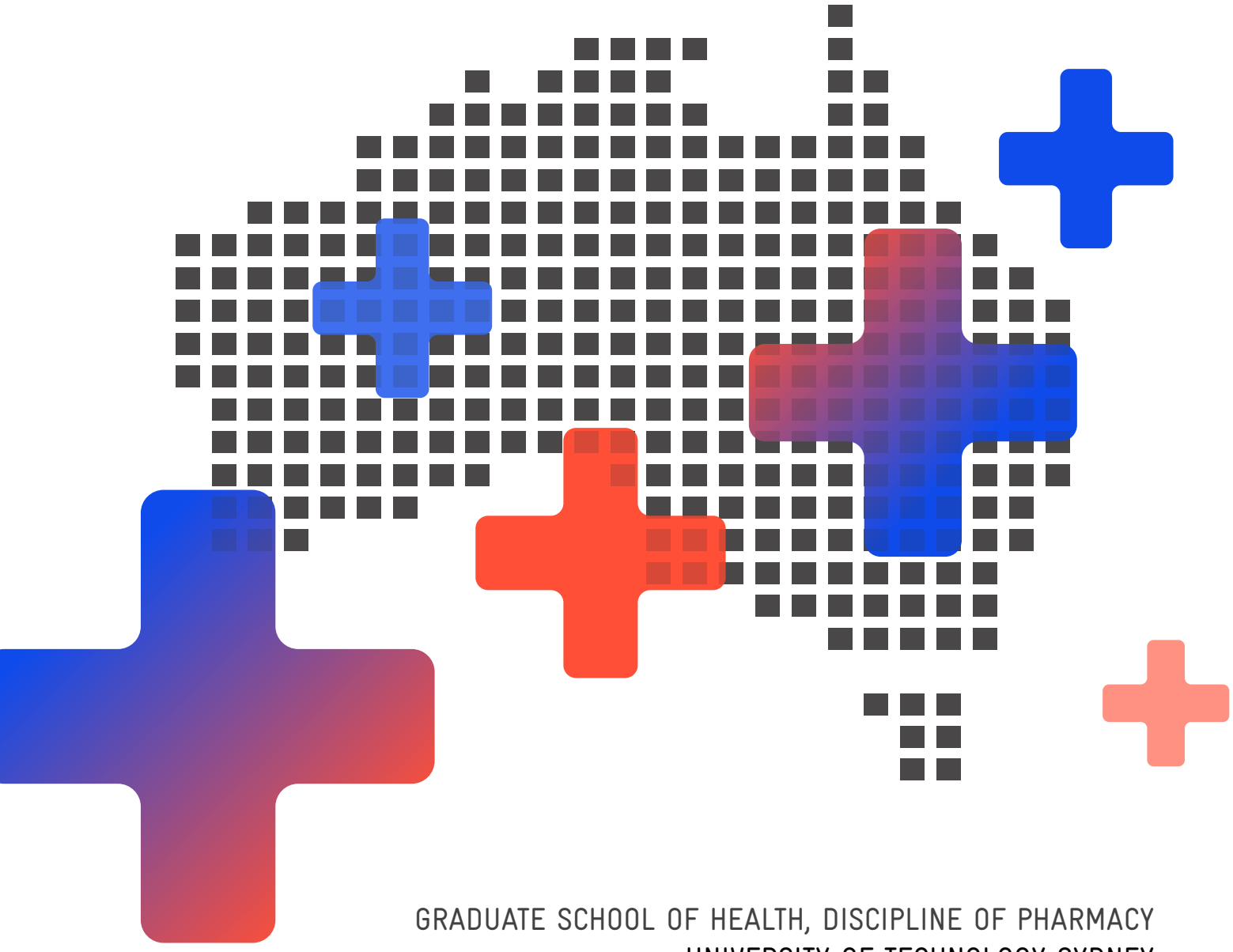
AN AUSTRALIAN MINOR AILMENTS SCHEME

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

REPORT OCTOBER 2019



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ABBREVIATIONS

ACPs	Advanced clinical practitioners
AIHW	Australian Institute of Health and Welfare
ARTG	Australian Register of Therapeutics Goods
ASMI	Australian Self Medication Industry
AMAS	Australian Minor Ailments Service
ATs	Area teams
CAMs	Complementary and alternative medicines
CCGs	Clinical commissioning group
CEA	Cost-effectiveness analysis
CI	Confidence interval
CPS	Community Pharmacy Scotland
cRCT	Cluster randomised controlled trial
CUA	Cost-utility analysis
DMIRS	Digital Minor Illness Referral Service
ED	Emergency department
EDPPs	Emergency department pharmacist practitioners
EQ-VAS	EuroQoL visual analogue scale
FEV	Forced expiratory volume
GAP	Global Access Partners
GP	General practitioner
HCP	Healthcare professional
HREC	Human research ethics committee
HRQOL	Health-related quality of life
ICER	Incremental cost-effectiveness ratio
IT	Information technology
JMIR	Journal Medical Research Institute
MAS	Minor ailment scheme
MAUI	Multi-attribute utility instrument
MBS	Medicare Benefits Schedule
MRPs	Medication related problems
NHS	National Health Service
NI	Northern Ireland
NQPHN	North Queensland primary health network
NSAIDs	Non-steroidal anti-inflammatory drugs
NUMSAS	NHS Urgent Medicine Supply Advanced Service
NZ	New Zealand
PBAC	Pharmaceutical Benefits Advisory Committee
PCFs	Practice change facilitators
PGA	Pharmacy Guild of Australia
PH	Pharmacy
PGDs	Patient group directions

PHN	Primary Health Network
PPMA	Pharmacist prescribing for minor ailments program
PSA	Pharmaceutical Society of Australia
PSNC	Pharmaceutical Services Negotiating Committee
QALY	Quality adjusted life year
QOL	Quality of life
RR	Rate ratio
SR	Symptom resolution
TGA	Therapeutics Goods Administration
UK	United Kingdom
UC	Usual care
UTIs	Urinary tract infections
UTS	University of Technology Sydney
WHO	World Health Organisation
WSMI	World Self Medication Industry
WSPHN	Western Sydney primary health network

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- 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;
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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.

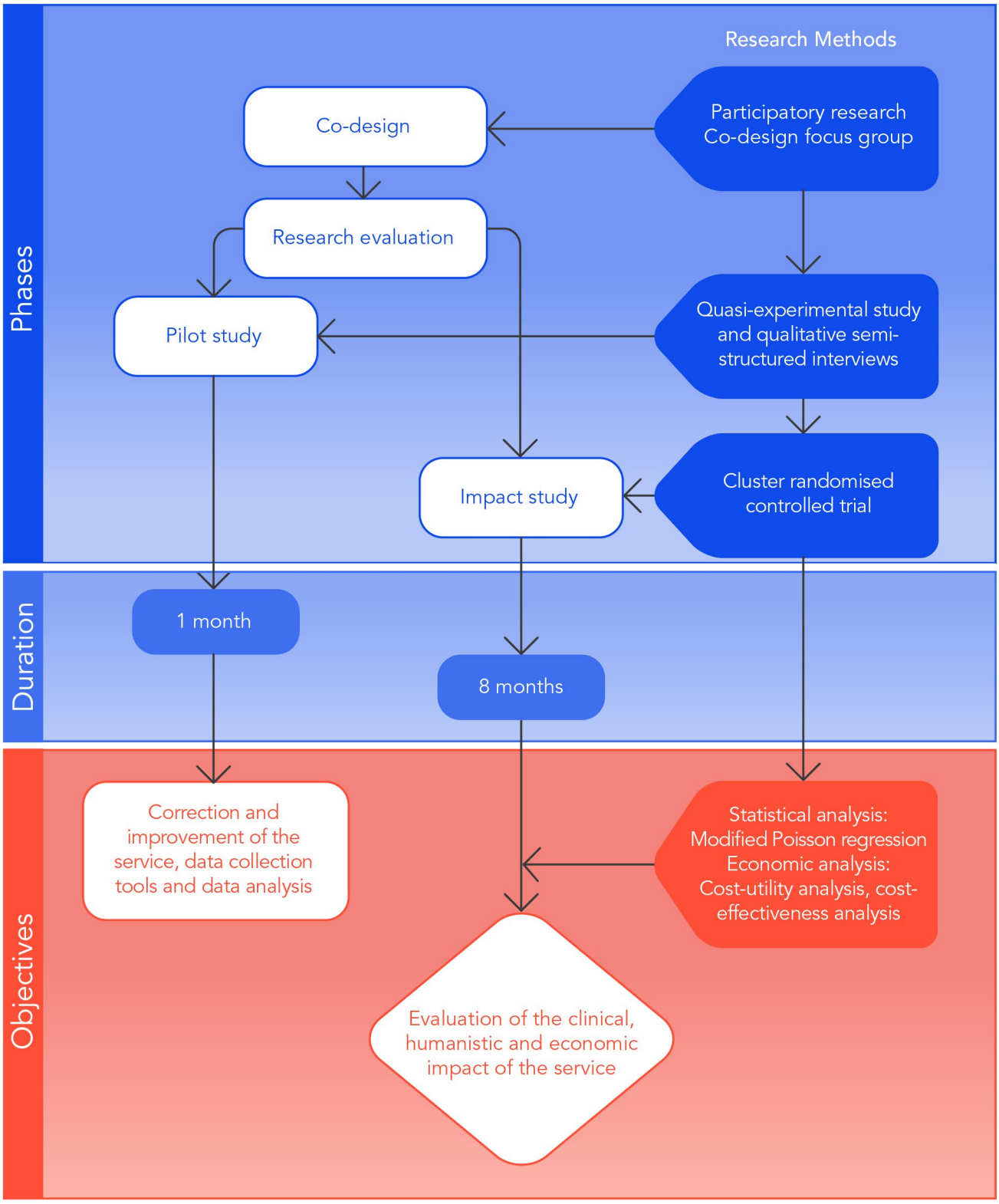
The guiding principles were integration of community pharmacy practice into the health care system, collaboration with general medical practitioners and patients, high quality and safe use of nonprescription medicines and appropriate treatment of minor ailments. The research was divided into three phases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

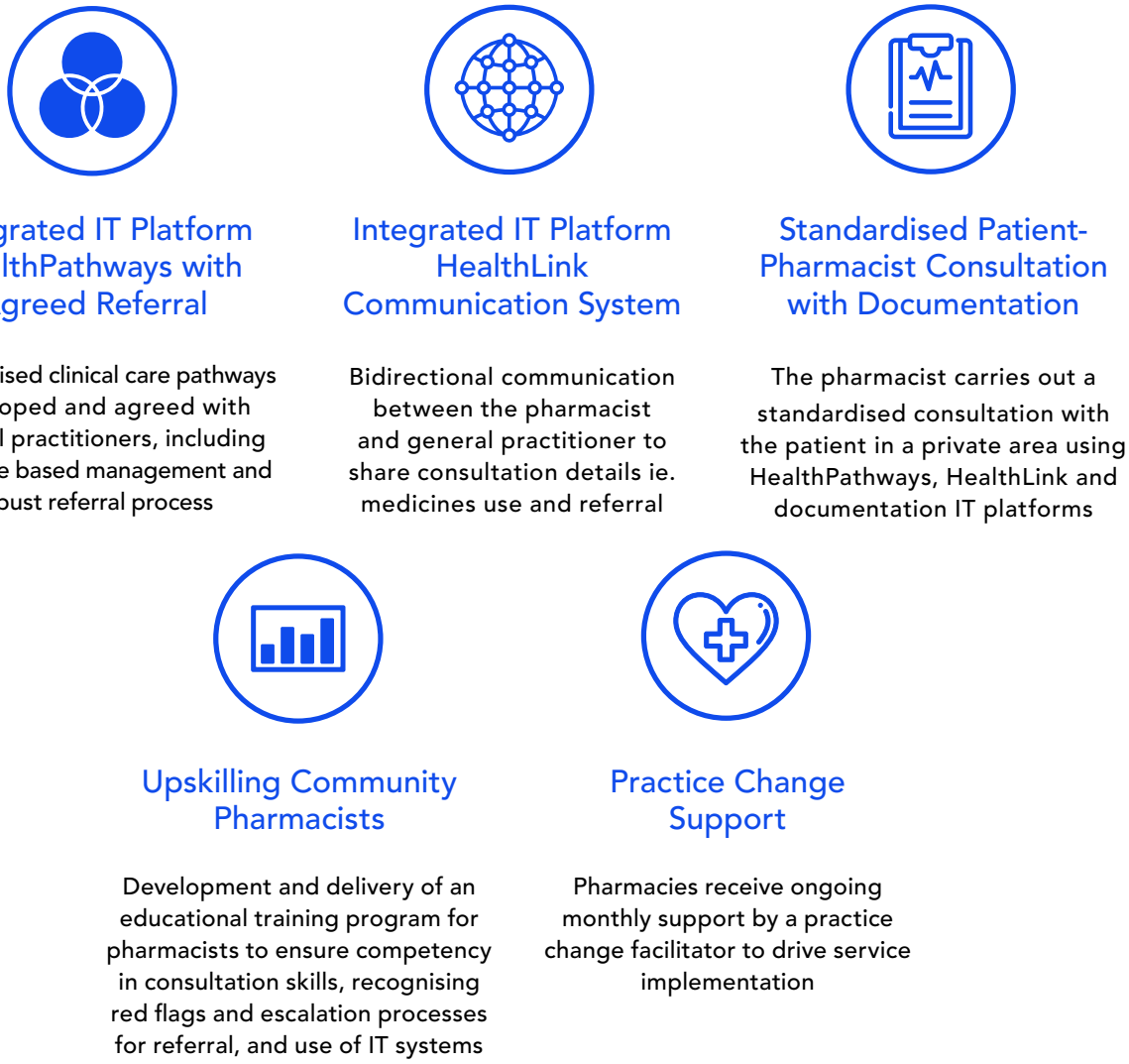
Figure 1 Flow chart of study phases and methods



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.

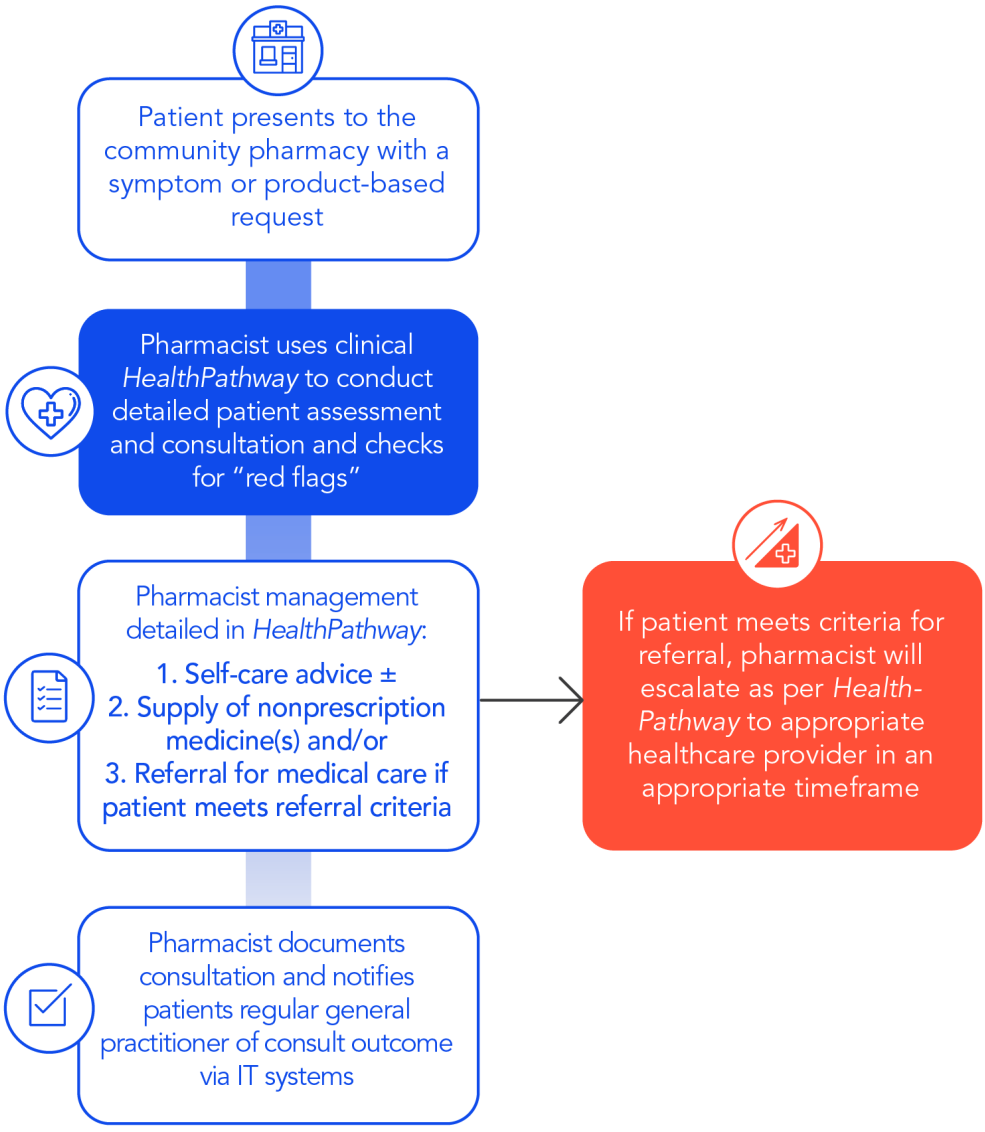
INTEGRATED HEALTH PLATFORM: HEALTH LINK

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

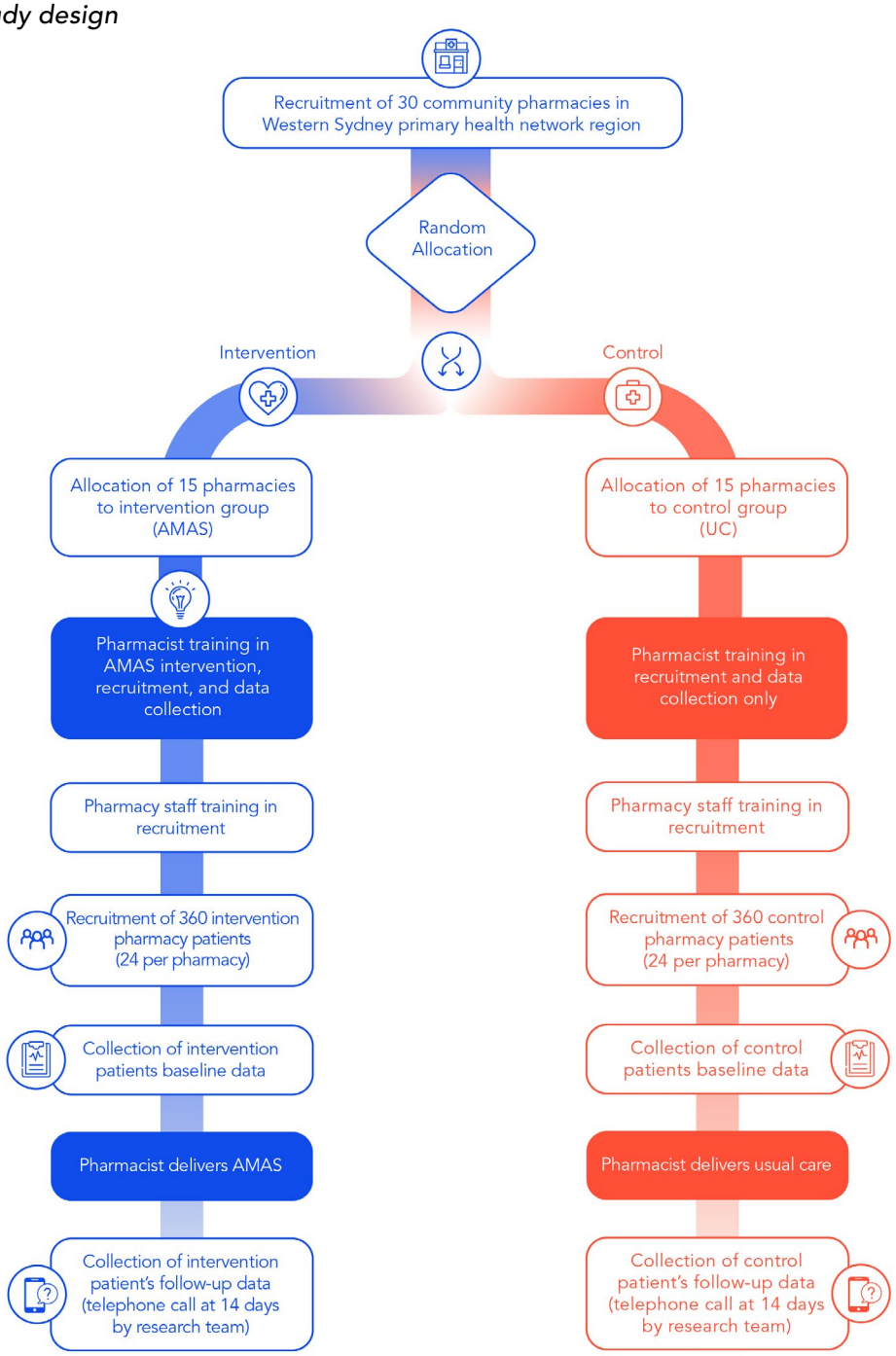
The AMAS was tested for feasibility in a two group quasi-experimental study (usual care and the AMAS) between October and December 2017 using a convenience sample of seven community pharmacies in WSPHN. Adult patients were included in the study presenting to the pharmacy with a symptom or product-based 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.

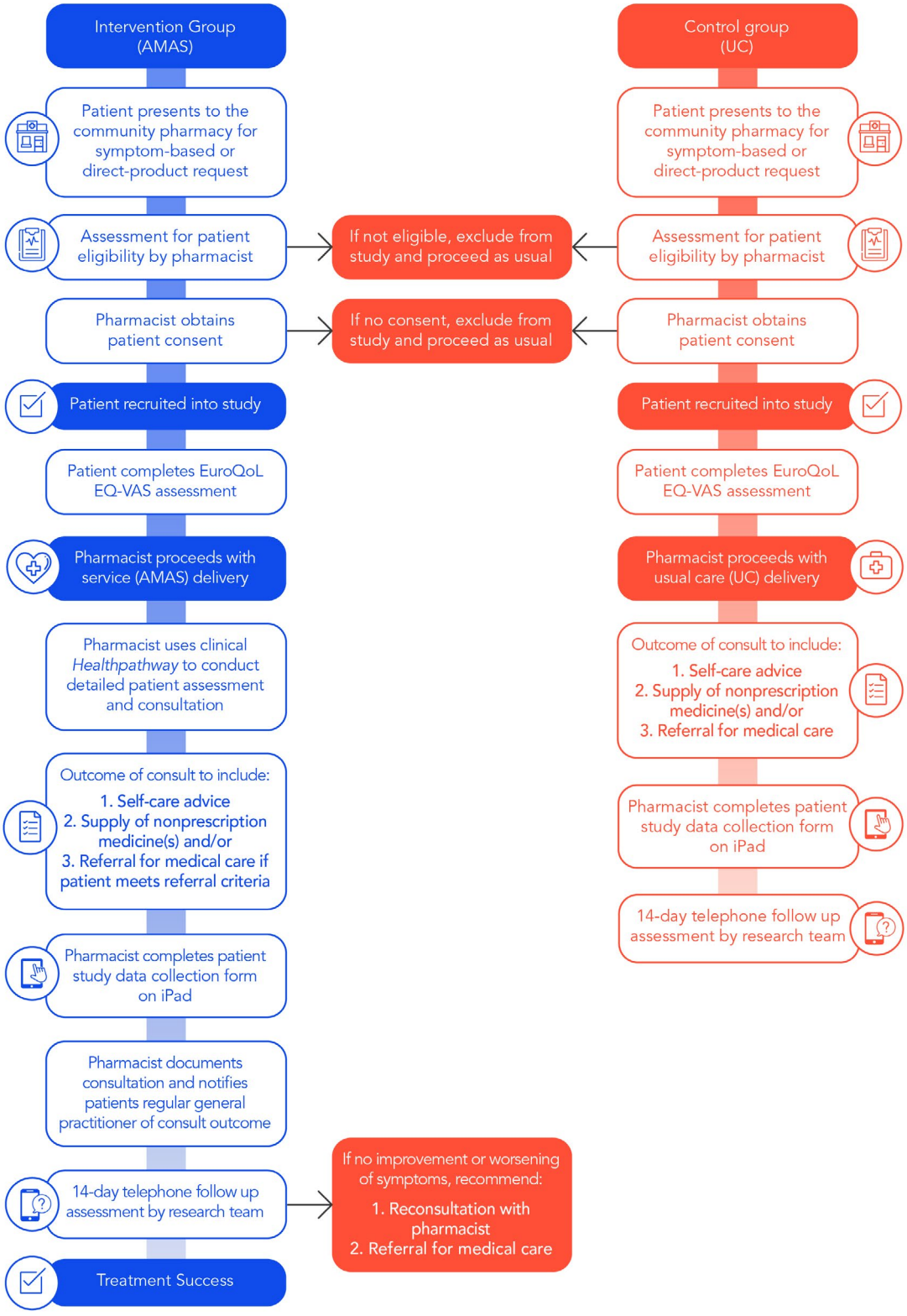
Figure 4 cRCT study design



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).

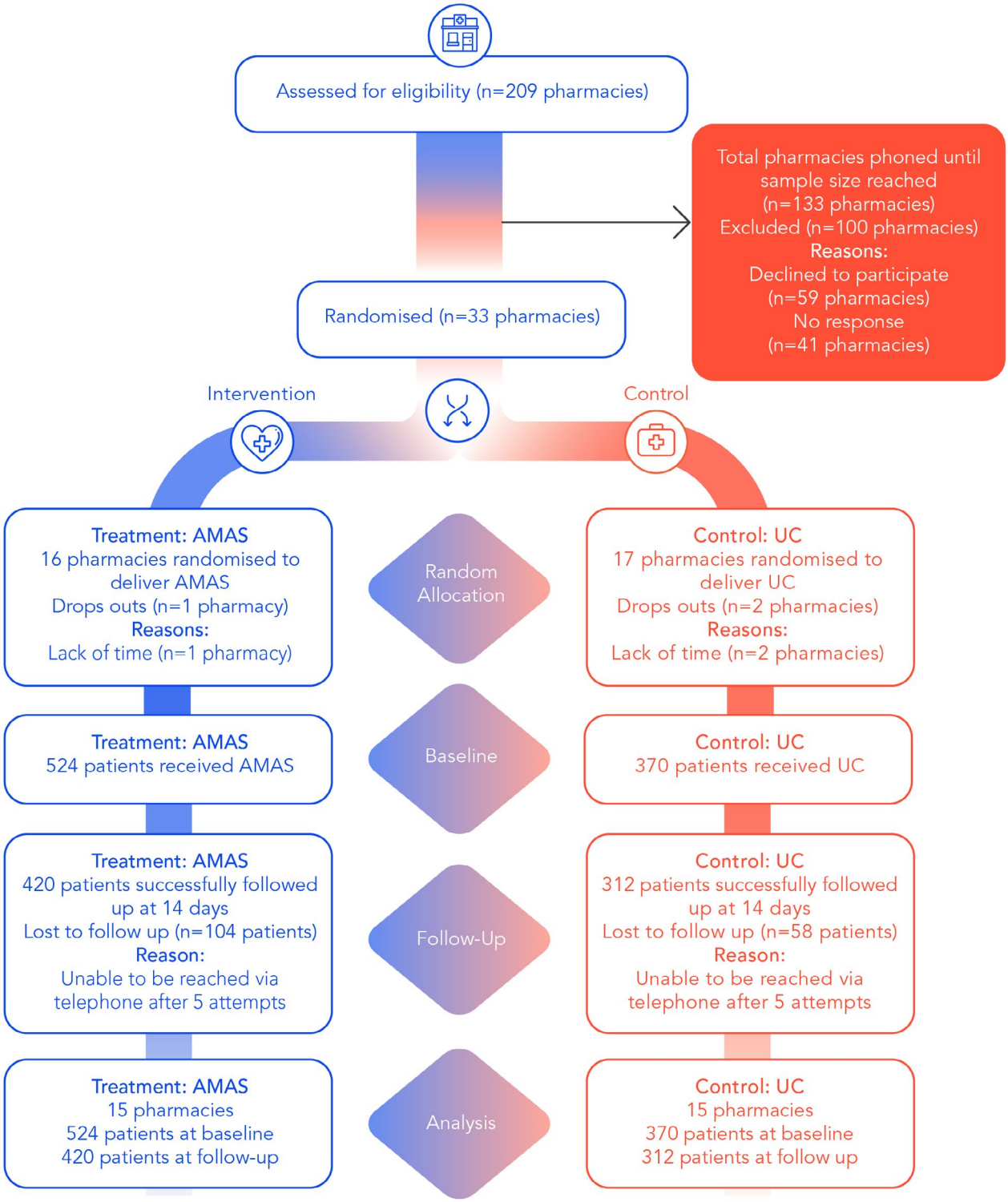
Patients presented to the pharmacy in one of three ways (i) symptom-based presentation; (ii) direct product request to self-medicate; or (iii) a combination of both. Overall, the majority of patients were documented with a symptom-based presentation in both study arms (Table 2).

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.

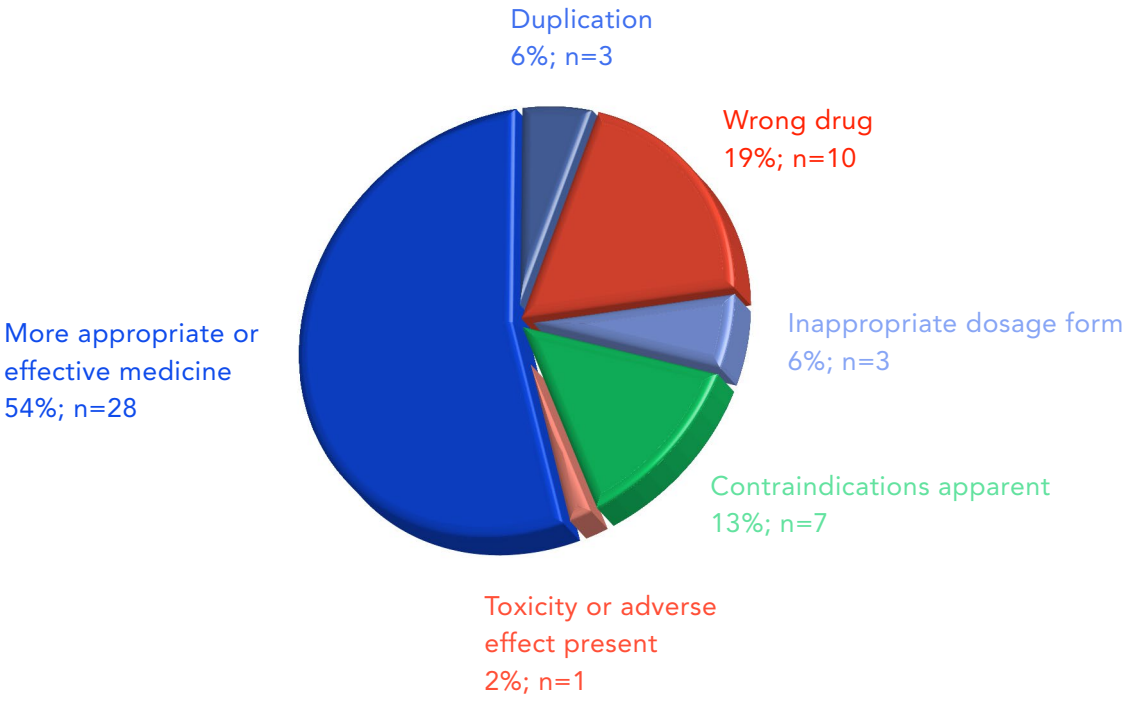
APPROPRIATE RATE OF NONPRESCRIPTION MEDICINE RECOMMENDATION

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.

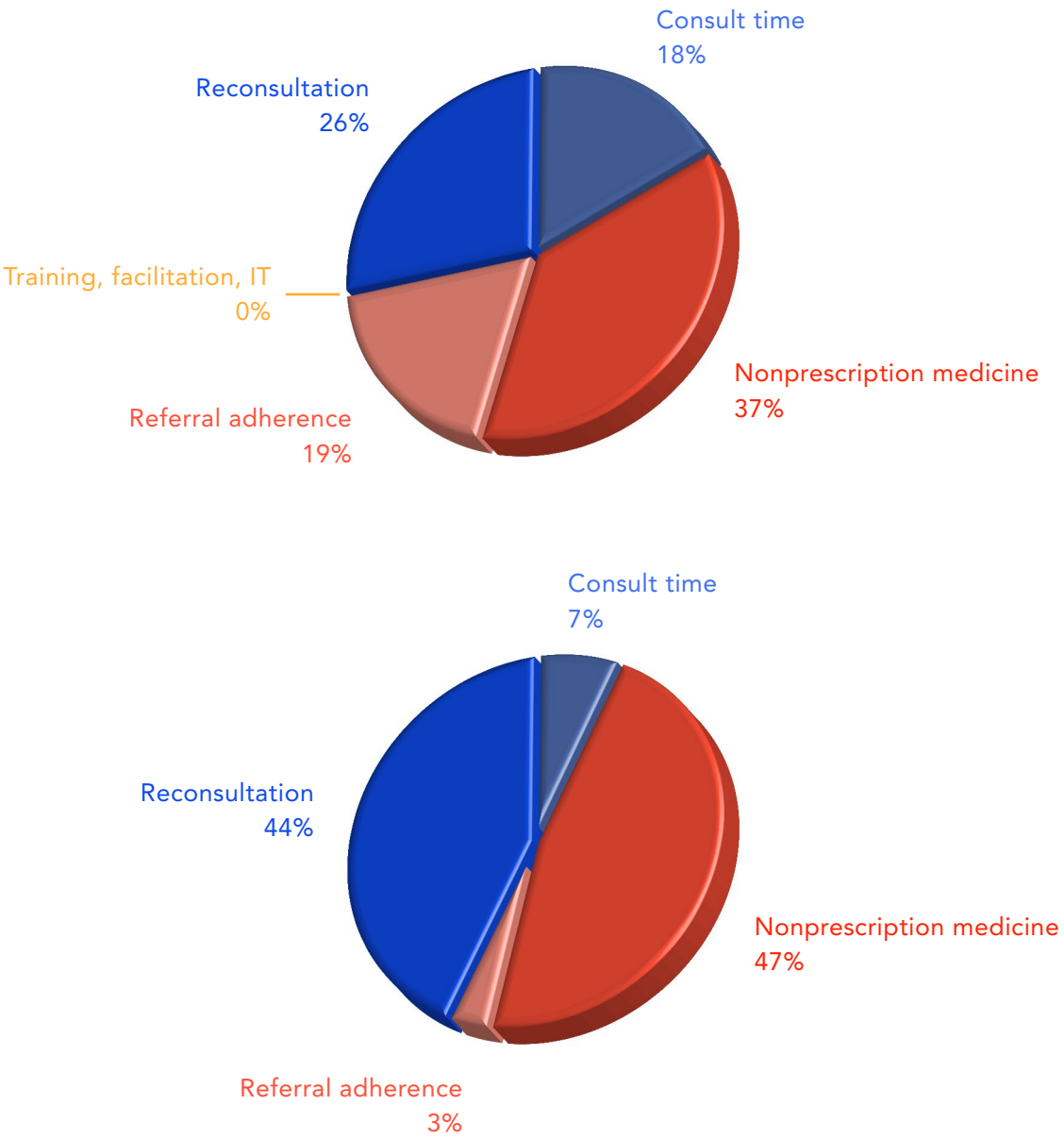
Table 6 Results of cost analysis

	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.

CHAPTER 1

BACKGROUND

CHAPTER 1: BACKGROUND

INTEGRATED CARE

Internationally, healthcare systems are faced with the rising rates of chronic and complex illness. The associated clinical and economic burden represents a major challenge to the optimal provision of healthcare (1-3). A key issue that needs to be addressed is how to connect services and healthcare professionals to achieve integrated services for consumers and health professionals as models of care evolve to deliver a person-centred approach (4). Health professionals strive to deliver the best possible care, but due to many organisational and payment factors it is often fragmented and siloed (5). In 2017, the Australian Government's Productivity Commission released a report identifying key issues with the Australian healthcare system including the lack of integrated care, insufficient patient-centered care, the need to focus funding towards innovation or clinical and economic outcomes, with a greater focus on quality of health (6).

Integrated care is a possible solution to meet the rising demand of healthcare services and a means of contributing to the sustainability of Australian healthcare (7). The benefits of an integrated primary care system have been universally recognised (8). Evidence indicates that health systems with integrated primary health care are effective in improving patient outcomes, efficient at delivering high-quality appropriate services (9, 10), and are associated with lower national health care costs (11). An integrated health system is one that is easy to navigate and access, and provides more choice and opportunities for patients to actively engage with the health system. It also enables and supports an ongoing relationship between providers to deliver consistent, coherent and connected health services to patients (12). The NSW Health 2018 Strategic Framework for Integrating Care report (12) sets an overarching vision of integrated care in Australia for better outcomes for individuals and the broader health system. These outcomes include:

1. Coordination of health care across different settings;
2. Reduced duplication in investment and services and more effective use of resources;
3. Improved health and wellbeing of the population, with greater health literacy and self-care (12). Integrated care in Australia is underpinned by the Quadruple aim (Figure 1) for improvements in patient and provider experience, health outcomes and cost efficiency (12).

The Australian and state/territory governments have made substantial policy progress to deliver integrated care (12). Multiple strategies have been employed including structural health reform, implementation of new integrated service delivery models and specific targeted community-based programs (13-18). A substantial investment in integration was made in July 2015 with the introduction of Primary Health Networks (PHNs) (10, 19). Thirty one PHNs were funded by a total of $900 million, replacing 61 Medicare Locals that had previously evolved from the 112 Divisions of the Department of Health's General Practice Program (20). PHNs were established to lead improvements in the quality and delivery of primary health care and align with local hospital networks to drive efficiencies and better direct health funding to the delivery of frontline health care services (21). 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 (22).

Figure 1 Quadruple aim

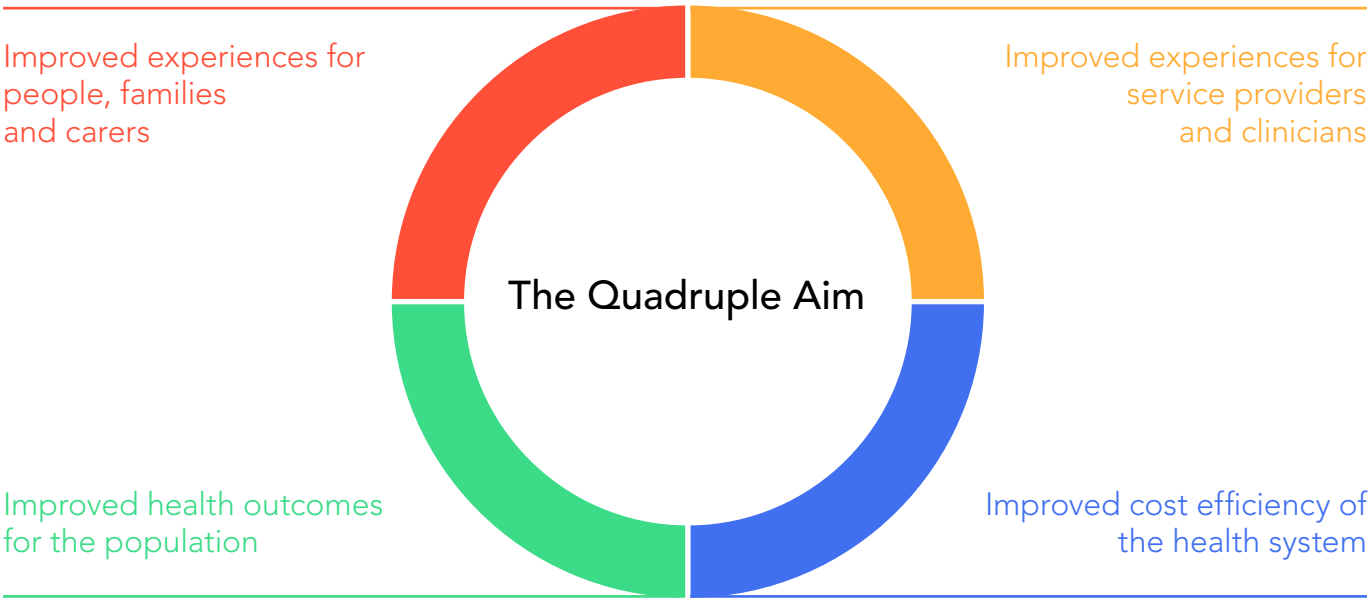


Figure adapted from the NSW Health Strategic Framework for Integrating Care Report 2018 (12)

PHARMACISTS AS PART OF INTEGRATED CARE

In Australia, community pharmacists are increasingly being integrated into the healthcare system (23) and also increasingly collaborating with other health professionals to ensure that medicines-related management is part of a more collaborative approach to patient care. The National Association of Primary Care identifies community pharmacy 'as an integral component of primary care' (24). Collaboration of community pharmacists with other health professionals is driven by the need for greater system efficiency, the provision of integrated care and cost-effective health outcomes (23, 25). The Pharmaceutical Society of Australia's (PSA) Pharmacists in 2023 report envisages pharmacists practising at their full scope to drive greater efficiencies (26). The Pharmacy Guild of Australia (PGA) in their Community Pharmacy 2025 report identifies community pharmacy as an integral part of a more coordinated and collaborative approach to patient care within the Australian health care system (23). The Guild's 2025 vision envisages community pharmacies as health hubs that build on a core expertise in medicines and facilitate the provision of an array of essential, cost-effective and integrated health services to an empowered and informed consumer (27).

EMERGING ROLES FOR PHARMACISTS

The profession is broadening the scope of practice of community pharmacists in both the provision of dispensing and professional services (28-31). Pharmacists' roles continue to expand and incorporate greater patient care responsibilities and provision of more individualised care (32). The core medicines role of community pharmacists has started to evolve from the current focus on dispensing to medicine experts to deliver individualised care for their patients through a combination of medicines supply, self-care advice, and working in collaboration with other health professionals. The shift to a service provider model is driven primarily by leadership of national and international professional organisations, innovative practitioners, education, government policies, remuneration and patient needs (33).

Professional services are defined as:

"an action or set of actions undertaken in or organised by a pharmacy, delivered by a pharmacist or other health practitioner, who applies their specialised health knowledge personally or via an intermediary, with a patient, population or other health professional, to optimise the process of care, with the aim to improve health outcomes and the value of healthcare" (34).

The implementation of professional services continues to remain a crucial aspect of the future professional and economic viability of the sector (35). The focus on new professional services suggests that the profession is changing its practices and continues to realise the professional and financial benefit of service implementation and its integrated role within the broader healthcare system (36).

INTERNATIONAL CONTEXT

The evolution of community pharmacy in Australia is mirrored internationally. In New Zealand (NZ) there has been an emphasis on integration, spanning primary and secondary care (37). This has also been seen in the United Kingdom (UK), which wants to see pharmacists become part of an integrated solution to patient and healthcare demands (37). In the United States, pharmacists are being recognised as part of integrated teams, with opportunities provided by a proliferation of new models such as medical homes, and community-based care teams (38). Several provinces in Canada have adopted a new interprofessional community practice model that integrate pharmacists into primary care teams (39). Canada, the UK and NZ are arguably advanced in terms of the profession enhancing its role in areas such as minor ailment or common clinical conditions services, pharmacist prescribing, personalised medicines support and screening and chronic disease prevention (40).

Internationally pharmacists providing primary health care are working in a variety of settings, and in different operational environments, from general practice and nursing homes, to urgent care settings such as NHS 111 and emergency departments. The scope of practice for pharmacists includes the ability to order and interpret laboratory tests, administer injectable drugs and vaccines, prescribe medications, shifting pharmacists from the traditional dispensing role with medicines expertise to that of an integrated care provider (41). This calls upon an extended skill-set. For example, the Scottish Government expects all clinical pharmacists to be NHS accredited independent prescribers by 2023 (42). Several challenges have been highlighted regarding integrated models of care for community pharmacy, including the arrangements for commissioning community pharmacy and securing GP support (43).

There are different models of GP-pharmacist collaboration offering the community pharmacy network to be better integrated into general practice or urgent and emergency care systems. One example in the UK is the provision of integrated out-of-hours services, such as the Digital Minor Illness Referral Service (DMIRS) (44, 45). The service, commissioned by NHS England's Pharmacy Integration Fund, evaluates the way in which patients with self-limiting minor ailments who are contacting urgent services can be directed to community pharmacists instead of being booked for an urgent GP appointment or signposted to their GP. It also moves toward better integration of the national community pharmacy network into urgent and emergency care and general practice systems. Pharmacy providers are required to provide the same or higher quality of care as traditional out-of-hours locations closer to home with a focus on self-care (46). Another example of shifting care to community pharmacy is the NHS Urgent Medicine Supply Advanced Service (NUMSAS). This service enables NHS 111 to refer patients to the community pharmacist for a repeat supply of a prescription where there is an immediate need (47).

A recent study in the UK examined the emerging roles for pharmacists as part of the emergency care workforce and determined what extent pharmacists could undertake clinical management of patients. In a categorisation of over 18,000 emergency department (ED) presentations, it was demonstrated that community pharmacists could manage up to 8% of presentations in ED (48). With additional training, such as a 12-month diploma in clinical examination skills, clinical health assessment and diagnostics, a further 28% of cases could be managed in the ED (48). These pharmacists, collectively termed Emergency Department Pharmacist Practitioners (EDPPs), take clinical responsibility for certain patients with minor ailments and minor traumas in hospital emergency departments (48).

Since 2006, clinical pharmacists in the UK have been able to undertake further training to become independent prescribers (49). In March 2015, there were 2191 pharmacists with independent prescribing rights registered with the General Pharmaceutical Council. Clinical pharmacist independent prescribers may benefit from further training beyond prescribing, such as the recently introduced educational programme to become Advanced Clinical Practitioners (ACPs) (50). Pharmacists with ACP training can conduct comprehensive physical examinations, request and interpret tests, diagnose and treat illnesses and injuries, and counsel patients on preventive healthcare. The proposed extended role for pharmacists with ACP training is not intended to replace the existing workforce, but to become a complementary group of clinicians who can diversify and become part of a fully integrated team to clinically manage patients (50).

MINOR AILMENTS

Major questions exist surrounding how health care systems can address minor ailments more efficiently by delivering care at the appropriate level in an integrated capacity (51, 52).

Minor ailments have been defined in the international literature as:

"...common or self-limiting or uncomplicated conditions which may be diagnosed and managed without medical (i.e., doctor) intervention" (53-55).

The Pharmaceutical Society of Australia has defined minor ailments as:

"...conditions that are often self-limiting, with symptoms easily recognised and described by the patient and falling within the scope of pharmacist's knowledge and training to treat" (56).

This may include, but not limited to, conditions such as common colds, strains and sprains, acute diarrhea, constipation, muscle aches and pains, allergies, headache, rash, dermatitis and eczema, fevers, foot conditions such as corns and callouses and others (57).

It is already known that patients self-manage conditions to a large extent (58) and encouraging people to exercise greater levels of self-care, either for acute or chronic problems, has significant potential to directly affect demand for, and shift costs from, medical health care. Pharmacists are positioned to facilitate consumer self-care and appropriate self-medication (59, 60). Undoubtedly, the expansion of nonprescription medicines has given consumers greater choice providing community pharmacy with an opportunity to demonstrate real and tangible benefits to consumers by facilitating this process (59).

SELF-CARE AND SELF-MEDICATION

Self-care has been highlighted by the World Health Organisation (WHO) as integral to primary health care and is defined as:

"the ability of individuals, families and communities to promote health, prevent disease and maintain health and to cope with illness and disability with or without the support of a healthcare provider" (61).

Self-care covers hygiene (general and personal), nutrition (type and quality of food), lifestyle (sports activities, leisure time, etc.), environmental (living conditions, customs), social, or, socioeconomic factors (level of income, cultural beliefs, etc.) and self-medication (selection and use of medicines, by people, with the purpose of treating diseases or symptoms that they themselves can identify). The self-care process empowers patients to take a proactive role in identifying and appropriately managing their health conditions. Self-care is the preferred method of managing minor illness for many patients (62) and the need to support patients with self-care has been acknowledged as a priority in Australia (63).

Self-medication is a fundamental component of self-care and has been defined by WHO as:

"the selection and use of medicines by individuals to treat self-recognised illnesses or symptoms" (64).

Self-medication with nonprescription medicines recognises consumer autonomy and encourages greater independence in health decisions (65).

Australia's National Medicines Policy aims to optimise health and economic outcomes through a number of objectives, including 'timely access to the medicines that Australians need, at a cost individuals and

the community can afford' (66). Medicines that are assessed to have low associated risk are unscheduled and available for general sale from retail outlets, while medicines that are assessed to have potential risks are classified into schedules, the progression through which signifies increasingly restrictive regulatory controls (67). Community pharmacists can recommend nonprescription medicines, which are divided into two schedules. Legislation in Australia requires these medications to be supplied under the supervision of a registered pharmacist. Schedule 2 medicines ("pharmacy medicines") are only available in a pharmacy and must be sold under the supervision of a pharmacist. A pharmacy assistant may hand these medicines to patients, but this must be done in the presence of a registered pharmacist. Schedule 3 medicines ("pharmacist only medicines") must be handed out by pharmacists themselves (68). Schedule 4 (S4) Prescription Only Medicines and Schedule 8 (S8) Controlled Drugs require a prescription for supply (69).

Australia's nonprescription medicines market is a AUD5.4 billion industry growing at 2.5% (70), providing choice and access to approximately 16,000 nonprescription medicines on the Australian Register of Therapeutics Goods (ARTG) (71). Community pharmacy remains the dominant channel for nonprescription products. A review by the Global Self-Care Federation (formerly the World Self-Medication Industry (WSMI)) states that nonprescription products are widely and responsibly used by consumers (72), and access to these medicines has enabled the practice of self-care for minor ailments.

Globally, access to relevant medicines has improved through increased reclassification of medicines from prescription to nonprescription availability (73). Research undertaken by Precision Health Economics estimates that self-medication contributes $120 billion in healthcare savings globally (74). An additional cost to the health system of $3.86 billion each year has been estimated if the eight largest nonprescription medicine categories were unavailable without prescription. The availability of medicines without prescription increases patients' timely access to treatment and promotes self-medication for the self-treatment of common ailments. Research conducted by Consumer Healthcare Products Australia (formerly the Australian Self-medication Industry (ASMI)) on consumers' use and attitudes toward nonprescription medicines showed that 83% of consumers had used more than one nonprescription medicine in the past month, with cough and cold medicines, analgesics, gastrointestinal, allergy or sinus products being commonly used. Of these, 77% were purchased from the pharmacy. More than half of consumers surveyed indicated they would visit their GP if unable to obtain their nonprescription medicine from the pharmacy. This would further impact health care costs and adversely impact on the availability of GPs (57).

While nonprescription medicines are often perceived by the public as being safer than prescription medicines (75), many are also known to contain potent pharmacological agents and have the potential for adverse drug reactions and drug interactions. Their use demands an equal degree of care to prescription medicines (76). Pharmacists and pharmacy staff are often required to make recommendations based upon symptom information, other medical conditions, other medications being used, as well as the health status of patients. A number of specific nonprescription medicines and therapeutic groups have recognised adverse effects. The likelihood of serious adverse effects is further increased in patients with altered pharmacokinetics, pharmacodynamics, impaired renal function, reduced hepatic blood flow and liver size, increased body fat, decreased lean body mass, changes in receptor sensitivity, and increased number of co-morbid conditions. A national census reported more than two million Australians over the age of 50 take nonprescription medicines daily (77). The frequent or continued inappropriate use of nonprescription medications in this population increases the risks of medication-related adverse events (78). Inappropriate self-medication with nonprescription medicines has also shown to contribute to hospital admissions (79).

Many consumers independently manage their prescription and nonprescription medications. While patients consider pharmacies a logical place to start the care process (80-83), it must be noted that the public tend to self-medicate for their minor ailments before seeing any health care provider (84-87). For example, in an observational study in 16 primary care networks in 12 European countries, 55.4% reported self-medicating

before consulting with a primary care provider, and 21.5% after consultation, most frequently with paracetamol, antitussives, and mucolytics (88). This of course varies with the nature of the illness (89-91). GPs and pharmacists may be unaware of their patients' use of nonprescription medicines (including medicines purchased outside of pharmacy) and problems associated with their use may go undetected. Patients may also be unaware of the potential side effects and drug interactions associated with nonprescription medications when taken with prescription medications or certain medical conditions. In some instances, their long-term use at inappropriately high doses, or use by persons with contraindications may result in serious adverse effects, including gastrointestinal haemorrhage, cardiovascular toxicity, renal toxicity, and hepatotoxicity (92-94). Presently, there is no system whereby GPs could access patients use of nonprescription medicines.

Patients report that the advice of a pharmacist is one of the most important factors in decision-making when selecting a nonprescription medicine (95). Their use demands a degree of care along with professional advice that is objective and evidence-based (96). Pharmacists have an important role in responsible self-medication, by serving as a point of access for reliable sources of information. They maintain a critical role in safeguarding their patients from potentially inappropriate use limiting further healthcare utilisation, such as GP or ED visits. Pharmacists are able to facilitate this process, converting self-medication by the patient into responsible self-medication practices, meaning the medicines are safe, of quality, are effective; are suitable for conditions that can be self-treated, with the correct formulation, dosage and form of administration.

INTERNATIONAL MINOR AILMENT INITIATIVES

Promoting the appropriate supply of nonprescription medicines has been identified as a priority for community pharmacy practice improvement. Delivering cost-effective minor ailment care through pharmacist-directed self-medication can form part of the solution for a sustainable health system (97). Internationally, governments have been investing in supporting pharmacists to take on an expanded role to support self-care for health system efficiency. Pharmacists are treating illnesses (ie. bacterial conjunctivitis with chloramphenicol eye drops or symptomatic management of cold and flu) that may otherwise take up time and resources at general practice or the emergency department (98). The NHS England evidence base from the Urgent and Emergency Care Review published in 2013 highlighted a potential role for community pharmacy in providing accessible care. Minor ailments accounted for 18-20% of GP workload and 8% of ED visits (5, 99, 100). This included patients presenting with upper respiratory or gastrointestinal symptoms, and certain types of pain which were considered appropriate for pharmacist-directed care as determined by a primary care physician and community pharmacist (5).

There is consistent evidence that pharmacy-based minor ailment schemes (MASs) provide the right level of care, mitigate funding and system inefficiencies as patients access professional support for conditions that can be self-managed (101). A total of 94 international schemes are identified in the literature, including the UK (England, Scotland, Northern Ireland and Wales) and regions of Canada (known as Minor Ailments Prescribing Services) (101, 102). These initiatives were implemented in Scotland in 1999, England since 2000, Northern Ireland since 2009, Wales in 2013 and in Canada since 2007 (56). Other countries, such as Spain (103) and New Zealand (37), are currently evaluating the feasibility of introducing similar minor ailment initiatives, while a pilot study is being undertaken in Ireland (104).

International MASs were introduced with various objectives including (17, 101):

1. Contributing to the sustainability of health systems and optimising healthcare costs, through treating patients with common ailments at an appropriate level with nonprescription medicines indicated for these health problems;
2. Improving accessibility by providing timely treatment for patients with common ailments through the community pharmacy network in both urban and rural areas;
3. Increasing the primary care capacity and availability of general practice for medical provision in chronic and complex patients, through the transfer of common ailment consultations from general practice to community pharmacy;
4. Improving collaboration and communication among health professionals (ie. community pharmacists and physicians) through consensus of standardised protocols of work particularly the referral of patients;
5. Facilitating self-care of conditions which can be self-treated and patients' skills in responsible self-medication practices through community pharmacy.

A systematic review published in 2013 of international MASs has recognised the patient and economic benefits (17). The review showed low reconsultation and high symptom-resolution rates with MAS, suggesting minor ailments are being dealt with appropriately in pharmacy (17). The proportion of patients reporting symptom resolution ranged between 68% and 94.4% (17). The rate of reconsultation ranged from 2.4% to 23.4% (17). The impact of MASs on GP workload and number of consultations has been reported to be variable. Paudyal et al. reports a range from 1.4-56.6% reduction in GP minor ailments consultations (17). It is reported that despite a reduction in the total volume of minor ailment consultations (17), the total number of GP consultations remain unchanged (101, 105). This is not in itself surprising as there is an

increasing need for GP services and any reduction will be quickly filled. The promotion of self-care through the MAS is a collaborative effort among professionals, as it happens in 18% of services in England in which the inclusion of a patient in the service is through referral from a GP or staff to pharmacy. Additional clinical training is required in nearly half of the international MASs (98, 101).

CANADA: PHARMACISTS PRESCRIBING FOR COMMON AILMENTS

Minor ailment assessment and prescribing is the nomenclature used in Canada to represent a pharmacy service that allows pharmacists to prescribe certain drug groups for the treatment of self-diagnosed and/or self-limiting conditions (151). Eight of thirteen provinces in Canada operate a Minor Ailments Prescribing Service (101). Alberta became the first province in 2007 to allow pharmacists to prescribe medications, but their legislation went beyond minor ailments (102). All the remaining provinces have since adopted various degrees of prescriptive authority (106). The variety of minor ailments treated by Canadian-based MAS varies from 12-34 minor ailments including vaginal thrush, allergic rhinitis, haemorrhoids and canker sores (101). Nova Scotia gave pharmacists authority to prescribe certain medications for minor ailments in 2011. Saskatchewan became the first province to remunerate for minor ailments prescribing by pharmacists for selected conditions (mild acne, thrush, cold sores, canker sores, diaper dermatitis, insect bites, and seasonal allergic rhinitis). An $18 CAD remuneration fee is offered with consultations that result in a prescription (101). Example agents under the program include valacyclovir for cold sores, and intranasal mometasone for seasonal allergies (107). In 2008, pharmacists in New Brunswick were given the ability to diagnose and manage 32 ailments following mandatory training (108). In Alberta, pharmacists have obtained additional prescribing authority to prescribe medication in areas they have demonstrated clinical competency (with the exception of narcotics and controlled drugs) (101). Pharmacists are required to practice within their own competency and skill area. Assessment of patients with minor ailments and prescribing of medicines is soon to be among the responsibilities of community pharmacists in Ontario (108). In April 2019, Health Minister Christine Elliott indicated the Ontario government will support pharmacists to practice at the full extent of their expertise to alleviate the growing economic burden on ED services, and GP services (108).

SCOTLAND: MAS

Scotland was the first country to implement a national scheme (109, 110). The national Pharmacy First scheme was introduced in Scotland in 2006, for children, patients aged over 60 years, those with a medical exemption certificate, or people on certain benefits. Currently, the Scottish service specification treats 25 minor ailments. Scottish MASs are also associated with Patient Group Directions (PGDs) allowing pharmacists to supply or administer prescription-only medicines to patient groups presenting with certain conditions (101). Prescription medicines available under Scottish PGDs include chloramphenicol 0.5% eye drops and fluconazole 150mg capsules. Pharmacies are remunerated by the National Services Scotland. Reimbursement is according to a monthly capitation fee dependant on the number of patients registered. Additional reimbursement is provided for the cost of medicines (80). The national formulary is the reference point for the reimbursement of products delivered under the MAS (109, 111).

The Scottish Government following a successful pilot in Glasgow announced in September 2018 the expansion of a universally available MAS irrespective of age and social circumstance (112). It is expected the national service will cover a wider range of conditions than the current MAS such as uncomplicated urinary tract infections and impetigo (112). This coincides with a report commissioned by Community Pharmacy Scotland (CPS) in 2018 demonstrating the popularity of the Scottish MAS among patients. For those surveyed, 90% of patients reported their MAS consultation experience as "excellent" (113), while 60% indicated they would have utilised other healthcare alternatives such as general practice if MAS was not available. In April 2019, the Scottish Government announced an additional GBP2.6m in community pharmacy funding in the 2019/20 financial year (114). Funding for the Pharmacy First scheme remains at GBP1.1 million per year (112).

ENGLAND: MAS AND DMIRS

In England, 89 MAS services are commissioned by individual Clinical Commissioning Groups (CCGs) or Area Teams (ATs). The variety of minor ailments under the schemes varies up to 47 conditions (101). Usually these schemes are only open to patients who would otherwise be eligible for free prescriptions (over 60 years, under 16 years, or pregnancy) and pharmacists are remunerated by the NHS (115, 116). Jag Sangha, pharmaceutical adviser at Dudley CCG, indicated "the quickest and easiest way for patients to get advice and medicines for a range of minor health conditions is at a local community pharmacy. MAS will bring productivity and cost savings to the health system, along with improving the experience of care for patients" (117).

Eighteen percent of English MASs are associated with PGDs allowing pharmacists to treat presenting minor ailments with more complex products (101) including the influenza vaccine, oral antivirals, antibiotics (i.e. trimethoprim tablets), chloramphenicol eye drops and fusidic acid cream. Trained pharmacists in the North Midlands Staffordshire and Shropshire region may provide self-care for impetigo and simple urinary tract infections (UTIs) and, where appropriate, supply certain antibiotics under the NHS (118). In Devon, 186 pharmacies provide MAS and PGDs allow supply of certain prescription medicines for coughs, skin rashes and eye infections. The service has reduced demand on GP appointments and ED visits.

The remuneration structure in England is determined by local CCGs. Remuneration consists of reimbursement for costs of medicines and for consultation costs. Pharmacies may be remunerated depending on the number of items supplied to patients, a banded capitation fee, one off standard payment, retainer fees, cost of medicine supplied and/or pharmacist consultation fees (101). Typically CCGs use a combination of these payment structures to provide remuneration (101). Pharmacies are provided remuneration for the consultation and product supplied in 94% of English schemes.

Since 2017, there has been strong emphasis on further integration of community pharmacy into local NHS urgent care pathways through the DMIRS service (44, 45). This new model involves a digital referral from NHS 111 (urgent and emergency care helpline) or GP to the community pharmacy following an assessment by a call advisor where the patient is streamlined for a consultation with a community pharmacist (ie. MAS) if appropriate. The service is intended to increase primary care capacity and relieve pressure on existing ED, GP in hours and out-of-hours services (44). This has been achieved through:

- **Referral of significant numbers of patients to community pharmacy, and increasing capacity in urgent primary care locations;**
- **Promoting a strong self-care message to patients;**
- **Robust use of Information Technology (IT) for referrals from NHS 111;**
- **Ensuring patient safety and high levels of patient satisfaction.**

In 2019, NHS England is exploring the national rollout of DMIRS, as part of negotiations led by the Department of Health and Social Care with the Pharmaceutical Services Negotiating Committee (PSNC) on the Community Pharmacy Contractual Framework. These potential changes, if implemented, are estimated to have an impact in reducing in-hours and out-of-hours workload for GPs (119).

NORTHERN IRELAND: MAS

The MAS was initially introduced in Northern Ireland (NI) in 2005. This service was later withdrawn because of disputes regarding pharmacy reimbursements between the Department of Health, Social Services, Patient Safety, and the Pharmaceutical Contractors Committee of Northern Ireland (56). In 2009, the MAS was reintroduced as a national scheme to support self-care. It aimed to:

- **Encourage patient ability to self-treat minor ailments;**
- **Support the use of the pharmacy as a first point of call for health advice;**
- **Improve patient accessibility to treatment without the need of an appointment;**
- **Provide an alternative to a GP consultation for patients who don't pay prescription charges and reduce the number of inappropriate GP consultations for minor ailments;**
- **Benefit other parts of the healthcare service particularly emergency departments and out-of-hours medical services (56).**

The NI MAS is available to all patients over three months of age registered with a NI GP practice (120). Similar to the Scottish MAS, a single administration, record keeping, remuneration and training scheme exists. Individuals access the scheme by self-referral, pharmacist referral or referral by other health care practitioners. Like other schemes, pharmacists can offer individuals advice, treatment or referral options to manage minor ailments. However, only a maximum of two products can be issued in each minor ailment consultation. Medication is provided at no cost to the patient. Pharmacies are remunerated by a banded capitation fee determined by the number of consultations, as well product costs (56). Between 2013 and 2017, the cost of MAS was GBP14,196,513. This sum comprised GBP6,366,089 for the cost of medicines supplied, and GBP7,830,424 in consultation fees paid to community pharmacies providing the service (121). The NI government channelled GBP11.1 million in funding to community pharmacy up to March 2020, which included GBP2.1m for a minor ailments scheme (122).

WALES: MAS

Wales implemented a single MAS in 32 pharmacies in the Betsi Cadwaladr and Cwm Taf health board areas, with the intention of implementing a national MAS across all 714 community pharmacies in Wales (56). The Choose Pharmacy Scheme, which includes a common ailments service, discharge medicines reviews and an emergency supply service, began its rollout across the country in 2016 (123). It has successfully piloted a NHS 111 service, which it hopes to roll out nationally (123). The Welsh government channelled an extra GBP1.4 million in funding from April 2019 to community pharmacy (123) and in May 2019, GBP100,000 towards pharmacists' training in minor ailments (123).

RATIONALE FOR AN AUSTRALIAN MAS

Pharmacists providing self-care advice for common ailments, the availability of nonprescription medicines through pharmacies, and referral to other health care professionals is a well-established activity within Australian pharmacy practice. However, there is limited standardisation and protocolisation for consultations and procedures for escalating referral. There is minimal integration with general practice systems and no formal method of physician-pharmacist collaboration or communication relating to minor ailments and patients use of nonprescription medications. The nature and extent of collaboration may be seen as both episodic and informal. This invariably limits appropriate self-medication practices. In addition, there are no mechanisms to monitor or document patient interactions, resulting in missed opportunities to identify patients who require referral, and inappropriate or unnecessary continued use of nonprescription medicines. Moreover, if we implemented a MAS in Australia, we could achieve similar outcomes to international MAS.

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

- There is no national self-care policy;
- There is increasing use of GP and ED services leading to increased health spending;
- Patients are seeking care for common ailments at an inappropriate level of care (i.e. GP and ED);
- Accessibility to primary care is limited in rural and remote regions of Australia;
- Patients are 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;
- Pharmacist-directed 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.

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

SELF-CARE POLICY IN AUSTRALIA

Structural reform and health service orientation in Australia is impeded by the lack of a national health policy framework and a strategic national effort to promote self-care. Whilst there is strong and increasing evidence that self-care is important and beneficial, self-care in Australia is not yet an established policy concept and it remains an 'add-on' in decision-making about health for governments. In comparison, in similar health systems like the UK, there has been a significant strategic shift towards policy support for self-care focusing on 'patient activation' at every stage of healthcare including the prevention and care of illness, symptom relief and chronic illness (124). A recent UK inquiry recommended an enhanced range of options to better support self-care across the primary care sector, including greater integration between general practice, pharmacy and other health care services (125).

A 2014 Global Access Partners (GAP) report describes "the role of pharmacies and nonprescription medicines

Figure 2 Modifying trends in health service utilisation through investment in self-care

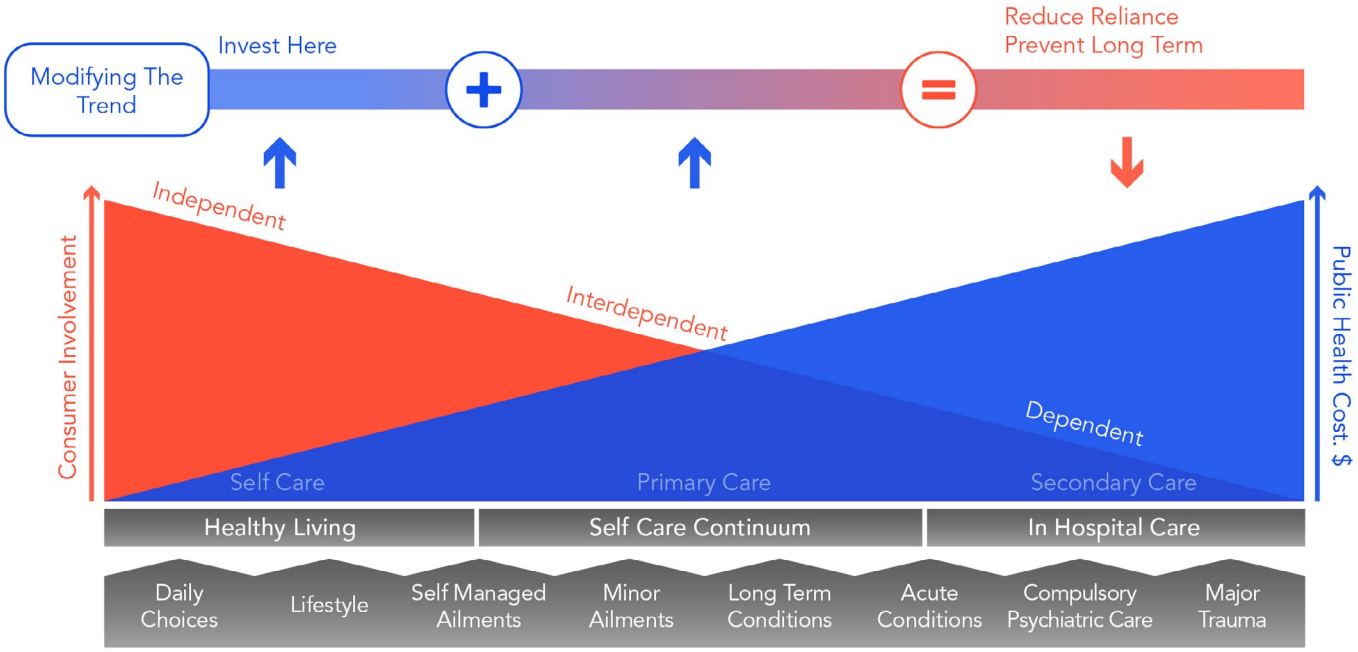


Figure adapted from Duggan et al. The State of Self Care in Australia. Australian Health Policy Collaboration (124)

in supporting responsible self-care and reducing government expenditure for a more efficient health system" (126). Developing strong policy and practice in relation to self-care is a complex undertaking. Enhancing the ability of the Australian population to undertake self-care requires whole-system policy development and action. Figure 2 illustrates the ways in which policy reform and targeted investment in self-care is required to modify current trends in health service utilisation (124).

INCREASING DEMAND FOR ED AND GP SERVICES IS LEADING TO INCREASED HEALTH SPENDING

Health expenditure in Australia grew by 50% between 2006-07 and 2015-16, from $113 billion to $170 billion (12). ED attendances accounted for $4.7 billion of total expenditure (127). The most recent Australian Institute of Health and Welfare (AIHW) report demonstrated a national average annual increase in ED presentations between 2012-13 and 2016-17 (128). Increased pressures are attributed to increased patient need, increased patient waiting times, increased volumes of hospital admissions, difficulty accessing community primary care services and increased presentations of minor attendances (128, 129). Increased usage, linked with inpatient bed limitations are contributing to prolonged length of stays in the ED, disrupted timely access to urgent care and are a potential threat to patient safety (127). Similarly, there has been an increased demand for GP services in Australia (130). One hundred and forty-eight million GP services were supplied to Australians in 2016-17 costing the health system $7.4 billion (130). More than 35% of Australians visited a GP at least six times in 2012-13 (130).

A significant volume of non-urgent presentations to ED has contributed to the increased pressure on ED and GP resources in Australia. Of the 7.2 million ED presentations in 2014, 9% were considered non-urgent (131). A survey conducted by the Neilson Company found 39% of Australians reported seeing a GP first line for their most recent minor ailment. One Australian report undertaken for the ASMI, used weekly IMS Australian Medical Index

data from 420 GPs across Australia to quantify the impact of the treatment of minor ailments on overall GP workload (111). This study estimated that 7-21% of all GP consultations in Australia are partly or totally spent on minor ailments (111). The most frequently treated minor ailments by general practice in Australia include acute upper respiratory tract conditions, diarrhoea, low back pain, cough, headache and constipation (111), and account for 58% of all minor ailment attendances to a GP (111).

Internationally, increases in GP and ED presentations are driving governments to review policy to provide an alternative to the ED and GP for minor ailment care that is accessible and appropriate. It has been estimated that 13% of GP consultations and 8% of ED consultations for minor ailments could be transferred to community pharmacies (54, 55), promoting better allocation of ED and GP time. It has been estimated that implementation of a MAS aimed at transferring minor ailment care to community pharmacies from GP services in Australia could potentially save up to $260 million annually (132) and reduce GP workload by up to 13 million consultations per year providing greater time for more complex consultations (133).

ACCESSIBILITY TO PRIMARY CARE CAN BE HAMPERED IN RURAL AND REMOTE REGIONS OF AUSTRALIA

In rural and remote Australia, where 5% of the population live (134), individuals' access to primary care is limited by the availability of GP services (135, 136). The number of GPs per capita is significantly lower in regional (145 per 100,000) and remote areas (113 per 100,000) than in major urban cities (228 per 100,000) (134). The shortage of GPs in remote, rural and regional Australia restricts or delays access to GP appointments, with longer waiting times (136). Forty-two per cent of Australians who live outside capital cities need to wait at least three days for a GP appointment (137). Australians residing in the 'worst-served' areas pay a greater amount of out of pocket costs, compared to individuals living in 'best-served' areas (136). People living in rural, remote and regional areas suffer from worse health than individuals living in urban areas, with higher mortality rates and more health risks (136, 138). Australia's 5,500 community pharmacies are the primary distribution points for prescription and nonprescription medicines (139). Community pharmacies receive 300 million patient visits per year, many of which are for minor ailments, making them the most visited health care destination (139). Community pharmacies are well embedded in local communities including major urban areas and regional and local areas (139). With this comes increased accessibility to timely and efficient care for minor ailments in the community setting.

CARE DELIVERY AT THE APPROPRIATE LEVEL, WITH ROBUST REFERRAL PROCESSES

Patients may be subject to situations where health providers and services are fragmented or delivered in siloed manner (12); or where there is a lack of structures or clinical governance systems to support integration, such as unreliable referral systems, no electronic records or secure information sharing (140). This may lead to:

- **Duplication of services being provided;**
- **Delayed care being provided to patients who require it most;**
- **Delayed or inconsistent transfer of information between different providers.**

There are no standardised triage processes, no mechanisms to monitor or record patient-pharmacist interactions, no follow up processes in place to support best practice. This may result in missed referral opportunities, detection of inappropriate use or continued use of nonprescription medicines when a condition is no longer minor in nature. Systems to support this needed coordinated approach are currently lacking. No agreed clinical care pathways and referral processes exist to facilitate appropriate referral and escalation for timely care from pharmacy to the rest of the health system. This limits capacity for collaboration, accountability, evaluation and continuous quality improvement.

Pharmacists, as the first point of contact, can triage patients to make health systems more efficient. In a Victorian report, the impact of pharmacist triage and the need for development of triage tools to assist pharmacists to sort and prioritise consumers for treatment was assessed (4). The results showed pharmacists are capable

of providing primary health care including triage for a wide range of ailments (4). The report concludes that Australian pharmacists have the skills and attributes to triage appropriately and manage minor ailments in community pharmacies (4). Inward and outward referral services to and from community pharmacy would also improve the patient experience allowing for more seamless transitions between providers, for instance from urgent care services to community pharmacy for treatment and advice to support people with self-care for minor ailments. Lastly, Chapman et al. recommended the implementation of a MAS to support recording, referral and return (follow up) for an effective consultation process (4). This will improve pharmacy links with the rest of the primary care sector.

Efficient and effective primary care demands strong collaboration and coordination between physicians and pharmacists to ensure that the patient receives the care that is required. The creation of standardised clinical processes in conjunction with robust referral processes is the platform needed upon which such a dynamic primary health care system can be created. The integration of community pharmacists into GP and ED systems would better enable minor ailment care to be delivered in a structured manner. The protocolisation of clinical decision making through relatively easy-to-update protocols would improve service navigation and the patient journey.

INCREASED COLLABORATION

An increasing number of patients, in particular with chronic disease or illness, are requiring treatment by healthcare providers from different disciplines (141). The practice and delivery of healthcare is argued to be fundamentally and critically dependent on effective and efficient communication. Poor communication in health care can indeed lead to various negative outcomes: discontinuity of care, compromised patient safety, adverse events, inefficient use of valuable resources, patient dissatisfaction, overworked providers and economic consequences (142, 143).

Trends in self-medication and the increasing availability of nonprescription medicines increase the need for sharing information between pharmacists and GPs to ensure continuity of care, in an integrated capacity (59). There is a clear need for a structured communication approach, addressing both content (ensuring the required items for referral, assessment and management) and timeliness of information sharing between pharmacists and GPs. Pharmacists and their staff are often required to make recommendations based upon incomplete symptom information, other medical conditions, other medications being used, as well as the health status of clients. Irrespective of pharmacist involvement, physicians may too not be fully aware of the vast amount of self-care and self-medication that takes place for such conditions and problems associated with their use may go undetected. Suboptimal communication between providers during community pharmacy consultations has also been highlighted as an area for improvement (144, 145) and is associated with limited or inappropriate outcomes (145-147). Increased interprofessional team work and collaboration for care coordination between providers as a result of a MAS would increase the likelihood of reaching treatment goals and positive patient outcomes.

INCREASED APPROPRIATE SELF-MEDICATION

Many consumers rely on self-medication to treat common medical conditions such as the common cold, pain, diarrhoea, and constipation. However, most are unaware of safety factors such as appropriate dosing, side effects, contraindications, adverse drug reactions, and possible medication interactions of nonprescription medicines (65, 148, 149). Pharmacists have an important role in responsible self-medication, by serving as a point of access for reliable sources of information and medicines, which are safe and effective when used as directed for self-diagnosed or self-limiting conditions. Pharmacists play an important role in safeguarding their patients, especially the elderly, ensuring nonprescription medicines are safe, of quality and are effective with the correct formulation, dosage and form of administration. Pharmacists consider the safety profile of medicines, patient contraindications, allergies and previous adverse effects as examples for best patient outcomes.

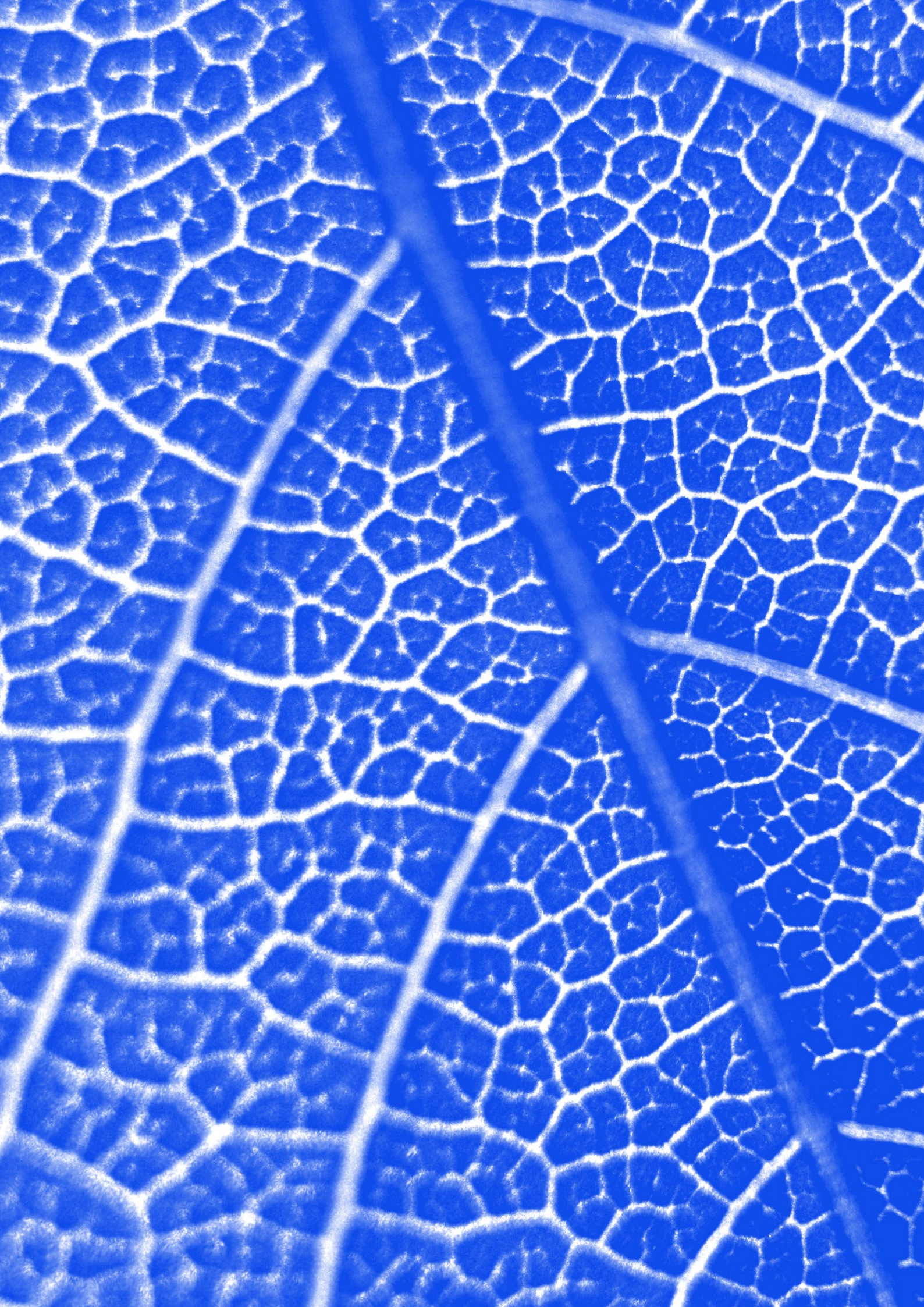
CONCLUSION

There are no MAS models in Australia and consequently there is no literature in the Australian context and evaluation of a MAS. It is evident that pharmacists could contribute to the Australian healthcare system in a way that is cost-efficient and clinically effective through an integrated approach to facilitate self-care. However, evidence is needed before large-scale implementation of a MAS in Australia. Building on this concept, there should be systems to support seamless triage within community pharmacy, facilitating self-care and responsible self-medication and referral on through local care pathways.

There appear to be good prospects for system efficiency gains within current institutional and funding arrangements for pharmacists to provide a MAS. There is a growing awareness, both in Australia and internationally, that pharmacists are an under-utilised resource in the health system, and are potentially a part of the solution for containing healthcare costs (150).

In summary, provision of MAS in the Australian primary care setting, which is driven by self-care policy, can have many benefits including:

- **Coordination of services** (increased collaboration between health providers, improved flow of patients between various health services to ensure best outcomes for patients at the best cost, use of health technologies, and integration to improve flow of information between primary care services).
- **Efficiencies** (cost-effective treatment of common ailments, increased capacity of primary care by transferring consultations from general practice and emergency departments to the community pharmacy, optimisation of costs through use of less expensive settings).
- **Effectiveness** (best clinical outcome for patients).



CHAPTER 2

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

CHAPTER 2: RESEARCH METHODS FOR THE DESIGN AND EVALUATION OF AN AUSTRALIAN MAS MODEL

A MAS model applicable to the Australian health care system and context was codesigned. 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. Our guiding principles were 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.

The research was divided into three phases (Figure 1). A mix methods approach was employed.

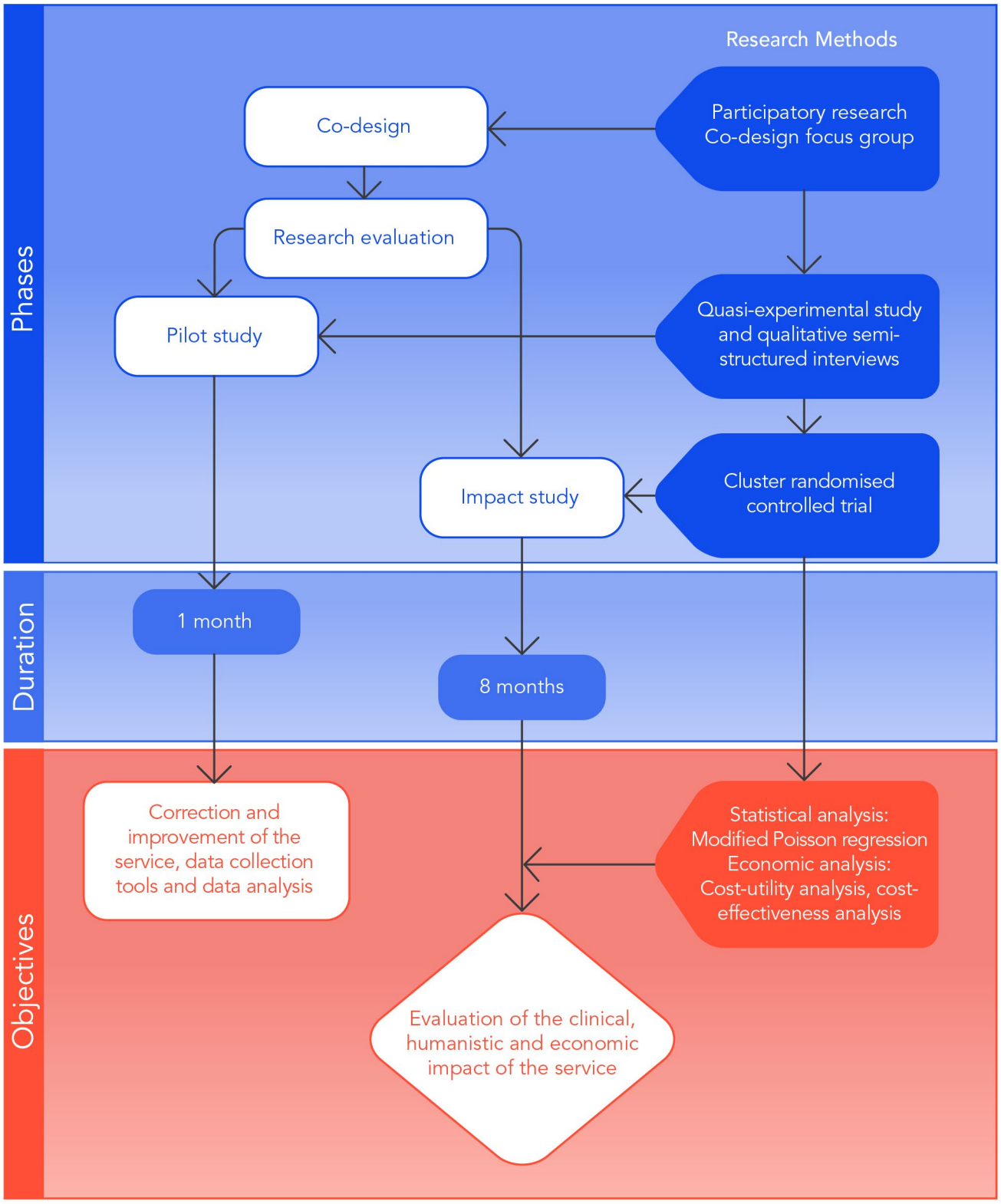
The aims of each phase of the research are outlined below:

1. Co-design:
   - To investigate stakeholder perspectives for theco-design and collaborative agreement on service elements and operational characteristics of a MAS in Australia to ensure future 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.

Figure 1 Flow chart of study phases and methods used



CO-DESIGN AND STAKEHOLDER ENGAGEMENT

- **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 implementation and facilitate integration into practice.**

Co-design is the act of creating with stakeholders that combines professional expertise within the developmental process of health services ensuring the highest quality of care can be provided – care that is clinically effective, safe, integrated and offers a positive experience for patients and professionals (1, 2). In this process, all stakeholders are equal collaborators and are encouraged to share their ideas, knowledge and expertise leading to higher quality, better-differentiated services which can be evaluated. Benefits of health service co-design are sustained in the longer term and may include improved relationships between service providers and their patients, increased levels of support and enthusiasm for innovation and change (1, 2). Research from implementation science consistently highlights promising interventions shown to be initially successful with proven effectiveness often fail to translate into meaningful patient outcomes in practice (3, 4). The co-design approach assists in helping to inform intervention design and adaptation for future implementation and sustainability.

To guide the service co-design process, international literature was considered which identified the fundamental elements and features of pharmacy-based MASs (5). WSPHN facilitated direct local engagement with clinicians, community pharmacists and consumers to provide the basis of collaboration and integration. The process used qualitative research methods. A 2-hour focus group was conducted at WSPHN with stakeholders purposively selected (6), including: two leading general medical practitioners involved in PHN clinical governance, two potential service users (patients), two community pharmacists, two management leaders from WSPHN, one representative from the Pharmaceutical Society of Australia and 1 representative from the UTS research team.

The chief investigator (SB) moderated the group discussion between participants taking a peripheral role in the focus group discussion (7-9). The objectives were to explore stakeholders' perspectives on service elements and structural characteristics, which led to the conceptualisation of the theoretical service model. Eighteen questions were posed to the group to ascertain what the service should look like, how the service would fit within existing GP and pharmacy systems to best facilitate integration, and barriers and facilitators for service implementation. The focus group was audio taped and transcribed verbatim. Ethics approval for this study was obtained by the Human Research Ethics Committee of the University of Technology Sydney (UTS HREC: ETH17-1348). All participants provided written consent.

Data were managed in QSR NVivo (12) data management software and analysed using the framework approach to identify themes. Data were also analysed descriptively (ie. categories were formed directly from participants responses) by one researcher (SDG) and reported to co-investigators (VGC, KW, SB) for their comments.

The mix of stakeholders added great depth to the discussion on health service integration. Responses underlined the need for seamless care for patients between pharmacy and general practice. Effective communication between pharmacies and general practices were emphasised as being especially important by all stakeholders. One of the clear benefits of co-design that emerged in this study was beginning the design process from the reality of people's everyday work environment rather than designing from theory something that 'should' work for them. The input of patient representatives in the workshop was invaluable, bringing rich experience of their perception of how healthcare teams worked, communicated with each other and their impressions of relationships among healthcare team members. They helped the team to keep focus on the ultimate goals of the research project.

From the health care professional perspective, it was felt that current mechanisms for communication were insufficient and resulted in siloed working. Regular communication was emphasised particularly by GPs as a

requirement to maximise quality use of nonprescription medicines and pharmacy treatment of minor ailments. HCPs recognised well-established communication channels were important and the communication methods would need to be agreed upon to facilitate successful integration. A number of strategies were recommended to facilitate integration and collaborative practice including the development of agreed care pathways (HealthPathways), agreed GP-pharmacist IT communication systems for two-way communication facilitating quality referrals from pharmacies to GP practices. These ideas were a positive development in addressing the siloed approach to working that has previously precluded the integration of pharmacy services into routine practice. The co-design process was predominantly driven by the integration component, which provided the fundamentals for the developed service. Overall, participant stakeholders agreed on the potential role of pharmacists in facilitating appropriate and timely referral and discussed how the service could be adequately integrated to enhance current minor ailment care.

The research team fed into the co-design process from their backgrounds and experience, from literature reviews and studies of existing practice. These inputs were delivered on a planned and structured basis but also in response to the topics that were emerging throughout the co-design process. Ongoing stakeholder engagement was agreed to be fundamental to the success of the co-design model and the following stages for further team activity identified:

(i) Development of HealthPathways with GP clinical leads, pharmacists and the WSPHN Planning Group through a series of working meetings;

(ii) Early engagement of GPs and pharmacists in service planning to ensure their priorities informed service design;

(iii) Joint working meetings and regular communications with WSPHN representatives for advice and guidance on project matters;

(iv) Development of strategy for successful engagement of GPs and pharmacists with WSPHN;

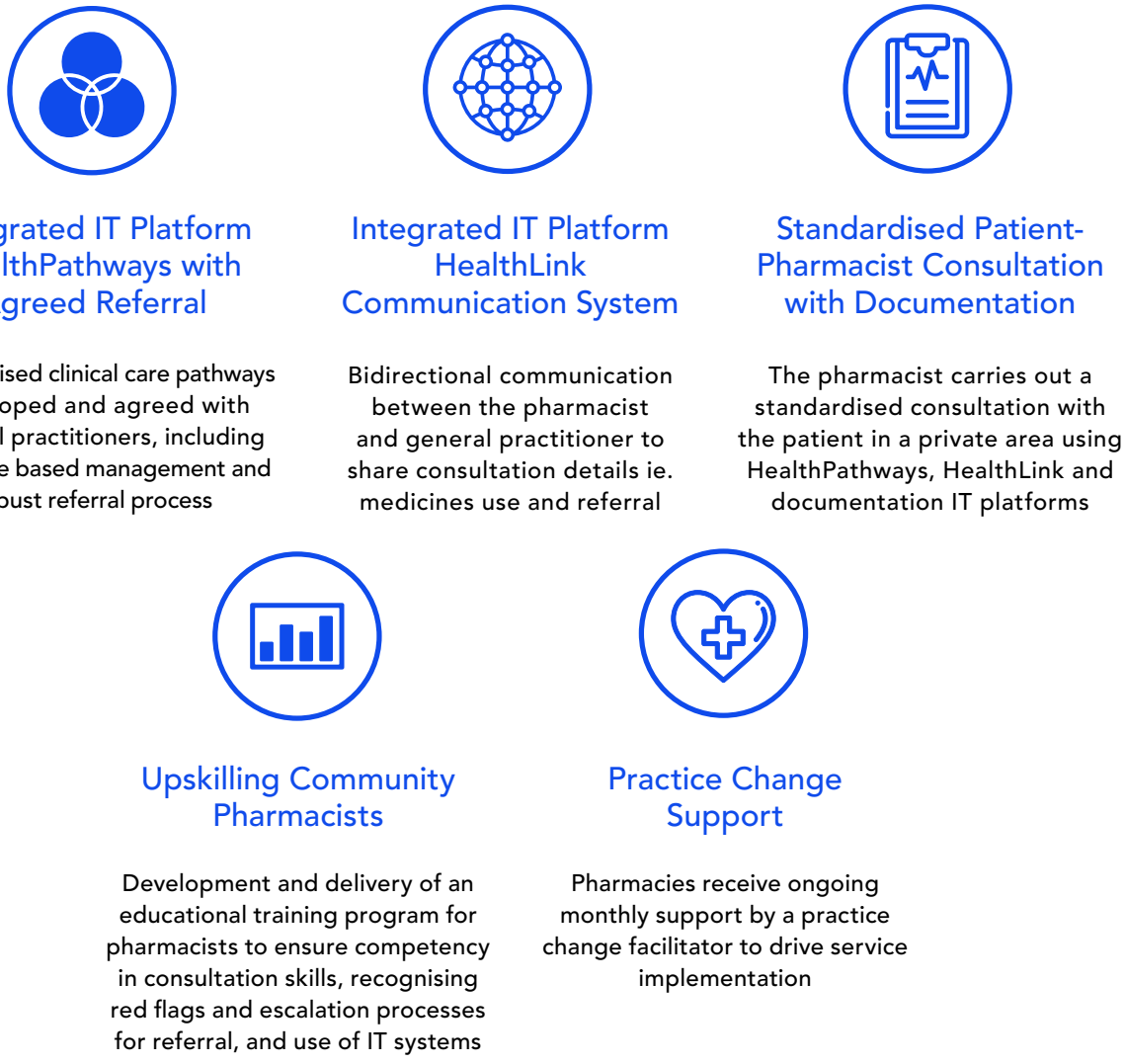
(v) GP involvement in upskilling pharmacists to recognise red flags, referral and to use the HealthPathways system;

(vi) WSPHN support for registration and licensing of pharmacists to IT systems.

AMAS MODEL

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 provided the foundation of the five key elements of the AMAS model. Stakeholder engagement with GPs and WSPHN played a role in ensuring these core values were upheld and shaped each service feature, identified below (Figure 2).

Figure 2 AMAS Model



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

Briefly, the key service elements include:

1. Integration and use of existing GP IT systems
   (i) *HealthPathways* to support a standardised patient-pharmacist consultation through use of care pathways developed and agreed with GPs, to facilitate appropriate self-medication and appropriate referral using a robust referral framework;
   (ii) *HealthLink* to communicate and improve clinical information sharing with general medical practitioners regarding consultation outcome;

2. Standardised IT based patient-pharmacist consultation with documentation
   The pharmacist conducts a standardised patient-pharmacist consultation, using agreed GP systems on iPad supported IT platforms (ie. HealthPathways, HealthLink) at the point of care. The pharmacist documents consultation information in a secure central database on an iPad supported documentation IT platform (ie. REDCap);

3. Upskilling community pharmacists
   The pharmacist attends training to ensure competency in consultation skills, recognising red flags and escalation processes for referral, and use of IT systems;

4. Practice change support
   Pharmacies receive ongoing monthly support by practice change facilitators to drive service implementation.

A more detailed examination of each key element as follows:

1.Integration and use of existing GP IT systems

Health Link

The stakeholder engagement process identified existing GP IT systems to share data and work together through a single platform. HealthLink secure messaging, offered access to the largest GP messaging network in Australia (10). 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 accustomed to use this system and further facilitates integration of minor ailments into their 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.

Health Pathways

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 now used in many PHNs in Australia (11). Information in the portal is peer reviewed and region specific. Each health jurisdiction 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 (12). Care pathways, in effect, localise and operationalise clinical guidelines, and are likely to optimise resource allocation (13).

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 surrounding the use of nonprescription medicines is being shared between providers and patients are receiving care at the appropriate level, with sequencing of care from the AMAS by pharmacists through referral that is agreed for health system efficacy and optimal quality (14-19). The development of HealthPathways through co-design followed a literature review undertaken by UTS of international and national clinical guidelines for the management of pre-agreed minor ailments, and Therapeutic Goods Administration (TGA) approved indications for nonprescription medicines. This process was undertaken following

WSPHN processes with the GP clinical lead, the HealthPathways planning group and GP clinical editor at WSPHN. Through consultation, these pathways were endorsed via WSPHN governance processes.

The development, localisation and review of each pathway were carried out for seven primary health conditions by WSPHN GP Clinical Editors and the HealthPathways Planning Group 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, acute low back pain.

Pathways specific to each ailment included questioning, assessment, management recommending a particular course of action including self-care, and/or a nonprescription medicine for symptomatic relief. A robust framework for agreed referral was also built-in, which indicate red flag criteria to trigger escalation processes, and the time frame within which a patient was recommended to seek care from a particular health care provider. For each pathway the same structure was followed, and included:

- **Red flag referral criteria:** signs, symptoms or events recognised as likely to be more serious in nature and point to the need for immediate referral for assessment;
- **Pharmacist clinical assessment:** symptoms (duration, frequency and severity), past history of symptoms, medications used for this episode of symptoms or other health problems, known allergies and intolerances, other concomitant diseases or medicines;
- **Evaluation:** assessment of referral criteria, contraindications and drug interactions;
- **Action:** endpoints of the consultation may include: (i) self-care advice only; (ii) self-care advice plus supply of a nonprescription medicine; (iii) self-care advice plus referral; (iv) self-care advice, plus supply of a nonprescription medicine plus referral.
- **Referral:** critical time of symptom evolution after which the pharmacist may suspect that it is not a minor ailment, as well as other symptoms or signs that point to the need for assessment by the GP or another health care provider, and the timeframe within which a patient is recommended to seek care;
- **Resources:** resources consulted in the preparation of the pathway and patient self-care resources (including PSA self-care cards).

2. Standardised IT based patient-pharmacist consultation

It was agreed during the co-design phase the pharmacist would undertake a standardised consultation with patients presenting to the pharmacy for one of the agreed conditions (directly requesting a product or with symptoms) (Figure 3). On presentation, the pharmacist would conduct a face-to-face consultation in a private area of the pharmacy (eg. the pharmacy consultation room). The pharmacist will assess the patient's symptoms using a structured approach provided in HealthPathways at the point of care. The pharmacist will identify any concurrent medication or medical conditions, and consider past medical history and current medications to assess appropriateness of medicines requested on presentation for self-treatment. Pharmacists will use HealthPathways as part of the consultation to ensure that 'Red Flags' or other referral criteria are recognised and responded to appropriately. The pharmacist will use the agreed treatment protocols to determine the management approach.

All patients who access the service will be provided with verbal advice, and printed information and/or electronic resources relevant to their condition (in HealthPathways). The information will include self-care, expected duration of symptoms, red flag symptoms, when and where to go for further advice or treatment.

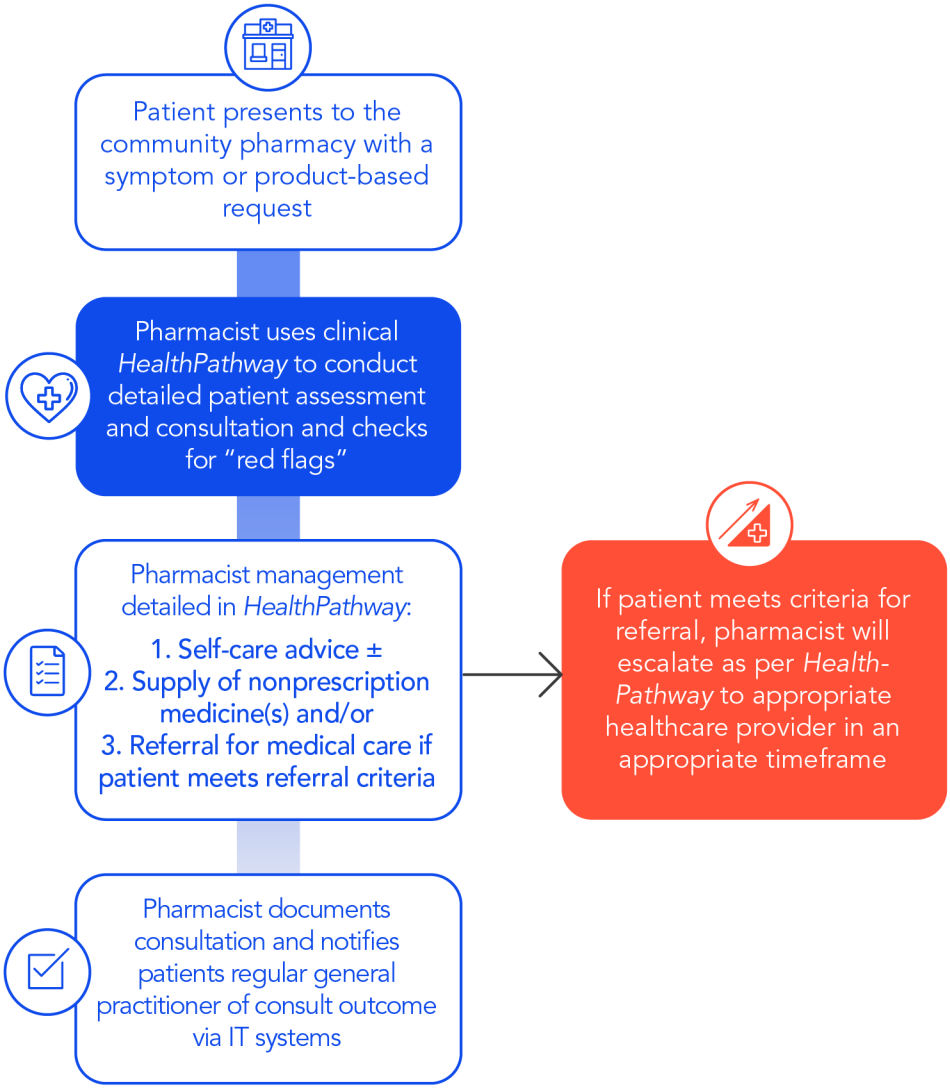
The standardised consultation will allow for data collection as part of the pharmacists' practice. The AMAS IT documentation system (REDCap) will be used (via iPad or desktop computer) to document relevant clinical assessment, observations and outcomes of the consultation in a secure central database. The pharmacy will maintain a record of the consultation including advice, or nonprescription medicines supplied as a result of the service.

In the need to refer the patient to another setting or healthcare professional, the pharmacist will provide

referral details to the patient, advising them to attend within a set time period (as outlined in HealthPathway). Higher acuity care locations requiring same day referral may include emergency departments, immediate in-hours or after-hours GP appointments.

A GP notification will be made for all consultations to ensure the patient's primary care record held by their GP is updated. An electronic message (on consent) will be forwarded to the GP via the HealthLink IT system.

Figure 3 Service flow



3. Pharmacist training

Pharmacists will be trained for 7.25 hours at WSPHN. Training aims 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 (20) and the PSA's Professional Practice Standards (v5) (21), 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 will include a combination of lecture presentations, interactive workshops including role-play scenarios, supplemented by pre-reading materials. Workshops will be delivered by the research team and general medical practitioners.

4. Practice change support

Pharmacies will be supported by a Practice Change Facilitator (PCF) to incorporate the delivery of the AMAS into their usual work flow. The PCF will perform onsite monthly facilitation visits and telephone support to pharmacies. The PCF will be 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. Change facilitation processes and activities will include:

- an initial analysis of implementation factors (barriers and facilitators) through direct observation, checklists and semi-structured interviews. A facilitator checklist of implementation factors was designed for this purpose;
- an individualised implementation plan targeting barriers identified in the initial analysis and identification of suitable strategies to enhance service implementation;
- ongoing monitoring and evaluation of barriers at each visit to support implementation;
- nomination of a pharmacist 'champion' to lead the implementation of the service within the pharmacy;
- collection of quantitative and qualitative data onsite for evaluation.

PILOT STUDY

- **To assess the feasibility of the MAS service 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.**

The AMAS was evaluated in a two group quasi-experimental study (usual care and the AMAS) between October and December 2017. The objective of this pilot phase was to assess the feasibility of the service in practice and the research methodology to determine if the study protocol or the AMAS model required refinement before progressing to the impact study.

More specifically the pilot study was undertaken to:

1. Explore the appropriateness of two potential primary outcomes including:
(i) Appropriate recommendation of nonprescription medicines rate;
(ii) Appropriate medical referral rate;

2. Explore potential secondary outcomes including:
(i) Self-reported symptom resolution;
(ii) Reconsultation rate;
(iii) Health-related quality of life (HRQOL);

3. Conduct a preliminary quantitative analysis of data to:
(i) Estimate the effect size to project the sample size required for the impact study, using the primary outcome data;

4. Test the feasibility of:
(i) IT systems (HealthPathways, HealthLink) on iPads;
(ii) Recruitment methods;
(iii) Documentation procedures;
(iv) Selection of outcome assessment measures ie. EQVAS;

5. Undertake qualitative research to:
(i) Evaluate the pilot training program;
(ii) Evaluate perceived barriers and facilitators to the delivery of the service.

The AMAS was evaluated 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. Ethics approval was granted by the University of Technology Sydney Human Research Ethics Committee (UTS HREC: ETH17-1350; ETH17-1827). Written informed consent was obtained from all study participants.

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 can be found in the pilot study report (22).

As a result of the pilot phase, recommendations were made for the impact study and included:

- Further research using a cluster randomised controlled trial to assess the clinical, humanistic and economic impact of the AMAS, compared to usual care;
- Two additional secondary outcomes were recommended for the impact study including: (i) pharmacist intervention rate (or clinical intervention rate) for direct product requests, and (ii) adherence to referral advice;
- Refinement of documentation processes using a secure IT platform known as REDCap®;
- Refinement of pharmacists training to focus on IT systems, providing example consultation scenarios and demonstration through role play;
- Development of a GP engagement strategy with WSPHN.

IMPACT STUDY

- **To evaluate the clinical, humanistic and economic impact of the MAS in Australia, compared with usual pharmacist care.**

The specific study objectives of the impact phase were to:

1. Evaluate the clinical impact of an AMAS for adult patients who present to the community pharmacy with a symptom-based or direct-product request for specific minor ailments, compared to usual pharmacy care.

Clinical impact was defined by the following variables:
(i) Appropriate medical referral rate
(ii) Adherence to referral advice rate

(iii) Appropriate recommendation of nonprescription medicine rate
(iv) Pharmacist intervention rate (or clinical intervention rate) for direct product requests
(v) Self-reported symptom resolution or improvement rate
(vi) Reconsultation rate

2. Evaluate the humanistic impact of an AMAS for adult patients who present to the community pharmacy with a symptom-based or direct-product request for specific minor ailments, compared to usual pharmacy care.

Humanistic impact was defined by the following variables:

(i) Change in self-reported health related quality of life

3. Evaluate the economic impact from a societal perspective of an AMAS for adult patients receiving care for minor ailments in Australian community pharmacies.

Economic impact was defined by the following objectives:

(i) Examine the cost-utility and cost-effectiveness of an AMAS in community pharmacy compared to the alternative of usual care.
(ii) Assess the robustness of the cost effectiveness results through one-way and multi-way sensitivity analysis.
(iii) Estimate the potential cost reductions associated with transferring patients with minor ailment conditions from the ED and GP setting to community pharmacy (AMAS) at the Western Sydney Primary Health Network, state and national level.

This study used a cluster randomised controlled trial (c-RCT) design, comparing individuals receiving a structured intervention (AMAS) with those receiving usual care for specific health ailments. Participants were community pharmacies, general practices, and patients located in WSPHN region. 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.

The detailed study protocol with specific methodology for the c-RCT addressing individual research objectives has undergone peer review and is published in JMIR Research Protocols (August 2019) (23). The results for this phase are reported in Chapter 3.

JMIR RESEARCH PROTOCOLS Dineen-Griffin et al

Protocol

Evaluation of a Collaborative Protocolized Approach by Community Pharmacists and General Medical Practitioners for an Australian Minor Ailments Scheme: Protocol for a Cluster Randomized Controlled Trial

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Abstract

Background: Internationally, governments have been investing in supporting pharmacists to take on an expanded role to support self-care for health system efficiency. There is consistent evidence that minor ailment schemes (MASs) promote efficiencies within the health care system. The cost savings and health outcomes demonstrated in the United Kingdom and Canada open up new opportunities for pharmacists to effect sustainable changes through MAS delivery in Australia.

Objective: This trial aims to evaluate the clinical, economic, and humanistic impact of an Australian Minor Ailments Service (AMAS) compared with usual pharmacy care in a cluster randomized controlled trial (cRCT) in Western Sydney, Australia.

Methods: The cRCT design has an intervention group and a control group, comparing individuals receiving a structured intervention (AMAS) with those receiving usual care for specific health ailments. Participants will be community pharmacies, general practices, and patients located in Western Sydney Primary Health Network (WSPHN) region. A total of 30 community pharmacies will be randomly assigned to either intervention or control group. Each will recruit 24 patients, aged 18 years or older, presenting to the pharmacy in person with a symptom-based or product-based request for one of the following ailments: reflux, cough, common cold, headache (tension or migraine), primary dysmenorrhea, or low back pain. Intervention pharmacists will deliver protocolized care to patients using clinical treatment pathways with agreed referral points and collaborative systems boosting clinician-pharmacist communication. Patients recruited in control pharmacies will receive usual care. The coprimary outcomes are rates of appropriate recommendation of nonprescription medicines and rates of appropriate medical referral. Secondary outcomes include self-reported symptom resolution, health services resource utilization, and EuroQoL Visual Analogue Scale. Differences in primary outcomes between groups will be analyzed at the individual patient level accounting for correlation within clusters with generalized estimating equations. The economic impact of the model will be evaluated by cost-utility and cost-effectiveness analysis compared with usual care.

Results: The study began in July 2018. Thirty community pharmacies were recruited. Pharmacists from the 15 intervention pharmacies were trained. A total of 27 general practices consented. Pharmacy patient recruitment began in August 2018 and was completed on March 31, 2019.

Conclusions: This study may demonstrate the efficacy of a protocolized intervention to manage minor ailments in the community and will assess the clinical, economic, and humanistic impact of this intervention in Australian pharmacy practice. Pharmacists supporting patient self-care and appropriate self-medication may contribute to greater efficiency of health care resources and integration of self-care in the health system. The proposed model and developed educational content may form the basis of a national MAS service in Australia, using a robust framework for management and referral for common ailments.

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Trial Registration: Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12618000286246; http://www.anzctr.org.au/ACTRN12618000286246.aspx

International Registered Report Identifier (IRRID): DERR1-10.2196/13973

(JMIR Res Protoc 2019;8(8):e13973) doi:10.2196/13973

KEYWORDS

pharmacy; pharmacists; general practitioners; primary health care; community pharmacy services; nonprescription drugs; self care; self medication; randomized controlled trial; Australia

Introduction

Integrated care is a possible solution to the rising demand in facilitating appropriate delivery of health services and limiting fragmentation between health care providers. Evidence indicates that health systems with strong integrated primary health care are effective in improving patient outcomes and efficient at delivering high-quality appropriate services [1,2]. Many countries have undergone major health reforms to deliver effective and efficient health care, moving toward sustainable health systems that are both durable and resilient to withstand impending and ongoing challenges [3-6]. As an example, the Australian health system has undertaken significant reform and restructuring to improve value for investment in health care [2,7] through the establishment of Primary Health Networks (PHNs). Their objectives are delineated as (1) delivering health care services that increase the efficiency and effectiveness for patients and (2) strengthening the degree of coordination and connectivity of care, ensuring patients receive the right care, in the right place, at the right time [8].

Major questions exist surrounding how health care systems can address minor ailments more efficiently through the use of administering care in less expensive settings such as community pharmacy [9,10]. Minor ailments have been defined as "conditions that are often self-limiting, with symptoms easily recognized and described by the patient and falling within the scope of pharmacist's knowledge and training to treat" [11]. It is already known that patients self-manage conditions to a large extent [12], and encouraging people to exercise greater levels of self-care, either for acute or chronic problems, has significant potential to directly affect demand for, and shift costs from, medical health care. Pharmacists are positioned to facilitate self-care and appropriate self-medication processes [13]. Undoubtedly, the expansion of nonprescription medicines has given patients greater choice, providing community pharmacy with an opportunity to demonstrate real and tangible benefits by facilitating this process [13]. Community pharmacy has been transforming to a service provider model driven primarily by leadership of professional organizations, government policies, remuneration, and patient needs. The community pharmacy sector has undergone changes such as enhancing the pharmacists' role in providing professional pharmacy services to optimize the process of care [14]. Community pharmacy provides a range of remunerated commissioned and noncommissioned professional pharmacy services that have shown to be cost-effective compared with other health care settings and contribute to improved health outcomes for patients [15-18]. Importantly, pharmacists can be better integrated within primary care. Effective collaboration between general medical teams and community pharmacies will be integral to achieve the highest level of patient care [8,19].

There is consistent evidence at an international level that pharmacy-based minor ailment schemes (MASs) promote efficiencies of use within the health care system [20]. MASs were introduced for patients to access professional support for conditions that can be self-managed with the objectives of increasing accessibility, providing the right level of care and mitigate funding and system inefficiencies [21]. A total of 94 international schemes are identified in the literature across 103 regions, including the United Kingdom (England, Scotland, Northern Ireland, and Wales) [20,22-26]. Minor ailment assessment and prescribing is the nomenclature used in Canada, representing a pharmacy service that allows pharmacists to prescribe certain drug groups for the treatment of minor, self-diagnosed, and/or self-limiting conditions. Of 13 provinces in Canada, 8 operate a Minor Ailments Prescribing Service [27-28]. Each of these services is slightly unique in its feature and structural design parameters [20]. MASs have been included in the policy agenda in Australia [29-31] and New Zealand [32]. Paudyal et al explored the effect of MAS on patient health and cost-related outcomes [21]. The review showed low reconsultation and high symptom resolution rates of up to 94% with MAS, suggesting minor ailments are being dealt with appropriately in pharmacy [21]. The positive economic impact has shown international MAS to be cost-effective compared with more expensive health care services, such as general practice and accident and emergency (A&E) departments [16]. There are different models of general practitioner (GP)-pharmacist collaboration offering the community pharmacy network to be better integrated into general practice or urgent and emergency care systems. One example in the United Kingdom is the provision of integrated out-of-hours services by community pharmacy, such as the Digital Minor Illness Referral Service [12]. The service evaluates the way in which patients with self-limiting minor ailments who are contacting urgent services can be supported by community pharmacists instead of being booked for an urgent GP appointment or signposted to their own GP.

Pharmacists treating patient's common ailments, the exclusive availability of nonprescription products through pharmacies to provide symptomatic relief, and referral to other health care professionals is a well-established activity within pharmacy practice. Unfortunately, in Australia, there is limited standardization and protocolization for consultations and procedures for escalating referral. There is minimal integration with general practice systems and no formal method of

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physician-pharmacist collaboration or communication relating to minor ailments, and the nature and extent of collaboration may be seen as both episodic and informal. This invariably limits facilitated self-medication practices. In addition, there are no mechanisms to monitor or document patient interactions, resulting in missed opportunities to identify patients who require referral, limiting the ability to detect inappropriate or continued use of nonprescription medicines. The potential for community pharmacists to moderate patients' needs for the treatment and management of minor ailments and alleviate health system pressure in Australia has been recognized [33,34].

The Australian Minor Ailments Service (AMAS) is a practice model with key elements, such as agreed referral points, communication systems between pharmacists and general practitioners (GPs), and clinical treatment pathways, that is, *HealthPathways*. The conceptualized 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. Input into design and agreement with stakeholders have progressed the development of collaborative referral pathways, providing a robust framework for community pharmacists to deliver evidence-based minor ailment care. In essence, these pathways seek to improve the coordination and delineation of health care provider roles for minor ailments with sequencing of care through referral that is agreed between pharmacists and general practice for health system efficacy and optimal quality [1,12,35-39]. Specifically, assurance of quality in health service provision may be achieved through the evaluation of standardized condition management and differential diagnosis tools such as *HealthPathways* [40], robust referral processes for escalation, and service delivery by the pharmacist themselves.

In achieving the stated objectives, we may provide evidence that a scheme would be successful in Australia. Community pharmacists offering an enhanced self-care model can make a significant contribution to Australian health care and reduce the substantial burden on other primary care providers with pharmacists providing the appropriate level of care for minor ailments and checking on patients who are self-medicating. The integration of community pharmacists into primary health care would better enable primary care to be delivered in a structured manner. In addition, the systematization of clinical decision making and referrals through relatively easy-to-update protocols would improve service navigation and the patient journey. The development of new clinical pathways in the area of minor ailments seeks to standardize practice according to the best available evidence and reduce variations in current practice. Increased interprofessional teamwork and collaboration between GPs and community pharmacists for care coordination would increase the likelihood of reaching treatment goals and improving patient outcomes. Community pharmacists will gain from having evidence-based guidance, and the community will benefit from another mechanism to ensure that advice from a pharmacist is based on the latest available evidence. AMAS facilitates increased access to care for individuals to receive minor ailment treatment in a timely and efficient manner.

This paper describes a research protocol to evaluate a collaborative protocolized AMAS to improve the management of common ailments in Australia. The AMAS intervention outlined in this study protocol offers a unique and innovative approach to address self-medication and formalize triage processes in the Australian primary care system. The principal aim of this study is to evaluate the clinical, economic, and humanistic impact of AMAS on adult patients attending Australian community pharmacies compared with usual pharmacist care.

Methods

Study Design and Setting

The study will use a community pharmacy-based cluster randomized controlled trial (cRCT) design with an intervention group and a control group following the Standard Protocol Items: Recommendations for Interventional Trials checklist [41] (Multimedia Appendix 1). The study will be performed over 8 months in community pharmacies throughout Western Sydney Primary Health Network (WSPHN) region.

Recruitment of Study Participants

Participant recruitment will occur at 3 levels: community pharmacy, general practice, and patient level.

Pharmacy Level

Community pharmacies located in WSPHN region with a pharmacist available to attend specialized training to deliver the AMAS service will be eligible to participate in the study. Contact information of pharmacies will be retrieved from publicly available lists, and those meeting criteria for inclusion will be invited to join the study by telephone. The lead researcher will arrange face-to-face discussion for those expressing interest and to obtain written consent for participation. Randomization will be at the level of the community pharmacy. Pharmacies will be sequentially numbered according to their order of acceptance into the study. An independent researcher will assign the pharmacies (units of randomization) to either the intervention group or control group based on unrestricted random sampling using a computer-generated random number list with a ratio of 1:1 in Excel 2016 (Microsoft Corporation).

General Practice Level

Representatives from WSPHN will assist in the engagement and recruitment of general practices within WSPHN into the study. An expression of interest will be forwarded by a blast email to all practices located within the region. The WSPHN representative will provide follow-up information for those expressing interest, and consent will be sought at the practice level from GP practice managers overseeing the work of the surgery or group of surgeries. Each practice manager will be requested to ensure individual GPs within the consented practice are made fully aware of their role within the study before commencement. Study information will be circulated to individual practitioners detailing GP involvement, and given the option of contacting the research team with further questions. Signed practice consent forms will be forwarded to the lead

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researcher. Informed consent will be essential to receive information from the pharmacist. The details of individual GP involvement in the study are provided below.

Patient Level

Patients will be recruited from participating pharmacies. Consecutive recruitment will be used. The recipients of the AMAS service or usual care will be patients who request management for their minor ailment symptoms (symptom-based request) and/or self-select a product to self-treat their ailment (product-based request). The patient may either initiate an interaction or wait to be approached by a member of pharmacy staff while self-selecting a product. The pharmacy team member will refer the patient to the pharmacist who will offer participation in the study if eligible to participate. Patients aged 18 years or older will be identified as eligible if meeting all the qualifying criteria, including (1) attending the pharmacy in person, (2) presenting with a symptom-based and/or product-based request for one of the included minor ailment conditions from 3 specific symptom groups (Table 1), (3) ability to provide written informed consent to participate in the study, and (4) accessible by telephone.

Eligible patients identified by the pharmacist will be provided a Participant Information and Consent Form (PICF) explaining the study and given the opportunity to ask questions. Further discussion will be conducted at a private area in the pharmacy or an area appropriate for the discussion to be performed in a confidential manner. Those agreeing to participate will be asked by the pharmacist to provide signed consent. On the basis of which pharmacy they attend, patients will receive the intervention or usual care (Figure 1).

Table 1. Minor ailment conditions.

Classification	Minor ailments to be included in the study
Gastrointestinal	Reflux or indigestion
Respiratory	Cough and common cold
Pain	Headache (tension or migraine), primary dysmenorrhea (period pain), and low back pain

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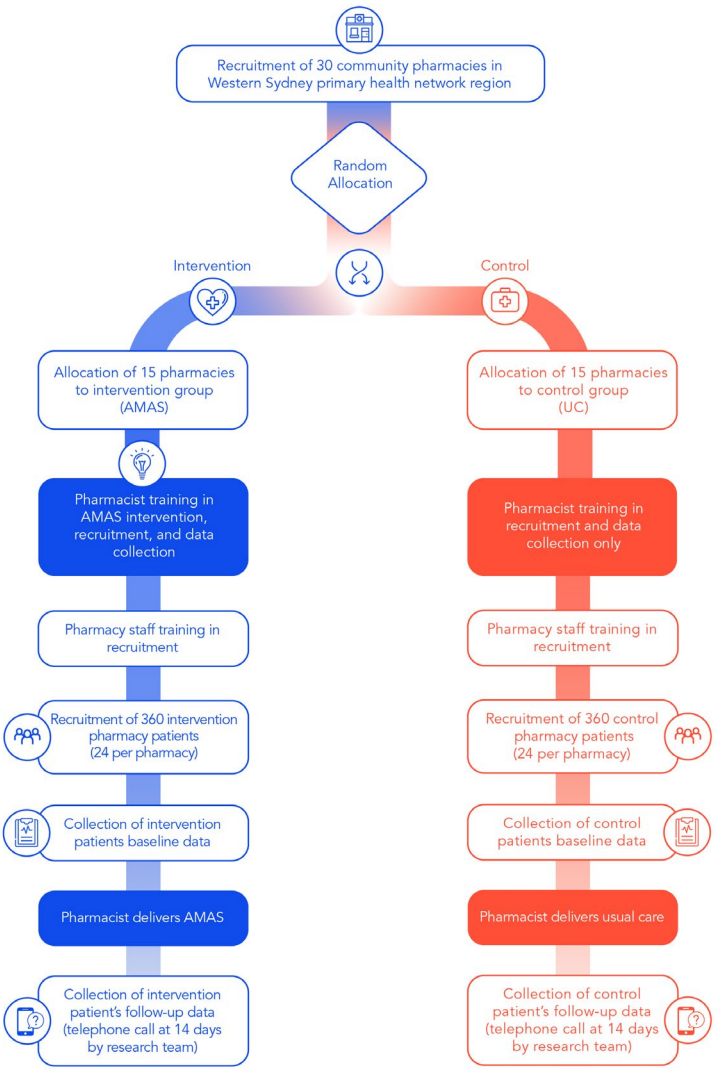
Figure 1. Study design. AMAS: Australian Minor Ailments Service.



Description of Intervention

As we are aiming to evaluate the impact of an enhanced service compared with the one that is already being delivered in routine practice, intervention patients will receive AMAS on presentation to the pharmacy. This will involve a protocolized face-to-face pharmacist-patient consultation. Pharmacists will follow a number of steps in the patient encounter (Figure 2). Patients will be followed up at 14 days after the initial patient-pharmacist consultation through telephone by the research team to assess for resolution of symptoms and health care utilization for the same ailment.

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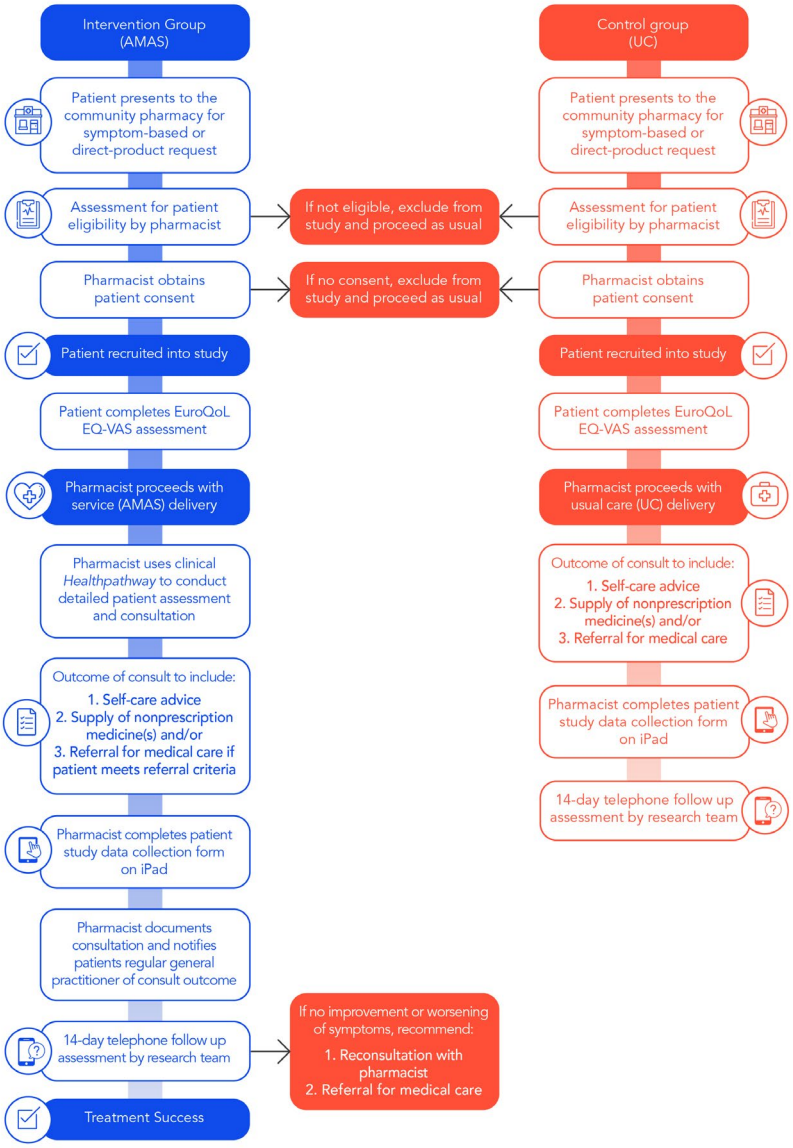
Figure 2. Usual care versus intervention: clinical management algorithm. AMAS: Australian Minor Ailments Service; EQ-VAS: EuroQoL Visual Analogue Scale.



We are proposing a number of innovative features to AMAS, which are described below.

Collaborative Treatment Pathways for Minor Ailments

Clinical pathways are "document-based tools that provide recommendations, processes, and time frames for the management of specific medical conditions or interventions" [42]. They define a process of care agreed by local clinicians and pharmacists and are informed by existing evidence, guidelines, and protocols. *HealthPathways* is a proprietary system of clinical pathways developed in New Zealand and adopted by clinicians throughout PHNs in Australia [40]. These pathways seek to serve as guidance for desired standards of practice and are ultimately intended to promote consistency and uniformity of care.

The collaborative clinical pathways for each minor ailment (Table 1) are intended for use by community pharmacists delivering AMAS. Each ailment has the same structure and format to make the process of finding and using the information easy and practical. These pathways include types of questions, assessment, management approach recommending a particular course of action including self-care, and/or a nonprescription medicine for symptomatic relief, specific to each ailment. Included is a robust framework for referral, indicating red flag criteria to trigger escalation processes, and the time frame within which a patient is recommended to seek care from a particular health care provider (ie, the patient is recommended to see a GP within 24 hours). A red flag is a symptom that is recognized as likely to be of a more serious nature and requires immediate referral. The research and writing of these clinical pathways followed a literature review of contemporary international and

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national clinical guidelines in consultation with leading general medical professionals involved in PHN governance with comprehensive experience in *HealthPathways* development.

Pharmacist-Directed Care and Data Collection

Pharmacists will undertake a consultation with eligible patients for symptom-based and product-based requests in the community pharmacy. Intervention pharmacists will use the agreed clinical pathways to recommend a particular course of action, including self-care and/or nonprescription medicine recommendation for symptomatic relief and/or referral. In case of the need to refer, the pharmacist will appropriately escalate if the patient meets criteria for referral for further assessment and/or prescribing of prescription-only medicine.

Collaborative Approach to Management, Follow-Up, and Data Collection

The *HealthLink* system is used by clinicians in Australia [43]. This system allows for the encrypted transmission of clinical and patient confidential information securely and reliably between GPs and community pharmacists. For AMAS patients who have identified a regular GP during the patient-pharmacist consultation, the consultation will be documented and forwarded from the pharmacist to the GP, outlining clinical assessment undertaken, observations, presentation, and consult outcomes (ie, medication supply, pharmacist-directed self-care, and/or details of referral). Details of the consultation will not be provided if (1) the patient has not consented, (2) the patient has not identified a regular GP, (3) the practice has not consented to partake in the study, or (4) the practice is not using HealthLink software. Importantly, the use of this communication system has been agreed with local clinicians within WSPHN. The process of rolling out this system to pharmacies, set up, and licensing will be facilitated by the PHN and project team. If a patient's identified GP has not consented to the study or does not use this software in practice, the pharmacist will still provide the AMAS service (ie, following management pathways and referral if required), yet GPs will not receive feedback on details of their patient's consultation.

Training Pharmacists to Deliver Australian Minor Ailments Service

Intervention pharmacists will attend one of two 7.5-hour training workshops at WSPHN before delivery of AMAS. The aim of educational training is to ensure pharmacists competency in delivering the service. The 2016 National Competency Standards Framework for Pharmacists in Australia [44] and the Pharmaceutical Society of Australia's Professional Practice Standards (version 5) [15] informed the development of content emphasizing competencies to enhance the pharmacist's role in service provision. The training program will also be a refresher about current best practice in common ailments. The workshop will include a combination of lecture presentations and interactive sessions including role-play scenarios. Self-care information and resources for consumers, clinical treatment pathways, communication and data collection software are available on provided iPads to be used at the point of care. Given that pharmacy assistants are likely to be the very first point of contact in the pharmacy, a researcher will visit each intervention pharmacy to train pharmacy assistants in recruitment and will be given the opportunity to ask questions. During this visit, training materials will be revisited with a *champion* pharmacist who will have attended one of the training days before commencing recruitment.

Practice Change Facilitation to Support Intervention Pharmacies

Practice change facilitators (PCFs) will visit intervention pharmacies at least monthly to support the delivery of AMAS. The PCF will be involved in a range of change facilitation processes and activities during visits with the objective of ensuring recruitment targets are met, quality of service provision, quality of data entry, and adherence to the intervention protocol. PCFs will be trained to ensure these objectives are met. These include addressing any barriers to change using evidence-based strategies. PCFs will be collecting both quantitative and qualitative data on-site. This role works closely with the research team.

Control Group

Pharmacies randomized to the usual care arm will receive training in the use of data collection materials and recruitment only. One training night (2 hours) in data collection and recruitment will be provided at WSPHN. A researcher will visit each of the 15 control pharmacies to deliver study materials, and pharmacists unable to attend the training night will be trained in-store. Materials to be provided include study information detailed in the PICF, data collection software for use on provided iPads, and detailed instructions for data collection. Training will be provided to pharmacy staff to support recruitment for the pharmacist. Patient recruitment will begin immediately after this visit. The pharmacist will check patient eligibility, obtain informed consent, and will document control patients' baseline data and proceed with usual care using their own clinical judgment, processes, and resources. Patients will be followed up at 14 days after the initial patient-pharmacist consultation by the research team to assess for resolution of symptoms and health care utilization.

Data Collection Methods

Data will be collected at 2 time points in both intervention and control arms—baseline and 14 days after the consultation. All patients will complete a baseline questionnaire in the pharmacy, including demographic characteristics, and EuroQoL Visual Analogue Scale. Additional data about patient's ailment history, their contact details, and pharmacist intervention will be collected by pharmacists using forms on iPads provided for that purpose. The time taken per patient to deliver the intervention or usual care will be recorded to inform the economic analysis. Follow-up telephone questionnaires will be conducted by research assistants using forms provided for that purpose. Follow-up at 14-days is considered appropriate because of the nature and duration of minor health symptoms. Study data will be collected and managed using Research Electronic Data Capture (REDCap) tools hosted at the University of Technology Sydney (UTS) [45]. REDCap is a secure, web-based application designed to support data capture for research studies, providing (1) an interface for validated data entry, (2) audit trails for

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tracking data manipulation and export procedures, (3) automated export procedures for data downloads to statistical packages, and (4) procedures for importing data from external sources [45]. All data collected in pharmacies will be returned to the research team on the day of recruitment to allow for timely follow-up. The chief investigator will have access to the trial data.

Study Measurements and Outcomes

The evaluation of MAS compared with usual care will be achieved by comparing the primary and secondary outcomes [46] as set out in Multimedia Appendix 2.

Sample Size

The primary joint outcome measures of the study are appropriate medical referral rate and appropriate recommendation of nonprescription medicines. Sample size calculation was based on an assumed baseline appropriate medical referral rate of 85% and assumed baseline appropriate recommendation of nonprescription medicines rate of 82% [47,48]. Pharmacies are the primary unit of randomization with individual patients nested within pharmacies. The rate of the joint outcomes will be compared between the treatment and control arms in the study. To test for a 10% absolute increase in primary outcomes (appropriate medical referral rate: 85%-95% and appropriate recommendation of nonprescription products 82%-92%) with ≥0.9 power, alpha of .05, equal allocation ratio, and assuming intracluster correlation is 0.01, we would need 30 pharmacies (15 in each arm) with 24 participants per pharmacy (allowing for 10% dropout) for an overall sample of 720 patients.

Blinding

Given the cluster design, it will not be possible for participating pharmacies to be blinded to group assignment. However, the patient, research assistants conducting follow-up, and the data analyst will be blinded to treatment assignment.

Postrecruitment Retention Strategies

All recruited pharmacies will be contacted by telephone in the first 2 weeks of commencing patient recruitment to address any teething issues with study procedures. Support to resolve any problems will be offered by PCFs (for intervention) or a study researcher (for control). Intervention fidelity will also be monitored by PCFs. Regular newsletters and emails will be sent to all pharmacies during the study period for encouragement, provision of feedback surrounding data quality, and strategies to enhance recruitment to meet desired targets. Pharmacies not meeting target recruitment will be offered additional in-pharmacy support by the study researcher. Recruited patients will be contacted by telephone. Attempts to contact nonresponders will continue until contact is made or for a maximum of either 1 week or 5 call attempts.

Statistical Methods and Analysis

Data will be analyzed using Stata 16 for Windows [49]. Baseline pharmacy and patient level information will be summarized by treatment arm. Continuous variables will be summarized with mean and standard deviation with median and interquartile range provided if the data are skewed. Categorical variables will be summarized by frequency and proportion. Generalized estimating equations will be used to account for within-cluster correlation [50] using an exchangeable correlation structure. A modified Poisson regression approach will be used for the analysis to estimate relative rates (RRs) [51,52]. If the estimation of RR is not computationally achievable, we will estimate odds ratios with logistic regression [50]. As a secondary analysis, we will adjust for key baseline covariates at both the pharmacy level (eg, pharmacy type) and the patient level (eg, age and sex). We plan to conduct an exploratory subgroup analysis by treatment classification (respiratory, pain, and gastrointestinal) and type of inquiry (symptom presentation, direct product request, and both). Standard model diagnostics will be conducted to check for model assumptions. All analyses will be intention-to-treat. Multiple imputation (MI) by chained equations [53] will be applied to account for missing patient outcomes. A total of 30 imputations (including using pharmacy type, age, and sex in the MI model) will be performed. A detailed statistical analysis plan will be developed by blinded investigators before unblinding and locking the study database.

A cost-utility analysis (CUA) and cost-effectiveness analysis (CEA) will be performed through examining the resource use of adult patients in the context of the randomized controlled study designed to investigate the efficacy of AMAS compared with the control group. A healthcare perspective will be applied for the analysis. Costs will be estimated in Australian dollars at the 2018-2019 financial year. Costs during the 2-week follow-up period will be analyzed for all patients included in the cRCT. Costs will be grouped into 4 main categories: (1) pharmacist time, (2) medications, (3) referrals and reconsultation, and (4) training and facilitation costs. The pharmacist cost will consider the working time for a community pharmacist and time consumption to deliver the service. Patient out-of-pocket costs (for all medicines supplied during the 14-day period) will be estimated by the average unit price across pharmacy banner groups. Health service utilization will be based on the cost of medical services recorded in the study, with unit prices sourced from Medicare Benefits Schedule prices, Australian National Hospital Cost Data [54], and the Pharmacy Industry Award [55]. Finally, capital costs for training of pharmacists, facilitation, information technology, and program setup will be counted.

The trial-based outcome measures used for the economic evaluation will be symptom resolution rates and appropriateness of pharmacy care (as a proxy of health gain). Utility values from the literature for symptom resolution and nonsymptom resolution of minor ailments will be used to estimate quality-adjusted life years (QALYs). Other intermediate outcomes will be used to adjust the utilization of resources including referral and reconsultation rates. A decision analytic modeling technique will be used. The model inputs will be informed by data from the trial supplemented with published literature. Results of the CUA will be expressed in terms of an incremental cost per QALY (incremental cost-effectiveness ratio), calculated by dividing the difference in total costs and QALYs between intervention and control groups (incremental costs/incremental QALYs). In addition to the CUA, 2 CEAs will be conducted where the clinical effect measure will be an extra episode of appropriate pharmacy care and extra patient achieving symptom

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resolution for their ailment. The cost-effectiveness results will be expressed in terms of extra cost per additional episode of appropriate pharmacy care and extra cost per additional patient achieving symptom resolution.

Ethics Approval and Consent to Participate

This project has been approved by the UTS Human Research Ethics Committee (HREC) (UTS HREC approval number: ETH17-1350). All participants (pharmacies, general practices, and patients) will complete a consent form to participate in this research.

Results

Statistical and economic analyses will be completed in July 2019. Following this, research findings will be disseminated through peer-reviewed publication.

Discussion

Integrated Care

Globally, health care is changing to address a number of challenges including the needs of an aging population, escalation in consumer knowledge and their expectations of the health service, rapid advances in scientific and technical capacity, and the increasing cost of health care [56]. With this, a key issue that needs to be addressed is how to connect services and health care professionals to achieve integrated services for consumers and health professionals as models of care evolve to deliver a person-centered approach [57]. There are excellent services and health professionals all striving to deliver the best possible care, but it is often in a fragmented and siloed manner [2]. The increasing longitudinal care requires both effective oral and *technology-enabled* communication between health care team members.

Innovative thinking and tools are needed to deliver better and cost-effective care. This study is unique, as it enables and evaluates integrated electronic technology systems in Australian primary care for common ailments. This ensures health care providers have access to the best information available to deliver excellent patient care. Although the journey to integrated care is complex, technology can help to support it; this applies to care management and referral (*HealthPathways* [40]), collection of data (*REDCap* [45]), and interprofessional clinician-pharmacist communication (*HealthLink Messaging Software* [43]). This approach offers innovative technologies to move from the traditional health care delivery model, which centers on individual disciplines operating in isolation, to solutions that integrate systems to provide a centralized, complete patient view to health care providers.

This research supports an integrated approach in managing common minor ailments. Drawing on expertise from a range of stakeholders, an AMAS service has been co-designed to complement general practice and promotes collaboration between professions. With the development of agreed clinical *HealthPathways* for a number of common ailments [40], the service aims to standardize practice according to the best available evidence and reduce variations in current practice using a robust framework for referral and treatment. To our knowledge, there is no study investigation or published research relating to a protocolized MAS intervention delivered by community pharmacists for minor ailment presentations in Australian health care. This research will evaluate an Australian MAS reporting on patient outcomes, including health status, and resolution of symptoms and will provide full economic analyses. This evaluation focuses on specific minor ailments for relevant comparisons of both health-related and cost-related outcomes.

Comparison With Literature

The literature internationally suggests that minor ailment services enhance the delivery of primary care, promote efficiencies, and reduce overall health care costs [20]. Pharmacy-based minor ailment services were introduced internationally over a decade ago with the aim of supporting consumers to self-care and provide professional support for conditions that can be self-managed [20]. Previous evidence includes the studies by Paudyal et al [21], Watson et al [16], Aly et al [20], and Rafferty et al [58] reporting on minor ailment services. From the UK perspective, studies have compared outcomes of minor ailment management in settings such as pharmacy, emergency departments (EDs), and general practice [16]. The positive economic impact of MAS has been demonstrated through reduced pressure on other health services and cost-effectiveness compared with more expensive health care services, such as general practice and A&E [16]. Comparatively, Rafferty et al have identified community pharmacy as the most cost-effective option for minor ailment care in Saskatchewan, Canada [58]. The scope of complexity and the varied nature of conditions treated by pharmacists under MASs highlight their skills in being able to assist consumers to self-care, facilitating self-medication, ensuring appropriate use of medicines, and timely medical referral [20]. Comparative evaluations identified in the literature compare general practice or ED settings to the community pharmacy or interventions delivered by health care professionals in ED and GP (ie, physicians or nurses) as a comparator to community pharmacy-based MAS [16,59,60]. Within the various studies, there is no clear distinction between whether pharmacists or members of pharmacy staff deliver the MAS intervention. Our study delineates the role of pharmacist in delivering the MAS intervention, and is not delivered by support staff under pharmacist supervision in the pharmacy.

We report 2 primary outcome measures (appropriate medical referral and appropriate recommendation of nonprescription medicine by pharmacist). Referrals (and importantly, red flag referrals) were a critical point that came up in the codesign process with GPs. GPs wanted to see patients quickly if there were any doubts and ensure patients are being referred in an appropriate and timely manner to the correct health provider. We also wanted to assess pharmacist's impact of MAS on self-medication processes. Further strengths to the study include the adoption of clinical and humanistic outcomes (as secondary outcome measures) recommended by Paudyal et al in a systematic review published in 2018 [61]. Clinical outcomes identified in this international review included symptom status (such as resolution of symptoms, symptom severity, and pattern).

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Reconsultation with the GP was identified as a surrogate follow-up measure of clinical outcome assessment. Our study will evaluate reconsultation with the pharmacist, GP, and other health professionals within 14 days for the same ailment. Quality of life outcomes using EuroQoL have also been previously collected in a number of studies [61,62]. Our intervention was developed using available evidence and theory, with key elements. Methods of recruitment, data collection, and study variables were tested during a feasibility and piloting stage. This helped to identify methods to improve recruitment rate, limit documentation time, and confirm relevance and appropriateness of study outcomes to Australian health care.

We present the design of a cRCT in international literature to determine the clinical, humanistic, and economic effectiveness of a protocolized intervention for minor ailments compared with usual care. This study improves on other research evaluating MAS directly using a randomized study design. The randomized controlled trial has a number of important features that make it the *gold-standard* evaluation method [63]. Our choice of cluster randomization at the level of the pharmacy decreases the potential for contamination, as each pharmacist in either the intervention group or the control group will only be providing either AMAS or control, not both. In this respect, the study is novel and will provide information on the impact of the service on clinical, economic, and humanistic outcomes and barriers to implementation compared with usual pharmacy care. However, some limitations to the study should be discussed. Although a cluster randomized design is being used to overcome contamination between study arms, the study design may be susceptible to some methodological biases. Cluster randomized trials often do not, or cannot, conceal treatment allocation. Participants awareness of the allocation can lead to biased recruitment [63]. The Hawthorne effect may also influence research subjects, that is, the consequent effect of being observed or awareness of being studied which can potentially impact on participants' behavior [63]. Finally, one of the main limitations of this type of study is that, by definition, a minor ailment is a self-limiting health problem and implicitly involves resolution, regardless of the intervention performed by the pharmacist. Careful attention has been placed to the design of our cluster trial to minimize the potential for biases.

Conclusions

Collectively, the findings from this study will act as the first stage of implementation of MAS in Australian pharmacy practice and may be extended to facilitate the growing prominence of self-care. The study may also provide groundwork for the optimal design of a MAS intervention tailored for greater patient autonomy and boost the clinician-pharmacist relationship for greater discussion surrounding both the appropriate and inappropriate use of nonprescription medicines. This study evaluates the best possible care to the current level of care provided by pharmacists to patients with common ailments in the Australian population. AMAS presents a key opportunity for pharmacists to intervene, as communication of patient-centric clinical information between health care providers will be essential to support effective patient management in Australian health care.

The delivery of safe and high-quality health services that are fully integrated into the health system are of high importance. Research from high-quality evaluations should be used to inform the strategic direction for health service delivery internationally. Implementation research may be applied to MAS to translate evaluation findings into practice for meaningful improvements in patient care outcomes. This paper is a key step in the dissemination process, outlining the aims and methodology that will be used. Along with providing community pharmacists a framework to patient management and the practical skills to engage patients to self-care and self-medicate appropriately, this study may also contribute to the literature with evidence that an intervention of this nature may lead to more efficient resource use in the provision of primary health care in Australia.

Dissemination Plan

To support this study's contribution to wider knowledge, the research findings will be disseminated through peer-reviewed publications and conferences, both nationally and internationally, targeting service users, health care providers, academics, service commissioners, and policymakers.

Trial Status

The study began in July 2018. A total of 30 community pharmacies were recruited. Pharmacists from the 15 intervention pharmacies were trained. 27 general practices consented. Patient recruitment began in August 2018 and was completed on March 31, 2019.

Protocol Amendments

Any protocol amendments will be submitted to the UTS HREC for approval and noted in the registered protocol at the Australian New Zealand Clinical Trials Registry. Trial participants will be notified should relevant protocol changes be made.

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Authors' Contributions

SDG contributed to background research, manuscript preparation, writing, and review. SDG, VGC, KW, and SB contributed extensively to study design, methodology, review, and editing. KR contributed extensively to the development of the statistical methods, statistical analysis plan, and sample size calculation. All authors have read and approved the final manuscript. The study funders did not have any influence on study design, writing of the manuscript, or decision to submit for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Standard Protocol Items: Recommendations for Interventional Trials checklist.
[PDF File (Adobe PDF File), 89KB - resprot_v8i8e13973_app1.pdf]

Multimedia Appendix 2

Summary of measurements and study outcomes.
[PDF File (Adobe PDF File), 43KB - resprot_v8i8e13973_app2.pdf]

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Abbreviations

A&E: accident and emergency
AMAS: Australian Minor Ailments Service
CRCT: cluster randomized controlled trial
CEA: cost-effectiveness analysis
CUA: cost-utility analysis
ED: emergency department
GPs: general practitioners

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HREC: Human Research Ethics Committee
MAS: minor ailment schemes
MI: multiple imputation
PCF: practice change facilitator
PHN: primary health network
PICF: Participant Information and Consent Form
QALYs: quality-adjusted life years
REDCap: Research Electronic Data Capture
RR: relative rate
UTS: University of Technology Sydney
WSPHN: Western Sydney Primary Health Network

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APPENDIX 1: STUDY OUTCOMES

Variable	Operational definition	Group	Type	T0[a]	T2[b]	Data source	Completed by
Clinical							
Appropriate medical referral rate	Defined as meeting the action agreed in the HealthPathways for each patient referred. Each referral made will be independently assessed against the action outlined within the HealthPathways for each minor ailment indication (which were preagreed with GPs[c] in the codesign process). The referral is considered appropriate if it meets the reason for referral, recommended time frame to seek care, and health care provider referred to. In which case, the appropriateness of referral will be calculated as the proportion of patients appropriately referred divided by the total number of patients referred for treatment and control arms.	IG[d], UG[e]	1°[f]	X	__g	Patient consultation record	Pharmacist
Appropriate recommendation of nonprescription medicine rate	Defined as meeting the action agreed in the HealthPathways for each product recommended. Each product recommendation will be independently assessed against the action outlined within the HealthPathways for each minor ailment indication (which were preagreed with GPs in the codesign process). The recommendation is	IG, UG	1°	X	__	Patient consultation record	Pharmacist

[a]**T0:** baseline
[b]**T2:** follow-up at 14 days
[c]**GP:** general practitioner
[d]**IG:** intervention group
[e]**UG:** usual care group
[f]**1°:** primary outcome
g__: not applicable
[h]**2° :** secondary outcome.
[i]**AMAS:** Australian Minor Ailments Service
[j]**EQ-VAS:** EuroQoL Visual Analogue Scale

Variable	Operational definition	Group	Type	T0[a]	T2[b]	Data source	Completed by
Appropriate recommendation of nonprescription medicine rate	considered appropriate if it meets the entire requirement as approved in Product Information by the Therapeutic Goods Administration including correct indication for use, dose, frequency, duration of use, and contraindications. The appropriateness of medicine recommendation will be calculated as the proportion of patients receiving an appropriate medicine recommendation by the pharmacist divided by the total number of patients who received a medicine during the consult for treatment and control arms.	IG, UG	1°	X	__	Patient consultation record	Pharmacist
Pharmacist intervention rate (or clinical intervention rate) for direct product requests	Defined as the identification and attempted resolution of an actual or potential drug-related or symptom-related problem arising from a patient self-selecting a medicine to self-treat. An investigation of the pharmacist's identification and response (ie, change in product to a safer or more appropriate alternative) will be made. In which case, the clinical intervention rate will be calculated as the proportion of patients recommended an alternative product by the	IG, UG	1°	X	__	Patient consultation record	Pharmacist

[a]**T0:** baseline
[b]**T2:** follow-up at 14 days
[c]**GP:** general practitioner
[d]**IG:** intervention group
[e]**UG:** usual care group
[f]**1°:** primary outcome
g__: not applicable
[h]**2° :** secondary outcome.
[i]**AMAS:** Australian Minor Ailments Service
[j]**EQ-VAS:** EuroQoL Visual Analogue Scale

Variable	Operational definition	Group	Type	T0[a]	T2[b]	Data source	Completed by
Pharmacist intervention rate (or clinical intervention rate) for direct product requests	pharmacist divided by the total number of patients who present to the pharmacy directly requesting a product for self-treatment for treatment and control arms.	IG, UG	1°	X	__	Patient consultation record	Pharmacist
Self-reported symptom resolution rate	Participants will be asked at follow-up to indicate whether their minor ailment symptoms have (1) completely resolved, (2) improved but not completely resolved, and (3) not improved or have worsened. Complete resolution has been defined as the complete absence of minor ailment symptoms at 14-day follow up. In which case, the symptom resolution rate will be calculated as the proportion of patients reporting complete symptom resolution at 14-day follow-up divided by the total number of patients successfully followed up for treatment and control arms.	IG, UG	2°[h]	__	X	Telephone data collection record	Research team member
Economic							
Health services resource utilisation associated with the minor ailment	Defined as the individual's use of pharmaceutical, GP, hospital, and emergency department services within 14 days following the initial consultation with the pharmacist for treatment and control arms.	IG, UG	2°	X	X	Patient consultation record, telephone data collection record	Pharmacist and research team member

[a]**T0:** baseline
[b]**T2:** follow-up at 14 days
[c]**GP:** general practitioner
[d]**IG:** intervention group
[e]**UG:** usual care group
[f]**1°:** primary outcome
g__: not applicable
[h]**2° :** secondary outcome.
[i]**AMAS:** Australian Minor Ailments Service
[j]**EQ-VAS:** EuroQoL Visual Analogue Scale

Variable	Operational definition	Group	Type	T0[a]	T2[b]	Data source	Completed by
Time and resources of service delivery	Defined as the time and personnel consumptions for AMAS[i] delivery and usual care	IG, UG	2°	X	X	Patient consultation record, facilitators database	Pharmacist, research team member, and practice change facilitator
Humanistic							
Change in self-reported EQ-VAS[j]	Defined as patient's overall measure of health status at (1) the initial consultation with the pharmacist and (2) 14 days following the initial consultation with the pharmacist for treatment and control arms	IG, UG	2°	X	X	EuroQoL Visual Analogue Scale [46]	Patient

[a]**T0:** baseline
[b]**T2:** follow-up at 14 days
[c]**GP:** general practitioner
[d]**IG:** intervention group
[e]**UG:** usual care group
[f]**1°:** primary outcome
g__: not applicable
[h]**2° :** secondary outcome.
[i]**AMAS:** Australian Minor Ailments Service
[j]**EQ-VAS:** EuroQoL Visual Analogue Scale

CHAPTER 3

CLINICAL AND HUMANISTIC IMPACT EVALUATION

CHAPTER 3: CLINICAL AND HUMANISTIC IMPACT EVALUATION

The results presented in this chapter address the following objectives:

1. Evaluate the clinical impact of an AMAS for adult patients who present to the community pharmacy with a symptom-based request or direct-product request for specific minor ailments, compared to usual pharmacy care.

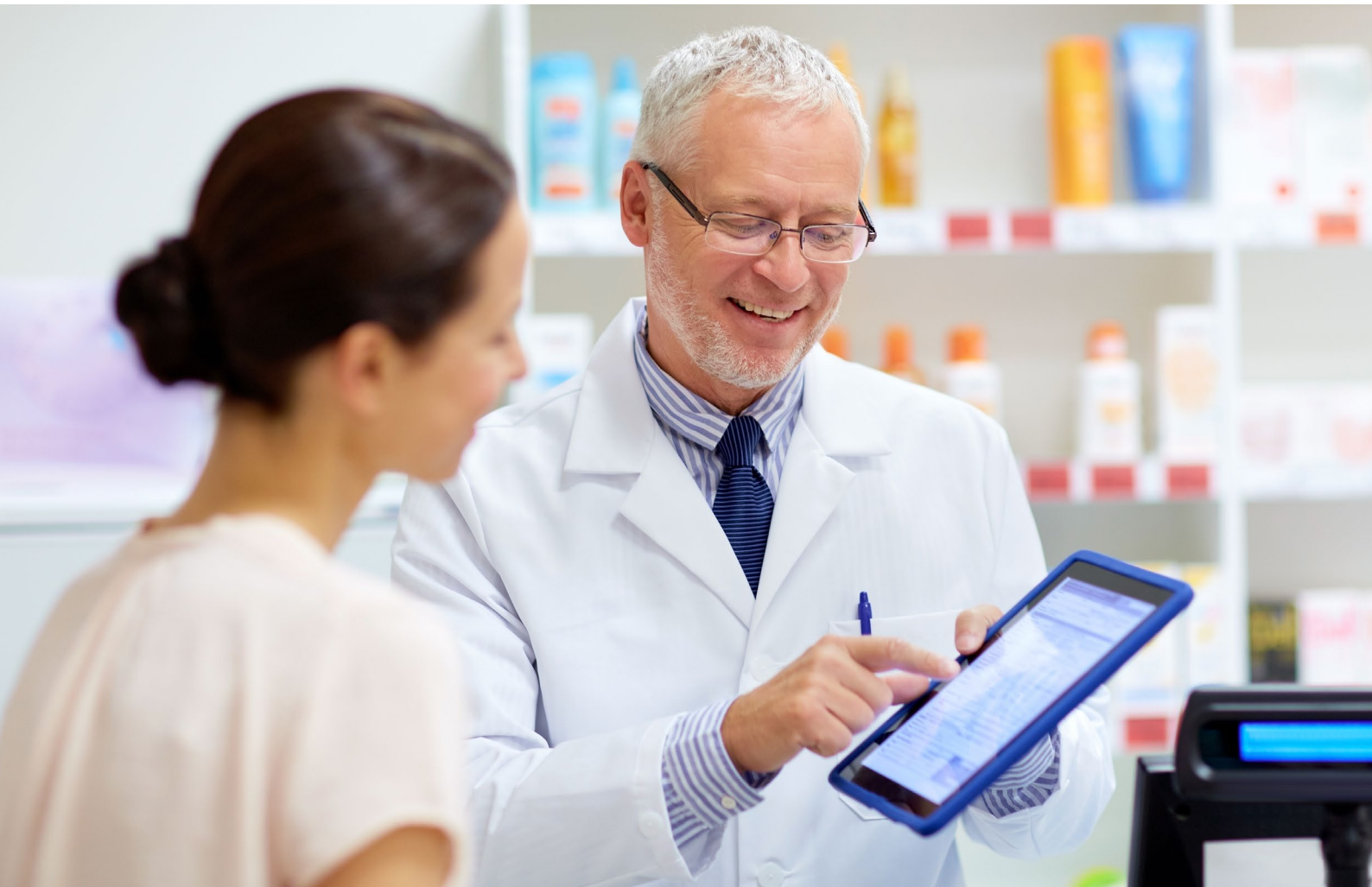
Clinical impact was defined by the following variables:

(i) Appropriate medical referral rate
(ii) Adherence to referral advice rate
(iii) Appropriate recommendation of nonprescription medicine rate
(iv) Pharmacist intervention rate (or clinical intervention rate) for direct product requests
(v) Self-reported symptom resolution or improvement rate
(vi) Reconsultation rate

2. Evaluate the humanistic impact of an AMAS for adult patients who present to the community pharmacy with a symptom-based or direct-product request for specific minor ailments, compared to usual pharmacy care.

Humanistic impact was defined by the following variables:

(i) Change in self-reported health related quality of life



RESULTS

PHARMACY CHARACTERISTICS

A total of 33 community pharmacies in WSPHN participated in the impact study. Sixteen were randomly assigned to deliver AMAS (intervention) and 17 were assigned to provide usual care (UC) (control). Three pharmacies withdrew during the first month of the study period and did not recruit patients (AMAS: n=1, UC: n=2). Thirty pharmacies (n=30) were included in the final analysis. Surrounding general practices (n=27 practices with 150 GPs) consented to receive referral information and details of the pharmacy consultation for their patients.

The majority of pharmacies were located on a street or strip (80% in both AMAS and UC arms) (Table 1). The mean number of pharmacists employed per pharmacy was 2.9 (SD 1.7) in AMAS and 2.6 (SD 0.9) in UC arms. Pharmacies had a mean of 8 (SD 6.6) pharmacy staff employed per pharmacy in the AMAS arm and 7 (SD 2.6) pharmacy staff per pharmacy in the UC arm.

Table 1 Baseline pharmacy characteristics (n=30 pharmacies)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL	30	100%	15	100%	15	100%
Pharmacy Type						
Banner	16	53.3%	11	73.3%	5	33.3%
Independent	14	46.7%	4	26.7%	10	66.7%
Pharmacy Location						
Street / Strip	24	80.0%	12	80.0%	12	80.0%
Shopping Centre	6	20.0%	3	20.0%	3	20.0%

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

PHARMACIST CHARACTERISTICS

Fifty-five pharmacists enrolled in the study (AMAS: n=35; UC: n=20). Half of all pharmacists were pharmacy owners and the rest were employees holding various positions. The mean age was 38 years (SD 9.4) and 40 years (SD 9.2) in AMAS and UC arm, respectively (Table 2).

Table 2 Baseline pharmacist characteristics (n=55 pharmacists)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL	55	100%	35	100%	20	100%
Gender						
Male	20	36.4%	9	25.7%	11	55.0%
Female	35	63.6%	26	74.3%	9	45.0%
Position						
Pharmacist Owner	27	49.1%	14	40.0%	13	65.0%
Pharmacist Manager	3	5.4%	1	2.9%	2	10.0%
Pharmacist In-Charge	5	9.1%	5	14.2%	0	0%
Pharmacist	16	29.1%	12	34.3%	4	20.0%
Intern Pharmacist	4	7.3%	3	8.6%	1	5.0%

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

PATIENT CHARACTERISTICS

In total, 894 patients were recruited during the study period with 894 consultations recorded. Of these, 524 (59%) and 370 (41%) patients were recruited into AMAS and UC arms, respectively. Table 3 outlines the baseline patient demographics. The mean age of patients was 42 years (SD 16.6) in the AMAS arm and 48 years (SD 17.3) in UC. The majority of patients did not identify as Aboriginal and/or Torres Strait Islander (97% and 97% for AMAS and UC arms, respectively). There was a similar distribution of males and females in both study arms (AMAS: male 45% (n=233); UC: male 40% (n=149)).

Table 3 Baseline patient characteristics: both study arms (n=894 patients)

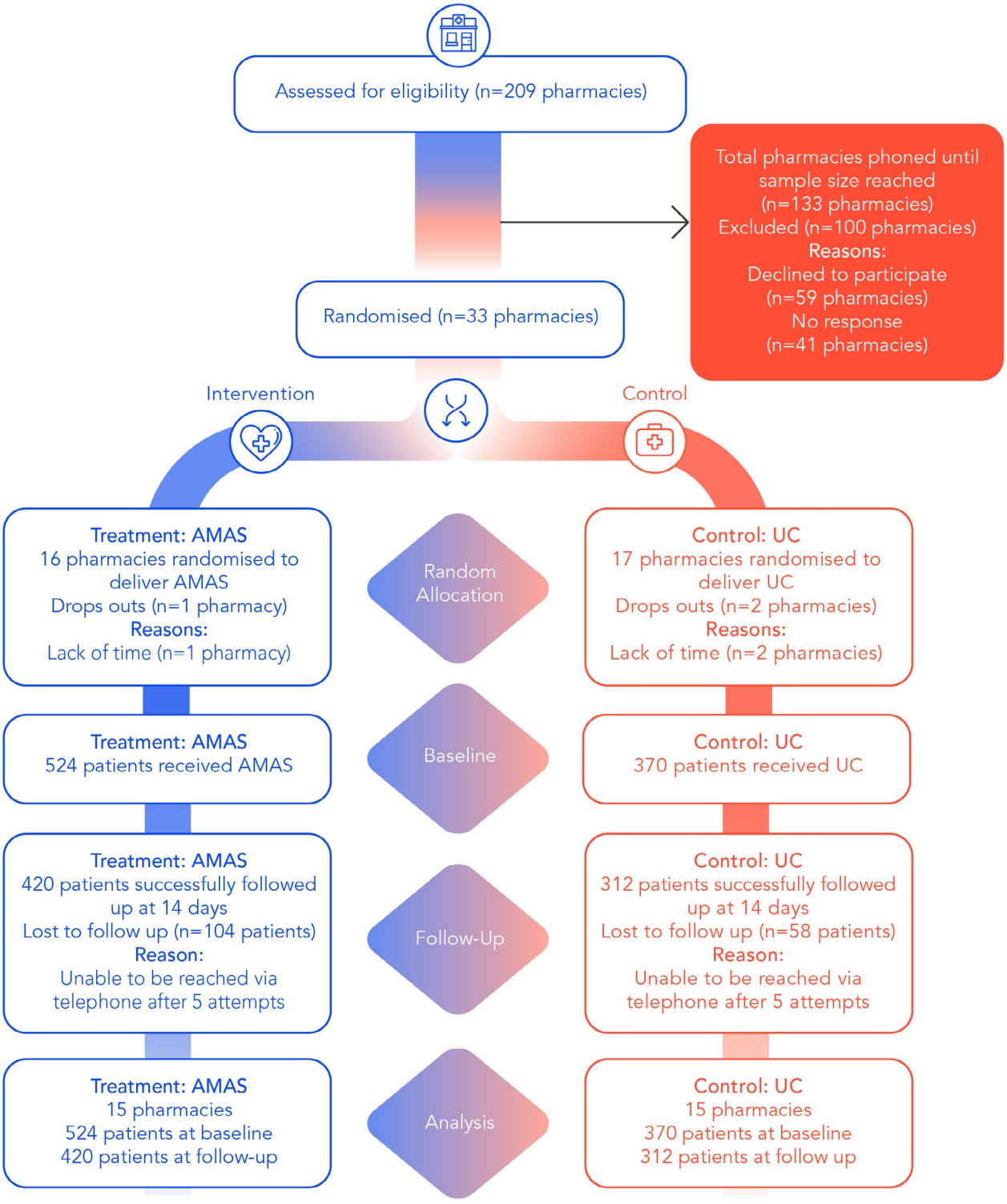
	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL	894	100%	524	100%	370	100%
Gender						
Male	382	42.7%	233	44.5%	149	40.3%
Female	510	57.1%	290	55.3%	220	59.4%
Other	2	0.2%	1	0.2%	1	0.3%
Nationality (*)						
Australian	3	5.4%	1	2.9%	2	10.0%
Other	5	9.1%	5	14.2%	0	0%
Aboriginal and/or Torres Strait Islander origin						
Yes	30	3.4%	17	3.2%	13	3.5%
No	864	96.6%	507	96.8%	357	96.5%
Highest educational attainment (*)						
Postgraduate Degree	105	11.7%	92	17.6%	13	3.5%
Graduate Diploma or Graduate Certificate	54	6.0%	31	5.9%	23	6.2%
Bachelor Degree	197	22.0%	139	26.5%	58	15.7%
Advanced Diploma or Diploma	119	13.4%	71	13.5%	48	13.0%
Year 12 or equivalent	216	24.2%	108	20.6%	108	29.2%
Year 10 or equivalent	154	17.2%	64	12.2%	90	24.3%
Year 9 or below	45	5.0%	16	3.1%	29	7.8%
Never attended school	4	0.5%	3	0.6%	1	0.3%
Employment status						
Employed, working full-time	458	51.2%	283	54.0%	175	47.3%
Employed, working part-time	167	18.7%	106	20.2%	61	16.5%
Unemployed, looking for work	44	4.9%	22	4.2%	22	5.9%
Not seeking to be in the labour force	225	25.2%	113	21.6%	112	30.3%

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

** indicates baseline patient demographics and characteristics with statistical differences between groups, p>0.05 including (1) patient nationality, (2) highest educational attainment, (3) presentation type (symptom request, product request, both) and (4) patients who had experienced the same symptoms previously. Baseline differences were adjusted for in the analysis of study outcomes (see Table 7 for adjusted analysis).*

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 1).

Figure 1 Consort 2010 Flow Diagram



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

PRESENTATION CHARACTERISTICS

Patients presented to the pharmacy in one of three ways:
(i) symptom-based presentation;
(ii) direct product request to self-medicate;
(iii) a combination of both.
Overall, the majority of patients were documented with a symptom-based presentation in both study arms (74% and 57% in AMAS and UC arms, respectively). Direct product requests accounted for 22% (n=114) of presentations in the AMAS arm and 35% (n=131) in UC (n=245). Moreover, 6% (n=51) sought care with both a symptom-based and product-based request (see Table 4).

Table 4 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.*
** indicates baseline patient demographics and characteristics with statistical differences between groups, p>0.05 including (1) patient nationality, (2) highest educational attainment, (3) presentation type (symptom request, product request, both) and (4) patients who had experienced the same symptoms previously. Baseline differences were adjusted for in the analysis of study outcomes (see Table 7 for adjusted analysis).*

Half of all presentations (50%; n=446) were cough or cold related. In the AMAS arm, 38% of patients presented with symptoms or directly requested medicines to self-treat symptoms of common cold (n=197), cough in 26% of presentations (n=136) and reflux in 14% (n=74) (Table 5). In the arm receiving UC, common cold, cough and tension headache were more commonly presented (39%; 24%; 11% respectively).

Table 5 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.*

Patients attending AMAS pharmacies were more likely to present with a respiratory related request (cough and common cold) for all presentation types (direct product request, symptom request, or both) (Figure 2).

Figure 2 Presentation type by ailment category: AMAS arm (n=524)

Symptom presentation (n=386)

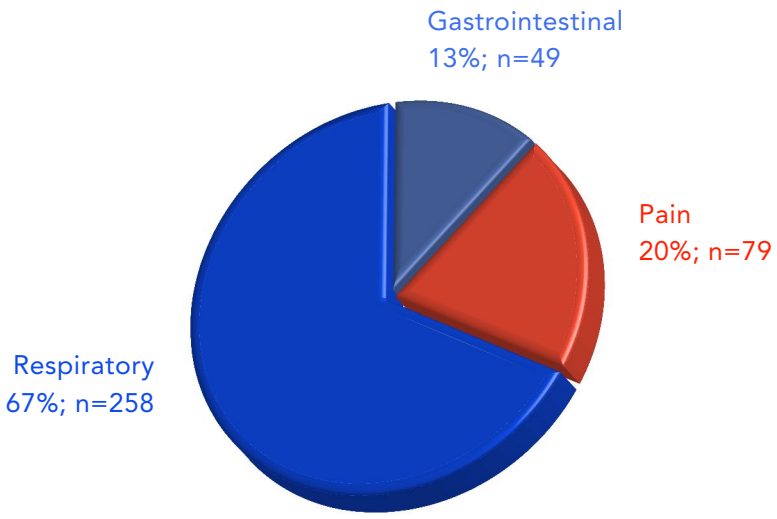
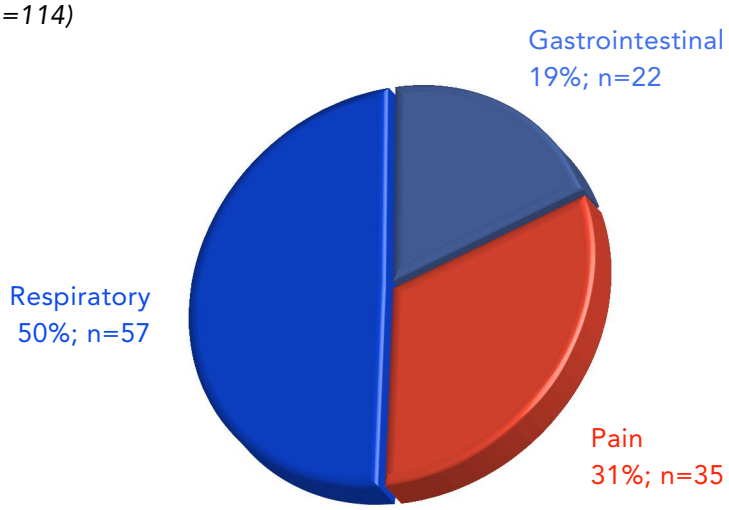
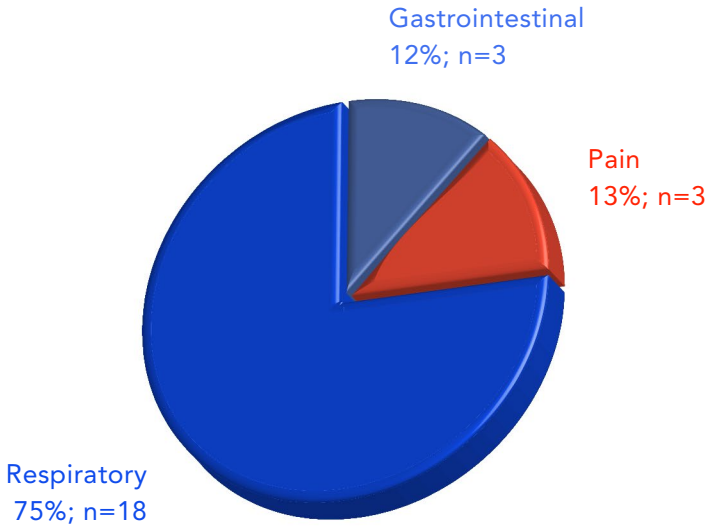


Figure 2 Presentation type by ailment category: AMAS arm (n=524) (continued)

Direct product request (n=114)



Both symptom-based and product-based request (n=24)



PATIENT HISTORY AND ASSESSMENT

Interestingly, 12% of AMAS patients (n=64) presented having experienced their current episode of symptoms greater than 28 days, compared with 11% (n=40) in UC. In the UC arm, 86% (n=319) of patients indicated having experienced the same or similar symptoms previously, compared with 78% (n=406) of patients in the AMAS arm. Within AMAS, 45% (n=234) of patients indicated their current symptoms were spreading or worsening, compared with 41% (n=151) in UC. Furthermore, 47% (n=248) of patients receiving AMAS indicated they had self-medicated for their current symptoms prior to presenting to the pharmacy, compared with 37% (n=137) of patients in the UC arm. Half of patients (49%; n=258) indicated they had previously consulted a health professional for past episodes of symptoms in AMAS, compared with 32% (n=118) of patients in UC. Moreover, 40% (n=211) of AMAS patients indicated having at least one other health problem, and 43% (n=224) were taking regular medicines (including prescribed and non-prescribed medicines ie. nonprescription

or complementary or alternative medicines (CAMs)). Patients in the UC arm indicated having other health conditions in 49% of cases (n=181), while 56% were taking regular prescribed or non-prescribed medicines (n=206).

All baseline variables were similar between groups (p>0.05) however significant baseline differences existed for (1) patient nationality, (2) level of education, (3) presentation type (symptom request, product request, both) and (4) experience of the same symptoms previously. Baseline differences were adjusted for in the main analyses (Table 6).

Table 6 Patient history: both study arms (n=894 patients)

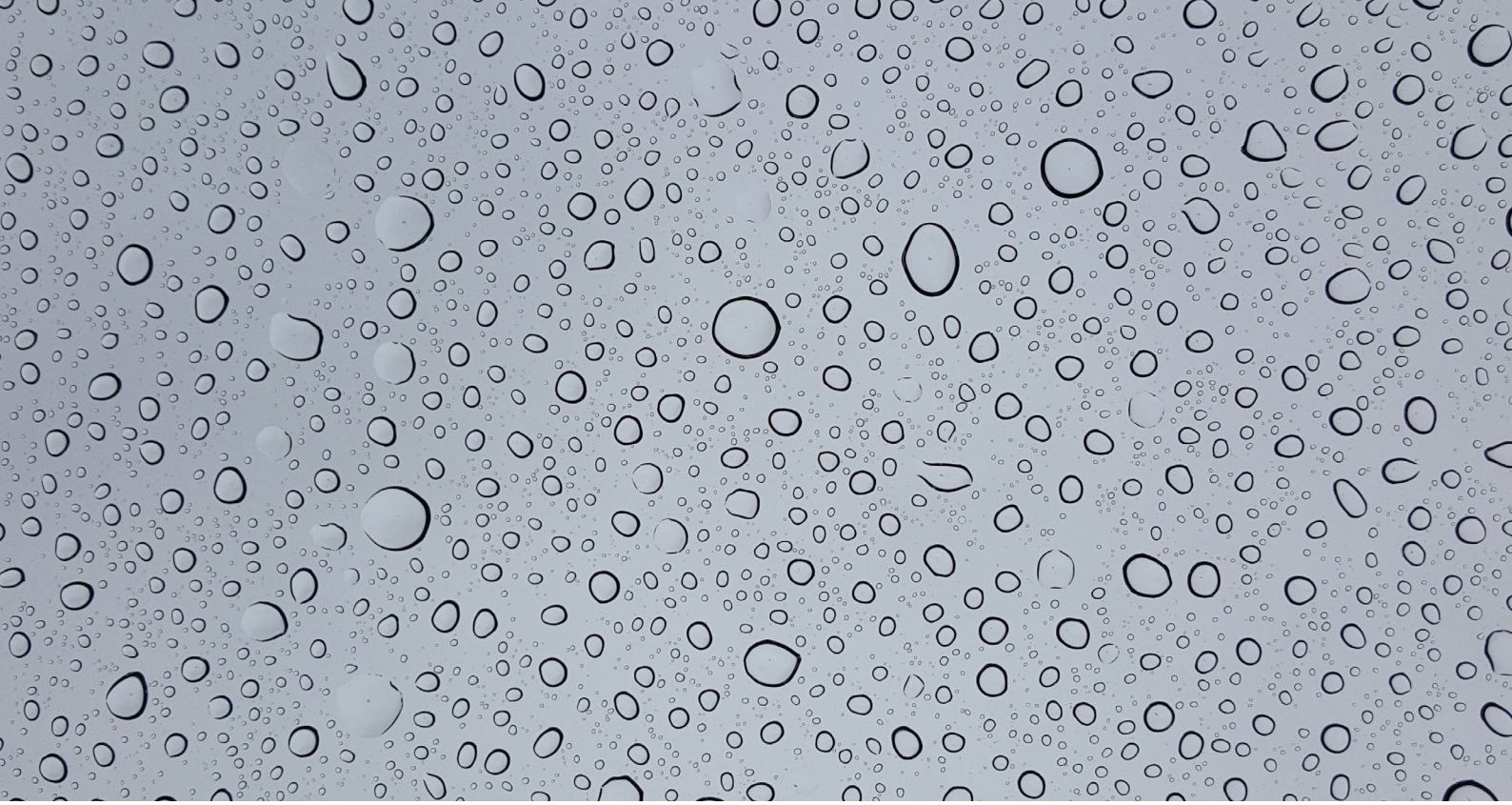
	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL	894	100%	524	100%	370	100%
Duration experienced current episode of symptoms						
< 1 day	103	11.5%	58	11.1%	45	12.2%
> 1 day and 2 days	220	24.6%	119	22.7%	101	27.3%
> 2 days and 7 days	337	37.7%	203	38.7%	134	36.2%
> 7 days and 14 days	81	9.1%	48	9.2%	33	8.9%
> 14 days and 28 days	49	5.5%	32	6.1%	17	4.6%
> 28 days	104	11.6%	64	12.2%	40	10.8%
*Experienced same or similar symptoms previously **						
Yes	725	81.1%	406	77.5%	319	86.2%
No	169	18.9%	118	22.5%	51	13.8%
Symptoms spreading or worsening						
Yes	385	43.1%	234	44.7%	151	40.8%
No	509	56.9%	290	55.3%	219	59.2%
Self-medicated for current episode of symptoms						
Yes	385	43.1%	248	47.3%	137	37.0%
No	509	56.9%	276	52.7%	233	63.0%
Consulted another HCP for previous episodes of symptoms						
Yes	376	42.1%	258	49.2%	118	31.9%
No	518	57.9%	266	50.8%	252	68.1%

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
Other health conditions						
Yes	392	43.8%	211	40.3%	181	48.9%
No	502	56.2%	313	59.7%	189	51.1%
Taking other prescribed or non-prescribed medicines #						
Yes	430	48.1%	224	42.7%	206	55.7%
No	464	51.9%	300	57.3%	164	44.3%

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

***** *indicates baseline patient demographics and characteristics with statistical differences between groups, p>0.05 including (1) patient nationality, (2) highest educational attainment, (3) presentation type (symptom request, product request, both) and (4) patients who had experienced the same symptoms previously. Baseline differences were adjusted for in the analysis of study outcomes (see Table 7 for adjusted analysis).*

 # Non-prescribed medicines include nonprescription medicines (ie. Schedule 2 or Schedule 3 medicines) and complementary or alternative medicines (CAMs).



SUMMARY OF KEY RESULTS: 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 considered baseline differences in the sample and results were adjusted accordingly.

The RRs indicate positive clinical and humanistic improvements in all outcome measures with AMAS except for reconsultation rate, compared with UC. In summation, our clinical results revealed patients receiving AMAS were 1.5 times more likely to receive an appropriate referral for medical care meeting the agreed protocols by their pharmacist, 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 referral advice and seek medical care within an appropriate timeframe (adjusted RR 5.08; 95% CI 2.02 to 12.79; p=0.0006). AMAS pharmacists were 1.2 times more likely to recommend an appropriate nonprescription medicine during the consultation (adjusted RR 1.2; 95% CI 1.1 to 1.3; p<0.0001) and were 2.6 times more likely to make a clinical intervention and recommend a safer or more appropriate medicine for direct product request presentation types (adjusted RR 2.62, 95% CI 1.28 to 5.38; p=0.0087), compared with UC. 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). However, 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). Table 7 provides a summary of primary and secondary outcome results.

Table 7 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; UC: usual care.*
**indicates AMAS shows a statistically significant improvement in outcome, compared with UC.*
 # Applies to all presentation types (symptom, product request, both).
% Patients referred at baseline consultation who actually went to see the healthcare provider as advised.
& Defined as the identification and attempted resolution of an actual or potential drug-related or symptom-related problem arising from a patient self-selecting a medicine to self-treat. An investigation of the pharmacist's identification and response (ie, change in product to a safer or more appropriate alternative) will be made. In which case, the clinical intervention rate will be calculated as the proportion of patients recommended an alternative product by the pharmacist divided by the total number of patients who present to the pharmacy directly requesting a product for self-treatment for AMAS and UC arms.
~ Includes pharmacist, GP, ED, nurse, allied health, dentist and specialist.

OBJECTIVE 1.1 APPROPRIATE MEDICAL REFERRAL RATE

REFERRAL RATE

Referral to another healthcare professional was provided to 20% (n=104) of patients in the AMAS arm, compared to 5% (n=19) in the UC arm (Table 8). 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 symptoms, yet the pharmacist re-referred the patient back to the GP for medical assessment knowing this information. While forty-four of the 104 AMAS referrals (42%) had not previously been medically assessed, 25 patients (57%) were already self-medicating.

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

Duration and frequency of the patient's symptoms were identified as the main reasons for referral (38%; n=39) in the AMAS arm. Patients' symptoms were persisting beyond the timeframe within the agreed treatment protocols for what was considered a self-limiting or minor ailment condition. Prolonged duration and frequency of symptoms were criteria for referral which require medical assessment to eliminate conditions which may be chronic or require prescribed treatment. For example, referral for medical assessment was pre-agreed for patients presenting with persistent low back pain progressively worsening beyond four weeks (n=3), cough greater than 2 weeks or recurrent cough (especially smoker with > 20 year pack history) (n=11), common cold with no symptom improvement despite treatment and duration of illness greater than ten days (n=5), reflux symptoms with no improvement after two weeks of proton pump inhibitor (PPI) therapy (n=4), reflux symptoms which persist or relapse frequently (n=13), patients experiencing six headaches per month (n=2) or headaches lasting greater than two weeks (n=1). Similar to the above, 26 of the 39 patients (67%) had previously seen a GP for past episodes of symptoms, and the pharmacist re-referred back to the GP for medical assessment knowing this information.

Table 8 Referral rate: both study arms (n=894 patients)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL	123	100%	104	100%	370	100%
Referred	123	13.8%	104	19.8%	19	5.1%
Not referred	771	86.2%	420	80.2%	351	94.9%

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

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

APPROPRIATE MEDICAL REFERRAL RATE

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. AMAS patients were 1.5 times more likely to receive a referral meeting the agreed protocols[2] by their pharmacist compared with UC patients (adjusted RR 1.51; 95% CI 1.07 to 2.11; p=0.0175) (Table 9).

Table 9 Appropriate referral meeting agreed protocols: referred patients only (n=123 patients)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL *	894	100%	524	100%	19	100%
Appropriate referral meeting agreed protocols	112	91.1%	98	94.2%	14	73.7%
Referrals outside agreed protocols	11	8.9%	6	5.8%	5	26.3%

Abbreviations: *AMAS: Australian minor ailments scheme; UC: usual care.*
** Patients who were referred during the consultation only.*

[2] Defined as meeting the action agreed in the HealthPathways for each patient referred. Each referral made was independently assessed against the action outlined within the HealthPathways for each minor ailment indication (which were pre-agreed with GPs in the codesign process). The referral was considered appropriate if it met the reason for referral, recommended time frame to seek care, and health care provider referred to.

REFERRAL TIMEFRAMES

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 (Table 10).

Table 10 Referral timeframes: referred patients only (n=123 patients)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL *	123	100%	104	100%	19	100%
ED – immediately	1	0.8%	1	0.9%	0	0%
GP – immediately	13	10.6%	12	11.5%	1	5.3%
GP - within 24 hours	15	12.2%	15	14.4%	0	0%
GP - between 1-3 days	40	32.5%	38	36.5%	2	10.5%
GP - next scheduled visit, within 2-3 weeks	38	30.9%	30	28.9%	8	42.1%
After-hours clinic	2	1.6%	2	1.9%	0	0%
Dentist	1	0.8%	15	14.4%	0	0%
Allied Health	8	6.5%	38	36.5%	2	10.5%
Other	5	4.1%	2	1.9%	0	0%

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

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

OBJECTIVE 1.2 ADHERENCE TO REFERRAL ADVICE RATE

Of those successfully followed up, 52% of patient reported adhering to the pharmacist's referral advice and seeking medical care following AMAS, compared to 16% in UC. AMAS patients were five times more likely to adhere to the referral advice by their pharmacist than those referred by UC pharmacists (adjusted RR 5.08; 95% CI 2.02 to 12.79; p=0.0006) (Table 11).

Table 11 Adherence to referral advice (n=114 patients)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL #	114	100%	95*	100%	19	100%
Adherence to referral advice	52	45.6%	49	51.6%	3	15.8%
Non-adherence to referral advice	62	54.4%	46	48.4%	16	84.2%

Abbreviations: *AMAS: Australian minor ailments scheme; UC: usual care.*
 # Total includes only participants referred during consultation and successfully followed up at 14 days.
** Lost 9 patients to follow up in all AMAS.*

OBJECTIVE 1.3 APPROPRIATE RECOMMENDATION OF NONPRESCRIPTION MEDICINE RATE

As a result of the consultation, UC pharmacists supplied at least one nonprescription medicine to 95% of patients (n=350) compared with 84% (n=441) of AMAS patients. There was no evidence of difference between groups (p=0.10) (Table 12).

Table 12 Provision of non-prescription medicine(s) during consultation with the pharmacist: 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%
Yes	791	88.5%	441	84.2%	350	94.6%
No	103	11.5%	83	15.8%	20	5.4%

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

Of the consultations resulting in the supply of a nonprescription medicine, AMAS patients were 1.2 times more likely to receive a nonprescription medicine recommendation meeting the agreed protocols[3] by their pharmacist, than patients receiving UC (adjusted RR 1.2; 95% CI 1.1 to 1.3; p<0.0001).

Table 13 Appropriate recommendation of nonprescription medicine(s) (n=791 patients)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL *	791	100%	441	100%	350	100%
Appropriate medicine recommendation meeting agreed protocols	677	85.6%	400	90.7%	277	79.1%
Recommendations outside agreed protocols	114	14.4%	41	9.3%	73	20.9%

Abbreviations: *AMAS: Australian minor ailments scheme; UC: usual care.*
**Applies only to patients provided a nonprescription medicine as a result of consultation with the pharmacist.*

Self-care advice was provided in almost all AMAS consultations (98%), compared to 62% in UC (p=0.05). AMAS pharmacists provided self-care advice only to 11% of patients (n=56) without the supply of a nonprescription medicine, compared to 4% (n=15) receiving UC. UC patients were much more likely to be supplied a medicine without self-care advice (UC 35%; n=129; AMAS 2%; n=12). AMAS patients were supplied a mean of 1.4 (SD 0.7) nonprescription medicines per consultation, compared to 1.2 (SD 0.5) in the UC arm (Table 14).

Table 14 Provision of self-care advice: 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%
Yes	740	82.8%	511	97.5%	229	61.9%
No	154	17.2%	13	2.5%	141	38.1%

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

[3] Defined as meeting the action agreed in the HealthPathways for each product recommended. Each product recommendation was independently assessed against the action outlined within the HealthPathways for each minor ailment indication (which were pre-agreed with GPs in the codesign process). The recommendation was considered appropriate if it met the entire requirement as approved in Product Information by the Therapeutic Goods Administration including correct indication for use, dose, frequency, duration of use, and contraindications.

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, and 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 all medicines supplied and included combination antacids, histamine-2 receptor antagonists and PPIs (Table 15).

Table 15 Recommended nonprescription medicines grouped by category: both study arms (n=1051 medicines)

	Medicines supplied (n)	Medicines supplied (%)
TOTAL	1051	100%
Fixed dose combination cold and cough preparations	239	22.7%
NSAIDs (oral)	105	10.0%
Opioid cough suppressants	88	8.4%
Analgesics (oral)	67	6.4%
Mucolytic cough preparations	60	5.7%
Combination mucolytic-expectorant cough preparations	51	4.9%
Analgesics (combination)	49	4.7%
Antiseptic agents (lozenge)	41	3.9%
Complementary and alternative medicines (CAMs)	39	3.7%
Proton pump inhibitors	37	3.5%
Decongestants (oral)	30	2.9%
Less sedating antihistamines (oral)	29	2.8%
Combination antacids	28	2.7%
Histamine-2 receptor antagonists	23	2.2%
Expectorant cough preparations	20	1.9%
Saline (intranasal)	18	1.7%
Antiseptic agents (throat gargle)	17	1.6%
Decongestants (intranasal)	17	1.6%
Corticosteroids (Intranasal)	14	1.3%
Other	14	1.3%
Beta-2 agonists (inhaled)	13	1.2%
Saline (flush)	9	0.9%
Sedating antihistamines	9	0.9%
Oral rehydration solutions	9	0.9%

Table 15 Recommended nonprescription medicines grouped by category: both study arms (n=1051 medicines) (continued)

	Medicines supplied (n)	Medicines supplied (%)
NSAIDs (topical)	6	0.6%
Analgesics (topical)	4	0.4%
Laxatives	4	0.4%
Anticholinergics (oral)	3	0.3%
Antibacterial (eye drop)	2	0.2%
Anticholinergics (intranasal)	2	0.2%
Antihistamines (intranasal)	2	0.2%
Antidiarrheals	2	0.2%

Abbreviations: *CAMs: complementary and alternative medicines; NSAIDs: non-steroidal anti-inflammatory drugs.*

OBJECTIVE 1.4 PHARMACIST INTERVENTION RATE (OR CLINICAL INTERVENTION RATE) FOR DIRECT PRODUCT REQUESTS

This study defined a Clinical Intervention as a "professional activity undertaken by a pharmacist directed towards improving quality use of medicines and resulting in a recommendation for a change in the patient's medication therapy" (1). Findings revealed AMAS pharmacists were 2.6 times more likely to perform a clinical intervention for direct product request presentations (for example, recommending an alternative medicine deemed safer or more appropriate for the patient than the medicine requested by the patient), than UC pharmacists (adjusted RR 2.62, 95% CI 1.28 to 5.38; p=0.0087) (Table 16).

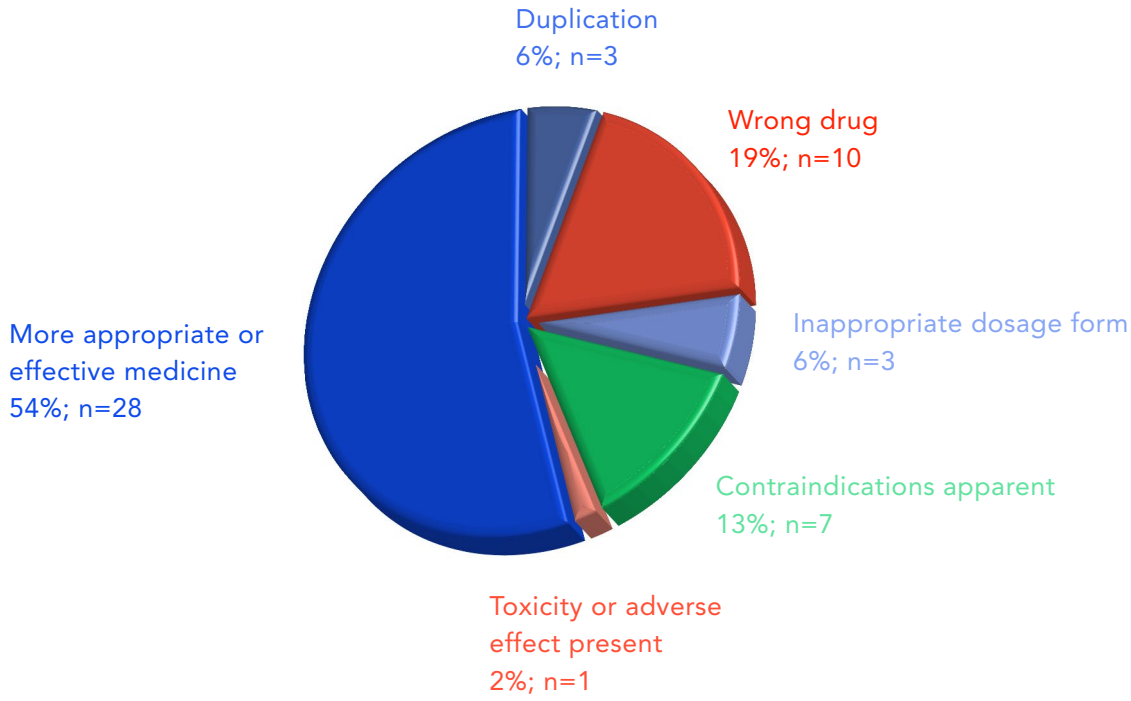
Table 16 Pharmacist intervention rate for direct product requests (n=296 patients)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL *	296	100%	138	100%	158	100%
Clinical intervention made	47	47	29	21.0%	18	11.4%
No clinical intervention made	249	249	109	79.0%	140	88.6%

Abbreviations: *AMAS: Australian minor ailments scheme; UC: usual care.*
**Applies to direct product request presentation types.*

Primarily, the reasons for recommending a change in medicine included: (i) providing a more appropriate or effective medicine[4] (54%), (ii) wrong drug selection[5] (19%), (iii) contraindications apparent (13%), (iv) drug duplication (6%), (v) inappropriate dosage form (6%) and, (vi) toxicity or adverse effects present (2%) (Figure 3).

Figure 3 Reasons for recommending a change in direct product requests: both study arms (n=47 clinical interventions made, with 52 reasons for recommending the change)



[4] ie. Pharmacist believes a more effective medicine is available and recommends it instead of the requested therapy.
[5] ie. Patient is requesting a medicine which they are currently self-medicating with incorrectly or inappropriately.

OBJECTIVE 1.5 SELF-REPORTED SYMPTOM RESOLUTION OR IMPROVEMENT RATE

FOLLOW UP RATES

Five call attempts within one week were made to contact all patients at two weeks following the consultation with the community pharmacist. Of the 894 patients who participated in the study, 82% (n=732) were successfully followed up by telephone (Table 17).

Table 17 Follow up rates at 14 days: both study arms (n=894)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL	894	100%	524	100%	370	100%
Followed up	732	81.9%	420	80.2%	312	84.3%
Lost to follow up	162	18.1%	104	19.8%	58	15.7%

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

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 (Table 18). Furthermore, AMAS patients were 1.06 times more likely to achieve complete symptom resolution or relief at follow up, than UC patients (adjusted RR 1.06; 95% CI 1 to 1.13; p=0.0353).

Table 18 Self-reported symptom resolution rates at 14 days: both study arms (n=732 patients)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL *	732	100%	420	100%	312	100%
Symptoms have completely resolved	423	57.8%	259	61.7%	164	52.6%
Symptom relief or improvement but not resolved	243	33.2%	134	31.9%	109	34.9%
Symptoms did not improve or have worsened	66	9.0%	27	6.4%	39	12.5%

Abbreviations: *AMAS: Australian minor ailments scheme; UC: usual care.*
**Includes only those patients successfully followed up at 14 days.*

OBJECTIVE 1.6 RECONSULTATION RATE

Patients not referred by the pharmacist self-reported if they had reconsulted with another healthcare professional within the two weeks following the consultation (Table 19). Patients in the AMAS group reconsulted for their same symptom episode in 22% (n=70) of cases. The rate of reconsultation was similar in the UC arm (22%; n=60). No changes were observed between groups (adjusted RR 0.98; 95% CI 0.75 to 1.28; p=0.89).

Table 19 Reconsultation rate to all health providers for the same symptoms within 14 days (n=603 patients)

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL *	603	100%	325	100%	278	100%
Yes	130	21.6%	70	21.5%	60	21.6%
No	473	78.4%	255	78.5%	218	78.4%

Abbreviations: *AMAS: Australian minor ailments scheme; UC: usual care.*
** Includes only participants not referred during consultation, and successfully followed up at 14 days.*

The majority of patients reconsulted with the GP (66%; n=49) in the AMAS arm. UC patients also primarily reconsulted with the GP (62%; n=44). In some instances, patients reconsulted with multiple providers (for example, patients who visited their GP also saw their pharmacist, patients who visited their GP further received care from an allied health professional, or received referral to a specialist) (Table 20). Interestingly, there was a high proportion (10%) of AMAS patients who reconsulted with a medical specialist. Three patients visited the emergency department following pharmacist's consultation. Two of these were from UC and both were hospitalised.

Table 20 Reconsultation by health care provider

	Sample population (n)	Sample population (%)	AMAS group (n)	AMAS group (%)	UC group (n)	UC group (%)
TOTAL*	145	100%	74	100%	71	100%
Pharmacist	23	15.9%	6	8.1%	17	23.9%
General practitioner	93	64.1%	49	66.2%	44	62.0%
Emergency department	3	2.1%	1	1.4%	2	2.8%
Nurse	2	1.4%	1	1.4%	1	1.4%
Specialist	8	5.5%	8	10.7%	0	0.0%
Allied health professional	14	9.6%	9	12.2%	5	7.1%
Hospitalisation (admission)	2	1.4%	0	0.0%	2	2.8%

Abbreviations: *AMAS: Australian minor ailments scheme; UC: usual care.*
**Some patients re-consulted with multiple healthcare professionals.*

OBJECTIVE 2.1 CHANGE IN SELF-REPORTED HEALTH RELATED QUALITY OF LIFE

At the time of consultation, patients who attended AMAS pharmacies reported a lower EQ-VAS (59.5; SD 19.1) than in the UC arm (63.9; SD 21.4) (Table 21). 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 (mean difference 4.08; 95% CI 1.23 to 6.87; p=0.0049).

Table 21 Mean difference in EQVAS at follow up (n=732)

	Sample population (n=732)	AMAS group (n=420)	UC group (n=312)
Mean EQ-VAS (initial consult)	61.3	59.5	63.9
SD	20.2	19.1	21.4
Mean EQ-VAS (follow-up)	83.1	85.3	80.2
SD	14.6	14.8	13.9
Change in EQ-VAS	21.8	25.8	16.3

Abbreviations: *AMAS: Australian minor ailments scheme; EQ-VAS: EuroQoL-visual analogue scale; UC: usual care.*

SUBGROUP ANALYSES

Table 22 provides the results of an exploratory subgroup analysis by initial presentation type (symptom, product request, both) and condition group (gastrointestinal, respiratory and pain). The results show treatment effects are consistent for all study outcomes between subgroups with AMAS.

Table 22 Exploratory subgroup analysis

OUTCOME	Effect of AMAS	Subgroup variable	Subgroup level	Estimate (CI)	p-value
Appropriate medical referral rate	Rate Ratio (AMAS/ UC)	Presentation type	Both symptom & product request	1.44 (0.80 - 2.61)	0.48
			Symptom presentation	1.70 (1.08 - 2.65)	
			Direct product request	1.17 (0.83 - 1.64)	
		Condition group	Gastrointestinal	1.08 (0.88 - 1.33)	0.14
			Pain	1.34 (0.84 - 2.16)	
			Respiratory	1.59 (1.01 - 2.50)	
Adherence to referral advice rate	Rate Ratio (AMAS/ UC)	Presentation type	Both symptom & product request	2.99 (0.40 - 22.07)	0.87
			Symptom presentation	4.18 (1.74 - 10.03)	
			Direct product request	6.05 (0.78 - 46.80)	
		Condition group	*	*	*
Appropriate recommendation of nonprescription medicine rate	Rate Ratio (AMAS/ UC)	Presentation type	Both symptom & product request	1.40 (1.02 - 1.93)	0.58
			Symptom presentation	1.19 (1.11 - 1.29)	
			Direct product request	1.17 (1.04 - 1.31)	
		Condition group	Gastrointestinal	1.09 (1.01 - 1.19)	0.18
			Pain	1.27 (1.09 - 1.47)	
			Respiratory	1.17 (1.09 - 1.26)	
Pharmacist intervention rate for direct product requests	Rate Ratio (AMAS/ UC)	Condition group	Gastrointestinal	5.07 (0.90 - 28.56)	0.23
			Pain	2.64 (0.76 - 9.25)	
			Respiratory	1.42 (0.64 - 3.15)	

Table 22 Exploratory subgroup analyses (continued)

OUTCOME	Effect of AMAS	Subgroup variable	Subgroup level	Estimate (CI)	p-value
Self-reported symptom resolution or improvement rate	Rate Ratio (AMAS/ UC)	Presentation type	Both symptom & product request	1.13 (1 - 1.29)	0.64
			Symptom presentation	1.06 (0.99 - 1.14)	
			Direct product request	1.09 (0.99 - 1.20)	
		Condition group	Gastrointestinal	0.99 (0.93 - 1.05)	0.19
			Pain	1.11 (1.02 - 1.22)	
			Respiratory	1.06 (1 - 1.13)	
Reconsultation rate	Rate Ratio (AMAS/ UC)	Presentation type	Both symptom & product request	1.09 (0.22 - 5.51)	0.88
			Symptom presentation	1.01 (0.67 - 1.53)	
			Direct product request	0.86 (0.52 - 1.41)	
		Condition group	Gastrointestinal	0.67 (0.27 - 1.68)	0.73
			Pain	0.99 (0.57 - 1.71)	
			Respiratory	0.97 (0.65 - 1.47)	
Change in self-reported health related quality of life	Mean Difference (AMAS/ UC)	Presentation type	Both symptom & product request	7.26 (-0.82 - 15.34)	0.27
			Symptom presentation	5.98 (3.67 - 8.28)	
			Direct product request	4.46 (-0.08 - 9.01)	
		Condition group	Gastrointestinal	8.85 (3.09 - 14.61)	0.27
			Pain	3.00 (-1.30 - 7.29)	
			Respiratory	6.06 (4.32 - 7.80)	

Abbreviations: *AMAS: Australian minor ailments scheme; CI: confidence interval; UC: usual care.*
**indicates missing sub-group analysis as quasi-separation in the data occurred during statistical analysis.*

IMPUTED ANALYSIS

Table 23 provides the results of an imputed analysis which accounts for patients lost to follow up (n=162 patients lost to follow up). Outcome measures included self-reported symptom resolution and relief rate, adherence to referral advice rate, reconsultation rate and health related quality of life. The results show that treatment effects are consistent with main study findings, when patients lost to follow up are accounted for in the analysis.

Table 23 Imputed analysis to account for patients lost to follow up

OUTCOME	Effect of AMAS	Estimate with MI	p-value
Self-reported symptom resolution or improvement rate	Rate Ratio (AMAS/ UC)	1.08 (1.02 - 1.14)	0.0047*
Adherence to referral advice rate	Rate Ratio (AMAS/ UC)	4.36 (1.68 - 11.31)	0.0025*
Reconsultation rate	Rate Ratio (AMAS/ UC)	0.97 (0.71 - 1.33)	0.85
Change in self-reported health related quality of life	Mean Difference (AMAS/ UC)	5.32 (2.8 - 7.84)	<0.0001*

Abbreviations: *AMAS: Australian minor ailments scheme; MI: multiple imputation; UC: usual care.*
**indicates AMAS shows a statistically significant improvement in outcome, compared with UC.*

DISCUSSION

KEY STUDY FINDINGS

The findings of our research reveal positive improvements in a number of clinical and humanistic indicators with the AMAS program when compared with UC in pharmacies located in WSPHN region. From a clinical viewpoint, there was strong evidence AMAS resulted in (i) patients more likely to receive an appropriate referral for medical care meeting the agreed protocols by their pharmacist, (ii) patients more likely to adhere to referral advice and seek medical care within an appropriate timeframe, (iii) pharmacists more likely to recommend an appropriate nonprescription medicine meeting agreed protocols during the consultation, (iv) pharmacists more likely to perform a clinical intervention for direct product request presentations, and (v) patients more likely to achieve symptom resolution or relief, compared to UC. Humanistic results revealed improved health related quality of life for AMAS patients, compared with UC. The imputed analysis produced consistent treatment effects confirming the robustness of our main study findings in improving clinical and humanistic outcome measures with AMAS.

IMPLICATIONS OF KEY STUDY FINDINGS

INTEGRATION AND COLLABORATION

Through the use of an agreed structured service specification, and agreed HealthPathways, pharmacists operated within a framework to differentially diagnose and manage a patient. The use of HealthPathways improved identification of patients requiring referral, particularly patients presenting with red flag clinical features or prolonged duration of symptoms requiring medical assessment. Our clinical results reveal an improved appropriateness in consultation outcomes ie. the decision to recommend treatment or refer a patient for medical care. Pharmacists were trained to use the pre-agreed evidence-based pathways and IT systems developed collaboratively with GPs in PHN clinical governance. Patients showed improvements in symptom resolution or relief (94% in AMAS, compared with 88% in UC) and improved health related quality of life (increase in EQ-VAS from baseline 4 points higher than UC patients at follow up) with AMAS, compared with patients receiving UC.

CARE DELIVERED AT THE APPROPRIATE LEVEL

The AMAS showed 94% of all referrals made from the pharmacist as appropriate meeting the agreed referral protocols. Comparatively, this was shown to be 74% in UC. This could be due to UC not having a standard approach to consultation and therefore showed variability in referral. Importantly, 2% of patients with red flag symptoms suggestive of possible serious conditions were identified by AMAS pharmacists, compared to none in UC. However, this raises the question of whether there were any red flag presentations to UC pharmacies. The research team did not undertake clinical assessment of individual patients to confirm this.

Identifying and interpreting red flags is an important part of clinical practice in pharmacy. Identification of signs and symptoms associated with other diseases are an important part of clinical assessment as further investigation and timely specific treatment is usually required by medical practitioners. Standardising triage for patients presenting with self-limiting conditions from those who require more urgent investigation has important implications for practice (ie. missed diagnoses and delay in appropriate treatment). For example, most low back pain in primary care is mechanical in nature and may not signify a dangerous underlying abnormality, but in a minority could indicate a serious condition (2). Gastroesophageal reflux disease can also manifest in a multitude of symptoms, the most common being heartburn and regurgitation (2). Even though in most cases it is benign, symptoms could also indicate more sinister pathology (2). The identification of red flags also depends on the patients account of their illness and symptom description, which is why a deeper and

protocolised consultative approach is suggested of higher value.

Pharmacists in both groups identified patients with less immediate referral criteria such as prolonged or persistent symptoms or patients inappropriately self-medicating for prolonged durations. These reasons were identified in 38% of referral cases with AMAS. Interestingly 67% of these patients had seen a GP for previous episodes of symptoms and were continuing to self-medicate. The pharmacist was re-referring patients back for medical assessment knowing this information and illustrates the value of a clinical consultation for patients with unresolved, undiagnosed symptoms who are continuing to self-medicate. The AMAS pharmacist during the consultation can take the appropriate actions to trigger another detailed medical assessment.

Referral processes were facilitated by pre-agreed HealthPathways and additional training. In terms of the timeliness and destination of referral, the most straight-forward quality measure was compliance with the HealthPathways. Our trial highlights the role community pharmacists play in triage to not only recognise potentially serious symptoms but appropriately respond and filter to the GP or ED. Timely referral is a crucial step to minimise the time between presentation for medical assessment, and treatment. A component of timely referral relates to the assessment of urgency and communicating this to patients. Delays may be encountered if patients are not being referred to the correct destination, in an appropriate timeframe, or if referral information is not adequately communicated to both the patient and other HCPs involved.

Patients who were referred by their pharmacist in AMAS were five times more likely to adhere to referral advice and seek medical care, compared with UC, and has implications for practice. Failure to adhere to referral advice might delay identification of underlying disease while rapid recovery may lead to the perception that no further assessment or treatment is necessary (3). Furthermore, non-adherence to referral advice may add additional costs to the health system if a patient develops complications or is hospitalised (4). There may be many important factors influencing adherence to referral, such as more time spent with the patient during consultation, pharmacist communication skills, health provider collaboration, and pharmacists emphasising patient compliance to referral advice during consultation. This suggests intervention pharmacists were trained in more structured triage and referral processes and patients are complying with referral recommendations. These referral actions lead to more efficient use of resources.

QUALITY USE OF MEDICINES

Our study demonstrated that 80% of patients directly requesting medicines were responsibly self-medicating for their symptoms. Conversely, 20% were identified by the pharmacist as self-medicating or potentially self-medicating inappropriately. Patients were self-selecting medicines, probably following self-diagnosis, self-treating for prolonged periods or selecting contraindicated medicines. Self-medication (be it appropriate or inappropriate) may stem from prior positive use of a product. Seeking pharmacist care following self-medication may be due to symptoms getting worse or not improving, or simply that patients want to purchase the same medicine to continue self-medicating. Half of patients in this study were self-medicating for their symptoms. Around 27% had experienced their current symptoms beyond seven days even before seeking advice at the pharmacy and 10% had experienced symptoms beyond four weeks. This raises questions as to why patients are not seeking care sooner and are continuing to self-medicate without medical assessment. This may be influenced by the patients own perception of their symptoms, including severity, and duration (5).

Pharmacists played a role in identifying medication related problems to ensure safe, appropriate and effective medicines were supplied during consultation. For example, AMAS pharmacists were 2.6 times more likely to perform a clinical intervention for direct product requests, than UC. The AMAS showed 91% of nonprescription medicine recommendations were considered appropriate meeting 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 a result of AMAS, compared with UC. It is evident that pharmacist intervention favourably affects health outcomes, including symptom resolution and quality of life. Pharmacists training, structured consultation and more time with the patient, documentation systems,

pre-agreed protocols and provider collaboration may be important factors influencing clinical intervention rates and the appropriate supply of medicines. The developed IT systems supported pharmacists to record clinical interventions consistently and allowed for follow up to be arranged whereby consultation history was available for re-assessment. While this information was transmitted to GPs, during the study we did not measure the use or value of this information to the GP.

Furthermore, the provision of self-care advice was included in almost all presentations (98%) with AMAS, compared with 62% in UC. Findings show 10% of patients were recommended self-care only, without the supply of a medicine or without referral, compared to 4% in UC. Pharmacists were in a strong position to facilitate responsible self-care as in some instances the supply of a product or referral was unnecessary.

COMPARISON TO LITERATURE

Our study builds on international MAS literature (6) and reports three new study outcomes: (i) appropriate rate of nonprescription medicine recommendation, (ii) appropriate medical referral rate and, (iii) rate of adherence to referral advice. To our knowledge, there have been no studies that have examined these outcomes in MAS literature. Currently, there is no gold standard with regard to the type of clinical outcomes that should be assessed and the methods of assessment that should be deployed for an intervention study targeting the management of minor ailments (6). Referrals (and importantly, red flag referrals) were a critical point discussed in the codesign process with GPs. GPs wanted to ensure patients were being referred in an appropriate and timely manner and were being seen quickly. We also thought it valuable to assess pharmacists' impact on patient self-medication processes. We build on international MAS literature by providing a direct comparison to usual pharmacist care and evaluate MAS using a cRCT study design. International MAS studies have previously used observational study designs and the evidence generated through the cRCT is much higher than through observational studies (6). Fourteen-day patient follow up is consistent with international studies evaluating MAS which ensures the follow up timeframe is appropriate for conditions that are self-limiting in nature (7).

Types of clinical outcomes reported in the literature and their methods of assessment presents a challenge for data interpretation and comparison of results. For example, diversity in the range of conditions considered minor ailments, the choice of clinical outcomes, the development and validation of data collection tools and the timelines for follow-up assessment are inherent issues in minor ailment research (6). There are limited evaluation studies specifically for MASs, and the available literature is reporting on pharmacy-based management of minor ailment symptoms, irrespective of whether they are delivering a MAS or not.

In the literature, studies evaluate a range of clinical outcomes (6, 7) and improvements in clinical outcomes have been reported across a number of studies evaluating minor ailment management in pharmacy (8-17). Studies in the international literature evaluating minor ailment management have previously focused on therapeutic areas such as cough (10, 17), cold (15), skin (19), gastrointestinal (14, 16, 20, 21) or multiple minor ailment conditions (8, 9, 12, 13, 22-25) for patients typically aged 18 years or over presenting with symptom based or direct product request type presentations (6). The types of presentations evaluated in this study are similar to those seen in a Tasmanian snapshot of pharmacy presentations which identified pain and respiratory-type conditions as the most common primary health requests in after-hours pharmacy (18). A NQPHN study reporting after hours management of minor ailments in pharmacy, documented 55% of presentations were symptom-based requests (26). The same study reported a referral rate of 20%, with 1% of referrals to ED, and a 10% clinical intervention rate for direct product requests. Comparatively, our results reveal a higher proportion of AMAS patients presenting with symptom-based requests (74%), a higher clinical intervention rate (21%) and a similar referral rate to that of the NQPHN after hours study (26).

SYMPTOM RESOLUTION RATE

Symptom resolution has been assessed in number of international studies (7, 8, 22, 27-32). Paudyal et al. in a systematic review of MASs undertaken in 2014 reported complete symptom resolution rates ranging from 68% to 94% (7). An observational study in 2015 with a prospective cohort design undertaken in Scotland by Watson et al. (8) reported symptom resolution rates to be similar across ED (37%), general practice (36%) and community pharmacy (44%) (8). A pilot study undertaken in Valencia (Spain) in 2017 reported patient symptom resolution rates of 72% in their MAS evaluation (30). A Canadian based study in Saskatchewan reported over 80% of participants with complete or significant improvement in minor ailment symptoms (22), while a study undertaken in Nova Scotia evaluating prescribing for minor ailments reported an 89% symptom resolution rate (32). Our results appear consistent with the literature available. Our findings reveal complete symptom resolution rates of 62%, and symptom resolution and improvement rates to be 94% with AMAS, compared with 53% and 88%, in UC (adjusted RR 1.06; 95% CI 1 to 1.13; p=0.0353). It is important to note studies in the literature report small sample sizes, sample size calculations are not always justified, do not use a randomised design and in some instances do not specify the member of staff involved in management, to directly compare our study results.

RECONSULTATION RATE

The extent of healthcare reconsultation after a MAS consultation is poorly reported in literature. International literature estimates generally report GP reconsultation rates only and do not include all healthcare reconsultation following consultation with the pharmacist. Reconsultation has been assessed in number of studies with different findings (7, 8, 27-29, 33-40). Paudyal et al. report GP reconsultation rates of 2% to 23% (7). The Mary Seacole Research Centre evaluated the Pharmacy First Minor Ailment Scheme in Leicester, UK where it was found 23% of the 145 Pharmacy First consultations led to a GP re-consultation (40). The Minor Ailment study ('MINA' study) undertaken in the UK reported a reconsultation rate of 33%, and an 18% reconsultation rate when considering GPs only (8). In contrast, our study found GP reconsultation rates to be 15% with AMAS, and 16% in UC. Reconsultation to all health providers was 22% in both arms. This indicates that reconsultation rates obtained in this study are consistent with evaluations in international literature. Although the appropriateness of reconsultation was not assessed in this study (ie. whether a patient should have reconsulted or not), prescription medicines such as antibiotic treatment, or PPI therapy for reflux as examples, were commenced in over one-third who reconsulted with a medical provider. Reconsultation with the same pharmacist as part of follow up accounted for 8% of all patients who reconsulted.

HEALTH RELATED QUALITY OF LIFE

HRQOL has previously been reported in four studies (8, 10, 16, 41). The EQ-VAS results of these studies do not provide a direct comparison given they are not evaluating MASs per se, but pharmacy-based management of minor ailments. As an example, Watson et al. reported change in EQ-VAS following pharmacy-based care compared with GP and ED care for patients with symptoms suggestive of minor ailments (8). Future studies reporting change in EQ-VAS with MAS may provide a direct comparison to our study results.

STRENGTHS AND LIMITATIONS

This is the first study in Australia to evaluate a community pharmacist AMAS intervention, and contributes a cRCT study design to the international literature. This study is unique as it compares AMAS to usual pharmacist care through an experimental study design. Evaluations identified in the literature compared general practice or ED settings to the community pharmacy or interventions delivered by healthcare professionals in ED and GP (ie. physicians or nurses) for the management of minor ailments (8). Within the studies, there is no clear distinction whether pharmacists or members of pharmacy staff delivered the care which was undergoing evaluation. Our study delineates the role of pharmacist in delivering AMAS and our comparator is UC delivered by the pharmacist, and is not delivered by staff under pharmacist supervision.

A randomised controlled trial has a number of important features that make it the gold-standard evaluation method (42). Our choice of cluster randomisation at the level of the pharmacy decreases the potential for contamination. The study provides information on the impact of the intervention on clinical and humanistic outcomes and barriers to implementation, compared to current practice. We have conducted an imputed statistical analysis to account for data lost to follow up to ensure robustness in our key findings. Failure to appropriately account for missing data in analyses may lead to bias and loss of precision (43). The results in the imputed analyses were consistent with our main study findings, confirming the effectiveness of AMAS in improving clinical and humanistic outcomes.

Some limitations to the study should be discussed. While a cluster randomised design is being used to overcome contamination between study arms, the study design may be susceptible to some methodological biases. Cluster randomised trials cannot conceal treatment allocation and participants awareness of the allocation can lead to biased recruitment (42). Careful attention has been placed to the design of our trial to minimise the potential for biases. The collection of clinical data was undertaken in one primary health network site. Further research could expand on this to include patient population demographics in other primary health network regions.

This study was powered to detect changes in two primary outcomes, including (i) appropriate medical referral rate, and (ii) appropriate rate of nonprescription medicine recommendation, and our sample size was reached. A limitation is that this study was not powered to detect changes in symptom resolution (a secondary outcome measure). While we saw a positive effect on symptom resolution rates with AMAS, this might be of use in future studies to determine whether symptom resolution rates result in differences between patients who reconsult and those who do not.

Furthermore, one of the main limitations of this type of study is that, by definition, a minor ailment is a self-limiting health problem and implicitly involves resolution regardless of the intervention performed by the pharmacist. We have defined minor ailments as 'conditions that are often self-limiting, with symptoms easily recognised and described by the patient and falling within the scope of pharmacist's knowledge and training to treat' (44). There is no agreed definition in the literature for minor ailments. This pragmatic definition encompasses conditions that have a range of severity. Such conditions include: back pain, heartburn, indigestion and migraine (45) which were included in this study. While symptoms might be considered a minor ailment by the patient, medical referral and consultation with a GP is certainly required for medical assessment.

While baseline differences between study arms were adjusted for in the main analyses, areas for potential bias should be discussed. Patients with more severe symptoms or high comorbidity levels may have been more likely to be enrolled. Given we would expect patients who are more severely ill as more likely to reconsult, our estimate of healthcare reconsultation and referral rates may be higher.

CONCLUSION

The results show AMAS, comprising one-to-one consultation with a community pharmacist and a protocolised approach to care, was effective in improving clinical and humanistic outcomes. These results are robust, supporting the triaging and management role for pharmacists for patients for system efficiency and improved patient outcomes. The scope, complexity and the varied nature of conditions under MASs highlight pharmacists' skills to assist consumers to self-care, facilitate responsible self-medication, and timely medical referral. The AMAS provides a system that is safe, sustainable and provides high quality care consistently. The study shows the relative value of integration of a clinical minor ailments scheme in primary care. Health systems are moving toward a more interprofessional approach to primary care and this team-based paradigm will have a significant impact on the role of community pharmacists. Pharmacists can support self-care and integration with backing and promotion by governments and PHNs.

CHAPTER 4

ECONOMIC IMPACT EVALUATION

CHAPTER 4: ECONOMIC IMPACT EVALUATION

This chapter addresses the following objectives:

To evaluate the economic impact from a societal perspective of an AMAS for adult patients receiving care for minor ailments in Australian community pharmacies.

The specific objectives were defined:

1. Economic evaluation

(i) To examine the cost-utility and cost-effectiveness of an AMAS in community pharmacy compared to the alternative of usual care.
(ii) To assess the robustness of the cost effectiveness results through one-way and multi-way sensitivity analysis.

2. Threshold analysis

(i) To estimate the potential cost reductions associated with transferring patients with minor ailment conditions from the ED and GP setting to community pharmacy (AMAS) at the Western Sydney Primary Health Network (WSPHN), New South Wales state and Australia national level.

ECONOMIC EVALUATION

METHODOLOGY: ADDRESSING OBJECTIVE 1

(i) To examine the cost-utility and cost-effectiveness of an AMAS in community pharmacy compared to the alternative of usual care.
(ii) To assess the robustness of the cost effectiveness results through one-way and multi-way sensitivity analysis.

STUDY DESIGN

A cost-utility analysis (CUA) and cost-effectiveness analyses (CEA) were performed alongside a cluster randomised controlled study to determine whether the implementation of AMAS compared to usual pharmacy care is a value for money intervention in Australia from a societal perspective. CUA and CEA compare the overall incremental costs associated to the assessed interventions (in this case AMAS) while reporting different outcome measures. The output in an economic evaluation is expressed by the incremental cost-effectiveness ratio (ICER), which is a summary measure that represents the economic value of the intervention (AMAS) compared with the alternative of usual care. The ICER is calculated by dividing the difference in total costs (incremental cost) by the difference in the chosen measure of health outcome or effect (incremental effect) providing a ratio reflecting the 'extra cost per extra unit of health effect' (1).

The trial was a cluster randomised controlled study conducted in community pharmacies in WSPHN from July 2018 to March 2019. Patients were followed up (14 days) following a consultation with the pharmacist in the pharmacy. Data were collected from adult patients who presented to pharmacies in WSPHN from July 2018 to March 2019, with a symptom-based request or direct product request for one of seven minor ailments including common cold, cough, low back pain, tension headache, migraine, primary dysmenorrhoea and reflux. As pharmacies were the unit of randomisation, depending on the pharmacy visited, patients received the AMAS (intervention group) or usual care (UC) (control group). Effectiveness of the AMAS was measured in terms of appropriateness of referral and recommendation of nonprescription medicines and patient symptom resolution (SR) rates, compared with UC. In order to examine potential differences in health related quality of life (HRQOL), QALYs were also used as a final outcome measure (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*

INTERVENTION: AMAS

A description of the intervention and cRCT study methodology can be found in Chapter 3. In summary, patients attending AMAS pharmacies received a face-to-face protocolised consultation with the pharmacist. Pharmacists utilised collaboratively agreed clinical pathways (HealthPathways) at the point of care during the consultation for clinical assessment, evaluation and action ie. to recommend a particular course of action including self-care and/or nonprescription medicine(s) for symptomatic relief and/or referral for medical care. For patients who identified a regular GP during the patient-pharmacist consultation, a summary of the consultation and referral was sent electronically via HealthLink secure messaging software. Patients were contacted by the research team by telephone 14 days following the consultation, to assess resolution of symptoms, health related quality of life (EQ-VAS assessment) and health care resource utilisation.

COMPARATOR: UC

Patients attending control pharmacies with a symptom based or direct product request for one of seven ailments (listed above) received UC by their pharmacist. UC was documented by pharmacists for research purposes only. Patients were followed-up in a similar manner to intervention patients.

DECISION MODEL STRUCTURE

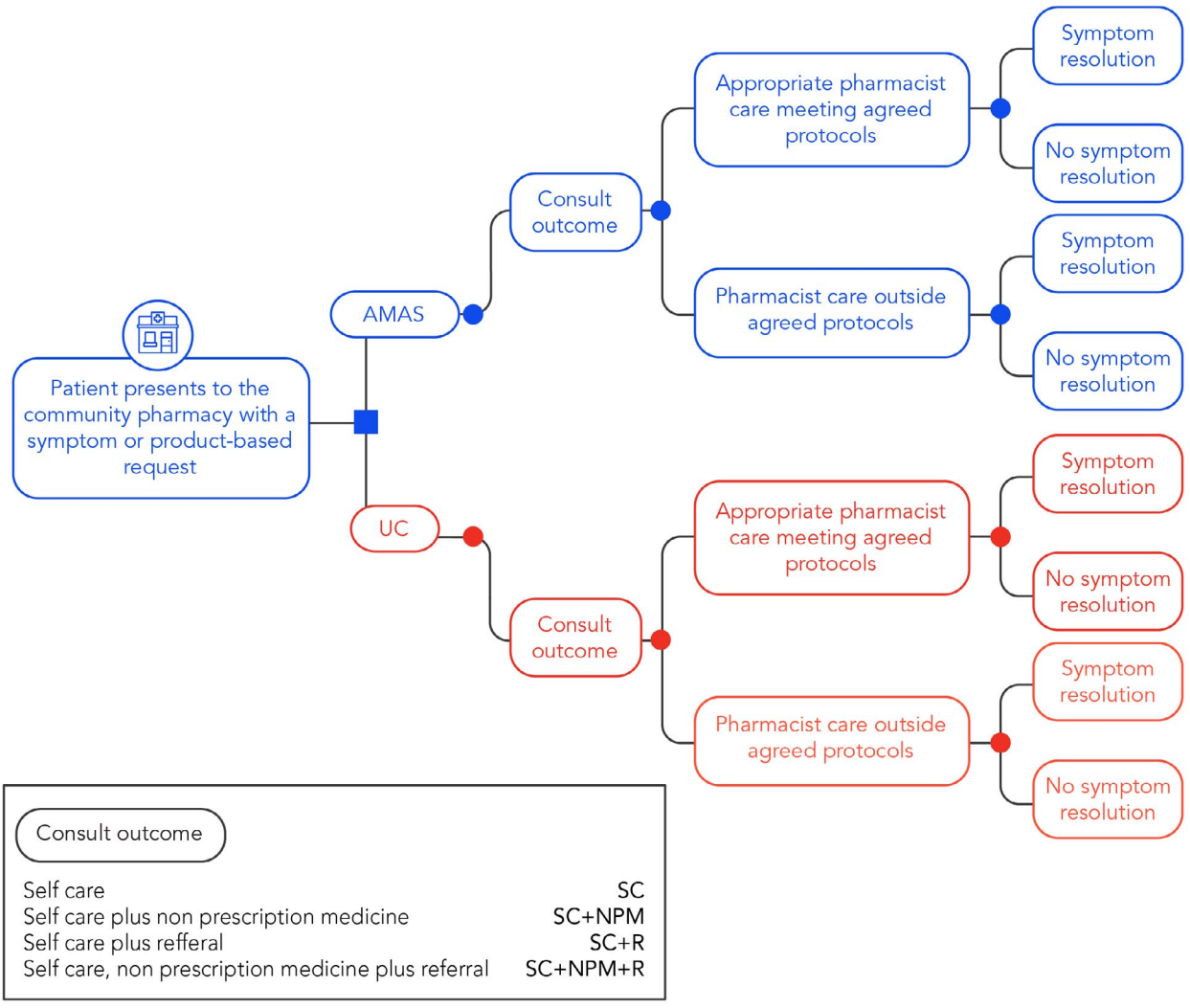
A decision analytic modelling technique was employed for the economic evaluation consisting of a decision tree[7] (Figure 1). The model took a societal perspective over a 14-day time horizon. The decision tree model was conceptualised in TreeAge Pro Healthcare 2019 R1.1 Software (2) and Microsoft Excel for Mac Version 16.16.10 was used for the analysis. The detailed model structure can be found in appendix 1.

[7] Decision trees are schematic representations of the question of interest and the possible consequences that occur from following each strategy.

There were two strategies being considered (AMAS and UC), as denoted by the two branches emanating from the decision node (represented by a square in Figure 1). The initial chance node represents one of four pharmacy consultation outcomes, consisting of (i) self-care advice only, (ii) self-care advice plus supply of nonprescription medicine(s), (iii) self-care advice plus referral for medical care, or (iv) self-care advice, supply of nonprescription medicine(s) plus referral. As a result of AMAS or UC, there was a chance the pharmacist provided appropriate care meeting the agreed *HealthPathway* protocols or care outside the agreed protocols. Appropriate pharmacist care was defined as providing self-care, appropriate nonprescription medicine recommendations and/or appropriate medical referral in line with the pre-agreed HealthPathway for each clinical condition (3). Appropriate pharmacist care was reported as an intermediate outcome measure for cost-effectiveness (as a proxy for health gain).

At 14-day follow up, patients indicated if their symptoms had completely or partially resolved, had not resolved or had worsened. The *terminal* node (represented by the triangle in Figure 1) represents the end point for the patient pathway, where patients either achieve symptom resolution or not (4). It was assumed patients reporting partial resolution of symptoms would achieve resolution given the self-limiting nature of a minor ailment (5).

Figure 1 Decision tree model structure



Abbreviations: *AMAS: Australian minor ailments scheme; SC: self care; SC_NPM: self care plus nonprescription medicine; SC_NPM_R: self care plus nonprescription medicine plus referral; SC_R: self care plus referral; UC: usual care*

ECONOMIC EVALUATION OUTCOMES

The primary outcome of the cost-utility analysis was the quality adjusted life year (QALY) (Table 2). The incremental cost-effectiveness ratio (ICER) in the case of our CUA includes in its denominator the QALY which, in turn, is tightly related to the term "utility". Utility is usually a number between 0 and 1 ("0" representing the worst health state and "1"—perfect health) (6). The model assigns utility values ranging between 0 and 1 based on symptom resolution status. Utilities values were estimated from the results previously published in the UK (MINA study) by Watson et al. (7). This study was a cohort study comparing health-related and cost-related outcomes of care for symptoms suggestive of minor ailments across different settings (pharmacy, general practice and emergency departments). Utility values were estimated in the MINA study from the results of the EuroQoL EQ-5D questionnaire, a multi-attribute utility instrument (MAUI) comprising five domains including: mobility, self-care, routine daily activities, pain/ discomfort, and anxiety/ depression (6). Resulting utilities derived from the MINA study were 0.91 and 0.77, for patients achieving symptom resolution or not achieving resolution, respectively (7).

In addition to the CUA, two cost effectiveness analyses were conducted where the clinical effect measure was an extra episode of appropriate pharmacy care and extra patient achieving symptom resolution for their ailment. The cost-effectiveness results are expressed in terms of extra cost per additional episode of appropriate pharmacy care and extra cost per additional patient achieving symptom resolution (Table 2).

Table 2 CUA and CEA effect outcomes

Method	Effect measure	Outcome(s)	Source
CUA	Utilities	QALYs	Refer to Watson study (7)
CEA	Natural units	(i) Episode of appropriate pharmacy care (ii) Extra patient achieving complete symptom resolution	Trial data

Abbreviations: *CEA: cost-effectiveness analysis; CUA: cost-utility analysis, QALYs: quality adjusted life years*

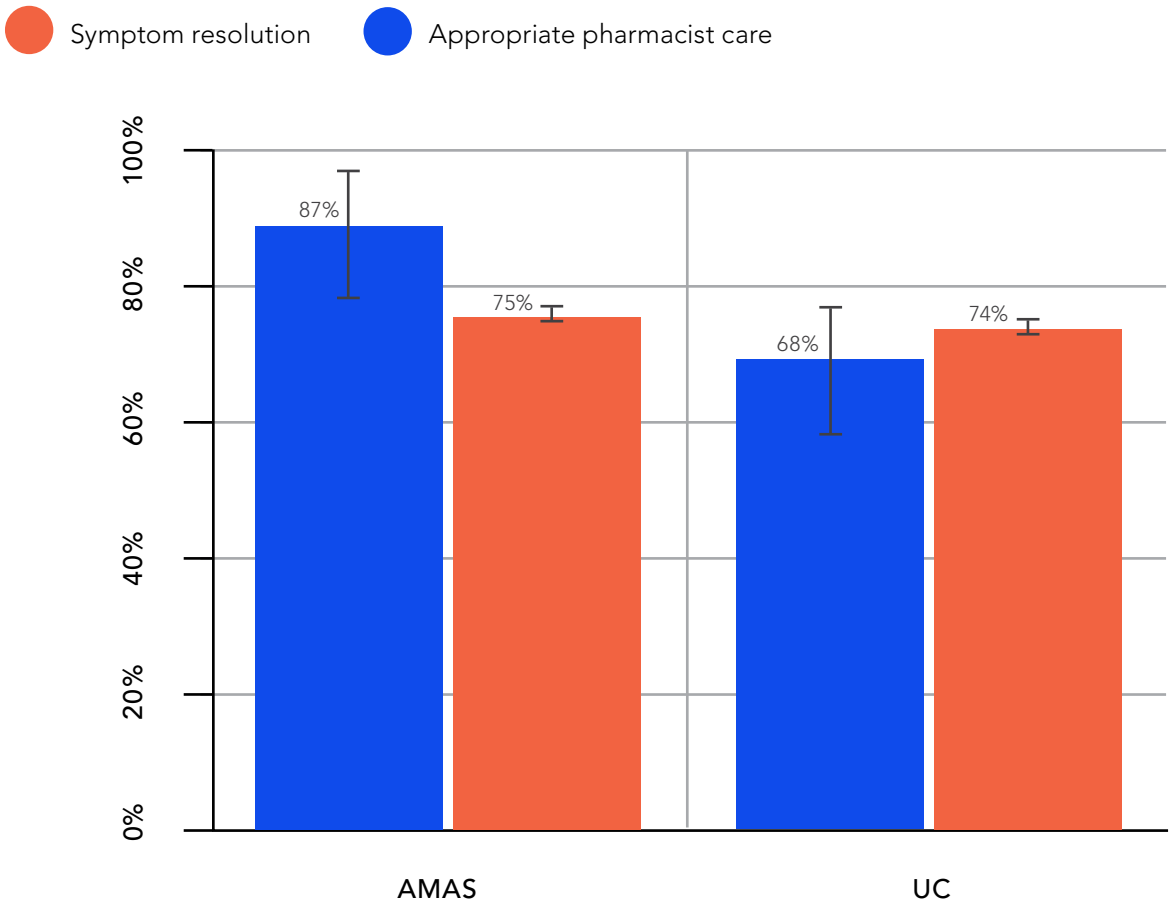
The model was populated with probabilities, costs and health status data using trial data obtained from the cRCT assigned to each chance node (represented by circles in Figure 1). We generated the difference in patient outcome and costs to allow derivation of the total incremental impact of AMAS compared with UC, in a cohort who received (i) appropriate pharmacist care and achieved symptom resolution, (ii) appropriate pharmacist care and did not achieve symptom resolution, (iii) care by the pharmacist outside of agreed protocols and achieved symptom resolution, or (iv) care by the pharmacist outside of agreed protocols and did not achieve symptom resolution. The adjusted probability of receiving appropriate pharmacist care in the AMAS group was 87% (95% CI 0.85 to 0.88), with 75% (95% CI 0.73 to 0.77) achieving symptom resolution. The probability of patients receiving appropriate pharmacist care in normal practice was 68% (95% CI 0.65 to 0.69), with 74% (95% CI 0.72 to 0.75) achieving symptom resolution (Table 3, Figure 2). A full table of assigned probabilities are detailed in appendix 2.

Table 3 Adjusted probabilities in model

		Outcome(s)	95% CI	
		Adjusted probability	Low	High
AMAS	Appropriate pharmacist care	0.87	0.85	0.88
	Symptom resolution	0.75	0.73	0.77
UC	Appropriate pharmacist care	0.68	0.65	0.69
	Symptom resolution	0.74	0.72	0.75

Abbreviations: *CEA: cost-effectiveness analysis; CUA: cost-utility analysis, QALYs: quality adjusted life years*

Figure 2 Adjusted probabilities



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

Deterministic incremental economic analyses were carried out. Considering the time horizon of the study (14 days), QALYs were estimated for both AMAS and UC by multiplying the duration of time spent in the health state (14 days), the utility value associated with that health state (in this case, symptom resolution or no symptom resolution), and the number of individuals within the trial achieving symptom resolution or not. This was combined with costs obtained alongside the trial. The CUA result is reported as the cost per additional QALY gained.

The incremental cost-per QALY generated by AMAS over UC was calculated using the following equation: $(Cost_{AMAS} - Cost_{UC}) / (QALY_{AMAS} - QALY_{UC})$
Mean ICERs for the different study endpoints are presented. The incremental cost and incremental effects have been depicted visually using an incremental cost–effectiveness plane[8].

COSTS

Costs were identified, measured and valued using trial-based data and local sources. A societal perspective was applied for the analysis. Costs were estimated in Australian dollars ($AUD) in the 2018/2019 financial year (8). Costs during the 2-week follow-up period were analysed for the 894 patients included in the cluster-randomised controlled trial detailed in Chapter 3.

The following model parameters were used to populate the economic model (Table 4).

Table 4 Summary of identified health resources and sources of data used

Health resource	*Model value*	*Unit*	*Low range*	*High range**
GP cost#	AUD44.07	per consult	AUD30.85	AUD57.29
Pharmacist	AUD29.37	per hour	AUD24.04	AUD34.30
AMAS trainings per year	1	training per year	0	2
AMAS time of consult	10.88	minutes	10.52	11.23
UC time of consult	3.29	minutes	2.88	3.71
Facilitation visit	60	minutes per month	n/a	n/a
Facilitator cost	AUD46.28	per hour	n/a	n/a
AMAS training and facilitation cost	AUD0.07	per patient	AUD0.00	AUD0.10
Average NPM price supplied in AMAS	AUD10.62	per patient	AUD10.20	AUD11.05
Average NPM price supplied in UC	AUD9.76	per patient	AUD9.39	AUD10.14
Average NPM supplied (AMAS: SC_NPM)	1.40	medicines	1.12	1.69
Average NPM supplied (AMAS: SC_NPM_R)	1.55	medicines	1.24	1.86

[8] The cost-effectiveness plane is a graphical way of presenting cost-effectiveness results, with the difference in costs on the vertical axis and the difference in health benefits on the horizontal axis.

Table 4 Summary of identified health resources and sources of data used (continued)

Average NPM supplied (UC: SC_NPM)	1.15	medicines	0.92	1.38
Average NPM supplied (UC: SC_NPM_R)	1.53	medicines	1.22	1.83
Average cost of medicines at reconsult	AUD9.79	per patient	AUD7.94	AUD11.64
AMAS average medicines at reconsult	1.30	medicines	1	3
UC average medicines at reconsult	1.41	medicines	1	3
Utility: symptom resolution	0.91		0.88	0.94
Utility: no symptom resolution	0.77		0.73	0.81

Abbreviations: *GP: general practitioner; AMAS: Australian minor ailments scheme; n/a: not applicable; NPM: nonprescription medicine; R: referral; SC: self-care; UC: usual care*

** Lower and upper bound values represent 95% CI; or upper and lower range from trial data.*

 # The average price of GP consultations was determined through examination of MBS report for GP services in WSPHN (for in hours and after-hours care).

Costs were grouped into four major categories: (1) pharmacists time; (2) nonprescription medicines; (3) referrals and reconsultation, and (4) training, facilitation and IT costs. Mean estimates of costs per patient were compared between AMAS and UC arms. The average time of an AMAS consultation was 10.9 minutes (SD 4.14) (including documentation time of consultation data in an iPad). The average time to deliver UC was 6.3 minutes (SD 4.04). Of this, 3 minutes was estimated for UC documentation of data for research purposes, with a consultation time of 3.3 minutes (Table 5). It is envisaged that the AMAS pharmacist will document the consultation as part of the service with implementation in future. Pharmacists wage was based on unit prices sourced from the Pharmacy Industry Award Australia (June 2018) (9). The hourly rate of a pharmacist was averaged accordingly based on the position held (ie. pharmacist in charge). An average hourly wage of AUD29.37 was multiplied by the time consumption to deliver AMAS, or UC.

Table 5 Consultation time (minutes)

	AMAS group (including documentation time)	UC group (including documentation time)	UC group (excluding documentation time)
Consultation time	10.9* (SD 4.14)	6.3 (SD 4.04)	3.3

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

**It is envisaged that the AMAS pharmacist will document the consultation as part of the service.*

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). The costs for the quantity closest to one-month supply (28-30 tablets or capsules) for oral preparations were used. For all other preparations, the cost of the smallest quantity was averaged to determine unit price.

Referral and reconsultation 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 medicine prices were determined using PBS and non-PBS prices. The average cost of a GP consultation of AUD44.07 was determined through examination of MBS reports for annual GP services in WSPHN (includes MBS items for services provided in- and after-hours).

A cost related to training, information technology and monthly facilitation was included for the AMAS patients only. The average hourly pharmacists 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. We have used a nominal number of patients per pharmacy based on industry data (10) presenting with symptom based or product-based requests for minor ailments to estimate the cost per patient for training, facilitation and IT setup. Details of this calculation are provided in appendix 3. Table 6 provides each cost category and sources of data used.

Table 6 Summary of identified health resources and sources of data

Cost category	Source of data
Pharmacist time	Australian Government Fair Work Ombudsman 2018 (9); trial data
Nonprescription medicines	Amcal, Chemist Warehouse, Priceline 2019 data; trial data
Adherence to referral	Medicare Benefits Schedule 2019 (11); PBS 2019; Amcal, Chemist Warehouse, Priceline 2019 data; trial data
Reconsultation	Medicare Benefits Schedule 2019 (11); PBS 2019; Amcal, Chemist Warehouse, Priceline 2019 data; trial data
Training costs	Australian Government Fair Work Ombudsman 2018 (9); UTS Award level HEW5 Step 1
Monthly facilitation	UTS Award level HEW5 Step 1
Information technology and setup	Purchase invoices

Abbreviations: *HEW: Higher education worker; PBS: Pharmaceutical Benefits Scheme; UTS: University of Technology Sydney.*

SENSITIVITY ANALYSIS

To address robustness of the results, a one-way and multi-way sensitivity analysis (SA) was conducted. For the one-way SA, all known variables (Table 4) were tested independently, ceteris *paribus*, considering plausible ranges (using upper and lower limits accordingly). The aim of this analysis was to assess how each parameter impacted the overall ICER. In addition, the multi-way SA assessed the impact of the highest possible cost of an AMAS consultation with multiple parameters, and another assessing the impact of 100 percent of patients adhering to referral advice with multiple parameters. A tornado diagram was produced showing the varying effects of different parameters on the ICER.

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 project team. This was carried out as review of model structure, inputs and outcomes. The computerised models were developed by the research teams and examined internally by the UTS Centre for Health Economics Research and Evaluation (CHERE).

THRESHOLD ANALYSIS

METHODOLOGY: ADDRESSING OBJECTIVE 2

(i) To estimate the potential cost reductions associated with transferring patients with minor ailment conditions from the ED and GP setting to community pharmacy (AMAS) at the WSPHN, state and national level.

The average modelled cost per AMAS consultation of AUD26.88 from a societal perspective including out-of-pocket patient costs for medicines(s) (obtained in objective 1) was used to estimate the cost reduction potential. Different patient transfer scenarios were assumed from ED or GP settings to AMAS, from a societal perspective. For this purpose, a threshold analysis was performed. The following key parameters were researched and analysed at the WSPHN, state and national level for input into the threshold analysis, including (i) the cost of a GP and ED service, (ii) total GP and ED services delivered annually, and (iii) the proportion of adult patients with symptoms suggestive of minor ailments seeking care at ED and GP settings who could potentially be transferred to receive care under the AMAS.

Multiple sensitivity analyses were conducted using:

(i) The modelled cost of an AMAS consultation of AUD14.49 as per model excluding patient out-of-pocket medicine expenses (SA1) for the nonprescription medicines, and prescription medicines as a result of adherence to referral and reconsultation without referral (AUD12.39).

(ii) The highest likely modelled cost of an AMAS consultation of AUD33.84 (including patient out-of-pocket medicine expenses) (SA2).

Different scenarios were considered applying various thresholds for actual patient transfer. The most optimistic scenario assumes 100 percent of eligible patients are transferred to receive the AMAS, to the most conservative assuming only 1 percent patient transferability. Table 7 outlines each parameter and sources of data used for the threshold analysis.

Table 7 Identified parameters and data sources for the threshold analysis

Parameters	*Value*	Source
Average modelled cost per AMAS consultation	AUD26.88*	Economic evaluation; trial data
Modelled cost per AMAS consultation excluding out-of-pocket patient cost of medicines (SA1)	AUD14.49	Economic evaluation; trial data
Highest modelled cost per AMAS consultation (SA2)	AUD33.84*	Economic evaluation; trial data
Cost per GP visit (does not include cost of medicine(s))	AUD44.07	The average cost of GP consultations was reported in the Medicare Benefits Schedule (MBS) data report for GP services in WSPHN for MBS item numbers associated with in-hours and after-hours GP care ($44.07 per GP service) (12).

Table 7 Identified parameters and data sources for the threshold analysis (continued)

Cost per non-admitted ED visit: WSPHN and NSW	AUD552.19	National hospital cost data for 2015-16 was used to determine the per presentation cost of non-admitted ED presentations. Cost per national ED visit (2016) of $533 taken from the Independent Hospital Pricing Authority (13). The mean cost was adjusted to AUD 2019 value (price deflator 3.6 percent).
Cost per non-admitted ED visit: Australia	AUD535.61	National hospital cost data for 2015-16 was used to determine the per presentation cost of non-admitted ED presentations. Cost per national ED visit (2016) of $517 taken from the Independent Hospital Pricing Authority (13). The mean cost was adjusted to AUD 2019 value (price deflator 3.6 percent).
Number of Annual GP services: WSPHN	5,997,914	Annual GP services in WSPHN (2016-17) in the MBS Data report for MBS item numbers associated with in-hours and after-hours GP care (12). See Results: Medicare analysis.
Number of Annual GP services: NSW	41,658,186	Annual GP services in NSW (2016-17) in the MBS Data report for MBS item numbers associated with in-hours and after-hours GP care (12). See Results: Medicare analysis.
Number of Annual GP services: Australia	125,410,350	Annual GP services in Australia (2016-17) in the MBS Data report for MBS item numbers associated with in-hours and after-hours GP care (12). See Results: Medicare analysis.
Number of Annual ED services: WSPHN	99,602	Annual GP services in Australia (2016-17) in the MBS Data report for MBS item numbers associated with in-hours and after-hours GP care (12). See Results: Medicare analysis.
Number of Annual ED services: NSW	2,880,287	Determined using 2016 census data and frequency of 10.5 percent of adults attending ED per year (14).
Number of Annual ED services: Australia	8,017,492	Annual ED services in NSW (2017-18) taken from the AIHW, Emergency Department Care 2017-2018 Report (15).

Abbreviations: ED: emergency department; GP: general practitioner; MBS: Medicare Benefits Schedule; NSW: New South Wales; WSPHN: Western Sydney primary health network.

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

TRANSFERRABLE ESTIMATES OF EMERGENCY DEPARTMENT SERVICES OBTAINED FROM LITERATURE

International ED minor ailment estimates

In a UK based study, Bednall et al. reported 8 percent of adult ED presentations were appropriate for community pharmacist management (16). Similarly, Fielding et al. reviewed ED presentations over a one-week period from an ED in Scotland. It was estimated that 5.3 percent of ED presentations were considered as minor ailments and could be managed by a pharmacist (17). Another UK paper found 11.5 percent of low acuity ED presentations could be directed to community pharmacy for management (18). A low acuity condition was defined as "one that can be clinically assessed by a community pharmacist and requires treatment and/or advice available from a community pharmacy" (18). The top presentations included earache, cough, skin rash, diarrhoea, sore throat, blisters, headache and low back pain (18). A Canadian based study by Alsabbagh et al. examined the proportion of emergency department visits that could potentially be managed by pharmacists with expanded scope of practice in Ontario (19). The retrospective study identified 49 conditions in ED considered to be manageable by pharmacists, representing 4.3 percent of all ED visits in Ontario (19). Lastly, a large study in the United States reported 6.3 percent of ED visits as suitable for management in primary care (20).

National ED minor ailment estimates

Previous studies have estimated 10 to 60 percent of ED presentations in Australia could be redirected to other healthcare settings (21). A recent study conducted by North Queensland primary health network (NQPHN) in collaboration with UTS estimated 2.9 to 10 percent of all ED presentations in Queensland to be low acuity pharmacy manageable presentations (22).

TRANSFERRABLE ESTIMATES OF GENERAL PRACTITIONER SERVICES OBTAINED FROM LITERATURE

International GP minor ailment estimates

The MINA study in the UK reported 13 percent of GP consultations are for minor ailments and could be transferred to community pharmacies for management (23). A similar finding by Fielding et al. in the UK reported 13 percent of GP visits categorised as minor ailments suitable for management in community pharmacies (17). Pillay et al. estimated that total consultations for minor ailments in the UK account for approximately 20 percent of total GP workload (24). The same study reported 88 percent of these minor ailment consultations were suitable for self-care and transferable to the pharmacy setting (24). Hassell et al. in the UK examined twelve self-limiting conditions resulting in the transfer of 38 percent of GP workload to community pharmacy (25). Comparatively, one European study in Norway estimated up to 28 percent of after-hours GP consultations were for minor ailments (26).

National GP minor ailment estimates

One Australian report undertaken for Consumer Healthcare Products Australia (formerly the Australian Self-medication Industry (ASMI)), used weekly IMS Australian Medical Index data from 420 GPs across Australia to examine the impact of minor ailments on overall GP workload (27). The study estimated 7 to 21 percent of all GP consultations in Australia as partly or totally spent on minor ailments (27). The most frequently treated minor ailments were acute upper respiratory tract conditions, diarrhoea, low back pain, cough, headache and constipation, accounting for 58 percent of all minor ailment presentations to a GP (27). Importantly to note, there is no specific Australian literature estimating the percentage of GP minor ailment presentations that can be suitably transferred for management by community pharmacists. Table 8 provides a summary of the percentage literature estimates of services for minor ailments transferrable from GP and ED to the AMAS.

Table 8 Summary of literature estimates and data sources: services transferrable to AMAS

	Services transferrable to pharmacy			*Data Sources*
	Range			
ED	2.9%	5.3%	11.5%	National estimates: (1) NQPHN study estimated 2.9 percent of all ED services are low acuity pharmacy manageable presentations (after hours) in QLD (22). International estimates: (1) Canadian study reported 4.3 percent of all ED visits in Ontario could be transferred to pharmacy (19). (2) UK study reported 5.3 percent of ED presentations were considered minor ailments that could be managed by a pharmacist (17). (3) UK study reported that 8 percent of adult ED presentations are appropriate for community pharmacist management (16). (4) UK study estimated 11.5 percent of ED presentations could be shifted from higher cost settings to community pharmacy (18).
GP	7.0%	13.0%	21.2%	National estimates: (1) ASMI study estimated 7-21.2 percent of all GP consultations in Australia are partly or totally spent on minor ailments (27). International estimates: (1) UK based MAS study reported 13 percent of GP consultations for minor ailments could be transferred to community pharmacies (23). (2) UK based study reported 13.2 percent of general practice visits were categorised as minor ailments suitable for management in community pharmacies (17). (3) UK study estimated that total consultations for minor ailments account for approximately 20 percent of the total available GP workload in the UK (24), with 88 percent of these transferable to the pharmacy setting (24).

Abbreviations: *AMAS: Australian minor ailments scheme; ASMI: Australian Self-Medication Industry; ED: emergency department; GP: general practitioner; NSW: New South Wales; NQPHN: North Queensland primary health network; QLD: Queensland; UK: United Kingdom; WSPHN: Western Sydney primary health network.*

RESULTS: ECONOMIC EVALUATION

RESULTS: ADDRESSING OBJECTIVE 1

(i) To examine the cost-utility and cost-effectiveness of an AMAS in community pharmacy compared to the alternative of usual care.
(ii) To assess the robustness of the cost effectiveness results through one-way and multi-way sensitivity analysis.

COST ANALYSIS

The mean cost per AMAS consultation was AUD29.56 which includes patient out-of-pocket medicine(s) costs, compared with AUD22.28 per UC patient (Table 9). Please note these costs are mean costs calculated from the total sample.

Table 9 Cost analysis

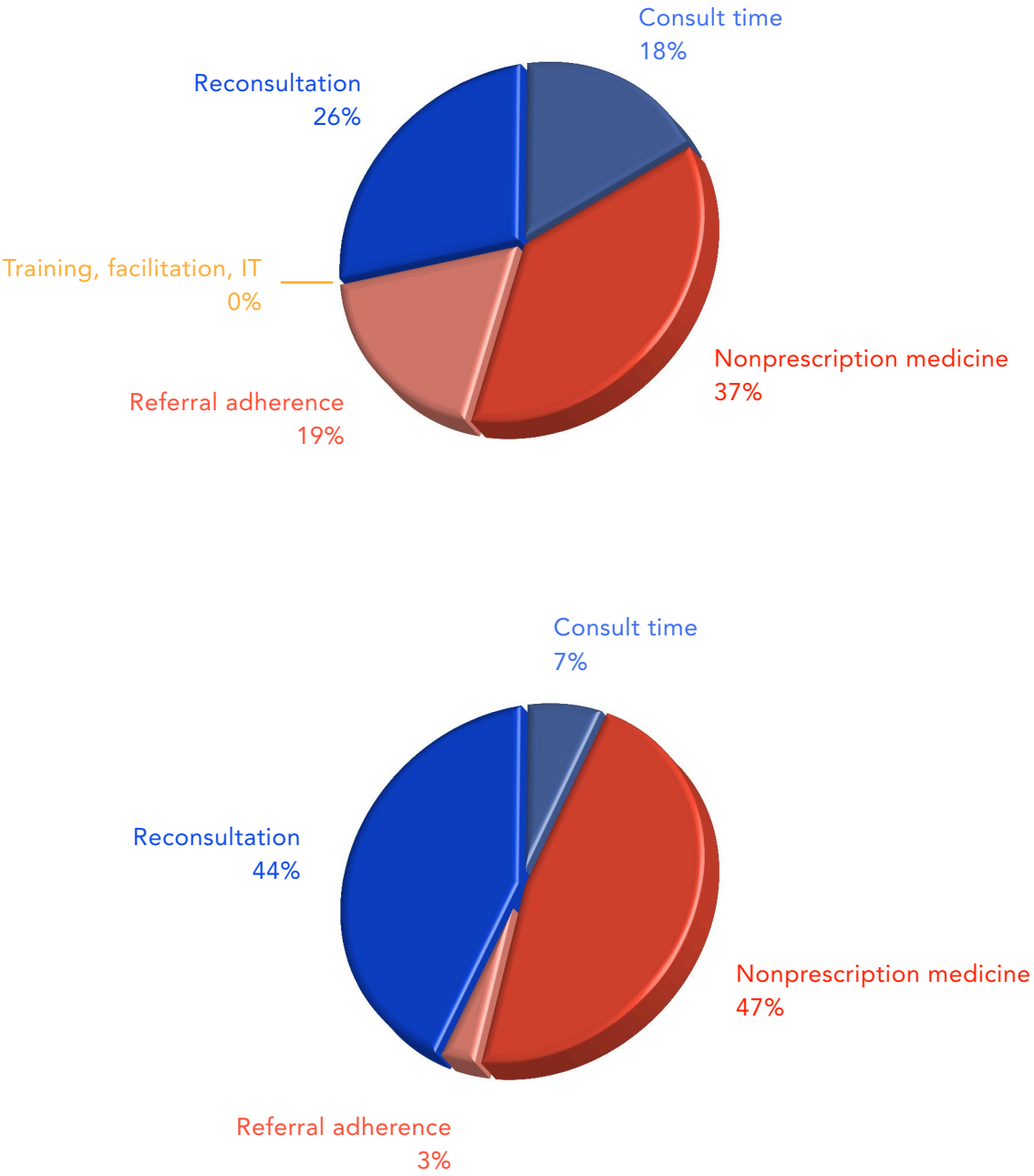
	AMAS average cost per patient (AUD $)	UC average cost per patient* (AUD $)
Consultation time	$5.33	$1.61
Nonprescription medicine	$10.85	$10.36
Referral adherence (incl. medicines)	$5.59	$0.61
Reconsultation (incl. medicines)	$7.73	$9.70
Training, facilitation, IT set-up	$0.07	-
Total	**AUD29.56***	**AUD22.28**

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 are different as a result of a decision tree modelled analysis that considers the proportion of patients in each arm receiving an outcome.*

In both arms, the largest cost was attributed to the average cost of a nonprescription medicine of AUD10.85 with the AMAS, 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.

Referral costs were included for those who adhered to pharmacist's referral advice and sought medical care. 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. Interestingly, the cost of reconsultation per patient (patients who weren't 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. Figure 3 provides a comparative breakdown of cost distribution for AMAS and UC.

Figure 3 Distribution of costs for AMAS and UC, respectively



COST-UTILITY ANALYSIS

Table 10 presents the results of the CUA. The total QALYs accrued during the 14-day time horizon were 0.0293 and 0.0261, for the AMAS and UC respectively. 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.

Overall, AMAS is costlier but it is also associated with greater positive health gains (see Chapter 3 for clinical effectiveness) hence lying in the north-east quadrant of the cost-effectiveness plane (Figure 4). The base case ICER was estimated at AUD2,277 per QALY gained.

Table 10 Incremental analysis (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

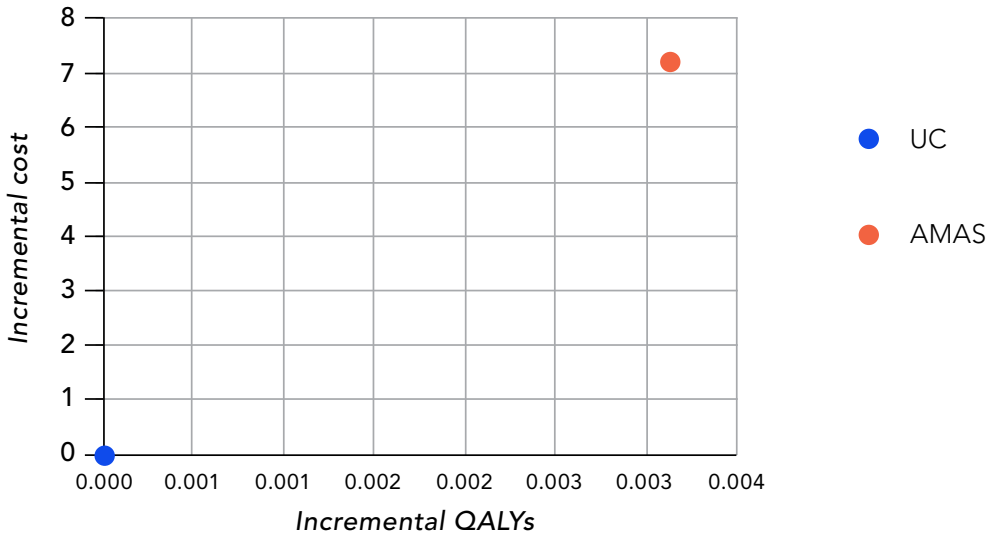
Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; QALY: Quality adjusted life year; UC: usual care*

**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.

As can be seen in Figure 4, the area above the horizontal (incremental cost) is cost-increasing, and to the right of the vertical is shown to be clinically superior (incremental QALYs). As expected, the AMAS adds clinical benefits at increased costs (upper right-hand quadrant).

Figure 4 Cost-effectiveness plane

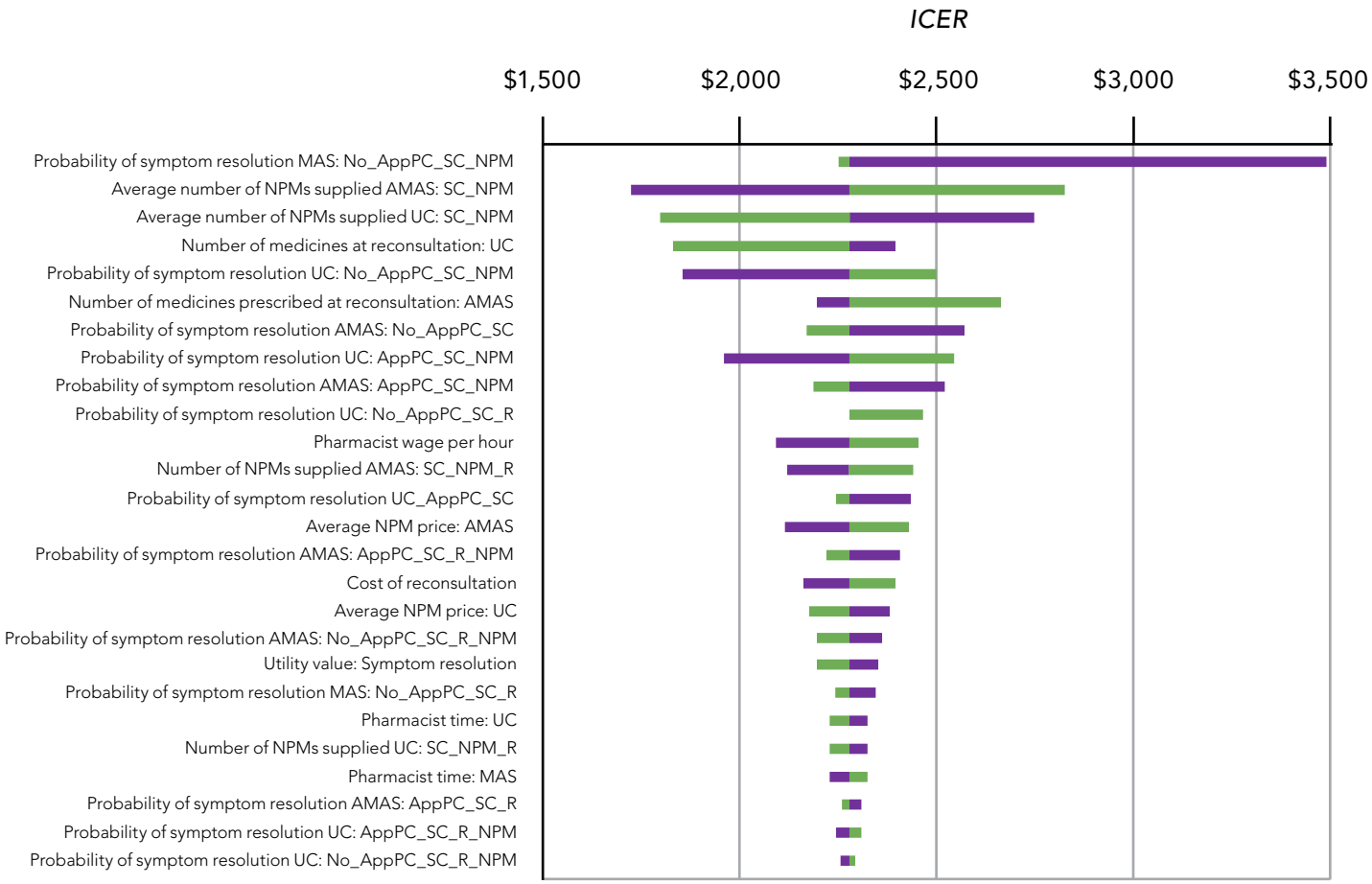


Abbreviations: *AMAS: Australian minor ailment scheme; QALYs: quality adjusted life years; UC: usual care*

SENSITIVITY ANALYSIS

A number of sensitivity analyses were undertaken to assess the robustness of the CUA results. The ICER was recalculated by changing each parameter using (i) upper and lower values of the 95 percent confidence interval, or, (ii) plausible ranges. The results of the one-way sensitivity analysis are shown in Figure 5. The result is displayed as a tornado graph, with bars for each input variable displaying the variation from the ICER value. The purple color indicates that a lower value for the variable is selected than the baseline. The green color indicates a higher value. The overall ICER ranged from AUD1,720 (min. ICER) to AUD3,510 (max. ICER) per QALY gained. The diagram indicates from high to low which variable has the greatest/smallest impact on the outcome measure. For instance, the highest impact on the ICER result, is the probability of the patient achieving symptom resolution, which heavily impacts the QALY result, ranging between AUD2,257 and AUD3,510 per QALY. As expected, the number of nonprescription medicines supplied during consultation is the next impact driver on the ICER result, ranging from AUD1,720 and AUD2,828 per QALY. The impact on the ICER is almost null when changing the parameters of pharmacist hourly rate, training costs, duration of consultation and reconsultation costs. The one-way SA results are tabulated in appendix 4.

Figure 5 Incremental cost-effectiveness ratio (ICER) tornado diagram for multiple 1-way sensitivity analyses



Abbreviations: *AMAS: Australian minor ailments scheme; AppPC: Appropriate pharmacist care meeting agreed protocols; AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; No_AppPC: Pharmacist care outside agreed protocols; NPM: nonprescription medicine; QALY: Quality adjusted life year; R: referral; SC: selfcare advice; UC: Usual care*

A multivariate sensitivity analysis was conducted using the highest possible cost of an AMAS consultation at AUD33.84 (Table 11) and another assuming 100 percent of referred patients adhered to referral and sought medical care on advice of the pharmacist in both arms (Table 12). Both represent the most conservative scenarios for the AMAS which still result in cost-effective ICERs.

Table 11 Cost utility results (effect= QALY): Multivariate SA (highest cost for MAS)

	Average cost per patient*	Total QALY	Inc. cost	Inc. QALY	ICER ($AUD/ QALY)
UC	AUD22.86	0.026			
AMAS	AUD33.84	0.030	AUD10.98	0.003	AUD3,502

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).*

Table 12 Cost utility results (effect= QALY): Multivariate SA (100 percent referral adherence)

Parameter	ICER ($AUD/QALY)
SA: assuming 100 percent referral adherence	AUD3,778

Abbreviations: *AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; QALY: quality adjusted life year; SA: sensitivity analysis*

COST-EFFECTIVENESS ANALYSES

Table 13 presents the results of the CEA (outcome = appropriate pharmacist care meeting the agreed protocols). The AMAS intervention resulted in an incremental score of 0.191 additional patients receiving appropriate pharmacist care with the AMAS, relative to UC. This resulted in an ICER of AUD37.42 per additional patient receiving appropriate pharmacist care meeting the agreed protocols, showing AMAS as cost-effective (28).

Table 13 Cost-effectiveness results (outcome = appropriate pharmacy 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) as a result of AMAS (ie. medicines paid by patient).*

Table 14 presents the results of the CEA (outcome = symptom resolution). This resulted in an incremental score of 0.012 additional patients achieving symptom resolution with the AMAS relative to UC. An ICER of AUD586.88 per additional patient achieving symptom resolution was reported, showing AMAS as cost-effective (28).

Table 14 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) as a result of AMAS (ie. medicines paid by patient).*

RESULTS: THRESHOLD ANALYSIS

RESULTS: ADDRESSING OBJECTIVE 2

(i) To estimate the potential cost reductions associated with transferring patients with minor ailment conditions from the ED and GP setting to community pharmacy (AMAS) at the WSPHN, state and national level.

MEDICARE ANALYSIS

Reports on GP services were obtained via MBS item numbers accessed from the Australian Government Medicare Benefits Schedule 2016-17 data page for primary health networks (PHNs) (12). MBS item numbers were evaluated comparing the usage of GP services and benefits at the WSPHN, NSW state and Australian national level. The MBS items for GP services in hours (in and outside GP rooms) and after hours (urgent and non-urgent; in and outside GP rooms; in sociable and unsociable hours) are represented in Table 15.

Table 15 GP services by MBS item number

Description	MBS item
Attendances in GP rooms	3, 23, 36, 44
Attendances outside GP rooms	4, 24, 37, 47
Urgent after hours attendance in sociable hours	597, 598
Urgent after hours attendances in unsociable hours	599, 600
Non-urgent after hours attendances in GP rooms	5000, 5020, 5040, 5060, 5200, 5203, 5207, 5208
Non-urgent after hours attendances outside GP rooms	5003, 5023, 5043, 5063

Abbreviations: *GP: general practitioner; MBS: Medicare Benefits Schedule*

Total GP services and total MBS expenditure was summarised for (i) WSPHN (ii) NSW and, (iii) Australia using the MBS data obtained for 2016-17 (Table 16). The Medicare analysis can be found in appendix 5.

Table 16 Summary: Medicare analysis number of services and costs for 2016-17

	Sum of GP services	Sum of Medicare benefits paid ($AUD
WSPHN	5,997,914	AUD264,301,585
NSW	41,658,186	AUD1,866,559,768
National	125,410,350	AUD5,678,423,784

Abbreviations: *AUD: Australian dollar; GP: general practitioner; MBS: Medicare Benefits Schedule; WSPHN: Western Sydney primary health network*

GENERAL PRACTITIONER SERVICES TRANSFERRABLE TO AMAS

National and international literature estimates were used to determine the proportion of GP services potentially transferrable to an AMAS in Australia. Applying the MBS data for total annual GP services (Table 16), we estimated the total number of GP services transferrable to the AMAS. It was estimated that between 419,854 and 1,271,558 annual GP services are potentially transferrable to community pharmacy in WSPHN. These numbers increase up to 8.8 million at the NSW state level. While at a national level, estimates show between 8.8 and 26.6 million GP services could potentially be transferred pharmacy (Table 17).

Table 17 Summary: GP services transferrable to pharmacy for AMAS care

	GP services transferrable to pharmacy		
	Range		
Percentage transferrable	**7%**	**13%**	**21.2%**
WSPHN	419,854	779,729	1,271,558
NSW	2,916,073	5,415,564	8,831,535
Australia	8,778,725	16,303,346	26,586,994

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

The total MBS expenditure of the GP services transferrable to pharmacy are shown in Table 18. Applying the base case scenario (7 percent of GP services transferred to pharmacy), the MBS cost associated is AUD8.5 million, AUD130.7 million and AUD397 million, in WSPHN, NSW and Australia respectively.

Table 18 Summary: Total MBS cost of GP services transferrable to pharmacy for AMAS care

	Cost of GP services transferrable to pharmacy ($AUD)		
	Range		
Percentage transferrable	**7%**	**13%**	**21.2%**
WSPHN	$18,501,111	$34,359,206	$56,031,936
NSW	$130,659,184	$242,652,770	$395,710,671
Australia	$397,489,665	$738,195,092	$1,203,825,842

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

ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE GP SERVICES

A threshold analysis was conducted to identify the proportion of GP transferrable patients to the AMAS for (i) WSPHN (ii) NSW and (iii) Australia. Various thresholds for each scenario were applied, from 100 percent to 1 percent reflecting best case and worst-case scenarios respectively. The average modelled cost per AMAS consultation of AUD26.88 (including patient out-of-pocket costs for medicines) was applied to account cost offsets. The average cost of AUD44.07 for a GP attendance was applied (not including patient out-of-pocket medicine costs). The potential cost reduction of AUD17.19 per patient was estimated for each patient transferred from the GP setting to receive the AMAS.

Multiple sensitivity analyses were conducted using:

(i) The modelled cost of an AMAS consultation of AUD14.49 as per model excluding patient out-of-pocket medicine expenses (SA1) for the nonprescription medicines, and prescription medicines as a result of adherence to referral and reconsultation without referral (resulting in the potential cost reduction of AUD29.58 per patient transferred from GP to receive the AMAS).

(ii) The highest likely modelled cost of an AMAS consultation of AUD33.84 (including patient out-of-pocket medicine expenses) (SA2) (resulting in the potential cost reduction of AUD10.23 per patient transferred from GP to receive the AMAS).

ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE GP SERVICES IN WSPHN

Assuming a scenario where 7 percent of GP services are transferred to an AMAS, the cost reduction potential in WSPHN ranges from -AUD7.22 million (best case assuming 100 percent actual transfer) to -AUD72,154 (most conservative case assuming 1 percent transfer). Assuming a scenario where 21.2 percent of GP services are transferred to an AMAS, the cost reduction potential in WSPHN ranges from -AUD21.85 million (best case assuming 100 percent actual transfer) to -AUD218,525 (most conservative case assuming 1 percent actual transfer) (Table 19).

Table 19 Annual cost reduction potential of pharmacy manageable GP services in WSPHN

Scenario: 7% transfer				
	Services	Benefits paid ($AUD)		
7%	419,854	$18,501,111		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of GP (AUD44.07)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$11,285,675	$-	-$7,215,436	-$12,417,427
80%	$9,028,540	$3,700,222	-$5,772,349	-$9,933,941
60%	$6,771,405	$7,400,444	-$4,329,262	-$7,450,456
40%	$4,514,270	$11,100,667	-$2,886,174	-$4,966,971
20%	$2,257,135	$14,800,889	-$1,443,087	-$2,483,485
10%	$1,128,567	$16,651,000	-$721,544	-$1,241,743
5%	$564,284	$17,576,055	-$360,772	-$620,871

Table 19 Annual cost reduction potential of pharmacy manageable GP services in WSPHN (continued)

2%	$225,713	$18,131,089	-$144,309	-$248,349
1%	$112,857	$18,316,100	-$72,154	-$124,174
Scenario: 13% transfer				
	Services	Benefits paid ($AUD)		
13%	779,729	$34,359,206		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of GP (AUD44.07)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$20,959,111	$-	-$13,400,095	-$23,060,935
80%	$16,767,289	$6,871,841	-$10,720,076	-$18,448,748
60%	$12,575,466	$13,743,682	-$8,040,057	-$13,836,561
40%	$8,383,644	$20,615,524	-$5,360,038	-$9,224,374
20%	$4,191,822	$27,487,365	-$2,680,019	-$4,612,187
10%	$2,095,911	$30,923,285	-$1,340,010	-$2,306,094
5%	$1,047,956	$32,641,246	-$670,005	-$1,153,047
2%	$419,182	$33,672,022	-$268,002	-$461,219
1%	$209,591	$34,015,614	-$134,001	-$230,609
Scenario: 21.2% transfer				
	Services	Benefits paid ($AUD)		
21.2%	1,271,558	$56,031,936		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of GP (AUD44.07)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$34,179,473	$-	-$21,852,463	-$37,607,064
80%	$27,343,578	$11,206,387	-$17,481,971	-$30,085,651
60%	$20,507,684	$22,412,774	-$13,111,478	-$22,564,238
40%	$13,671,789	$33,619,162	-$8,740,985	-$15,042,826
20%	$6,835,895	$44,825,549	-$4,370,493	-$7,521,413
10%	$3,417,947	$50,428,742	-$2,185,246	-$3,760,706
5%	$1,708,974	$53,230,339	-$1,092,623	-$1,880,353
2%	$683,589	$54,911,297	-$437,049	-$752,141
1%	$341,795	$55,471,617	-$218,525	-$376,071

Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; GP: general practitioner; WSPHN: Western Sydney primary health network*

ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE GP SERVICES IN NSW

Assuming a scenario where 7 percent of GP services are transferred to AMAS, the cost reduction potential in NSW ranges from -AUD52.28 million (best case assuming 100 percent actual transfer) to -AUD522,751 (most conservative case assuming 1 percent transfer). Assuming a 21.2 percent transfer of GP services to an AMAS, the cost reduction potential ranges from -AUD158.32 million (best case assuming 100 percent actual transfer) to -AUD1.58 million (most conservative case assuming 1 percent transfer) (Table 20).

Table 20 Annual cost reduction potential of pharmacy manageable GP services in NSW

Scenario: 7% transfer				
	Services	Benefits paid ($AUD)		
7%	2,916,073	$130,659,184		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of GP (AUD44.07)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$78,384,043	$-	-$52,275,141	-$88,405,286
80%	$62,707,234	$26,131,837	-$41,820,113	-$70,724,229
60%	$47,030,426	$52,263,674	-$31,365,085	-$53,043,171
40%	$31,353,617	$78,395,510	-$20,910,056	-$35,362,114
20%	$15,676,809	$104,527,347	-$10,455,028	-$17,681,057
10%	$7,838,404	$117,593,265	-$5,227,514	-$8,840,529
5%	$3,919,202	$124,126,225	-$2,613,757	-$4,420,264
2%	$1,567,681	$128,046,000	-$1,045,503	-$1,768,106
1%	$783,840	$129,352,592	-$522,751	-$884,053
Scenario: 13% transfer				
	Services	Benefits paid ($AUD)		
13%	5,415,564	$242,652,770		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of GP (AUD44.07)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$145,570,365	$-	-$97,082,405	-$164,181,245
80%	$116,456,292	$48,530,554	-$77,665,924	-$131,344,996
60%	$87,342,219	$97,061,108	-$58,249,443	-$98,508,747
40%	$58,228,146	$145,591,662	-$38,832,962	-$65,672,498
20%	$29,114,073	$194,122,216	-$19,416,481	-$32,836,249

Table 20 Annual cost reduction potential of pharmacy manageable GP services in NSW (continued)

10%	$14,557,037	$218,387,493	-$9,708,240	-$16,418,124
5%	$7,278,518	$230,520,131	-$4,854,120	-$8,209,062
2%	$2,911,407	$237,799,714	-$1,941,648	-$3,283,625
1%	$1,455,704	$240,226,242	-$970,824	-$1,641,812
Scenario: 21.2% transfer				
	Services	Benefits paid ($AUD)		
21.2%	8,831,535	$395,710,671		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of GP (AUD44.07)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$237,391,672	$-	-$158,318,998	-$267,741,722
80%	$189,913,338	$79,142,134	-$126,655,199	-$214,193,378
60%	$142,435,003	$158,284,268	-$94,991,399	-$160,645,033
40%	$94,956,669	$237,426,403	-$63,327,599	-$107,096,689
20%	$47,478,334	$316,568,537	-$31,663,800	-$53,548,344
10%	$23,739,167	$356,139,604	-$15,831,900	-$26,774,172
5%	$11,869,584	$375,925,137	-$7,915,950	-$13,387,086
2%	$4,747,833	$387,796,457	-$3,166,380	-$5,354,834
1%	$2,373,917	$391,753,564	-$1,583,190	-$2,677,417

Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; GP: general practitioner; NSW: New South Wales*

ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE GP SERVICES IN AUSTRALIA

Assuming a scenario where 7 percent of national GP services are transferred to AMAS, the cost reduction potential ranges from -AUD161.52 million (best case assuming 100 percent actual transfer) to -AUD1.62 million (most conservative case assuming 1 percent actual transfer). With a 21.2 percent transfer of GP services to an AMAS, the cost reduction potential ranges from -AUD489.2 million (best case assuming 100 percent actual transfer) to -AUD4.89 million (most conservative assuming 1 percent actual transfer) at a national level (Table 21).

Table 21 Annual cost reduction potential of pharmacy manageable GP services in Australia

Scenario: 7% transfer				
	Services	Benefits paid ($AUD)		
7%	8,778,725	$397,489,665		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of GP (AUD44.07)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$235,972,115	$-	-$161,517,550	-$270,285,947
80%	$188,777,692	$79,497,933	-$129,214,040	-$216,228,758
60%	$141,583,269	$158,995,866	-$96,910,530	-$162,171,568
40%	$94,388,846	$238,493,799	-$64,607,020	-$108,114,379
20%	$47,194,423	$317,991,732	-$32,303,510	-$54,057,189
10%	$23,597,211	$357,740,698	-$16,151,755	-$27,028,595
5%	$11,798,606	$377,615,182	-$8,075,878	-$13,514,297
2%	$4,719,442	$389,539,872	-$3,230,351	-$5,405,719
1%	$2,359,721	$393,514,768	-$1,615,176	-$2,702,859
Scenario: 13% transfer				
	Services	Benefits paid ($AUD)		
13%	16,303,346	$738,195,092		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of GP (AUD44.07)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$438,233,927	$-	-$299,961,165	-$501,959,616
80%	$350,587,142	$147,639,018	-$239,968,932	-$401,567,693
60%	$262,940,356	$295,278,037	-$179,976,699	-$301,175,769
40%	$175,293,571	$442,917,055	-$119,984,466	-$200,783,846
20%	$87,646,785	$590,556,074	-$59,992,233	-$100,391,923

Table 21 Annual cost reduction potential of pharmacy manageable GP services in NSW (continued)

10%	$43,823,393	$664,375,583	-$29,996,116	-$50,195,962
5%	$21,911,696	$701,285,337	-$14,998,058	-$25,097,981
2%	$8,764,679	$723,431,190	-$5,999,223	-$10,039,192
1%	$4,382,339	$730,813,141	-$2,999,612	-$5,019,596
Scenario: 21.2% transfer				
	Services	Benefits paid ($AUD)		
21.2%	26,586,994	$1,203,825,842		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of GP (AUD44.07)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$714,658,404	$-	-$489,167,438	-$818,580,296
80%	$571,726,723	$240,765,168	-$391,333,951	-$654,864,237
60%	$428,795,042	$481,530,337	-$293,500,463	-$491,148,178
40%	$285,863,362	$722,295,505	-$195,666,975	-$327,432,119
20%	$142,931,681	$963,060,674	-$97,833,488	-$163,716,059
10%	$71,465,840	$1,083,443,258	-$48,916,744	-$81,858,030
5%	$35,732,920	$1,143,634,550	-$24,458,372	-$40,929,015
2%	$14,293,168	$1,179,749,325	-$9,783,349	-$16,371,606
1%	$7,146,584	$1,191,787,584	-$4,891,674	-$8,185,803

Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; GP: general practitioner*

SENSITIVITY ANALYSIS

A sensitivity analysis (SA2) was conducted using the highest cost (most conservative) of an AMAS consultation (AUD33.84 including patient out-of-pocket medicine expenses) and assuming a 7 percent transfer rate of GP services to an AMAS. This results in a cost reduction of AUD10.23 per patient per GP service transferred to AMAS. The cost reduction potential ranges from -AUD100.46 million (best case assuming 100 percent actual transfer) to -AUD1 million (most conservative case assuming 1 percent actual transfer) at a national level (see appendix 6 for full results).

EMERGENCY DEPARTMENT SERVICES TRANSFERRABLE TO AMAS

National and international literature estimates were used to determine the proportion of ED services potentially transferrable to community pharmacies. ED data was obtained from the AIHW Emergency Department Care 2017-18 Report. The minimum (2.9 percent) and maximum (11.5 percent) percentages of ED services transferrable was obtained from the literature and were applied to estimate the number of ED services transferrable to AMAS in WSPHN, NSW and Australia (Table 22). It is estimated 99,602 ED services are provided annually in WSPHN, 2.88 million in NSW and 8.02 million nationally (14, 15). Of these, between 2,888 and 11,454 ED services were estimated to be potentially transferrable to pharmacy in WSPHN, up to 331.2 thousand are potentially transferrable in NSW and up to 922 thousand are potentially transferrable at a national level.

Table 22 Summary: ED services transferrable to pharmacy for AMAS care

	ED services transferrable to pharmacy		
	Range		
Percentage transferrable	**2.90%**	**5.30%**	**11.50%**
WSPHN	2,888	5,279	11,454
NSW	83,528	152,655	331,233
Australia	232,507	424,927	922,012

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

The expenditure associated with the ED services transferrable are shown in Table 23.

Table 23 Summary: expenditure for ED services transferrable to pharmacy for AMAS care

	Cost of EP services transferrable to pharmacy ($AUD)		
	Range		
Percentage transferrable	**2.9%**	**5.3%**	**11.5%**
WSPHN	$1,594,976	$2,914,956	$6,324,905
NSW	$46,123,338	$84,294,376	$182,902,891
Australia	$124,533,683	$227,596,041	$493,840,466

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

ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE ED SERVICES

Similarly, a threshold analysis was conducted to identify the proportion of ED transferrable patients at which AMAS would not results in cost reductions for (i) WSPHN (ii) NSW and (iii) Australia. Various thresholds for each scenario were applied, from 100 percent to 1 percent reflecting best case and worst-case scenarios respectively. The average cost per AMAS consultation of AUD26.88 (including out-of-pocket patient costs for medicines) was applied to account cost offsets. The average cost of an ED attendance of AUD535.61 or AUD552.19 in Australia and NSW respectively (adjusted to AUD2019 values) was applied. This results in a potential cost reduction of AUD508.73 or AUD525.31 per patient in Australia and NSW respectively, transferred from the ED setting to receive AMAS.

Multiple sensitivity analyses were conducted using:

(i) The average cost of an AMAS consultation of AUD14.49 excluding patient out-of-pocket medicine expenses (SA1) (resulting in the potential cost reduction of AUD521.12 or AUD537.70 per patient in Australia and NSW transferred from ED to receive the AMAS).

(ii) The highest likely cost of an AMAS consultation of AUD33.84 (including patient out-of-pocket medicine expenses) (SA2) (resulting in the potential cost reduction of AUD501.77 or AUD518.35 per patient in Australia and NSW transferred from ED to receive the AMAS).

ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE ED SERVICES IN WSPHN

Assuming a scenario where 2.9 percent of ED services are transferred to receive an AMAS, the cost reduction potential in WSPHN ranges from -AUD1.52 million (best case assuming 100 percent actual transfer) to -AUD15,173 (most conservative case assuming 1 percent actual transfer). Assuming an 11.5 percent transfer of ED services to an AMAS, the cost reduction potential in WSPHN ranges from -AUD6.02 million (best case assuming 100 percent actual transfer) to -AUD60,170 (most conservative case assuming 1 percent actual transfer) (Table 24).

Table 24 Annual cost reduction potential of pharmacy manageable ED services in WSPHN

Scenario: 2.9% transfer				
	Services	Benefits paid ($AUD)		
2.9%	2,888	$1,594,976		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of ED (AUD552.19)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$77,642	$-	-$1,517,334	-$1,553,122
80%	$62,114	$318,995	-$1,213,867	-$1,242,498
60%	$46,585	$637,990	-$910,400	-$931,873
40%	$31,057	$956,986	-$606,934	-$621,249
20%	$15,528	$1,275,981	-$303,467	-$310,624
10%	$7,764	$1,435,478	-$151,733	-$155,312
5%	$3,882	$1,515,227	-$75,867	-$77,656

Table 24 Annual cost reduction potential of pharmacy manageable ED services in WSPHN (continued)

2%	$1,553	$1,563,077	-$30,347	-$31,062
1%	$776	$1,579,026	-$15,173	-$15,531
Scenario: 5.3% transfer				
	Services	Benefits paid ($AUD)		
5.3%	5,279	$2,914,956		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of ED (AUD552.19)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$141,897	$-	-$2,773,059	-$2,838,465
80%	$113,518	$582,991	-$2,218,447	-$2,270,772
60%	$85,138	$1,165,983	-$1,663,835	-$1,703,079
40%	$56,759	$1,748,974	-$1,109,224	-$1,135,386
20%	$28,379	$2,331,965	-$554,612	-$567,693
10%	$14,190	$2,623,461	-$277,306	-$283,846
5%	$7,095	$2,769,208	-$138,653	-$141,923
2%	$2,838	$2,856,657	-$55,461	-$56,769
1%	$1,419	$2,885,807	-$27,731	-$28,385
Scenario: 11.5% transfer				
	Services	Benefits paid ($AUD)		
11.5%	11,454	$6,324,905		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of ED (AUD552.19)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$307,891	$-	-$6,017,015	-$6,158,933
80%	$246,312	$1,264,981	-$4,813,612	-$4,927,146
60%	$184,734	$2,529,962	-$3,610,209	-$3,695,360
40%	$123,156	$3,794,943	-$2,406,806	-$2,463,573
20%	$61,578	$5,059,924	-$1,203,403	-$1,231,787
10%	$30,789	$5,692,415	-$601,701	-$615,893
5%	$15,395	$6,008,660	-$300,851	-$307,947
2%	$6,158	$6,198,407	-$120,340	-$123,179
1%	$3,079	$6,261,656	-$60,170	-$61,589

Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; ED: emergency department; WSPHN: Western Sydney primary health network*

ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE ED SERVICES IN NSW

Assuming a scenario where 2.9 percent of ED services are transferred to the AMAS, the cost reduction potential in NSW ranges from -AUD43.88 million (best case assuming 100 percent actual transfer) to -AUD438,781 (most conservative cost assuming 1 percent actual transfer). Assuming an 11.5 percent transfer of ED services to AMAS, the cost reduction potential ranges from -AUD174 million (best case assuming 100 percent actual transfer) to -AUD1,739,993 (most conservative cost assuming 1 percent actual transfer) (Table 25).

Table 25 Annual cost reduction potential of pharmacy manageable ED services in NSW

Scenario: 2.9% transfer				
	Services	Benefits paid ($AUD)		
2.9%	83,528	$46,123,338		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of ED (AUD552.19)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$2,245,241	$-	-$43,878,096	-$44,913,012
80%	$1,796,193	$9,224,668	-$35,102,477	-$35,930,410
60%	$1,347,145	$18,449,335	-$26,326,858	-$26,947,807
40%	$898,097	$27,674,003	-$17,551,239	-$17,965,205
20%	$449,048	$36,898,670	-$8,775,619	-$8,982,602
10%	$224,524	$41,511,004	-$4,387,810	-$4,491,301
5%	$112,262	$43,817,171	-$2,193,905	-$2,245,651
2%	$44,905	$45,200,871	-$877,562	-$898,260
1%	$22,452	$45,662,104	-$438,781	-$449,130
Scenario: 5.3% transfer				
	Services	Benefits paid ($AUD)		
5.3%	152,655	$84,294,376		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of ED (AUD552.19)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$4,103,372	$-	-$80,191,004	-$82,082,402
80%	$3,282,698	$16,858,875	-$64,152,803	-$65,665,921
60%	$2,462,023	$33,717,750	-$48,114,602	-$49,249,441
40%	$1,641,349	$50,576,625	-$32,076,401	-$32,832,961
20%	$820,674	$67,435,501	-$16,038,201	-$16,416,480
10%	$410,337	$75,864,938	-$8,019,100	-$8,208,240

Table 25 Annual cost reduction potential of pharmacy manageable ED services in NSW (continued)

5%	$205,169	$80,079,657	-$4,009,550	-$4,104,120
2%	$82,067	$82,608,488	-$1,603,820	-$1,641,648
1%	$41,034	$83,451,432	-$801,910	-$820,824
Scenario: 11.5% transfer				
	Services	Benefits paid ($AUD)		
11.5%	331,233	$182,902,891		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of ED (AUD552.19)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$8,903,543	$-	-$173,999,347	-$178,103,324
80%	$7,122,835	$36,580,578	-$139,199,478	-$142,482,659
60%	$5,342,126	$73,161,156	-$104,399,608	-$106,861,995
40%	$3,561,417	$109,741,734	-$69,599,739	-$71,241,330
20%	$1,780,709	$146,322,312	-$34,799,869	-$35,620,665
10%	$890,354	$164,612,602	-$17,399,935	-$17,810,332
5%	$445,177	$173,757,746	-$8,699,967	-$8,905,166
2%	$178,071	$179,244,833	-$3,479,987	-$3,562,066
1%	$89,035	$181,073,862	-$1,739,993	-$1,781,033

Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; ED: emergency department; NSW: New South Wales*

ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE ED SERVICES IN AUSTRALIA

Assuming a scenario where 2.9 percent of ED services are transferred to AMAS, the cost reduction potential at a national level ranges from -AUD118.28 million (best case assuming 100 percent actual transfer) to -AUD1.18 million (most conservative case assuming 1 percent actual transfer). With an 11.5 percent transfer of ED services to AMAS, the cost reduction potential ranges from -AUD469.06 million (best case assuming 100 percent actual transfer) to -AUD4.69 million (most conservative case assuming 1 percent actual transfer) (Table 26).

Table 26 Annual cost reduction potential of pharmacy manageable ED services in Australia

Scenario: 2.9% transfer				
	Services	Benefits paid ($AUD)		
2.9%	232,507	$124,533,683		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of ED (AUD552.19)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$6,249,795	$-	-$118,283,887	-$121,164,653
80%	$4,999,836	$24,906,737	-$94,627,110	-$96,931,722
60%	$3,749,877	$49,813,473	-$70,970,332	-$72,698,792
40%	$2,499,918	$74,720,210	-$47,313,555	-$48,465,861
20%	$1,249,959	$99,626,946	-$23,656,777	-$24,232,931
10%	$624,980	$112,080,315	-$11,828,389	-$12,116,465
5%	$312,490	$118,306,999	-$5,914,194	-$6,058,233
2%	$124,996	$122,043,009	-$2,365,678	-$2,423,293
1%	$62,498	$123,288,346	-$1,182,839	-$1,211,647
Scenario: 5.3% transfer				
	Services	Benefits paid ($AUD)		
5.3%	424,927	$227,596,041		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of ED (AUD552.19)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$11,422,040	$-	-$216,174,001	-$221,438,848
80%	$9,137,632	$45,519,208	-$172,939,201	-$177,151,078
60%	$6,853,224	$91,038,416	-$129,704,401	-$132,863,309
40%	$4,568,816	$136,557,625	-$86,469,600	-$88,575,539
20%	$2,284,408	$182,076,833	-$43,234,800	-$44,287,770
10%	$1,142,204	$204,836,437	-$21,617,400	-$22,143,885
5%	$571,102	$216,216,239	-$10,808,700	-$11,071,942
2%	$228,441	$223,044,120	-$4,323,480	-$4,428,777
1%	$114,220	$225,320,081	-$2,161,740	-$2,214,388

Table 26 Annual cost reduction potential of pharmacy manageable ED services in Australia (continued)

Scenario: 11.5% transfer				
	Services	Benefits paid ($AUD)		
11.5%	922,012	$493,840,466		
Transferrable patients	Cost of AMAS (AUD26.88) including cost of medicines	Cost of ED (AUD552.19)	Cost reduction ($AUD)	SA1: Cost reduction excluding cost of medicines (AUD14.49)
100%	$24,783,671	$-	-$469,056,795	-$480,480,519
80%	$19,826,937	$98,768,093	-$375,245,436	-$384,384,415
60%	$14,870,203	$197,536,187	-$281,434,077	-$288,288,311
40%	$9,913,469	$296,304,280	-$187,622,718	-$192,192,207
20%	$4,956,734	$395,072,373	-$93,811,359	-$96,096,104
10%	$2,478,367	$444,456,420	-$46,905,680	-$48,048,052
5%	$1,239,184	$469,148,443	-$23,452,840	-$24,024,026
2%	$495,673	$483,963,657	-$9,381,136	-$9,609,610
1%	$247,837	$488,902,062	-$4,690,568	-$4,804,805

Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; ED: emergency department*

SENSITIVITY ANALYSIS

A sensitivity analysis (SA2) was conducted using the highest cost of an AMAS consultation (AUD33.84 including patient out-of-pocket medicine expenses) and assuming a 2.9 percent transfer rate of ED services to an AMAS. This results in a potential cost reduction of AUD501.77 or AUD518.35 per patient in Australia and NSW respectively, transferred from the ED setting to AMAS. The cost reduction potential ranges from -AUD116.67 million (best case assuming 100 percent actual transfer) to -AUD1.17 million (most conservative case assuming 1 percent actual transfer) at a national level (see appendix 7 for full results).

OVERALL ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE GP AND ED SERVICES

It is evident that the higher the percentage of presentations that are transferred from high cost settings (ED and GP), the greater the cost reduction potential. We present the overall cost reduction potential (combined ED and GP transferable services) for (i) WSPHN (ii) NSW and (iii) Australia. At each level, we apply lower bound literature estimates (2.9 percent ED and 7 percent GP services transferrable to AMAS) and upper bound literature estimates (11.5 percent ED and 21.2 percent GP services transferrable to AMAS) to determine the overall cost reduction potential. Various thresholds are applied, from 100 percent to 1 percent reflecting best and worst-case scenarios respectively. Within the matrices we apply the average base case AMAS cost of AUD26.88. We present sensitivity analyses varying base case data so that alternative scenarios can be considered.

OVERALL COST REDUCTION POTENTIAL IN WSPHN

Within WSPHN, the overall cost reduction potential is presented in Table 27. Assuming the base case scenario (2.9 percent of ED services and 7 percent of GP services transferred to AMAS), the overall cost reduction potential ranges from -AUD8.73 million to -AUD87,328 (including patient out-of-pocket medicine costs). Applying upper bound literature estimates (or best-case scenario), the overall cost reduction potential ranges between -AUD27.87 million to -AUD278,695.

Table 27 Annual overall cost reduction potential of AMAS in WSPHN

Scenario: base case using 2.9% ED and 7% GP service transfer rate to AMAS						
	Transferrable services		Total AMAS cost (AUD26.88)	Total current cost ($AUD)		
GP	419,854		$11,285,67	$18,501,111		
ED	2,888		$77,642	$1,594,976		
	AMAS cost	GP cost	ED cost	Potential cost reductions for GP and ED without paying for AMAS	Potential cost reduction paying for AMAS (with product)	SA1: Potential cost reduction paying for AMAS (without product)
100%	$11,363,317	$-	$-	-$20,096,087	-$8,732,770	-$13,970,549
80%	$9,090,654	$3,700,222	$318,995	-$16,076,870	-$6,986,216	-$11,176,439
60%	$6,817,990	$7,400,444	$637,990	-$12,057,652	-$5,239,662	-$8,382,329
40%	$4,545,327	$11,100,667	$956,986	-$8,038,435	-$3,493,108	-$5,588,220
20%	$2,272,663	$14,800,889	$1,275,981	-$4,019,217	-$1,746,554	-$2,794,110
10%	$1,136,332	$16,651,000	$1,435,478	-$2,009,609	-$873,277	-$1,397,055
5%	$568,166	$17,576,055	$1,515,227	-$1,004,804	-$436,639	-$698,527
2%	$227,266	$18,131,089	$1,563,077	-$401,922	-$174,655	-$279,411
1%	$113,633	$18,316,100	$1,579,026	-$200,961	-$87,328	-$139,705

Table 27 Annual overall cost reduction potential of AMAS in WSPHN (continued)

Scenario: best case using 11.5% ED and 21.2% GP service transfer rate to AMAS						
	Transferrable services		Total AMAS cost (AUD26.88)	Total current cost ($AUD)		
GP	1,271,558		$34,179,473	$56,031,936		
ED	11,454		$307,891	$6,324,905		
	AMAS cost	GP cost	ED cost	Potential cost reductions for GP and ED without paying for AMAS	Potential cost reduction paying for AMAS (with product)	SA1: Potential cost reduction paying for AMAS (without product)
100%	$34,487,363	$-	$-	-$62,356,841	-$27,869,478	-$43,765,997
80%	$27,589,891	$11,206,387	$1,264,981	-$49,885,473	-$22,295,582	-$35,012,798
60%	$20,692,418	$22,412,774	$2,529,962	-$37,414,105	-$16,721,687	-$26,259,598
40%	$13,794,945	$33,619,162	$3,794,943	-$24,942,736	-$11,147,791	-$17,506,399
20%	$6,897,473	$44,825,549	$5,059,924	-$12,471,368	-$5,573,896	-$8,753,199
10%	$3,448,736	$50,428,742	$5,692,415	-$6,235,684	-$2,786,948	-$4,376,600
5%	$1,724,368	$53,230,339	$6,008,660	-$3,117,842	-$1,393,474	-$2,188,300
2%	$689,747	$54,911,297	$6,198,407	-$1,247,137	-$557,390	-$875,320
1%	$344,874	$55,471,617	$6,261,656	-$623,568	-$278,695	-$437,660

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

OVERALL COST REDUCTION POTENTIAL IN NSW

Within NSW, the overall cost reduction potential is presented in Table 28. Assuming the base case scenario (2.9 percent of ED and 7 percent of GP services transferred to AMAS), the overall cost reduction potential ranges from -AUD94 million to -AUD939,925 (including patient out-of-pocket medicine costs). Applying upper bound literature estimates (or best-case scenario), the overall cost reduction potential ranges between -AUD325.78 million to -AUD3.26 million.

Table 28 Annual overall cost reduction potential of AMAS in NSW

Scenario: base case using 2.9% ED and 7% GP service transfer rate to AMAS						
	Transferrable services		Total AMAS cost (AUD26.88)	Total current cost ($AUD)		
GP	2,916,073		$78,384,043	$128,498,461		
ED	83,528		$2,245,241	$46,123,338		
	AMAS cost	GP cost	ED cost	Potential cost reductions for GP and ED without paying for AMAS	Potential cost reduction paying for AMAS (with product)	SA1: Potential cost reduction paying for AMAS (without product)
100%	$80,629,284	$-	$ -	-$174,621,799	-$93,992,515	-$131,157,576
80%	$64,503,427	$25,699,692	$9,224,668	-$139,697,439	-$75,194,012	-$104,926,061
60%	$48,377,570	$51,399,385	$18,449,335	-$104,773,079	-$56,395,509	-$78,694,545
40%	$32,251,714	$77,099,077	$27,674,003	-$69,848,720	-$37,597,006	-$52,463,030
20%	$16,125,857	$102,798,769	$36,898,670	-$34,924,360	-$18,798,503	-$26,231,515
10%	$8,062,928	$115,648,615	$41,511,004	-$17,462,180	-$9,399,252	-$13,115,758
5%	$4,031,464	$122,073,538	$43,817,171	-$8,731,090	-$4,699,626	-$6,557,879
2%	$1,612,586	$125,928,492	$45,200,871	-$3,492,436	-$1,879,850	-$2,623,152
1%	$806,293	$127,213,477	$45,662,104	-$1,746,218	-$939,925	-$1,311,576

Table 28 Annual overall cost reduction potential of AMAS in NSW (continued)

Scenario: best case using 11.5% ED and 21.2% GP service transfer rate to AMAS						
	Transferrable services		Total AMAS cost (AUD26.88)	Total current cost ($AUD)		
GP	8,831,535		$237,391,672	$389,166,769		
ED	331,233		$8,903,543	$182,902,891		
	AMAS cost	GP cost	ED cost	Potential cost reductions for GP and ED without paying for AMAS	Potential cost reduction paying for AMAS (with product)	SA1: Potential cost reduction paying for AMAS (without product)
100%	$246,295,216	$-	$-	-$572,069,660	-$325,774,444	-$439,301,145
80%	$197,036,172	$77,833,354	$36,580,578	-$457,655,728	-$260,619,555	-$351,440,916
60%	$147,777,129	$155,666,708	$73,161,156	-$343,241,796	-$195,464,666	-$263,580,687
40%	$98,518,086	$233,500,061	$109,741,734	-$228,827,864	-$130,309,778	-$175,720,458
20%	$49,259,043	$311,333,415	$146,322,312	-$114,413,932	-$65,154,889	-$87,860,229
10%	$24,629,522	$350,250,092	$164,612,602	-$57,206,966	-$32,577,444	-$43,930,115
5%	$12,314,761	$369,708,431	$173,757,746	-$28,603,483	-$16,288,722	-$21,965,057
2%	$4,925,904	$381,383,434	$179,244,833	-$11,441,393	-$6,515,489	-$8,786,023
1%	$2,462,952	$385,275,101	$181,073,862	-$5,720,697	-$3,257,744	-$4,393,011

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

OVERALL COST REDUCTION POTENTIAL IN AUSTRALIA

National estimates of the overall cost reduction potential are presented in Table 29. Assuming the base case scenario (2.9 percent of ED and 7 percent of GP services transferred to AMAS), the overall cost reduction potential ranges from -AUD269.16 million to -AUD2.69 million. Applying upper bound literature estimates (or best-case scenario), the overall cost reduction potential ranges between -AUD926 million to -AUD9.26 million.

Table 29 Annual overall cost reduction potential of a national AMAS

Scenario: base case using 2.9% ED and 7% GP service transfer rate to AMAS						
	Transferrable services		Total AMAS cost (AUD26.88)	Total current cost ($AUD)		
GP	8,778,725		$235,972,115	$386,839,625		
ED	232,507		$6,249,795	$124,533,683		
	AMAS cost	GP cost	ED cost	Potential cost reductions for GP and ED without paying for AMAS	Potential cost reduction paying for AMAS (with product)	SA1: Potential cost reduction paying for AMAS (without product)
100%	$242,221,910	$-	$-	-$511,373,307	-$269,151,397	-$380,800,559
80%	$193,777,528	$77,367,925	$24,906,737	-$409,098,646	-$215,321,118	-$304,640,447
60%	$145,333,146	$154,735,850	$49,813,473	-$306,823,984	-$161,490,838	-$228,480,335
40%	$96,888,764	$232,103,775	$74,720,210	-$204,549,323	-$107,660,559	-$152,320,224
20%	$48,444,382	$309,471,700	$99,626,946	-$102,274,661	-$53,830,279	-$76,160,112
10%	$24,222,191	$348,155,662	$112,080,315	-$51,137,331	-$26,915,140	-$38,080,056
5%	$12,111,095	$367,497,643	$118,306,999	-$25,568,665	-$13,457,570	-$19,040,028
2%	$4,844,438	$379,102,832	$122,043,009	-$10,227,466	-$5,383,028	-$7,616,011
1%	$2,422,219	$382,971,228	$123,288,346	-$5,113,733	-$2,691,514	-$3,808,006

Table 29 Annual overall cost reduction potential of a national AMAS (continued)

Scenario: best case using 11.5% ED and 21.2% GP service transfer rate to AMAS						
	Transferrable services		Total AMAS cost (AUD26.88)	Total current cost ($AUD)		
GP	26,586,994		$714,658,404	$1,171,571,434		
ED	922,012		$24,783,671	$493,840,466		
	AMAS cost	GP cost	ED cost	Potential cost reductions for GP and ED without paying for AMAS	Potential cost reduction paying for AMAS (with product)	SA1: Potential cost reduction paying for AMAS (without product)
100%	$739,442,075	$-	$-	-$1,665,411,901	-$925,969,825	-$1,266,806,407
80%	$591,553,660	$234,314,287	$98,768,093	-$1,332,329,521	-$740,775,860	-$1,013,445,126
60%	$443,665,245	$468,628,574	$197,536,187	-$999,247,140	-$555,581,895	-$760,083,844
40%	$295,776,830	$702,942,861	$296,304,280	-$666,164,760	-$370,387,930	-$506,722,563
20%	$147,888,415	$937,257,147	$395,072,373	-$333,082,380	-$185,193,965	-$253,361,281
10%	$73,944,208	$1,054,414,291	$444,456,420	-$166,541,190	-$92,596,983	-$126,680,641
5%	$36,972,104	$1,112,992,863	$469,148,443	-$83,270,595	-$46,298,491	-$63,340,320
2%	$14,788,842	$1,148,140,006	$483,963,657	-$33,308,238	-$18,519,397	-$25,336,128
1%	$7,394,421	$1,159,855,720	$488,902,062	-$16,654,119	-$9,259,698	-$12,668,064

Abbreviations: *AMAS: Australian minor ailments scheme; AUD: Australian dollars; ED: emergency department; GP: general practitioner*

SENSITIVITY ANALYSIS

A sensitivity analysis (SA2) was conducted using the highest cost of an AMAS consultation (AUD33.84 including patient out-of-pocket medicine expenses) and assuming a 2.9 percent transfer rate of ED services and 7 percent of GP services to an AMAS. The cost reduction potential ranges from -AUD206.43 million (best case assuming 100 percent actual transfer) to -AUD2.06 million (most conservative case assuming 1 percent actual transfer) at a national level (see appendix 8 for full results).

PHARMACIST WORKFORCE CAPACITY REQUIREMENTS

To support the minimum and maximum transferrable services from GP and ED to AMAS at a national level, each pharmacy is to provide 0.5-1.4 AMAS services each hour (Table 30). Details of this calculation can be found in appendix 9.

Table 30 Capacity requirements for a national AMAS

Estimated annual community pharmacy manageable services				Community pharmacy capacity		
	GP services (n)	ED services (n)	Combined services (n)	National number of pharmacies (29)	Average opening hours per week (30)	AMAS services per hour per pharmacy
Minimum	8,778,725	232,507	9,011,232	5,723	64.9	0.5
Maximum	26,586,994	922,012	27,509,006	5,723	64.9	1.4

Abbreviations: *AMAS: Australian minor ailments scheme; ED: emergency department; GP: general practitioner*

DISCUSSION

KEY STUDY FINDINGS

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 cluster randomised controlled study designed to investigate the effectiveness of AMAS compared with UC. Our CUA was undertaken from a societal perspective (which included 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). The AMAS generated a mean of 0.003 more QALYs per patient. The results of the CUA show slightly higher costs and also higher QALYs in the AMAS group with an incremental cost-effectiveness ratio (ICER) of AUD2,277 per QALY, compared with UC. The AMAS dominates UC in clinical effectiveness (see Chapter 3 for clinical effectiveness) hence lying 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 (28). Furthermore, previous decisions by the Pharmaceutical Benefits Advisory Committee (PBAC) to recommend a drug for reimbursement are associated with an ICER less than AUD30,000 per QALY (31). Based on the reference threshold of AUD28,033 per QALY, implementation of the AMAS is a highly cost-effective option. Our results must be interpreted within the appropriate geopolitical context compared to those from previous studies of health services that were accepted (or not) at clinical and policy levels in the Australian healthcare setting (32).

The inherent uncertainty contained in the model parameters was addressed by conducting a series of sensitivity analyses. The one-way sensitivity analysis resulted in ICERs ranging from AUD1,720 to AUD3,778 per QALY. Varying the costing input parameters of training, facilitation and IT setup costs provided small effects to the overall cost of AMAS and had almost null impact on the ICER. The multivariate sensitivity analysis showed small impact on the ICER when using the highest potential cost of an AMAS consultation (ICER AUD3,502) or assuming 100 percent of patients adhere to referral advice (ICER AUD3778). All ICERs within sensitivity analysis remain below the recommended ICER reference (using the AUD28,033 per QALY reference), further confirming robustness of our results showing AMAS to be a cost-effective option.

In addition to the CUA, two cost effectiveness analyses (CEAs) were conducted using the clinical effect measures of an extra episode of appropriate pharmacist care meeting the agreed protocols and an extra 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. The results of the second CEA revealed an ICER of AUD586.88 per additional patient achieving symptom resolution with AMAS, compared with UC.

THRESHOLD ANALYSIS

We estimate a total annual opportunity to liberate 232,507 to 922,012 ED services through effective integration and implementation of a national AMAS (assuming 2.9 to 11.5 percent transfer of ED services to pharmacy). Moreover, 8.8 million to 26.6 million GP services are estimated to be released as a result of national implementation of an AMAS (assuming 7 to 21.2 percent transfer of GP services to pharmacy). Nationally, this equates from 9 million to 27.5 million GP and ED services potentially shifted to an AMAS. These cases do not need to be treated in ED or GP and are increasing healthcare costs unnecessarily.

It is essential not only to talk about the services released to GP and ED, but the cost reduction

potential associated with release of these services. From our analysis, the cost of AMAS pharmacy-based consultation was AUD26.88 (or AUD14.49 assuming the patient pays for nonprescription and prescription medicines). This is compared with a general practice consultation costing AUD44.07 and an ED visit costing AUD535.61. Importantly, the AMAS has demonstrated a cost reduction potential of AUD17.19 and AUD508.73 per GP and ED consultation shifted to an AMAS (or AUD29.58 and AUD521.12 when medicine costs are paid by the patient).

It has been estimated that 2.9 to 11.5 percent of ED services in Australia are transferrable to AMAS. We estimate a total national cost reduction potential ranging from AUD118 million to AUD469 million annually (from a societal perspective assuming 100 percent actual transfer). Considering only costs to the health care system (ie. nonprescription and prescription medicine costs are paid by the patient), the Australian health system can liberate between AUD121 million and AUD480 million per annum. Similarly, it has been estimated that 7 to 21.2 percent of GP services in Australia are transferrable to AMAS. The national cost reduction potential ranges from AUD162 million to AUD489 million annually (from a societal perspective assuming 100 percent actual transfer). Moreover, considering only costs to the health care system (ie. medicine costs are paid by the patient), the Australian health system can liberate AUD270 million to AUD819 million per annum.

Combining these estimates of ED and GP transfer, we estimate the total overall national cost reduction potential opportunity of AUD269million annually which represents a 2.9 percent and 7 percent of ED and GP services transferred to AMAS respectively (from a societal perspective). The national cost reduction potential is AUD926 million as a result of transfer of 11.5 percent and 21.2 percent of ED and GP services, respectively (from a societal perspective). Considering only costs to the health care system (ie. medicine costs are paid by the patient), the Australian health system can liberate in AUD381 million to AUD1.27 billion annually if it adopted an AMAS. The estimated total national expenditure annually associated with GP and ED care for symptoms suggestive of minor ailments ranges from AUD511 million to AUD1.67 billion. In order to support the minimum and maximum transferrable services from GP and ED nationally, each pharmacy in Australia is to provide 0.5 to 1.4 consultations through AMAS per hour.

IMPLICATIONS FOR POLICY AND PRACTICE

The results reported provide economic evidence that a structured service following agreed protocols with distinct referral pathways can lead to more efficient use of services and health care spending through care that is delivered at the appropriate level with high quality and safety. Transferring care provided in ED and GP settings for symptoms of minor illnesses (estimated up to 27.5 million services nationally annually) to community pharmacy could increase access to care, decrease waiting times or improve timely treatment for individuals who actually require medical assessment and treatment (33-36). Overall, this will contribute to increasing the efficiency and sustainability of the healthcare system.

Australian healthcare expenditure is increasing with an estimated AUD170 billion spent on health in Australia in 2016-17 (37). The two major areas of health care expenditure are primary and secondary care, together accounting for 74 percent (AUD125 billion) of total healthcare expenditure (37). Presentations to ED are increasing by 2.7 percent on average each year (38). More than 8 million patients presented to Australian public hospital emergency departments in 2017-18 accounting for AUD4.2 billion of total expenditure (38). The average cost of a non-admitted ED visit is AUD533 (13). A recent report released by the AIHW found in 2017–18, 37 percent (2.9 million) of all ED presentations were for lower urgency care (39). Lower urgency care (or low acuity) include presentations appropriate for community pharmacist or general medical practitioner care. Measures of lower urgency care were based on the 2018 National Health Agreement (NHA) indicator (40) and defined as 'ED presentations at a formal public hospital ED, where the patient (i) did not arrive by an emergency services vehicle, (ii) was assessed as needing semi-urgent or non-urgent care, and (iii) was discharged without referral to another hospital (39). The report recognises lower urgency emergency department (ED)

presentations may be avoidable through provision of other appropriate services in the community (39). The adoption of AMAS would be part of these strategies.

Patients seeking care from ED for conditions such as headaches, coughs and colds, earaches are an inefficient use of resources. The catalyst for pharmacists providing services to manage these types of conditions was to alleviate the pressures on ED units and the capacity issues within general practice (41). Building upon the established accessibility of community pharmacies in primary health care, it could be promoted that instead of going to ED, patients can visit their community pharmacist and through agreed protocols and communication systems through AMAS can determine what level of care is required, and treat or escalate appropriately. The significance of coordination and using resources efficiently cannot be overstated. Many of the improvements envisioned can be achieved by better use of health care resources through patients accessing the appropriate level of care with quality, safety and accessibility. Ultimately, this will improve the community's access to health services, lessen the burden on other healthcare providers such as hospitals and result in significant savings to the health system (42). Improving community awareness of the availability of AMAS could go a long way in reducing the high number of in-hours and after-hours use of EDs for lower urgency care presentations.

Similarly, increased healthcare spending in Australia is also a result of the gradual increase in GP services. There are 381,000 GP consultations made on average each day in Australia (43). Correspondingly, with the increase in GP services there is also an increase in MBS expenditure. In 2016-17, 148 million GP services were supplied to Australian's costing the health system AUD7.4 billion. It is estimated that 7 to 21.2 percent of all GP consultations could be transferred to a community pharmacy and there is good evidence that the advice provided by community pharmacists as part of a consultation 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 (7). Recently, England has seen the introduction of the NHS DMIRS (also known as the Community Pharmacist Consultation Service) which seeks to reduce the burden on general practice and ED by referring patients requiring advice and treatment for certain low acuity conditions from GP and NHS111 to a community pharmacist for assessment and treatment (44). Its aim is to ensure that patients have access to the same levels of care, close to home. The overarching policy aim is to move to self-care with full support so patients consult the GP or ED only when needed.

COMPARISON TO LITERATURE

Much of the evaluative work at this time has focused on community pharmacist management of minor ailments in the UK and Canada (7, 17, 45-52). No studies (to our knowledge) from other countries offer a comparative viewpoint in terms of cost-utility or cost-effectiveness of a minor ailment scheme compared with usual care (53). Overall, our study results are consistent with the available literature.

Watson and co-authors estimated the cost-related outcomes of pharmacy-based care of minor ailments, compared with minor ailment care derived at GP and ED settings in the UK. Mean overall costs per consultation were significantly lower for pharmacy (GBP29.30 (95% CI GBP21.60 to GBP37.00)) compared with general practice (GBP82.34 (95% CI GBP63.10 to GBP101.58)) and ED (GBP147.09 (95% CI GBP125.32 to GBP168.85)) (7). The study reports a mean (95% CI) incremental QALY gain for pharmacy participants compared with general practice and ED participants to be 0.001 (0.000 to 0.002) and 0.001 (−0.001 to 0.002), respectively. Our study reports AMAS pharmacist delivered care to be AUD26.88 (or AUD14.49 excluding patient out-of-pocket medicine costs), compared with general practice (AUD44.07) and ED based care (AUD535.61). Our study reports a mean incremental QALY gain for patients receiving AMAS compared with UC to be 0.003.

Comparatively, Rafferty et al. performed an economic impact analysis of the Pharmacists Prescribing for Minor Ailments (PPMA) program in Saskatchewan, Canada (50). The study measured costs for the PPMA program from the public payer and societal perspective, using pharmacists prescribing data for consultations undertaken in Saskatchewan. The study found the Saskatchewan PPMA program saved the

province approximately CAD546,832 in 2014. After 5 years of implementation, from a societal perspective, cumulative cost savings were projected to be CAD3.48 million. The Saskatchewan Ministry of Health funds an CAD18 assessment fee for self-care of a minor ailment resulting in the pharmacist prescribing a prescription drug (50). Therefore, the economic impact analysis from the societal perspective includes pharmacist remuneration for service delivery of CAD18 per consultation and the cost of publicly funded prescriptions. The study identified community pharmacy as the most cost-effective option for minor ailment care at CAD18, with the cost of a GP appointment of CAD66.40 and emergency department visit at CAD138 (49). Our study has identified consultation by the community pharmacist under the AMAS as the most cost-effective option for minor ailment care. Annual cost reduction shifting GP and ED services to AMAS has the potential to liberate up to 27.5 million services equating to AUD926 million respectively.

Furthermore, the Ontario Pharmacists Association (OPA) determined that the implementation of a PPMA program aimed at five practice areas, including (i) counselling and prescribing for smoking cessation, (ii) administering flu vaccinations, (iii) adapting patients' drug therapy, (iv) renewing prescriptions for stable chronic conditions, and (v) prescribing for minor ailments could save the Ontario health system CAD143 million over five years (54, 55). It was estimated that the implementation of a national PPMA in Canada would allow services to be received by an additional 2.4-4.7 million people, reducing waiting times by transferring up to 17 million medical consultations to the pharmacy and avoiding up to 6000 visits to emergency departments (54, 55).

Another study of data from the IMS health disease analyser database identified the number of visits to GPs that were associated with conditions suitable for self-care in the UK (48). Between 2006-07, there were 57 million GP visits for conditions that were appropriate for self-care of which 51.4 million visits were solely for the purpose of seeking treatment for minor ailments. To place this number in context, this is 20 percent of the total number of GP visits involved conditions suitable for self-care, and 18 percent of consultations were solely for such conditions (48). Various MAS programs in the UK have been evaluated. Comparatively, our study estimates between 8.8 and 26.6 million GP consultations nationally in Australia are suitable to be transferred to community pharmacy for minor ailment management.

STRENGTHS AND LIMITATIONS OF THE ECONOMIC EVALUATION

Strengths of this study are that we collected cost data from a societal perspective and included data on the costs and effectiveness which were collected in an Australian setting. Furthermore, we had high follow up rates (82 percent) in the main cRCT study which included patients self-reporting symptom resolution and reconsultation, increasing the generalisability of the results obtained in the economic evaluation. Multiple imputation was used to impute missing data in the main analyses which is currently considered the most appropriate technique to deal with missing data (56). We found evidence that the health status of AMAS users (as measured by the VAS scale of the EQ-5D) showed significant improvement. This should offer much greater reassurance to clinicians and policy makers that patients can be dealt with initially equally as well but at significantly less cost. The imputed analysis produced consistent treatment effects with the main analysis confirming the robustness of results and the effectiveness of an AMAS in improving clinical and humanistic outcome measures. Our analysis gives an estimate of clinical and economic impact in international literature, and is an important development. The study differs from most other evaluations in this area, and we have been able to generate cost-per-QALY statistics to inform decision making.

As for any modelling exercise and economic analysis that attempts to reflect practice while relying on study data, there are some clear limitations in our study. The decision tree model is a step forward in mapping minor illness interactions and their implications. It is also a simplification of reality and subject to the perennial trade-offs between data availability and a more complex model structure. Therefore, the study limitations are related to some of the assumptions we had to make in constructing the model and the data that are used to derive probabilities and costs.

Apart from general limitations associated with the use of modelling, specific model limitations in our study include the trial not being powered to analyse the effect of the AMAS on symptom resolution rates, however, similar trends have been found in the literature. The trial-based outcome measures used for the economic evaluation were appropriateness of pharmacist care (as a proxy of health gain) and symptom resolution. Our cRCT study was powered to detect changes in appropriate pharmacist care and this was assumed to lead to changes in symptom resolution. While we saw a positive effect on symptom resolution rates with AMAS, the differences in symptom resolution were small compared with UC. Moreover, a minor ailment is a self-limiting condition and implicitly involves symptom resolution regardless of pharmacist's intervention. Given symptom resolution probabilities were incorporated into our economic model, this impacts the results of our economic evaluation.

Furthermore, the utility values were not available from our main study data which is why we relied on utility values obtained from a 2015 prospective cohort study (MINA study) conducted across two geographic regions (East Anglia, England and Grampian, Scotland) by Watson et al (7) for estimation of QALYs in our study. Within the framework of economic evaluations, the transferability of utility scores between jurisdictions remains unclear. Thus, the utility weights may not represent Australian preferences. A review by Knies et al. (57) discusses the international transferability of utilities derived from EQ-5D questionnaires. The authors found substantial differences between national EQ-5D value sets, and discourage the uncritical application of utilities from other countries to the individual setting (57). The MINA study did not evaluate a minor ailment service per se - it compared the management of similar ailments across different health settings and those from community pharmacy were not selected on the basis of them being part of a minor ailments scheme, but simply because they were managed in a community pharmacy. Furthermore, the evaluation examines multiple clinical conditions including musculoskeletal aches or pains in arms, legs, back, hands and feet, eye discomfort, nausea, vomiting, diarrhoea, constipation, sore throat, cough, cold and sinus problems. It has been assumed that the QALY gain for these minor ailment conditions is equal to the QALY gain for all minor ailments as applied in our analysis. Another related issue is the assumption we made regarding patients lost to follow up in the main study. We have treated our study population as a full cohort and have assumed all patients who were lost to follow up behave similarly (ie. similar probability of adhering to referral advice or reconsulting within 14 days) and their health status resolves (ie. similar probability of achieving symptom resolution) in a similar way to those followed up at 14 days.

The estimates of minor ailment consultations transferrable to pharmacy in this evaluation are based on national and international literature. The studies in the literature that we used to help guide our health cost reduction potential typically cover a range of minor ailments some of which were included in our analysis. The figures outlined in our report however may be taken as a reasonable estimation of the burden of minor ailments on the Australian health system. Understanding that not all GP or ED visits for minor ailments can be transferred to a pharmacist, these numbers are still very powerful in suggesting that expanded capacity in EDs and GPs could be achieved. Our national projections extrapolate the results from our database analyses to national population estimates. The scenarios we tested seem realistic; solid and robust given this and other similar work both nationally and internationally. To the extent that the national population healthcare costs differ from that represented in our database, our national estimates may need adjustments. The estimates represent the best available sources for our analysis. Our cRCT to which our economic evaluation was based relied on patient's self-report of symptoms and health service resource utilisation. Even though a major strength of self-report data is that is comes directly from the study participant, this does not rule out the possibility of response bias or social desirability bias.

Finally, further refining the model by addressing some of its inherent limitations and confirming our transition probabilities in future evaluations would be useful to validate our economic findings. Furthermore, we did not conduct a probabilistic sensitivity analysis (PSA) to assess second order uncertainty. We only have a deterministic ICER which is what is recommended to be reported to the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia. A probabilistic sensitivity analysis will be conducted before peer reviewed publication.

CONCLUSION

This is the first comprehensive economic evaluation alongside a cRCT of patients receiving pharmacy minor illness care through an agreed structured protocolised service in Australia and internationally. In conclusion, the results of the CUA and CEAs presented above suggest that implementation of a national AMAS is highly cost-effective. Economic evidence is provided to support the widespread adoption of AMAS in Australian healthcare outlining the clear potential for health expenditure cost reduction through integration of AMAS in Australia, and the liberated ED and GP services as a result. Our study highlights the important issue of patients accessing the appropriate level of care with quality, safety and accessibility and through appropriate referral pathways for the sustainability of the Australian health system. The implicit assumption is that patients consulting in hospitals or general practice for these conditions could be reduced by transferring them to the pharmacy care setting. Although a range of estimates were used in the economic model, these figures suggest that institution of a national minor ailment program would help to create greater access to health services, both ED and GP, through fully utilising the primary health locations and primary health professionals in Australia. With this comes opportunity to leverage significant cost reduction potential through resource efficiency as a result of integration and early intervention in patient referral pathways. Consideration should be given to extending the AMAS to generate integrated referral pathways for other groups of minor illnesses. All calculations were made within current scope of practice for pharmacists. Expanding community pharmacists' scope through training as seen in the UK and Canada for other clinical areas such as minor abrasions, wounds, strains and sprains, minor burns etc or prescribing of certain prescription medicines within a collaborative model for certain conditions is likely to add further economic benefits. Obviously, if the magnitude can be further extrapolated then the potential for cost reduction is large. Our findings are likely to have applicability to other healthcare systems.

APPENDICES

Appendix 1: Detailed model structure
Appendix 2: Assigned probabilities
Appendix 3: Training, facilitation, IT setup costs calculation
Appendix 4: One-way SA results
Appendix 5: Medicare analysis
Appendix 6: SA2: Annual cost reduction potential of pharmacy manageable GP services using highest modelled AMAS cost (AUD33.84)
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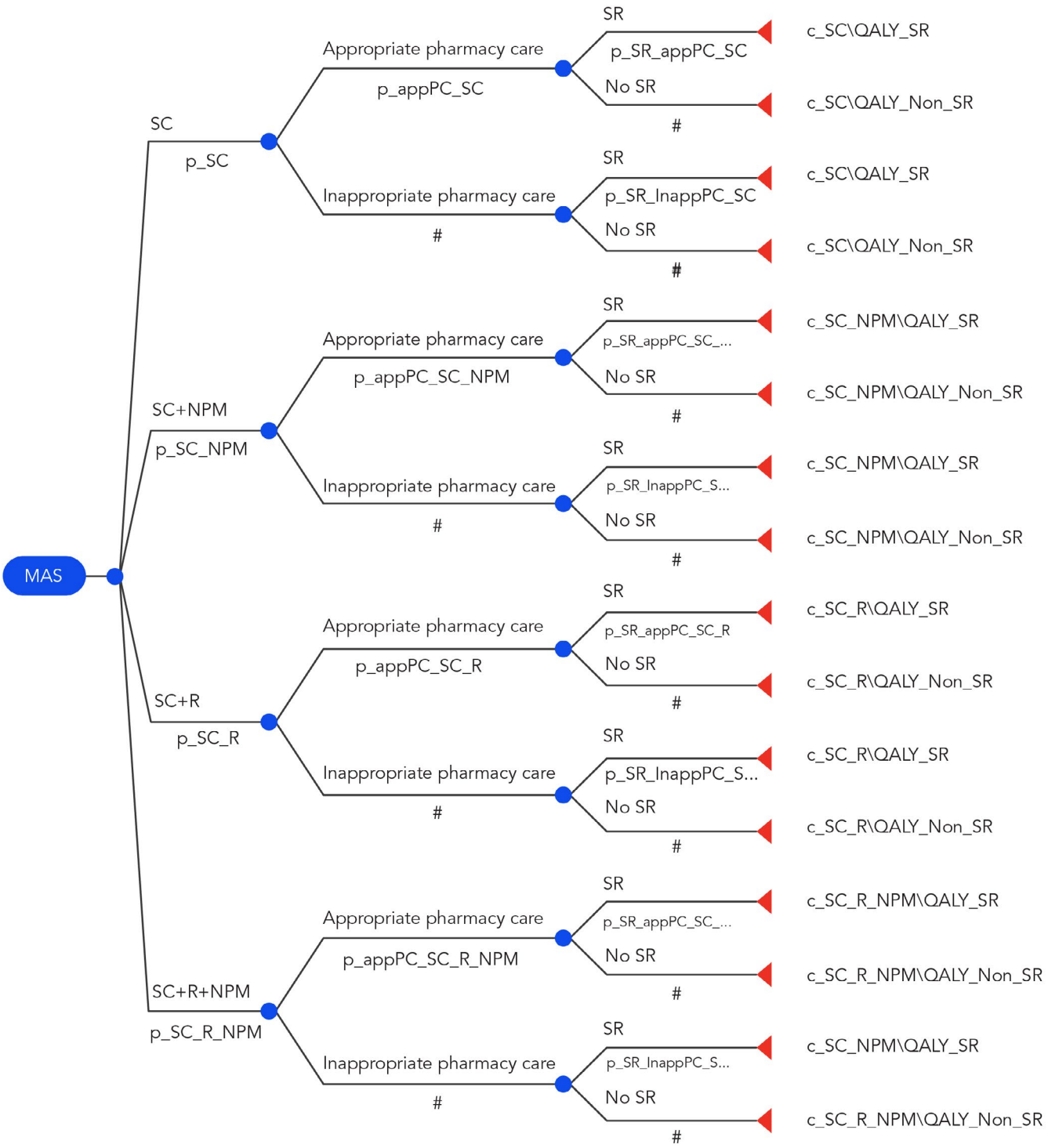
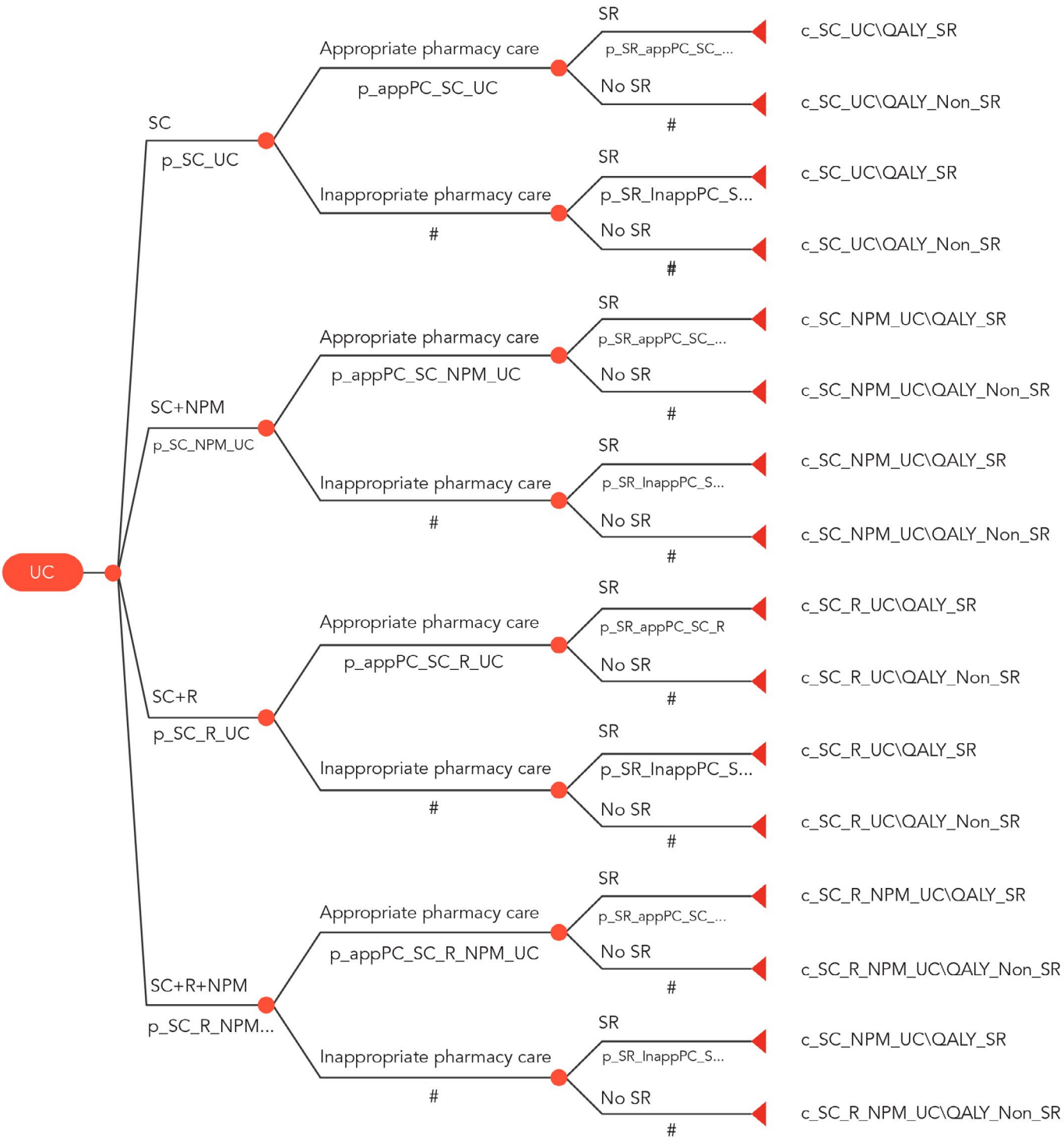
Appendix 8: SA2: Overall annual cost reduction potential of pharmacy manageable GP and ED services using highest AMAS cost (AUD 33.84)
Appendix 9: Pharmacist workforce capacity calculation

APPENDIX 1.
DETAILED MODEL STRUCTURE



APPENDIX 1.
DETAILED MODEL STRUCTURE (CONTINUED)



APPENDIX 2. ASSIGNED PROBABILITIES

	Initial distribution	Probability: Appropriate pharmacist care plus symptom resolution	Probability: Inappropriate pharmacist care plus symptom resolution	Probability: Appropriate pharmacist care plus no symptom resolution	Probability: Inappropriate pharmacist care plus no symptom resolution	Cost ($AUD)	QALY Symptom resolution	QALY No symptom resolution	QALY	Appropriate pharmacist care	Symptom resolution
AMAS											
Self-care	0.11	0.90	0.93	0.10	0.07	$1.61	0.003	0.000	0.003	53	41
Self-care plus nonprescription medicine	0.65	0.92	0.96	0.08	0.04	$17.54	0.020	0.000	0.020	297	270
Self-care plus referral	0.05	0.69	0.63	0.31	0.37	$1.10	0.001	0.000	0.001	21	13
Self-care, nonprescription medicine plus referral	0.19	0.87	0.95	0.13	0.05	$6.63	0.005	0.000	0.005	83	69
Total						**$26.88 AMAS total cost**	**0.029**	**0.000**	**0.0296 total QALYs**	**454 (87%)**	**393 (75%)**
UC											
Self-care	0.04	0.90	1.00	0.10	0.00	$0.59	0.001	-	0.001	13	13
Self-care plus nonprescription medicine	0.85	0.87	0.89	0.13	0.11	$15.93	0.023	0.000	0.023	220	240
Self-care plus referral	0.01	0.55	0.00	0.45	0.00	$0.00	-	-	-	5	2
Self-care, nonprescription medicine plus referral	0.09	0.62	0.68	0.38	0.32	$3.23	0.001	0.000	0.002	12	18
Total						**$19.75 UC total cost**	**0.026**	**0.0001**	**0.0257 total QALYs**	**250 (68%)**	**273 (74%)**

APPENDIX 3.
TRAINING, FACILITATION, IT SETUP COSTS CALCULATION

We have been provided data 60 patients present on average per pharmacy per day (industry average) (10) for symptom based or direct product requests (assuming a six day pharmacy working week). The AMAS pharmacist takes about 11 minutes per patient consultation which includes also the entry of research data into our iPad program. We have calculated that ONE pharmacist could reasonably deal with a **maximum of 44 patients per day** (working an 8-hour shift and considering the standard deviation of time and the proportion of symptom presenters and direct product requests). This number allows us to estimate the cost per patient for training and supporting the pharmacist. Data were calculated as follows:
8 hours (480 minutes) | 11 minute consultations = 44 consultations per 8 hour shift (maximum)

APPENDIX 4.
ONE-WAY SA RESULTS

		Mean	Min	Max	ICER ($AUD/QALY)
Base case ICER ($AUD/QALY)		$2,276	$1,720	$3,510	
Model Parameter	Lower bound	Upper bound	ICER ($AUD/ QALY)		Abs diff
Probability of symptom resolution MAS: No_AppPC_SC_NPM	0.88	0.96	$3,510	$2,257	$1,234
Average number of NPMs supplied AMAS: SC_NPM	1.12	1.69	$1,720	$2,828	$552
Average number of NPMs supplied UC: SC_NPM	0.92	1.38	$2,749	$1,782	$473
Number of medicines at reconsultation: UC	1.00	3.00	$2,389	$1,816	$460
Probability of symptom resolution UC: No_AppPC_SC_NPM	0.25	0.75	$1,855	$2,499	$421
Number of medicines prescribed at reconsultation: AMAS	1.00	3.00	$2,205	$2,661	$386
Probability of symptom resolution AMAS: No_AppPC_SC	0.79	1.00	$2,564	$2,164	$288
Probability of symptom resolution UC: AppPC_SC_NPM	0.84	0.89	$1,952	$2,532	$256
Probability of symptom resolution AMAS: AppPC_SC_NPM	0.89	0.93	$2,514	$2,177	$239
Probability of symptom resolution UC: No_AppPC_SC_R	0.56	0.75	$2,428	$2,460	$184
Pharmacist wage per hour	$24.04	$34.30	$2,082	$2,449	$174

APPENDIX 4. ONE-WAY SA RESULTS (CONTINUED)

		Mean	Min	Max	ICER ($AUD/QALY)
Base case ICER ($AUD/QALY)		$2,276	$1,720	$3,510	
Model Parameter	Lower bound	Upper bound	ICER ($AUD/ QALY)		Abs diff
Number of NPMs supplied AMAS: SC_NPM_R	1.24	1.86	$2,110	$2,439	$163
Probability of symptom resolution UC: AppPC_SC	0.83	0.92	$2,417	$2,245	$141
Average NPM price: AMAS	$10.20	$11.05	$2,131	$2,415	$139
Probability of symptom resolution AMAS: AppPC_SC_R_NPM	0.81	0.89	$2,399	$2,230	$123
Cost of reconsultation	$30.85	$57.29	$2,163	$2,383	$107
Average NPM price: UC	$9.39	$10.14	$2,374	$2,171	$99
Probability of symptom resolution AMAS: No_AppPC_SC_R_NPM	0.90	1.00	$2,364	$2,193	$88
Utility value: Symptom resolution	0.88	0.94	$2,358	$2,193	$83
Probability of symptom resolution MAS: No_AppPC_SC_R	0.42	0.74	$2,342	$2,242	$66
Pharmacist time: UC	2.88	3.71	$2,322	$2,223	$46
Number of NPMs supplied UC: SC_NPM_R	1.22	1.83	$2,321	$2,226	$45
Pharmacist time: MAS	10.52	11.23	$2,225	$2,319	$43
Probability of symptom resolution AMAS: AppPC_SC_R	0.56	0.75	$2,305	$2,257	$29
Probability of symptom resolution UC: AppPC_SC_R_NPM	0.47	1.00	$2,234	$2,299	$23
Probability of symptom resolution UC: No_AppPC_SC_R_NPM	0.25	0.75	$2,245	$2,289	$13
Utility value: No symptom resolution	0.73	0.81	$2,260	$2,285	$10
Cost of medicine at reconsultation	$7.94	$11.64	$2,284	$2,261	$8
Number of training sessions per year: MAS	-	2.00	$2,268	$2,278	$2
Probability of symptom resolution UC: AppPC_SC	0.71	0.90	$2,130	$2,274	$2
Probability of symptom resolution UC: No_AppPC_SC	0.84	0.91	$1,977	$2,273	$3
Probability of symptom resolution UC: AppPC_SC_R	0.36	0.69	$2,273	$2,273	$3

Abbreviations: *AMAS: Australian minor ailments scheme; AppPC: Appropriate pharmacy care; AUD: Australian dollars; ICER: Incremental cost effectiveness ratio; No_AppPC: No appropriate pharmacy care; NPM: nonprescription medicine; QALY: Quality adjusted life year; R: referral; SC: self-care advice; UC: Usual care*

APPENDIX 5. MEDICARE ANALYSIS

WSPHN		
MBS Item number	Sum of Services	Sum of Benefits paid ($AUD)
3	93,875	$1,592,272.40
23	4,333,515	$160,834,841.90
36	734,300	$52,772,099.20
44	62,759	$6,653,759.15
Total	**5,224,449**	**$221,852,972.65**
4	697	$23,579.35
24	18,663	$926,644.30
37	6,263	$566,076.00
47	2,346	$268,691.30
Total	**27,969**	**$1,784,990.95**
597	**14,336**	**$1,860,812.80**
598	**591**	**$48,830.00**
Total	**14,927**	**$1,909,642.80**
599	1,034	$158,202.00
600	178	$16,805.45
Total	**1,212**	**$175,007.45**
5000	8,263	$239,737.40
5020	623,573	$30,567,538.55
5040	70,895	$5,951,910.90
5060	4,513	$531,711.55
5200	23	$483.00
5203	9,913	$307,303.00
5207	695	$33,360.00
5208	440	$31,240.00
Total	**718,315**	**$37,663,284.40**
5003	142	$6,748.65
5023	7,690	$541,216.95

APPENDIX 5. MEDICARE ANALYSIS (CONTINUED)

5043	2,516	$266,614.95
5063	694	$101,106.20
Total	**11,042**	**$915,686.75**
Grand Total	**5,997,914**	**AUD264,301,585.00**
Average cost GP service		**AUD44.07**
NSW		
MBS Item number	Sum of Services	Sum of Benefits paid ($AUD)
3	1,051,418	$17,884,372.23
23	30,424,072	$1,134,066,987.40
36	5,886,286	$424,099,072.56
44	550,327	$59,189,409.21
Total	**37,912,103**	**$1,635,239,841.40**
4	5,922	$175,047.06
24	245,164	$12,204,922.58
37	72,669	$6,313,707.11
47	22,110	$2,606,869.80
Total	**345,865**	**$21,300,546.55**
597	288,511	$37,405,653.21
598	23,446	$2,330,552.95
Total	**311,957**	**$39,736,206.16**
599	39,376	$6,010,189.70
600	4,833	$572,550.60
Total	**44,209**	**$6,582,740.30**
5000	29,372	$852,264.10
5020	2,493,507	$122,328,573.05
5040	312,456	$26,250,066.60
5060	19,527	$2,345,529.19
5200	229	$4,809.00
5203	52,633	$1,633,524.25

APPENDIX 5. MEDICARE ANALYSIS (CONTINUED)

NSW		
5207	7,689	$377,182.80
5208	5,189	$406,546.25
Total	**2,920,602**	**$154,198,495.24**
5003	985	$46,823.35
5023	103,767	$7,364,763.60
5043	15,840	$1,680,945.35
5063	2,858	$409,406.25
Total	123,450	$9,501,938.55
Grand Total	**41,658,186**	**AUD1,866,559,768.20**
Average cost GP service		**AUD44.81**
Australia		
MBS Item number	Sum of Services	Sum of Benefits paid ($AUD)
3	3,094,748	$52,643,175.90
23	91,108,162	$3,397,988,161.07
36	17,352,769	1,250,388,620
44	1,577,377	$169,266,037.68
Total	**113,133,056**	**$4,870,285,994.32**
4	28,718	$708,026.71
24	722,724	$34,475,771.62
37	226,132	$19,128,295.05
47	74,336	$8,508,527.83
Total	**1,051,910**	**$62,820,621.21**
597	1,445,426	$187,498,156.81
598	84,624	$8,477,846.90
Total	1,530,050	$195,976,003.71
599	223,300	$34,133,511.00
600	19,450	$2,306,238.45
Total	**242,750**	**$36,439,749.45**

APPENDIX 5. MEDICARE ANALYSIS (CONTINUED)

Australia		
5000	85,776	$2,490,232.25
5020	7,560,845	$371,243,123.43
5040	972,587	$81,818,807.95
5060	74,693	$8,968,199.24
5200	805	$17,031.00
5203	182,799	$5,699,520.65
5207	32,728	$1,689,141.50
5208	24,255	$2,021,067.45
Total	**8,934,488**	**$473,947,123.47**
5003	4,595	$209,161.35
5023	457,087	$32,431,215.45
5043	48,116	$5,136,345.45
5063	8,298	$1,177,570.15
Total	**518,096**	**$38,954,292.40**
Grand Total	**125,410,350**	**AUD5,678,423,784.56**
Average cost GP service		**AUD45.28**

Abbreviations: *AUD: Australian dollar; GP: general practitioner; MBS: Medicare Benefits Schedule; NSW: New South Wales; WSPHN: Western Sydney primary health network*

APPENDIX 6.
SA2: ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE GP SERVICES USING HIGHEST MODELLED AMAS COST (AUD33.84)

WSPHN Scenario: 7% transfer and AMAS cost (AUD33.84)			
	Services	Benefits paid ($AUD)	
7%	419,854	$18,501,111	
Transferrable patients	**Cost of AMAS (AUD33.84) including cost of medicines**	**Cost of GP (AUD44.07)**	**Cost reduction ($AUD)**
100%	$14,205,801	$ -	-$4,295,310
80%	$11,364,641	$3,700,222	-$3,436,248
60%	$8,523,481	$7,400,444	-$2,577,186
40%	$5,682,321	$11,100,667	-$1,718,124
20%	$2,841,160	$14,800,889	-$859,062
10%	$1,420,580	$16,651,000	-$429,531
5%	$710,290	$17,576,055	-$214,765
2%	$284,116	$18,131,089	-$85,906
1%	$142,058	$18,316,100	-$42,953
NSW Scenario: 7% transfer and AMAS cost (AUD33.84)			
	Services	Benefits paid ($AUD)	
7%	2,916,073	$130,659,184	
Transferrable patients	**Cost of AMAS (AUD33.84) including cost of medicines**	**Cost of GP (AUD44.07)**	**Cost reduction ($AUD)**
100%	$98,665,622	$-	-$31,993,562
80%	$78,932,498	$26,131,837	-$25,594,849
60%	**$59,199,373**	**$52,263,674**	**-$19,196,137**
40%	$39,466,249	$78,395,510	-$12,797,425
20%	$19,733,124	$104,527,347	-$6,398,712
10%	$9,866,562	$117,593,265	-$3,199,356
5%	$4,933,281	$124,126,225	-$1,599,678

APPENDIX 6.
SA2: ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE GP SERVICES USING HIGHEST MODELLED AMAS COST (AUD33.84) (CONTINUED)

2%	$1,973,312	$128,046,000	-$639,871
1%	**$986,656**	**$129,352,592**	**-$319,936**
National Scenario: 7% transfer and AMAS cost (AUD33.84)			
	Services	Benefits paid ($AUD)	
7%	8,778,725	$397,489,665	
Transferrable patients	**Cost of AMAS (AUD33.84) including cost of medicines**	**Cost of GP (AUD44.07)**	**Cost reduction ($AUD)**
100%	$297,029,021	$-	-$100,460,644
80%	$237,623,217	$79,497,933	-$80,368,515
60%	$178,217,413	$158,995,866	-$60,276,386
40%	$118,811,608	$238,493,799	-$40,184,258
20%	$59,405,804	$317,991,732	-20,092,129
10%	$29,702,902	$357,740,698	-$10,046,064
5%	$14,851,451	$377,615,182	-$5,023,032
2%	$5,940,580	$389,539,872	-$2,009,213
1%	$2,970,290	$393,514,768	-$1,004,606

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

APPENDIX 7.
SA2: ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE ED SERVICES USING HIGHEST MODELLED AMAS COST (AUD33.84)

WSPHN Scenario: 2.9% transfer and AMAS cost (AUD33.84)			
	Services	Benefits paid ($AUD)	
2.9%	2,888	$1,594,976	
Transferrable patients	**Cost of AMAS (AUD33.84)**	**Cost of ED (AUD552.19)**	**Cost reduction ($AUD)**
100%	$97,732	$-	-$1,497,245
80%	$78,185	$318,995	-$1,197,796
60%	$58,639	$637,990	-$898,347
40%	$39,093	$956,986	-$598,898
20%	$19,546	$1,275,981	-$299,449
10%	$9,773	$1,435,478	-$149,724
5%	$4,887	$1,515,227	-$74,862
2%	$1,955	$1,563,077	-$29,945
1%	$977	$1,579,026	-$14,972
NSW Scenario: 2.9% transfer and AMAS cost (AUD33.84)			
	Services	Benefits paid ($AUD)	
2.9%	83,528	$46,123,338	
Transferrable patients	**Cost of AMAS (AUD33.84)**	**Cost of ED (AUD552.19)**	**Cost reduction ($AUD)**
100%	$2,826,598	$-	-$43,296,739
80%	$2,261,279	$9,224,668	-$34,637,391
60%	**$1,695,959**	**$18,449,335**	**-$25,978,044**
40%	$1,130,639	$27,674,003	-$17,318,696
20%	$565,320	$36,898,670	-$8,659,348
10%	$282,660	$41,511,004	-$4,329,674
5%	$141,330	$43,817,171	-$2,164,837
2%	$56,532	$45,200,871	-$865,935
1%	$28,266	$45,662,104	-$432,967

APPENDIX 7. SA2: ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE ED SERVICES USING HIGHEST MODELLED AMAS COST (AUD33.84) (CONTINUED)

National Scenario: 2.9% transfer and AMAS cost (AUD33.84)			
	Services	Benefits paid ($AUD)	
2.9%	232,507	$124,533,683	
Transferrable patients	**Cost of AMAS (AUD33.84)**	**Cost of ED (AUD552.19)**	**Cost reduction ($AUD)**
100%	$7,868,046	$-	-$116,665,637
80%	$6,294,437	$24,906,737	-$93,332,510
60%	$4,720,828	$49,813,473	-$69,999,382
40%	$3,147,218	$74,720,210	-$46,666,255
20%	$1,573,609	$99,626,946	-$23,333,127
10%	$786,805	$112,080,315	-$11,666,564
5%	$393,402	$118,306,999	-$5,833,282
2%	$157,361	$122,043,009	-$2,333,313
1%	$78,680	$123,288,346	-$1,166,656

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

APPENDIX 8.
SA2: OVERALL ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE GP AND ED SERVICES USING HIGHEST AMAS COST (AUD 33.84)

WSPHN Scenario: base case using 2.9% ED, 7% GP service transfer rate and AMAS cost (AUD33.84)					
	Transferrable services		Total AMAS cost (AUD26.88)	Total current cost ($AUD)	
GP	419,854		$14,207,859	$18,501,111	
ED	2,888		$97,746	$1,594,976	
	AMAS cost	GP cost	ED cost	Potential cost reduction without paying for AMAS	Potential cost reduction paying for AMAS (with product)
100%	$14,305,604	$-	$-	-$20,096,087	-$5,790,483
80%	$11,444,483	$3,700,222	$318,995	-$16,076,870	-$4,632,386
60%	$8,583,363	$7,400,444	$637,990	-$12,057,652	-$3,474,290
40%	$5,722,242	$11,100,667	$956,986	-$8,038,435	-$2,316,193
20%	$2,861,121	$14,800,889	$1,275,981	-$4,019,217	-$1,158,097
10%	$1,430,560	$16,651,000	$1,435,478	-$2,009,609	-$579,048
5%	$715,280	$17,576,055	$1,515,227	-$1,004,804	-$289,524
2%	$286,112	$18,131,089	$1,563,077	-$401,922	-$115,810
1%	$143,056	$18,316,100	$1,579,026	-$200,961	-$57,905
NSW Scenario: base case using 2.9% ED, 7% GP service transfer rate and AMAS cost (AUD33.84)					
	Transferrable services		Total AMAS cost (AUD26.88)	Total current cost ($AUD)	
GP	2,916,073		$42,253,898	$128,498,461	
ED	83,528		$1,210,325	$46,123,338	
	AMAS cost	GP cost	ED cost	Potential cost reduction without paying for AMAS	Potential cost reduction paying for AMAS (with product)
100%	$101,506,509	$-	$-	-$174,621,799	-$73,115,290
80%	$81,205,208	$25,699,692	$9,224,668	-$139,697,439	-$58,492,232
60%	$60,903,906	$51,399,385	$18,449,335	-$104,773,079	-$43,869,174
40%	$40,602,604	$77,099,077	$27,674,003	-$69,848,720	-$29,246,116
20%	$20,301,302	$102,798,769	$36,898,670	-$34,924,360	-$14,623,058
10%	$10,150,651	$115,648,615	$41,511,004	-$17,462,180	-$7,311,529

APPENDIX 8.
SA2: OVERALL ANNUAL COST REDUCTION POTENTIAL OF PHARMACY MANAGEABLE GP AND ED SERVICES USING HIGHEST AMAS COST (AUD 33.84)

5%	$5,075,325	$122,073,538	$43,817,171	-$8,731,090	-$3,655,764
2%	$2,030,130	$125,928,492	$45,200,871	-$3,492,436	-$1,462,306
1%	$1,015,065	$127,213,477	$45,662,104	-$1,746,218	-$731,153
National Scenario: base case using 2.9% ED, 7% GP service transfer rate and AMAS cost (AUD33.84)					
	Transferrable services		Total AMAS cost (AUD26.88)	Total current cost ($AUD)	
GP	8,778,725		$297,072,037	$386,839,625	
ED	232,507		$7,868,046	$124,533,683	
100%	$304,940,083	$-	$-	-$511,373,307	-$206,433,224
80%	$243,952,066	$77,367,925	$24,906,737	-$409,098,646	-$165,146,579
60%	$182,964,050	$154,735,850	$49,813,473	-$306,823,984	-$123,859,935
40%	$121,976,033	$232,103,775	$74,720,210	-$204,549,323	-$82,573,290
20%	$60,988,017	$309,471,700	$99,626,946	-$102,274,661	-$41,286,645
10%	$30,494,008	$348,155,662	$112,080,315	-$51,137,331	-$20,643,322
5%	$15,247,004	$367,497,643	$118,306,999	-$25,568,665	-$10,321,661
2%	$6,098,802	$379,102,832	$122,043,009	-$10,227,466	-$4,128,664
1%	$3,049,401	$382,971,228	$123,288,346	-$5,113,733	-$2,064,332

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*

APPENDIX 9.
PHARMACIST WORKFORCE CAPACITY CALCULATION

It is estimated 9,011,232 (minimum) to 27,509,006 (maximum) GP/ED services provided annually at a national level are transferrable to an AMAS. Recent Guild data has shown there are 5,723 community pharmacies nationally in Australia, open on average 64.9 hours per week (29, 30). Data were calculated as follows:

Minimum: 9,011,232 services | 5,723 pharmacies | 52 weeks | 64.9 hours per week = 0.5 AMAS consultations per hour

Maximum: 27,509,006 services | 5,723 pharmacies | 52 weeks | 64.9 hours per week = 1.4 AMAS consultations per hour

CHAPTER 5

CONCLUSION AND RECOMMENDATIONS

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

Three phases of research (co-design, pilot and impact study) were undertaken in WSPHN with the final objective of evaluating a minor ailment scheme in Australia. The AMAS model was codesigned with key stakeholders including general medical practitioners involved in WSPHN clinical governance, community pharmacists, WSPHN management leaders, patients and representatives from the PSA. The model was designed applying the 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 of 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 communication systems were agreed with general medical practitioners as a result of co-design.

Our pilot research demonstrated the service was both suitable and feasible and a preliminary assessment of outcomes showed apparent clinical effectiveness of the structured service, compared to usual care. Our impact study demonstrated the effectiveness of the AMAS for a number of clinical, humanistic and economic indicators. The clinical effectiveness evaluation revealed an improved appropriateness in consultation outcomes compared with usual care, including the pharmacist's treatment recommendation and decision to refer a patient for medical care. The AMAS service offered pharmacists a consistent framework to operate within, through pre-agreed *HealthPathways*, to differentially diagnose and manage a patient. Pharmacists were trained in *HealthPathways* and referral processes. The referral pathways together with use of existing IT systems provided a structure for communication, consultation and documentation. The systematisation and standardisation of clinical decision making and referrals was achieved through development of protocols, clinical expertise and collaborative 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 the emergency department). The structured consultation resulted in increased identification of medication related problems for direct product presentation types and pharmacists appropriately responded 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. Community pharmacists referred 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 identified instances where patients were continuing to self-medicate for persistent symptoms without seeking medical assessment by a GP.

The economic evaluation revealed AMAS as cost-effective. Further economic analyses using national and international data allowed for estimation of the proportion of patients seeking care for minor ailments in GP and ED settings in Australia. Applying various scenarios of transferability of these consultations to the pharmacy setting, the overall potential cost savings were calculated. Clearly the clinical and economic results of this study provide evidence for and support national AMAS implementation. The implementation of a national AMAS would contribute to greater efficient use of health care resources, encourage care to be delivered at an appropriate level, patients would be triaged effectively and referred by the pharmacist when medical assessment is required. This strategy would contribute to the sustainability of the Australian health care system.

RECOMMENDATIONS FOR PRACTITIONERS, POLICY AND FUNDING

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 (1). 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 (2-9).

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 integrated 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 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 (10). 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.

POTENTIAL FUNDERS

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 by inclusion in the 7th Community Pharmacy Agreement or as an MBS item (11). 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' (12). 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 (10). 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 (13). Pharmacies may also receive a small annual retainer of GBP50 to assist with set-up costs (13). 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 (13). 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 (13).

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.

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 NON-PRESCRIPTION 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 (14). 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 (14). 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 (15). Following on from the successful campaign, NHS England launched a promotional campaign in 2019 'Help Us Help You' (16).

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.

CONCLUSION

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 beneficial in Australia, and have demonstrated improved patient health outcomes as a result of more in-depth 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 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.

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. There is significant potential to expand on the operational elements of the AMAS service in future to maximise the integration of community pharmacists and quality use of medicines. Recommendations for improvements of operational service elements are outlined in appendix 1.

APPENDIX 1. RECOMMENDATIONS FOR FUTURE IMPROVEMENTS OF OPERATIONAL SERVICE ELEMENTS

RECOMMENDATION 1. FURTHER DEFINE AND AGREE ON PROVIDER ROLES AND RESPONSIBILITIES

High-quality referrals and transitions of care between pharmacy and other parts of the health system must be clearly defined, documented and collaboratively agreed. Further GP and ED physician involvement in stakeholder discussion is recommended to strengthen the current protocols and agree on referral points, processes and systems to facilitate referral from community pharmacy to ED settings. The continued development of protocols and agreement for other minor ailment conditions is recommended applying a similar co-design approach to the seven developed as part of this research. This would involve convening stakeholders at the national and local levels to take advantage the opportunity to ensure sustainable integration of community pharmacy. PHNs could take the leadership role to engage all stakeholders and action this recommendation.

RECOMMENDATION 2. OPERATE A TWO-WAY DIGITAL REFERRAL SYSTEM TO AND FROM PHARMACY TO GENERAL PRACTICE AND EMERGENCY DEPARTMENTS, WITH THE OPTION OF TRACKING REFERRALS

For effective continuity of care, an integrated digital referral system is recommended to link referrals sent to and from pharmacy electronically with GPs and EDs. Systems integrated with GP and dispensing software could be in place to support pharmacists referring patients to GPs and ED (with the option of fast-tracking if the pharmacist felt this was necessary), while GPs and ED physicians and staff could refer to pharmacy wherever appropriate and encourage patients to seek care from pharmacy first for self-treatable conditions. It is important to have an agreed structure for this process, supporting efficient, cost-effective, and quality care for the patient. It is also important these referrals are followed up as part of a collaborative process (particularly when patients do not adhere to referral advice).

Specific digital platforms in the UK have been developed to support the referral process to and from community pharmacy. In England, an integrated digital platform (PharmOutcomes) (17), is available to all community pharmacies, GPs and hospitals to manage referrals between settings (18). The system records minor ailment consultations, tracks referrals and sends GP notifications when certain Prescription Only medicines are supplied by pharmacists to patients (as part of an enhanced Common Ailments Scheme). Similarly, Wales have developed the national 'Choose Pharmacy' digital platform which allows for the transfer of electronic consultation records between Welsh community pharmacies. Pharmacists have access to relevant patient information from NHS Wales' hospital and GP systems, and electronic discharge advice letters. Pharmacists document in the application their consultations for minor ailments, medication reviews, and emergency supplies of prescribed medicines (19).

RECOMMENDATION 3. INCORPORATE PHARMACIST FOLLOW UP FOR PATIENTS AS PART OF AMAS WITH SAFETY-NET PROCEDURES IN PLACE

Follow up by the pharmacist could be incorporated as part of service design to ensure patients are reaching treatment goals and outcomes. This may allow a checkpoint for pharmacists to re-evaluate whether a patient requires referral for medical assessment. Furthermore, safety-net procedures should also be incorporated during the consultation. Communicating well with patients and providing them with appropriate advice is a key part of safe practice and can help to ensure that a patient with unresolved or worsening symptoms knows when and how to access further advice and the specific actions to take if red flag symptoms develop. This should be established as part of the consultation and pharmacists should document when safety net advice is provided to a patient.

RECOMMENDATION 4. ENABLE READ/ WRITE ACCESS FOR PHARMACISTS TO DOCUMENT CLINICAL CONSULTATIONS IN A PATIENT ELECTRONIC MY HEALTH RECORD

With wider adoption of My Health Record and secure messaging, pharmacy has the potential to greatly increase the flow of information between providers and improve the completeness of clinical information. It is recommended that community pharmacists have 'write' access in a patient's health record to document clinical consultations, including nonprescription medicine and referral data. Enabling pharmacists to write in health records would mean that the advice and treatment given in the pharmacy setting can be viewed by other health providers. Conversely pharmacists should, with patient consent, be able to read the My Health Record to assist them during consultations.

RECOMMENDATION 5. COLLABORATIVELY AGREE ON THE INFORMATION TO BE RECORDED DURING A CLINICAL CONSULTATION, AND STANDARDISE DOCUMENTATION REQUIREMENTS TO SUPPORT PATIENT REFERRAL AND FOLLOW UP

Documentation of pharmacists' interventions, their actions and impact on patient outcomes is important and should be organised and formatted in order for other healthcare providers to review. Currently, the developed digital systems with AMAS allow for pharmacists to record their consultation. However, integrated documentation tools (ie. with GPs) would further facilitate integration and collaboration within the system. This would especially be important to monitor if service outcomes are sustained long-term.

RECOMMENDATION 6. CONTINUE TO UPSKILL COMMUNITY PHARMACISTS TO EMPOWER PATIENTS TO SELF-CARE AND SELF-MANAGE AND SECONDLY, WITH GP SUPPORT, DEVELOP PHARMACIST'S CLINICAL CONSULTATION SKILLS, CLINICAL AND PHYSICAL EXAMINATION SKILLS, AND DOCUMENTATION SKILLS

A structured and standardised advanced CPD training may be developed for pharmacists to be able to provide patient-centred consultations and empower patient self-management. This may include behavioural change strategies such as motivational interviewing to increase self-care, decision-making and lifestyle changes for patients. In England, the CPCS educational program developed to enhance pharmacist's consultation skills, and clinical and physical examination skills is delivered by GPs. Emergency department physicians and GPs in Australia could be involved in training pharmacists to develop their clinical consultation skills, clinical and physical examination skills, and documentation.

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