for self-treatable conditions at an annual cost of AUD397 million to AUD1.2 billion to the Australian health system. The total costs to the Australian health system are therefore between AUD511 million to AUD1.67 billion a year. These resources could be better utilised in a health care system that is suffering from economic pressure. Surprisingly, there is no national policy that provides a framework for self-care. There is a need for renewed effort to ensure patients seek care at the appropriate accessible point of entry into the health care system. Empowering people to self-care will give them safe and effective relief from their minor ailments and ensure a more appropriate use of Australian health system resources, allowing efficiencies to be reinvested in other areas. An accessible community pharmacy network in Australia through an AMAS could be part of this policy framework.

Implementation of self-care policy has not been prioritised in Australia. There is significant potential to amplify self-care and self-medication in Australia. A crucial step is to strategically align the Australian health system so that responsibility for self-care is integral to the health system. A national strategy for self-care and a national lead are needed to provide leadership and co-ordinate work across primary and secondary care for significant progress to be made. Implementation of robust self-care policy in Australia should seek to promote self-care and self-medication capabilities, change the culture of dependency on more costly parts of the health system, and potentially allow the economic and professional practice resources to shift to health care practices with a preventative ethos. The Department of Health should ensure that where appropriate, more medicines are made available without prescription to support more people to self-care.

Recommendation 2: The federal government in consultation with stakeholders, primarily consumer organisations, develops a national self-care policy within its national health policy.

RECOMMENDATION 3. ESTABLISH A FUNDING MODEL TO REFLECT THE QUALITY, TIME AND COMPLEXITY OF COMMUNITY PHARMACIST CARE

To drive long-term behaviour change, where people become fully engaged in their health and self-care for minor ailment conditions, resources need to be provided at a national level to ensure self-care is a national priority and is effectively embedded across the Australian health system. Pertinent to a national AMAS system in Australia is funding and having a legal and regulatory framework in place establishing the current and potential contribution community pharmacy can make as part of an integrated system. Remuneration needs to reflect quality and value and incentivise pharmacists to focus on care which is of higher value and is of highest impact to the health system. This may mean revising remuneration models for clinical interventions (ie. to recognise higher significance interventions and quality recording), in addition to models of remuneration such as fee-for-service, practice allowance or based on the number of patients registered for the scheme (25). Funding would include time spent on educating patients to self-care. Incentives to engage in provider collaboration should be considered. What is clear, is that a remuneration model should have the objective of achieving patient accessibility and as well as supporting integration of community pharmacists into primary care.

Recommendation 3: A funding model for AMAS be negotiated between federal and/or state governments, with PSA and the Pharmacy Guild of Australia.

RECOMMENDATION 4. PROMOTE A SYSTEMS APPROACH TO IMPROVING QUALITY USE OF NONPRESCRIPTION MEDICINES AND MEDICATION SAFETY IN AUSTRALIA

Consideration should be placed on taking a systems wide approach at a policy level toward national quality use of medicines and medication safety. This would require the development of supportive infrastructure and alignment of resources, to train health care professionals and introduce agreed tools to support nonprescription medication safety. The AMAS standardised consultation is a means to improve quality medication use and safety in the health system. The community pharmacist serves as an important safety-net for the identification and resolution of clinical problems surrounding nonprescription drug use. There is need for national reporting of clinical interventions associated with nonprescription medicines, and prescription medication, from pharmacy. Measures for medicine safety across all settings and systems are warranted. The IT documentation system co-designed with AMAS provides a needed framework for community pharmacists to actually document clinical interventions made for patients who are self-selecting medicines which are inappropriate. National reporting would allow measurement of the nonprescription medicine safety contribution of pharmacists and the impact of this. Simplified adverse event reporting processes would also support the safe and quality use of nonprescription medicines.

Recommendation 4: A systems wide approach, at a policy level, toward national quality use of nonprescription medicines and medication safety.

RECOMMENDATION 5. NATIONAL PUBLIC AWARENESS CAMPAIGN FOR THE APPROPRIATE LEVEL OF CARE

A public awareness campaign directed predominantly at potential and actual service users could be developed and funded by the federal and state governments to promote and encourage the use of community pharmacy as a site for minor ailment interventions. PHNs in conjunction with the relevant stakeholders including pharmacy organisations can select and promote the types of conditions that are appropriate to be managed under AMAS. Marketing campaigns may target specific patient populations and demographic groups.

Similar strategies have been applied in the UK under the "Stay Well" pharmacy campaign in 2018 to use the community pharmacy for advice and treatment for self-treatable conditions (61). The 3-month campaign targeted parents and carers of children under 5 years of age, and patients over 65 years of age in winter, and as a result an additional 1.6 million visits were made to pharmacy and 13,500 less patients presented to ED (61). NHS England's second wave of the public awareness campaign encouraged the use of community pharmacy as a source of advice and treatment for winter ailments, helping reduce GP and ED demand (62). Following on from the successful campaign, NHS England launched a promotional campaign in 2019 'Help Us Help You' (63).

Recommendation 5: A public awareness campaign should be instigated to inform consumers seeking care for minor ailments to do so at the appropriate level of care.

Outlined above are five recommendations, which if implemented, could ensure Australian health system efficiency through self-care as a key policy area and community pharmacy integrated within the health system.

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AN AUSTRALIAN MINOR AILMENTS SCHEME

EVALUATION OF AN INTEGRATED APPROACH BY COMMUNITY PHARMACISTS AND GENERAL MEDICAL PRACTITIONERS

REPORT OCTOBER 2019

GRADUATE SCHOOL OF HEALTH, DISCIPLINE OF PHARMACY
UNIVERSITY OF TECHNOLOGY SYDNEY

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ISBN 9780646808833 Ebook