INVESTIGATING THE IMPLEMENTATION OF
ASTHMA GUIDELINES

TO COMMUNITY PHARMACY

Greater Consideration of Implementation is Required for
Translation of Clinical Guidelines into Practice

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This thesis is presented for the degree of Doctor of Philosophy at

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“Vision without execution is hallucination.”

(Thomas Edison)
Declaration

This thesis is presented as a series of five papers, which have been the subject of peer review and published in scholarly journals. This format is in accordance with rule 41.(1)(a) of the Doctor of Philosophy Rules of the University of Western Australia. The papers consist of a systematic literature review, qualitative study, cross-sectional study, controlled pre-post intervention study, and evaluation study. The papers form chapters of the thesis to create a cohesive story concluding with a summary of the investigation and implications for future research and health policy decisions.

All the studies presented were the candidate’s own composition, designed in consultation with primary and secondary supervisors. All sources have been acknowledged throughout the thesis. The contribution of co-authors is outlined in the section “Publications arising from this thesis” and all co-authors granted permission to include the papers in this thesis.

I, Kim Watkins, certify that:

This thesis has been substantially accomplished during enrolment in the degree.

This thesis does not contain material, which has been accepted for the award of any other degree or diploma in my name, in any university or other tertiary institution.

No part of this work will, in the future, be used in a submission in my name, for any other degree or diploma in any university or other tertiary institution without the prior approval of The University of Western Australia and where applicable, any partner institution responsible for the joint-award of this degree.
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The work(s) are not in any way a violation or infringement of any copyright, trademark, patent, or other rights whatsoever of any person.

The research involving human data reported in this thesis was assessed and approved by The University of Western Australia Human Research Ethics Committee. Approval: [RA/4/1/1588 and RA/4/1/5000].

Written patient consent has been received and archived for the research involving patient data reported in this thesis.

The work described in this thesis was funded by [Government of Western Australia, Department of Health G05707] [AstraZeneca Unrestricted PARTIES scholarship].

This thesis contains published work and/or work prepared for publication, some of which has been co-authored.

Signature: ____________________________

Date: 25th November 2016
Abstract

Assimilating healthcare research evidence into clinical practice can be challenging. Clinical guidelines are the tools designed to streamline this process. The increasing clinical role of pharmacists has seen an increase in the development of guidelines specifically for pharmacists. However, development and dissemination of clinical guidelines does not necessarily result in improved practice. Crucial to translating evidence is the process of implementation. Despite the importance of effective implementation of clinical guidelines, the scientific literature is inconclusive regarding ideal strategies. Furthermore, there is a significant gap in the literature related to clinical guideline implementation to the community pharmacy setting.

Asthma is a chronic disease associated with significant morbidity and mortality, and patients need the support of health professionals to appropriately self-manage this condition. Australia has unique legislation that provides patients with access to asthma reliever medications from community pharmacists, without the necessity for a prescription or consultation with a doctor. The Guidelines for the provision of a Pharmacist Only medication: short-acting beta agonists (SABA guidelines) were developed in 2010. These guidelines were developed specifically for Australian pharmacists to ensure appropriate use of SABAs and referral of patients with suboptimal asthma management. Research had demonstrated practice deficits in this area.

An initial implementation of the SABA guidelines and another resource, the Asthma Action Plan card (AAP card), was undertaken over four months from Nov 2010 to February 2011 in Western Australia. Implementation focused on education about the
resources and primarily used passive dissemination methods. The reliance on passive dissemination led to the hypothesis that the initial implementation had been unsuccessful. This thesis sought to undertake an innovative, evidence-based implementation-intervention of the SABA guidelines to improve guideline-based asthma management by pharmacists. The overarching aim of this thesis was to use the example of the SABA guidelines to “Investigate and evaluate strategies for successful implementation of clinical guidelines to community pharmacy.”

Five key research areas were identified as important in addressing the aims of this thesis:

1. A systematic review of the literature (Chapter 3)
2. A qualitative focus group study (Chapter 4)
3. A cross-sectional study (Chapter 5)
4. An implementation-intervention study (Chapter 6)
5. A retrospective evaluation study (Chapter 7)

The systematic review (Chapter 3) was undertaken to investigate the evidence for effective clinical guideline implementation strategies in the community pharmacy setting. Results indicated that a systematic and tailored approach should be taken when designing an implementation-intervention. It also highlighted the need to consider the impact of other stakeholders that might influence guideline-based care provided by pharmacists.

The qualitative focus group study (Chapter 4) was conducted to ascertain stakeholder opinions to understand the impact of the initial SABA guideline implementation.
Barriers and facilitators of optimal asthma management and guideline-based practice were also investigated. Results reinforced the notion of using a tailored approach to implementation, because of the many barriers to guideline-based asthma management identified. Barriers were related to knowledge, attitudes and behaviours using a pre-existing taxonomy to aid analysis. Many of the behavioural barriers were associated with environmental and organisational issues. For instance, results pointed to the importance of considering pharmacy assistants as stakeholders in the achievement of guideline-based care. As the first point of contact for patients, they play an integral role in handling patient requests for SABAs.

The cross-sectional study (Chapter 5) was completed to understand the patient with asthma routinely presenting in community pharmacies. Understanding the asthma management issues of patients allowed for consideration of the potential clinical roles for pharmacists in improving healthcare. Results verified the importance of this thesis by demonstrating the large number of patients presenting in community pharmacy with asthma management issues and needing health professional intervention. It also confirmed the importance of pharmacists as front-line primary health care professionals. Patient perceptions around asthma meant they were not always aware of sub-optimal management and therefore not necessarily seeking support or advice. Community pharmacists were shown to have opportunities to intervene where other health professionals may not. This established the importance of appropriate guideline-based care for patients presenting in community pharmacy.

An implementation-intervention study (Chapter 6) using a controlled pre-post (quasi-experimental) design was devised based on the information and evidence gathered
from the systematic review (Chapter 3), the qualitative stakeholder study (Chapter 4), and the cross-sectional patient study (Chapter 5). This pragmatic, evidence-based implementation-intervention of the SABA guidelines aimed to improve guideline-based practice and legislative compliance. This provided the opportunity to learn more about effective strategies for guideline implementation in community pharmacy. The implementation-intervention was delivered via small group workshops and adapted for delivery via academic detailing. The focus of the intervention was to formalise the role of pharmacy assistants in the non-prescription supply of SABAs in recognition that community pharmacists operate in a team-based environment.

The baseline practice measurements undertaken as part of the implementation-intervention study (Chapter 6) confirmed the hypothesis that SABA guideline-based practice remained poor, despite the initial implementation. Subsequent to the tailored implementation-intervention, practice improvements were noted in the key outcome of guideline-based patient medical referral. However, outcomes were variable and no improvements were observed in the internal referral of patients (in-store from pharmacy assistant to pharmacist), or inhaler device demonstration. The research confirmed the importance of tailoring an intervention and considering the role of the pharmacy assistant when implementing clinical guidelines to community pharmacy. It also highlighted logistical issues with education delivered via small group workshops in the community pharmacy setting.

The evaluation study (Chapter 7) was undertaken to investigate the individual elements of the implementation-intervention study (Chapter 6). This process provided an understanding of the elements, which are fundamental to the effectiveness of an
implementation strategy in the community pharmacy setting, thus addressing the central aim of this thesis. Results indicated that the pragmatic, tailored approach to the design of the implementation-intervention (Chapter 6) had been thorough and had a sound rationale to achieve practice change. However, evaluation also highlighted process issues related to logistics, adaptability and fidelity with the implementation-intervention. It also identified further issues such as duration, intensity and reinforcement that would need to be investigated to ensure maintenance of practice improvements. The complexity of the issues around effective guideline implementation in community pharmacy and the need for triangulated methods was made apparent by the evaluation study.

The collective findings of the studies demonstrate that implementation of clinical guidelines in community pharmacy can improve evidence-based practice by community pharmacists, confirming the hypothesis for this thesis. Key in selecting an effective strategy for this setting is consideration of the role of the pharmacy assistant as the first point of contact for most patients. This was found to be a barrier to the provision of SABA guideline based care. Subsequent tailoring of interventions to overcome identified barriers resulted in a sound rationale to achieve practice change. Small group workshops were an appropriate strategy from a design perspective in achieving behaviour change but had limited application in community pharmacy due to logistical issues. Academic detailing was feasible for high penetration as an implementation strategy. However, its reliance on internal pharmacy communication, to target pharmacy assistant behaviour, may have reduced implementation-intervention success.
Further research is required to understand the relative benefits, outcomes and limitations of each strategy. There is still much to learn about optimum strategies for effective implementation of guidelines in community pharmacy. This thesis addresses this substantial knowledge gap and assists in focusing future research.
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Original articles


Author contributions: KW conceptualised and designed this review, as part of her PhD studies, supervised by CS and RC. KW prepared a protocol, devised search terms and conducted the literature search, synthesised the literature, designed and utilised a data abstraction table, applied three quality assessment tools to the synthesized data, analysed the data and wrote the manuscript. HW conducted the literature search and data abstraction independently, as per review methodology. CS acted as a moderator where necessary, as per methodology. All co-authors critically reviewed the manuscript and approved the final paper.


Author contributions: KW conceptualised and designed this qualitative research as part of her PhD studies, guided and supervised by CS and RC. KW recruited all participants to the study, designed the methodology, developed all resources, was present at all focus group sessions as an observer and scribe, undertook thematic analysis of all transcripts and collated data from summary sheets. KW analysed and interpreted the data collected and wrote the manuscript. CF was the independent facilitator at sessions as per methodology. JM independently completed thematic
analysis of transcripts as per methodology. All co-authors critically reviewed the manuscript and approved the final paper.


**Author contributions:** KW conceptualised and designed this cross-sectional research as part of her PhD studies, guided and supervised by CS and RC. KW conducted a literature review on existing survey tools, designed and formatted a survey tool, recruited and trained staff at a pilot test site, analysed pilot results and refined methodology, recruited and coordinated training of 30 pharmacies to participate in the research, produced resources, coordinated and trained research assistants, assisted with data collection and data entry, liaised with statisticians on data analysis, interpreted data and wrote the manuscript. AB acted as an independent reviewer during the literature search. MT and KM assisted in statistical analysis. Master of Pharmacy students acted as research assistants administering the survey to recruited patients. All co-authors critically reviewed the manuscript and approved the final paper.


**Author contributions:** KW conceptualised and designed this intervention study as part of her PhD studies, guided and supervised by CS and RC. KW organised and conducted
all pharmacy asthma workshops, produced all workshops materials including webpage content, DVD and paper-based resources, scripted and directed two videos and was an actor in a role-play video. KW developed an academic detailing programme, trained academic detailers and participated in data collection and data entry as an academic detailer. KW organised data collection via simulated patients, conducted training sessions for simulated patients, assisted with data entry, liaised with statisticians on data analysis, interpreted data and wrote the manuscript. MT and KM assisted in statistical analysis. All co-authors critically reviewed the manuscript and approved the final paper.


**Author contributions:** KW conceptualised and designed this intervention study as part of her PhD studies, guided and supervised by CS and RC. LS assisted KW with the application of behavioural change theory using the COM-B model and Behaviour Change Wheel. KW prepared an initial draft paper with all authors contributing to subsequent drafts and approving the final manuscript.

**Conference presentations**


Awards

2013 Star Pharmacist of the Year – Role Model Pharmacist awarded by The Pharmaceutical Society of Western Australia.

I, Prof Rhonda Clifford (primary supervisor) certify that the student statements regarding their contribution to each of the works listed above are correct

Supervisor signature: [Signature]

Date: 25th November 2016
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<tr>
<td>S2</td>
<td>Schedule 2 “Pharmacy Only Medicines”</td>
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<td>S3</td>
<td>Schedule 3 “Pharmacist Only Medicines”</td>
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<td>S3R</td>
<td>Schedule 3 Recordable Medicines</td>
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<td>S4</td>
<td>Schedule 4 “Prescription Only Medicines”</td>
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<td>AAP card</td>
<td>Asthma Action Plan card</td>
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<td>ACAM</td>
<td>Australian Centre for Asthma Monitoring</td>
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<td>ACT</td>
<td>Asthma Control Test</td>
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<td>AFWA</td>
<td>Asthma Foundation of Western Australia</td>
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<tr>
<td>APEASE Criteria</td>
<td>Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Side-effects/safety and Equity Criteria</td>
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<td>APF</td>
<td>Australian Pharmaceutical Formulary</td>
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<td>ASK-12</td>
<td>Adherence Starts with Knowledge Questionnaire</td>
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<td>BCT</td>
<td>Behaviour Change Technique</td>
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<td>BCTTv1</td>
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<td>BCW</td>
<td>Behaviour Change Wheel</td>
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<td>CBA</td>
<td>Controlled Before and After Study</td>
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<td>CDSS</td>
<td>Computerised Clinical Decision Support Systems</td>
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<td>COM-B</td>
<td>Capability;Opportunity:Motivation-Behaviour system</td>
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<tr>
<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<td>CPA</td>
<td>Community Pharmacy Agreement</td>
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<td>CQ</td>
<td>Consumer Asthma Knowledge Questionnaire</td>
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<td>CVD</td>
<td>Cardiovascular Disease</td>
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<td>DALYs</td>
<td>Disability Adjusted Life Years per 100 000 population</td>
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<tr>
<td>DPI</td>
<td>Dry Powder Inhaler</td>
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<tr>
<td>DVD</td>
<td>Digital Video Disc</td>
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<tr>
<td>ECRHS</td>
<td>European Community Respiratory Health Survey</td>
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<tr>
<td>EBM</td>
<td>Evidence-Based Medicine</td>
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<tr>
<td>EC Checklist</td>
<td>Emergency Contraception Checklist</td>
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<tr>
<td>ED</td>
<td>Emergency Department</td>
</tr>
<tr>
<td>EPOC</td>
<td>Cochrane Effective Practice and Organisation Care Review Group</td>
</tr>
<tr>
<td>F&lt;sub&gt;2&lt;/sub&gt;NO</td>
<td>Fraction of Exhaled Nitric Oxide</td>
</tr>
<tr>
<td>FEV&lt;sub&gt;1&lt;/sub&gt;</td>
<td>Forced Expired Volume in one second</td>
</tr>
<tr>
<td>FVC</td>
<td>Forced Vital Capacity</td>
</tr>
<tr>
<td>GINA</td>
<td>Global Initiative for Asthma</td>
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<td>GOAL</td>
<td>Gaining Optimal Asthma Control Study</td>
</tr>
<tr>
<td>GRADE</td>
<td>Grading of Recommendations, Assessment, Development and Evaluation working group</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
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<tr>
<td>HAPA</td>
<td>Health Action Process Approach</td>
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<tr>
<td>HDWA</td>
<td>Health Department of Western Australia</td>
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<td>HREC</td>
<td>Human Research Ethics Committee</td>
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<tr>
<td>ICS</td>
<td>Inhaled Corticosteroid</td>
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<tr>
<td>ICU</td>
<td>Intensive Care Unit</td>
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<tr>
<td>IgE</td>
<td>Immunoglobulin E</td>
</tr>
<tr>
<td>ISSAC</td>
<td>International Study of Asthma and Allergies in Childhood</td>
</tr>
<tr>
<td>ITAX</td>
<td>Intervention Taxonomy</td>
</tr>
<tr>
<td>KASE-AQ</td>
<td>Knowledge, Attitude, and Self-Efficacy Asthma Questionnaire</td>
</tr>
<tr>
<td>LABAs</td>
<td>Long Acting Beta&lt;sub&gt;2&lt;/sub&gt; Agonists</td>
</tr>
<tr>
<td>LTRAs</td>
<td>Leukotriene Receptor Antagonists</td>
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<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>MRC</td>
<td>Medical Research Council</td>
</tr>
<tr>
<td>NAC</td>
<td>National Asthma Council of Australia</td>
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<tr>
<td>NACCHO</td>
<td>The National Aboriginal Community Controlled Health Organisation</td>
</tr>
<tr>
<td>NAEPP</td>
<td>National Asthma Education and Prevention Program</td>
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<tr>
<td>NHPA</td>
<td>National Health Priority Area</td>
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<tr>
<td>NMP</td>
<td>National Medicines Policy</td>
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<tr>
<td>NRCT</td>
<td>Non-Randomised Controlled Trial</td>
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<tr>
<td>PARiHS</td>
<td>Promoting Action on Research Implementation in Health Services Framework</td>
</tr>
<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
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<tr>
<td>PCAQ</td>
<td>The Perceived Control of Asthma Questionnaire</td>
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<tr>
<td>PEF</td>
<td>Peak Expiratory Flow</td>
</tr>
<tr>
<td>PICO Framework</td>
<td>Participants; Intervention; Comparator; Outcomes Framework</td>
</tr>
<tr>
<td>pMDI</td>
<td>Pressurised Metered-Dose Inhaler</td>
</tr>
<tr>
<td>PRISMA</td>
<td>Preferred Reporting Items for Systematic Reviews and Meta-Analyses</td>
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<tr>
<td>PROSPERO</td>
<td>International Prospective Register of Systematic Reviews</td>
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<tr>
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<td>Pharmaceutical Society of Australia</td>
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<td>PSWA</td>
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<tr>
<td>QCPP</td>
<td>Quality Care Pharmacy Program</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
</tr>
<tr>
<td>RE-AIM</td>
<td>Reach, Effectiveness, Adoption, Implementation, Maintenance Framework</td>
</tr>
<tr>
<td>SABAs</td>
<td>Short Acting Beta₂ Agonists</td>
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<tr>
<td>SABA Guidelines</td>
<td>Guidelines for the provision of a Pharmacist Only medication: short acting beta₂ agonists (salbutamol and terbutaline)</td>
</tr>
<tr>
<td>SE</td>
<td>Standard Error</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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</tr>
<tr>
<td>SIP</td>
<td>Service Incentive Payments</td>
</tr>
<tr>
<td>SMART</td>
<td>Single combination budesonide-eformoterol inhaler maintenance and reliever therapy</td>
</tr>
<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Sciences</td>
</tr>
<tr>
<td>SUSMP</td>
<td>Standard for the Uniform Scheduling of Medicines and Poisons</td>
</tr>
<tr>
<td>TIDieR</td>
<td>Template for Intervention Description and Replication</td>
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<tr>
<td>TDF</td>
<td>Theoretical Domains Framework</td>
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<tr>
<td>TREND</td>
<td>Transparent Reporting of Evaluations with Non-Randomised Designs</td>
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<tr>
<td>UWA</td>
<td>University of Western Australia</td>
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Chapter 1:

Introduction
1.1 Opening statement

There has been a substantial increase in the development and implementation of clinical guidelines in the healthcare sector in recent decades, intended to synthesise and translate the best available evidence into practice. However, there are indications that adherence to clinical guidelines is poor and an evidence-practice gap remains.\(^1\)\(^-\)\(^5\) Recognition of the difficulties in translation of evidence into practice has resulted in the development of a new field of research termed implementation science. Most of the current literature about guideline implementation pertains primarily to the medical profession and/or hospital setting.\(^6\)\(^-\)\(^9\) There is a scarcity of information on how to implement guidelines to change and sustain the routine practice of community pharmacists.\(^1\)\(^,\)\(^10\)

Community pharmacists are the most accessible health care professionals\(^11\)\(^-\)\(^13\) yet are an underutilised resource.\(^14\)\(^-\)\(^16\) However, the shift in focus by governments and health organisations to develop the primary healthcare sector represents an opportunity to further re-define the role of community pharmacists as significant contributors to patient-centred healthcare.\(^16\)\(^-\)\(^18\) This shift has commenced in many countries, including Australia,\(^19\) with remuneration pathways opening up to pharmacists based on health service provision and not just medication supply.\(^18\)\(^,\)\(^20\)\(^-\)\(^22\) To this end, the use of clinical guidelines by community pharmacists has the potential to enhance professionalism, standardise care and, in the longer term, improve patient outcomes. Research on clinical guideline implementation in community pharmacy is crucial given the lack of current literature, the recent proliferation of guidelines\(^6\)\(^,\)\(^23\)\(^,\)\(^24\) and the enhanced clinical role of community pharmacists.\(^13\)\(^,\)\(^25\)
Enhanced practice for community pharmacists and the utilisation of clinical guidelines encompasses a more significant and formalised role in chronic disease management.\textsuperscript{19,26} A literature review analysing the evolving role of the community pharmacist demonstrated their participation in the management of a range of conditions including asthma, arthritis, cardiovascular disease, diabetes, depression, hypertension, osteoporosis and palliative care.\textsuperscript{19} The majority of these diseases are considered National Health Priority Areas (NHPAs) in Australia,\textsuperscript{27} due to their impact on the health of Australians and the health care system. Pharmacists, therefore have the potential to reduce the burden of chronic disease through enhanced practice.

Asthma was added as an NHPA by the Australian government in 1999\textsuperscript{27} and a national service improvement framework was developed for asthma in 2006.\textsuperscript{28} Despite these initiatives, there is substantial evidence to suggest that asthma management in Australia remains suboptimal, and worldwide asthma continues to be a burden on society and individuals.\textsuperscript{29-31} Community pharmacists participating in asthma management programmes have demonstrated in research that they can impact on patient quality of life and clinical outcomes.\textsuperscript{19,32-36} However, while there is some research emerging that is helping to build a picture of asthma self-management,\textsuperscript{37} overall there is still a lack of information about the patients who routinely present to community pharmacies.\textsuperscript{14} It is also unclear whether interventions undertaken in a research setting can translate into routine clinical practice. Exploration of the potentially expanded role of pharmacists in asthma is warranted and consistent with the recommendations of The Global Asthma Report compiled in 2014.\textsuperscript{38} The report recommends that governments around the world should commit to research and interventions to reduce the burden of asthma.\textsuperscript{38} The report also recommends the use
Guidelines based on the non-prescription supply of medications to relieve the symptoms of asthma (short-acting beta agonists (SABAs)), were developed for pharmacists and published in Australia in 2011.\textsuperscript{39} The guidelines were developed in response to practice deficits identified by researchers indicating poor assessment and referral of patients with uncontrolled asthma, seeking to purchase reliever medications from community pharmacy.\textsuperscript{40,41} Successful implementation of these asthma management guidelines is vital because patients who inappropriately self-manage asthma with an over-reliance on reliever medications are at risk of serious exacerbations and even death.\textsuperscript{42,43} The legislation around SABA supply in Australia determines that community pharmacists may be the only health professional to have contact with patients who self-manage their asthma with SABAs.\textsuperscript{44}

The initial implementation of the SABA guidelines in Western Australia in 2010 was conducted over a short time frame with limited resources and in conjunction with another tool the Asthma Action Plan (AAP) card.\textsuperscript{45} An evidence-based approach was not applied in this first implementation. The initial implementation strategy included academic detailing to pharmacists and passive dissemination to other stakeholders.\textsuperscript{46} The hypothesis underlying this research was that practice remained sub-optimal subsequent to the initial implementation. In contrast, this thesis utilises an evidence-based approach to implementation to investigate how to successfully address the evidence-practice gap related to the SABA guidelines in community pharmacy. In doing so, it contributes to scholarship in implementation science, community pharmacy
practice and asthma management in the primary healthcare setting. It addresses the challenge of how to ensure community pharmacists assess, intervene and refer patients with asthma who may be at risk of serious health consequences.

The **aim** of this thesis is to investigate and evaluate the strategies for successful implementation of clinical guidelines, to community pharmacy, to improve evidence-based practice. Specifically this thesis is focused on the chronic disease, asthma, and the Australian Guidelines for the provision of a *Pharmacist Only* medication: short acting beta agonists (salbutamol and terbutaline) (SABA guidelines).

The **hypothesis** is that implementation of clinical guidelines to community pharmacy can improve evidence-based practice in asthma management.
1.2 Structure of this thesis

This thesis is presented as a series of five papers, which have been the subject of peer review and published in scholarly journals. The thesis comprises eight chapters: an introduction, methods, five scientific papers and a general discussion section to conclude, with each paper incorporated as a separate chapter. The scientific papers function as discrete pieces of work with individual introductions, methods, results and discussions. Inevitably this produces some repetition of the content in this thesis. Each chapter is also referenced separately to reflect the discrete nature of the papers. This facilitates convenient access for verification of evidence presented.

Chapter 1 opens with a statement that provides a clear indication of the contribution of this research and the aim. The structure of the thesis is outlined, and this is followed by background information. The background information provides an overview of the broader topics relevant to the research. There is information about clinical guidelines as tools of practice change; how they are developed, implemented and evaluated. Material about community pharmacy, the role of community pharmacists in managing asthma and specifically the legislation and guidelines that are applicable to asthma care. Information is provided about asthma including definition, epidemiology (to explain the extent of the issue), clinical presentation, diagnosis, management, medications, triggers and characteristics of the patient “at risk” and requiring health intervention. Finally, the scope of the research is contextualised into the background information presented.

Chapter 2 outlines the methodology used in achieving the aims of this thesis. It includes the following research: a systematic review, a qualitative study using focus
groups; a cross-sectional study using a questionnaire; a controlled intervention study using simulated patient methodology to report outcomes and a retrospective evaluation study using a theory-based framework and logistics taxonomy.

Chapter 3 considers what strategies have been successful in the implementation of clinical guidelines to community pharmacy. A systematic literature review was conducted to identify the evidence for successful strategies in this setting. The synthesis demonstrated variable and moderate beneficial effects from mostly educational strategies, but poor quality of evidence. There were indications of a greater need for identification of barriers, tailoring of interventions and formulation of a clear rationale, prior to implementation.

Chapter 4 investigates the initial implementation of the SABA guidelines and AAP card. It also explores the barriers and facilitators to the use of guidelines and optimal asthma management. This was achieved in a qualitative research study using focus groups. The results were used to inform the design of a subsequent implementation-intervention study (Chapter 6). The aim was to develop an intervention tailored to overcome barriers to practice change, as was consistent with recommendations from the literature in Chapter 3. Many barriers were identified related to knowledge, attitudes and behaviours. Of specific interest was the high involvement of pharmacy assistants in the sale of non-prescription asthma reliever medications, despite legislation requiring the direct involvement of pharmacists and pharmacy assistants’ lack of awareness of the SABA guidelines.
Chapter 5 represents a needs analysis. What are the needs of patients with asthma currently presenting in community pharmacies? Is intervention required? What are the key issues? This chapter describes a cross-sectional study, which collects data about asthma patients in community pharmacy, via a semi-structured questionnaire. It provides information about patients’ asthma control, medication adherence, quality of life, perceptions and beliefs, and knowledge. It also includes their medical history and demographics. The analysis relates the information collected about patients with asthma, to opportunities for intervention by community pharmacists. The results indicate that many of the patients routinely presenting in community pharmacy do require support, intervention and/or referral. The issues outlined also suggest the significant role that community pharmacists could play in improving health outcomes for patients.

Chapter 6 reports on an implementation-intervention study, which was designed using the information and evidence synthesised on: clinical guideline implementation, the initial SABA guideline implementation, and asthma management, from Chapters 3, 4 and 5.\textsuperscript{10,48,49} The study was a controlled pre-post design. The chapter describes the evidence-based strategy used in an implementation-intervention of the SABA guidelines, the resources developed and the results. The primary outcomes related to guideline and legislative compliant practice change in the community pharmacy. Outcome data were collected using covert simulated patient methodology, as has been used previously in this setting. The results were variable, but there were significant improvements in the referral of patients with uncontrolled asthma to medical professionals. This suggests some potential merit in the implementation-intervention strategy chosen.
Chapter 7 reflects on the implementation-intervention strategy designed and tested in Chapter 6.\textsuperscript{47} It evaluates the intervention using retrospective application of two published taxonomies: for behaviour change and logistics.\textsuperscript{50,51} It investigates if this newer approach to evaluation can indicate unresolved issues in the strategy used in this thesis. The scientific literature on implementation has expanded rapidly during the timelines of this research. There are now strong advocates for the use of a theory-based approach and the use of taxonomies, despite a current lack of evidence of their effectiveness in improving implementation initiatives.\textsuperscript{10,52} This evaluation takes this thesis to the forefront of research in implementation science.

Chapter 8 brings together and discusses all the elements of this research and considers the deeper implications of the results. What are the important considerations when implementing clinical guidelines for asthma to community pharmacy? What have we learnt and how much is still unclear? What were the key strengths and limitations? How can this research inform policy, practice and future research? We conclude with the answer to our thesis aim, which was to investigate and evaluate the strategies for effective implementation of clinical guidelines to community pharmacy.
Figure 1 below indicates how the research undertaken in Chapters 3, 4, 5, 6 and 7 contribute to this scope of this doctoral work.

Figure 1: Overview of thesis structure and scope of work
1.3 Background - Implementation Science

1.3.1 Evidence-based medicine and clinical guidelines

Evidence-based medicine (EBM) is defined as the “conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.” The meteoric rise, in recent decades, in the aspiration to practice according to this philosophy, has seen a proliferation in the development of clinical guidelines as a tool to facilitate this objective. Clinical guidelines are defined as “systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.” There are many proposed benefits to EBM and the use of clinical guidelines. Clinical guidelines are designed to improve the quality of healthcare by reducing unnecessary, ineffective or harmful interventions; promoting treatments with the greatest benefits; minimising adverse effects and improving cost-effectiveness of treatments. Patients are empowered by guidelines to make more informed healthcare choices. Healthcare professionals benefit through assistance in clinical decision-making, consistency of care and reassurance about the appropriateness of therapy. Clinical guidelines also have the ability to influence public policy by highlighting areas of unmet need in health and ensuring efficient use of limited resources. Furthermore, the development of guidelines can indicate evidence gaps that can lead to more focused research.

Despite contemporary healthcare embracing the ideals of EBM, there are still issues that challenge evidence-based clinical practice and the uptake of guidelines. The first issue in promotion of EBM is the synthesis of high-quality evidence. Ideally “gold standard” evidence should be derived from reviews of large, double-blinded
randomised controlled trials, but this information is not always readily available, and historically guidelines have not always been developed in this way.\textsuperscript{4,59,60} Secondly, the best available evidence then needs to be translated into health professional practice behaviours. However, bridging the divide between research evidence and health professional practice remains a challenge.\textsuperscript{1-5,60,61} This realisation has seen the emergence of a new field of research called implementation science. Implementation science is the “study of methods to promote the integration of research findings and evidence into healthcare policy and practice.”\textsuperscript{62-64} Increasingly there is awareness that the current expectations around what can be achieved by the development and dissemination of guidelines may be idealistic.\textsuperscript{24} The healthcare system is complex, and many factors can influence evidence-based practice, guideline adherence and patient care. Issues such as feedback on performance; patient engagement and empowerment; management quality; organisational factors; workplace culture; teamwork and leadership, along with appropriate remuneration pathways can all impact on healthcare-professional practice.\textsuperscript{4,60} Lack of awareness; lack of familiarity; lack of self-efficacy; lack of outcome expectancy; inertia and other external barriers may hamper guideline adherence.\textsuperscript{4} The difficulty and complexity in achieving sustained behaviour change in health professionals have seen implementation scientists turn their focus to the use of behavioural theory, frameworks and taxonomies to adopt a more logical approach to the issue.\textsuperscript{52,64-66} However the benefits of this approach are yet to be fully substantiated in the literature.

Meanwhile, critics of EBM claim that it promotes “cook book medicine”. Critics claim EBM results in a loss of individually tailored patient care, a reduced standard of patient care, deskillng of practitioners and replacement of highly trained healthcare
professionals with less-expensive and less-skilled practitioners, unable to respond to extraordinary circumstances.\textsuperscript{24,55} They point out health practitioners need to manage more complex clinical issues, in more heterogeneous populations, than guidelines address.\textsuperscript{60} Some researchers have also suggested that guidelines are expensive to develop and implement and thus have questionable cost-effectiveness if practitioner adherence and patient outcomes are not achieved.\textsuperscript{2,6,24}

A more systematic approach to the translation of research findings is required. Development of clinical guidelines does not necessarily result in uptake by health professionals, and there is substantial evidence to suggest that adherence to clinical guidelines is poor and an evidence-practice gap remains.\textsuperscript{1-5} There has been considerable investment in the development of guidelines and improving their quality, but much less consideration has been given to implementation and evaluation of the effect of guidelines on practice, patient and economic outcomes.\textsuperscript{6,67} Research focused on successful implementation strategies for guidelines to achieve practice change is the crucial next stage. Once practice change has been achieved, evaluations should consider the utility of practice change in terms of the patient and use of limited resources in health.

\textbf{1.3.2 Development, implementation and evaluation of clinical guidelines}

Development of clinical guidelines requires identification and synthesis of the best available evidence and an understanding of the level, quality, strength and relevance of the available evidence. However, it is also important that the recommendations in guidelines are clinically useful. Thus, even when there is strong evidence, utility of the evidence in clinical application is an important consideration.\textsuperscript{57}
When developing guidelines, the focus should be on desirable outcomes, which are patient focused. To achieve this, development should be by a multidisciplinary team that includes patients (consumers). The guidelines themselves need to be robust; flexible; adaptable to different locations; and be applicable to a variety of target populations. To be practical and economically feasible, health resource constraints and costs of treatment recommendations are an important consideration in the development of guidelines. Health resources include “all materials, personnel, facilities, funds and anything else that can be used for providing health care and services.”

Development, implementation and evaluation of guidelines should not be tackled as separate stages. Ideally, the target audience, dissemination and implementation strategies all need to be considered during guideline development. There also needs to be provision for on-going evaluation and revision to ensure guidelines remain contemporary and applicable. The characteristics of guidelines themselves can affect uptake into practice. Guideline complexity can be a barrier and health professionals may be more receptive to guidelines produced by members of their own profession. The type of health problem and the quality of the evidence for change may also be relevant to uptake.

Regardless of their characteristics, clinical guidelines cannot be effective unless they are successfully implemented to encourage practice change by health professionals and subsequent behaviour change in patients. This process is challenging, complex, and requires skill, determination, time, money and planning. There is still much to learn. Many potential barriers and strategies have been identified in the literature, but
there is little information on how to select or tailor implementation strategies to overcome barriers. Also, some of the evidence on guideline implementation remains inconclusive, such as the superiority of a multifaceted approach and the merits of using behavioural theory. There is consensus, however, that passive dissemination of guidelines is ineffective and that implementation strategies should be tailored to overcome barriers to practice change. Overall, reviews have found that few implementation studies are based on theory, barrier assessment or any other rationale. However, there is increasing interest in the use of theory to underpin interventions. Many different strategies have been utilised in clinical guideline implementation including: educational strategies (including educational outreach also called academic detailing); audit and feedback; mass media distribution; reminder and decision support; financial incentives and use of local opinion leaders.

Having developed and implemented a guideline, it is essential to evaluate outcomes. What has implementation of the guideline achieved? Ideally, a complete evaluation would encompass six components: assessment of guideline dissemination; assessment of adherence in clinical practice; assessment of health outcomes; assessment of the contribution of the guidelines to changes in clinical practice or changes in health outcomes; assessment of impact on patient knowledge and understanding and an economic assessment. Current evidence indicates that evaluations tend to focus on practice outcomes with limited evidence on patient and economic outcomes. Grimshaw also makes the point that the costs associated with the development and implementation of guidelines can frequently outweigh the
potential benefits. In such instances policy developers need to consider how to best utilise the limited resources in health.

Although a substantial amount of research has been undertaken on clinical guideline implementation in recent decades the evidence base is incomplete. Furthermore there are complexities in synthesising the existing evidence to community pharmacy. Most guideline implementation research has concentrated on medical practitioners: either general practitioners (GPs) in primary health or doctors in the hospital setting. A small number of reviews have examined allied health professional practice, but only a few of the studies included pharmacists and most examined pharmacy practice in the hospital setting. More research is required as community pharmacists expand their clinical service offering and more guidelines are developed for use in the community pharmacy setting.

1.4 Background - Community Pharmacy

1.4.1 Community pharmacy in Australia

In Australia, there are more than 5000 community pharmacies responsible for the provision of prescription medications, with most medicines being partially subsidised through the Federal Government’s Pharmaceutical Benefits Scheme (PBS). Community pharmacists operate in a retail environment which provides high accessibility for patients but it can undermine the community pharmacist’s status as a health professional. However, they are highly trained health professionals with a unique skill set in medication management which is currently under-utilised. Historically, practice has focused on product supply but in recent years the role of pharmacists in Australia and other countries, has evolved to encompass cognitive
pharmaceutical and other clinical services to improve patient health.\textsuperscript{19,80-82} Remuneration pathways are gradually becoming available to encourage this expanded role,\textsuperscript{20-22} along with guidelines to support professional practice. Meeting professional practice standards is encouraged via a national quality assurance, accreditation programme called the Quality Care Pharmacy Program (QCPP).\textsuperscript{83} The majority of pharmacies in Australia (>90%) participate in the accreditation process, which provides access to service-based, government-funded remuneration pathways. The aim of the accreditation process is to ensure a uniform approach to the delivery of patient care and professional services.

Developing the clinical role of community pharmacists aligns with Australia’s National Medicines Policy (NMP), which was launched in 1999. The NMP aims to improve positive health outcomes for all Australians through their access to and wise use of medicines.\textsuperscript{84} A central objective is “quality use of medicines”, which is integral to the expertise of pharmacists. A National Strategy for Quality Use of Medicines (QUM) further reinforces this objective.\textsuperscript{85} Also supporting an expanded role for community pharmacists in Australia is the recognition of the need to restructure the health system with a greater emphasis on primary health care service provision. In 2008 the World Health Organisation released a report “Primary Health Care: Now more than Ever,” that outlined the importance of a health system with a strong primary health care sector in producing fewer health inequalities and better outcomes. It demonstrated the cost-effectiveness of such a system, which could produce higher levels of health for the same investment, compared to a system from a country with similar economic development, but with less developed primary health services.\textsuperscript{17} Recognition of these
benefits has lead to the development of Australia’s first National Primary Health Care Strategy, to drive reform.\textsuperscript{86}

There is substantial research demonstrating the potential of community pharmacists to deliver clinical services that have a positive impact on patient health outcomes.\textsuperscript{25,80,87,88} However, the process of dispensing prescriptions still determines the workflows, organisation and majority of remuneration for most community pharmacies. Incorporation of clinical services into this environment has been challenging and slow.\textsuperscript{16,80,89-91} Nevertheless, gradual changes are being made to support expanded practice, such as incorporation of designated counselling areas in community pharmacies and installation of technologies to drive efficiencies in dispensing.\textsuperscript{92} Newer formalised clinical roles for community pharmacists in Australia include patient education, self-care support, health promotion, disease prevention, screening, monitoring, disease management and medication management.\textsuperscript{93} More recently in Australia, pharmacists have taken on a role in administration of vaccinations\textsuperscript{94} and continued supply of prescription medications.\textsuperscript{95}

The Pharmaceutical Society of Australia (PSA) is the national peak professional organisation representing a workforce comprising of approximately 29,000 pharmacists.\textsuperscript{96} PSA develops and publishes professional guidelines, standards and protocols for pharmacists indicating how pharmacists can best fulfil their duties and responsibilities.\textsuperscript{97} The number of guidelines specifically written for community pharmacists, has increased substantially in the last decade, as seen in each successive edition of the Australian Pharmaceutical Formulary (APF).\textsuperscript{98} Generally implementation has involved passive dissemination through publication in the APF and inclusion on the
PSA website, plus a few educational opportunities at the time of the release of guidelines. What is unclear is how dissemination of these guidelines has influenced evidence-based practice change. This is an important question, given the current evidence from other health care settings that dissemination of guidelines can provide awareness, but is unlikely to achieve behaviour change.6

In Australia, the current minimum requirement to practice pharmacy is the completion of a four-year bachelor’s degree followed by a period of supervised practice with duration of the equivalent of one year. It is also possible to enter the profession via a Master’s qualification (plus one year supervised practice), following completion of a relevant bachelor’s degree.99,100

Non-professional staff or “pharmacy assistants” support community pharmacists in their role. Pharmacy assistants do not require any specific training or education level for employment. Historically, training was provided by direct instruction on-the-job. However, a National Community Pharmacy Training Package was developed in 2000 comprising of four certificate qualifications (I-IV), based on Competency Standards for Pharmacy Assistants.101 The standards accreditation process (QCPP) for community pharmacies in Australia, also now requires pharmacy assistants, involved in handling non-prescription, scheduled-medicine sales, to complete an online training unit by the Pharmacy Guild of Australia, while under supervision in the workplace.102,103 In Australia, a national classification system based on schedules controls how medicines and poisons are made available to the public. This classification system is outlined in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), commonly called the Poisons Standard.104 Pharmacy assistants handling Schedule 2
“Pharmacy only medicines” and Schedule 3 “Pharmacist only medications” require training. A survey of pharmacy assistants undertaken in 2004 determined the levels of training of pharmacy assistants (including staff who worked in the dispensary). The survey indicated that 32% had completed secondary schooling to less than year 12, 57% had received on-the-job training, and 22% had received formal pharmacy training.¹⁰¹

1.5 Background - Asthma

The work in this thesis is around the implementation of asthma guidelines to community pharmacy. Asthma was chosen because it is an area of unmet need in terms of healthcare.³⁸ Furthermore, the legislation around asthma medications determines that the role of the pharmacist is even more crucial in ensuring timely intervention and prevention of negative health sequelae, for patients at risk.⁴⁴ A thorough understanding of the disease and its management underpins the methodology in addressing the aims of this thesis.

1.5.1 Definition of asthma

Asthma is a complex, heterogeneous, chronic disease that is difficult to define. Thus it is usually explained in terms of its clinical, physiological and pathological characteristics.⁴² The symptoms of asthma can be controlled, but currently there is no cure for the condition.⁴²,¹⁰⁵ Clinically asthma is characterised by excessive variable lung function and variable respiratory symptoms such as wheeze, cough, shortness of breath and chest tightness.⁴²,¹⁰⁵ Physiological features include airways hyper-responsiveness and intermittent airway narrowing or obstruction resulting from mucous, oedema and bronchoconstriction.⁴²,¹⁰⁵ Pathologically the underlying issue is
chronic airway inflammation. Asthma can result in structural changes to airways, which is sometimes known as remodelling.\textsuperscript{42,105}

1.5.2 Epidemiology of asthma

Asthma is a serious global health problem associated with significant morbidity, mortality and a reduced quality of life.\textsuperscript{38,42} Most recent estimates from the Global Burden of Disease Study undertaken in 2008-2010 suggest that approximately 334 million people worldwide have asthma.\textsuperscript{38} In other recent research, estimates of the prevalence of asthma in adults, in different countries, varies widely and ranges from 0.2\% in China to 21\% in Australia.\textsuperscript{106} However many of these estimates depend on the definition of asthma used. For instance, the prevalence of doctor-diagnosed asthma (in adults aged 18 to 45 years) worldwide has been estimated to be 4.3\% (equating to 301 million people). Using a less stringent definition based on the presence of respiratory symptoms, such as wheeze, puts the figure at 8.6\% (equating to 623 million people) (\textit{Figure 2}).\textsuperscript{106} It is not unreasonable to use a broader definition of asthma,\textsuperscript{106,107} as this ensures inclusion of statistics from developing countries, where limited access to healthcare and medication may not facilitate formal diagnosis.
Although many high-income countries have a high prevalence of asthma, the figures are stable or even decreasing in some age groups in high-income countries. However, the prevalence in low and middle-income countries is increasing. This trend means that variability in the prevalence of asthma across countries is decreasing, but the overall burden of asthma globally is increasing. The decreases in variability are possibly attributed to greater disease awareness and improved diagnosis, while higher prevalence has been linked to increased atopic sensitisation and urbanisation.

Asthma is one of the most common chronic childhood diseases. The International Study of Asthma and Allergies in Childhood (ISAAC) collected data from more than 700 000 school children from 56 countries. The results indicated that the difference in prevalence of asthma in children between countries was large. However, on average about 14% of children globally were likely to have experienced symptoms of asthma in the preceding 12 months.
This high prevalence of asthma in adults and children across the world manifests in a high burden of disease. The burden of a disease is commonly measured by Disability Adjusted Life Years (DALYs) per 100 000 population. A DALY represents the loss of 1 year of healthy life. Asthma accounts for approximately 1% of all DALYs lost, which worldwide, has been estimated to be 15 million per year.\textsuperscript{107} This figure is similar to the DALYs lost due to diabetes\textsuperscript{107} and represents a significant health issue requiring prioritisation.

Much of the burden of asthma comes from disability, especially in younger age groups, rather than years lost due to premature death.\textsuperscript{38} Deaths attributed to asthma are relatively low at less than 1% of all deaths in most countries, although there can be difficulties in determining death rates in older age groups due to confusion with other respiratory diseases.\textsuperscript{38,107} However deaths from asthma are significant and concerning because in most instances they can be prevented with appropriate medical treatment. In developing countries, the issues with mortality may relate to under-diagnosis,
suboptimal medical care and lack of access to high-quality, affordable medicines.\textsuperscript{107} However even in high-income countries, where people have access to high-quality healthcare, mortality rates from asthma remain unacceptably high. A National Review of Asthma Deaths in the United Kingdom in 2014 found that there were major preventable factors identified in the medical care of two-thirds of cases.\textsuperscript{43} It also identified that patients did not call for or receive medical assistance in 45\% of fatal attacks.\textsuperscript{43}

The prevalence of asthma in Australia is high by world standards.\textsuperscript{109} Statistics indicate that, for the year during 2007 to 2008, more than two million people had current asthma (approximately 10\% of the population). In 2014 there were 419 deaths\textsuperscript{110} (representing 0.3\% of all deaths in Australia) due to asthma. Australia added asthma to its list of National Health Priority Areas (NHPAs) in 1999,\textsuperscript{27} and the mortality rate from asthma declined by 45\% between 1997 and 2009.\textsuperscript{109} However mortality rates have remained stable in recent years\textsuperscript{109} and the number of deaths remains unacceptably high.

The disability associated with asthma relates to a reduced quality of life not only due to the physical effects of the disease but also psychological and social effects.\textsuperscript{111} Poor asthma control predicts a poorer disease-specific quality of life and general health status, independent of the severity of disease.\textsuperscript{112} Poor asthma control is characterised by daytime respiratory symptoms, limitations of activities, nocturnal awakenings, need for reliever medications and risk of exacerbations.\textsuperscript{42} Socially and psychologically asthma has been found to negatively impact on career development and be a source of embarrassment.\textsuperscript{113} Greater levels of absenteeism from the workplace and school,
occur in patients with asthma.\textsuperscript{109} It also stops participation in sports and leisure activities\textsuperscript{29} and can cause patients to limit their sexual activity.\textsuperscript{113} People with current asthma, have reported higher levels of psychological distress compared to those without asthma.\textsuperscript{109}

In Australia, in the year during 2007 to 2008, 15.6\% of people with asthma reported having days away from school or work due to their asthma.\textsuperscript{109} A telephone survey of people with current asthma conducted in the year during 2003 to 2004, reported that 14.3\% of adults and 21.4\% of children had an emergency visit to a general practitioner (GP) in the preceding 12 months.\textsuperscript{29} Emergency department (ED) presentations and hospitalisation are considered to be indicators of poorly controlled asthma.\textsuperscript{114} In the same survey, 8.5\% of adults and 15.1\% of children presented at a hospital ED in the preceding 12 months.\textsuperscript{29} While in the year during 2012 to 2013 Australian statistics indicate that there were 37 500 hospitalisations due to asthma.\textsuperscript{115}

Costs associated with hospitalisations, ED presentations and emergency GP visits represent only part of the economic burden of asthma. Medications, in the form of prescription pharmaceuticals, account for approximately 50\% of the total expenditure related to asthma, in Australia: a total, which was estimated at $655 million in the 2008 to 2009 financial year.\textsuperscript{115} However this figure doesn’t quantify the indirect costs associated with asthma. Indirect costs relate to lost productivity both by absenteeism and “presenteeism” (loss of functional capacity at work), as well as costs associated with travel, waiting times and years lost to premature death.\textsuperscript{116} A review of research seeking to quantify the economic burden of asthma found that indirect costs accounted for between 52 and 75\% of overall costs.\textsuperscript{116}
Epidemiological studies demonstrate that asthma continues to be a significant and unresolved health issue. Globally it is the cause of considerable burden to individuals and at a societal level. Australia is no exception and needs to continue efforts to improve asthma management to, reduce mortality, improve patient health and reduce costs associated with the disease.

1.5.3 Diagnosis and clinical presentation of asthma

Asthma can occur at any age, but many patients are diagnosed in childhood. Some children will apparently “grow out” of their asthma and enter long periods of apparent disease remission, with some relapsing in adulthood.\textsuperscript{117} The classic symptoms of asthma are wheezing, cough, chest tightness and dyspnoea.\textsuperscript{42,105,118} Although asthma is a chronic disease, symptoms generally are intermittent, and there can be episodes of acute exacerbations along with asymptomatic intervals.\textsuperscript{118} Some patients with persistent disease, however, can have daily symptoms.\textsuperscript{118} Symptoms are often worse at night or early in the morning but can vary between patients and exacerbations, which increases the diagnostic challenge.\textsuperscript{105,118} There is no single test to confirm a diagnosis of asthma; diagnosis is made based on patient history, physical examination, considering alternative pathologies and using lung function tests to document variable airflow limitation.\textsuperscript{105}

Patient history needs to be thorough given the variable nature of the clinical presentation of asthma. Considerations for diagnosis include the presence of symptoms in response to allergens and triggers, family history of asthma and atopic disease and recurrent symptom patterns. This information is balanced with information that tends to exclude asthma or indicate a differential diagnosis (Table 1).
Table 1: Clinical features relevant to suspected diagnosis of asthma in patients presenting with episodic symptoms

<table>
<thead>
<tr>
<th>Features favouring asthma diagnosis</th>
<th>Features NOT favouring asthma diagnosis</th>
<th>Potential differential diagnoses</th>
</tr>
</thead>
<tbody>
<tr>
<td>• More than one of the following symptoms:</td>
<td>• Dizziness, light-headedness, peripheral tingling</td>
<td>• Chronic Obstructive Pulmonary Disease (COPD)</td>
</tr>
<tr>
<td>o Wheeze</td>
<td>• Isolated cough with no other respiratory symptoms</td>
<td>• Eosinophilic bronchitis</td>
</tr>
<tr>
<td>o Breathlessness</td>
<td>• Chronic sputum production</td>
<td>• Bronchiectasis</td>
</tr>
<tr>
<td>o Chest tightness</td>
<td>• No abnormalities on examination when patient is symptomatic (over several visits)</td>
<td>• Cystic fibrosis</td>
</tr>
<tr>
<td>o Cough (with or without sputum)</td>
<td>• Vocal disturbances</td>
<td>• Chronic rhinosinusitis</td>
</tr>
<tr>
<td>• If the symptoms are:</td>
<td>• Symptoms only present during upper respiratory tract infections</td>
<td>• Gastroesophageal reflux</td>
</tr>
<tr>
<td>o Worse at night or early in the morning</td>
<td>• Significant smoking history (&gt;20 pack-years)</td>
<td>• Obesity</td>
</tr>
<tr>
<td>o Recurrent or seasonal</td>
<td>• Cardiovascular disease</td>
<td>• Hyperventilation and panic attacks</td>
</tr>
<tr>
<td>o Triggered by exercise, cold air, irritants, medicines, allergies, viral infections, laughter</td>
<td>• Normal peak expiratory flow or spirometry results during symptomatic episodes (for repeated tests)</td>
<td>• Vocal cord dysfunction</td>
</tr>
<tr>
<td>• History of atopic disorder (e.g. rhinitis, atopic dermatitis)</td>
<td>• Mechanical obstruction (e.g. tumours)</td>
<td>• Infections</td>
</tr>
<tr>
<td>• Family history of asthma or allergies</td>
<td>• Medications (e.g. ACE Inhibitors)</td>
<td>• Pulmonary embolism</td>
</tr>
<tr>
<td>• Symptom onset in childhood</td>
<td>• Pulmonary embolism</td>
<td>• Congestive heart failure, pulmonary hypertension</td>
</tr>
<tr>
<td>• Widespread wheeze audible on chest auscultation</td>
<td>• Congestive heart failure and pneumonia.</td>
<td></td>
</tr>
<tr>
<td>• Unexplained low peak expiratory flow or low FEV₁</td>
<td>• Eosinophilic bronchitis</td>
<td></td>
</tr>
<tr>
<td>• Unexplained eosinophilia or raised blood IgE levels</td>
<td>• Bronchiectasis</td>
<td></td>
</tr>
<tr>
<td>• Symptoms rapidly relieved by a SABA bronchodilator</td>
<td>• Cystic fibrosis</td>
<td></td>
</tr>
</tbody>
</table>

Adapted from Australian Asthma Handbook and Diagnosis of asthma in adults.105,119

While physical examination is used as a diagnostic tool in asthma, it is not particularly sensitive, due to the variability of the condition.42,119 Often physical examinations may be normal; therefore an absence of physical signs and symptoms does not exclude a diagnosis.119 Several examinations may be necessary to detect signs and symptoms of asthma and even then detection of wheeze does not exclude conditions such as COPD, congestive heart failure and pneumonia.119

Lung function testing provides an objective measure to confirm a suspected diagnosis of asthma. The results of lung function testing also allow for longitudinal disease...
monitoring and have prognostic importance in asthma. Measurements provide assessment of the severity of airflow limitations along with reversibility and variability. The two most widely used testing methods are spirometry, and peak expiratory flow (PEF). Spirometry is the preferred diagnostic tool, however, its reliability is determined by the use of trained and competent individuals to conduct tests and the use of maintained and appropriately calibrated equipment. It is an effort dependent test and currently has limited application in children of preschool age, which increase the difficulty of confirming a diagnosis of asthma in this cohort. The results of spirometry are also less reliable in the elderly (>70 years). Ideally the test is repeated multiple times and undertaken when the patient does not have a respiratory infection.

Spirometry measures the volume and the speed (flow) of air that can be inhaled and exhaled. The most commonly used spirometry measures include:

FVC (Forced Vital Capacity): The maximum volume of air that can be expired (or inspired) during a manoeuvre of maximal effort.

FEV$_1$ (Forced Expired Volume in one second): The volume expired in the first second of a maximal expiration following a maximal inspiration.

FEV$_1$/FVC: A ratio providing a clinically useful measure of airflow limitation.

These measurements can also be repeated post administration of rapid-onset beta$_2$-agonist bronchodilator, to assess response and reversibility of airflow limitation. Diagnostic criteria have been developed based on the results of spirometry testing (Table 2).
Table 2: Diagnostic criteria based on spirometry measures

<table>
<thead>
<tr>
<th>Indications of variable airflow beyond the range seen in a healthy population</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>Increase in FEV&lt;sub&gt;1&lt;/sub&gt;</strong> of at least 200ml and 12% from baseline for adults, or at least 12% from baseline for children, 10 to 15 minutes after the administration of bronchodilator</td>
</tr>
<tr>
<td>• <strong>Change in FEV&lt;sub&gt;1&lt;/sub&gt;</strong> of at least 20% with repeated measures (spirometry undertaken on several separate visits) over time</td>
</tr>
<tr>
<td>• <strong>Decrease in FEV&lt;sub&gt;1&lt;/sub&gt;</strong> of at least 200ml and 12% from baseline after exercise (formal laboratory-based exercise challenge to test for exercise-induced bronchoconstriction)</td>
</tr>
<tr>
<td>• <strong>Increase in FEV&lt;sub&gt;2&lt;/sub&gt;</strong> of at least 200ml and 12% from baseline after a trial of 4 weeks or more treatment with an inhaled corticosteroid</td>
</tr>
<tr>
<td>• <strong>Reduced ratio of FEV&lt;sub&gt;1&lt;/sub&gt;/FVC</strong> based on normal values derived from population studies</td>
</tr>
<tr>
<td>o 0.85 in people aged up to 19 years</td>
</tr>
<tr>
<td>o 0.80 in people aged 20-39 years</td>
</tr>
<tr>
<td>o 0.75 in people aged 40-59 years</td>
</tr>
<tr>
<td>o 0.70 in people aged 60-80 years</td>
</tr>
</tbody>
</table>

(The ratio is less useful in children because normal values vary considerably with age)

Reproduced from the Australian Asthma Handbook<sup>105</sup>

Newer methods are also being explored for diagnostic testing of asthma. It has been suggested that measurements of the fraction of exhaled nitric oxide ($F_{E}NO$) may be a useful non-invasive marker of asthma and patient responsiveness to anti-inflammatory therapy.<sup>123</sup> $F_{E}NO$ has been shown to be elevated in patients with asthma and vary with disease activity. Other biomarkers have also been identified which have the potential to be useful in diagnostic applications; however, there are still issues to be solved in determining standardised assessments and measurement techniques.<sup>124</sup>

Diagnosis of asthma is challenging, particularly in the primary care setting.<sup>125</sup> It is often prompted by a patient presentation with respiratory symptoms and a multifaceted assessment is required. Assessment requires thoroughness and expertise by doctors and confirmation should include objective demonstration of airflow limitation using lung function testing.<sup>119,125</sup> Accurate diagnosis is essential for appropriate treatment and drug therapy initiation. Despite the importance of a considered diagnosis, there is
evidence that there is a lack of objective measurement of lung function. Epidemiological studies in Australia indicate that only 52.9% of patients with self-reported asthma have ever had their breathing measured by a doctor.  

1.5.4 Triggers for asthma

With the burden of chronic diseases escalating globally, the importance of strategies focused on disease prevention and health promotion are increasing. Asthma research continues to investigate potential primary preventative measures, with a focus on genetics, phenotypes and allergic sensitisation (both prenatally and in early childhood). Several hypotheses have been postulated to explain the rising prevalence of asthma including increasing pollution, obesity, dietary changes, the hygiene effect, low levels of vitamin D, and early life exposure to paracetamol. While causation remains unproven, the strongest association with asthma development relates to environmental tobacco smoke and house dust-mite exposure. Current recommendations in Australia include exclusive breastfeeding during the first 4 to 6 months after birth and avoidance of tobacco smoke (both prenatally and postnatal passive-smoke).  

While there is limited and conflicting evidence on risk factors and how to prevent the development of asthma, secondary prevention is considered an important part of optimal asthma management. Secondary prevention is the prevention of symptoms, exacerbations or lung function deterioration for those who have asthma. A wide variety of factors (known as “triggers”) can increase asthma symptoms and precipitate exacerbations. Reducing patient exposure to trigger factors, where possible, is an important secondary preventative measure. Triggers vary between individuals and a person may be susceptible to multiple triggers. Some triggers are
avoidable, but others are ubiquitous and can’t be avoided.\textsuperscript{42,105} For this reason an individual approach is required to identify triggers and develop avoidance strategies. Types of trigger factors include allergens, airborne/environmental irritants, certain medicines, dietary triggers, respiratory infections, co-morbid medical conditions and physiological and psychological changes.\textsuperscript{105,132}

The scientific evidence for triggers and causation of asthma exacerbations is variable and may depend on a patient’s previous sensitisation and exposure. Respiratory tract viral infections have consistently been found to be the most frequent culprit in both adults and children.\textsuperscript{133,134} A recent review from 2014 concluded that environmental trigger exposures with sufficient evidence to show causation of asthma exacerbation include: cat allergen in sensitised individuals; cockroach allergen in sensitised individuals; outdoor mould exposure in sensitised individuals and dampness or dampness-related agents in children.\textsuperscript{131} A summary of common triggers is shown in (Table 3).
Table 3: Summary of asthma triggers

<table>
<thead>
<tr>
<th>Avoidable triggers</th>
<th>Unavoidable triggers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Always avoid</strong></td>
<td><strong>Do not avoid</strong></td>
</tr>
<tr>
<td>• Tobacco smoke</td>
<td>• Exercise</td>
</tr>
<tr>
<td></td>
<td>• Laughter</td>
</tr>
<tr>
<td><strong>Avoid or reduce</strong></td>
<td><strong>Manage</strong></td>
</tr>
<tr>
<td>(Where relevant and practical)</td>
<td></td>
</tr>
<tr>
<td><strong>Allergens</strong></td>
<td></td>
</tr>
<tr>
<td>• Animal allergens</td>
<td>• Certain medicines</td>
</tr>
<tr>
<td>• Cockroaches</td>
<td>• Aspirin</td>
</tr>
<tr>
<td>• House dust mites</td>
<td>• Anticholinesterases and cholinergic agents</td>
</tr>
<tr>
<td>• Moulds</td>
<td></td>
</tr>
<tr>
<td>• Occupational allergens</td>
<td></td>
</tr>
<tr>
<td>• Pollens</td>
<td></td>
</tr>
<tr>
<td>• Thunderstorms (airborne pollens, moulds)</td>
<td></td>
</tr>
<tr>
<td><strong>Airborne/environmental irritants</strong></td>
<td></td>
</tr>
<tr>
<td>• Cold/dry air</td>
<td>• Comorbid medical conditions</td>
</tr>
<tr>
<td>• Fuel combustion (nitrogen dioxide-emitting gas heaters)</td>
<td>• Allergic rhinitis/rhinosinusitis</td>
</tr>
<tr>
<td>• Home renovation materials</td>
<td>• Gastro-oesophageal reflux disease</td>
</tr>
<tr>
<td>• Household aerosols</td>
<td>• Nasal polyposis</td>
</tr>
<tr>
<td>• Moulds (airborne endotoxins)</td>
<td>• Obesity</td>
</tr>
<tr>
<td>• Occupational irritants</td>
<td>• Upper airway dysfunction</td>
</tr>
<tr>
<td>• Outdoor industrial and traffic pollution</td>
<td></td>
</tr>
<tr>
<td>• Perfumes/scents/incense</td>
<td></td>
</tr>
<tr>
<td>• Smoke (e.g. bushfires, indoor wood fires)</td>
<td></td>
</tr>
<tr>
<td>• Thunderstorms (multiple mechanisms)</td>
<td></td>
</tr>
<tr>
<td><strong>Certain medicines</strong></td>
<td></td>
</tr>
<tr>
<td>• Aspirin and NSAIDs</td>
<td></td>
</tr>
<tr>
<td>• Beta-blockers</td>
<td></td>
</tr>
<tr>
<td>• Bee products (pollen, propolis, royal jelly)</td>
<td></td>
</tr>
<tr>
<td>• Echinacea</td>
<td></td>
</tr>
<tr>
<td><strong>Dietary triggers</strong></td>
<td></td>
</tr>
<tr>
<td>• Food chemicals/additives</td>
<td></td>
</tr>
<tr>
<td>• Thermal effects (e.g. cold drinks)</td>
<td></td>
</tr>
</tbody>
</table>

Reproduced from the Australian Asthma Handbook^105

To effectively manage asthma, patients need an understanding of their trigger factors and how they impact on their asthma. The relationship between triggers, symptoms and the pathophysiology of asthma is shown in (Figure 4). Health professional support is essential. For instance, data from 2007-08 in Australia indicated 22.9% of adults with asthma continue to smoke^109, despite evidence that smoking increases the severity of asthma symptoms, accelerates decline in lung function and impairs response to
inhaled corticosteroid medications. The presence of co-morbidities can also compromise asthma management and is associated with increased disease severity. These complexities require a holistic approach to patient care to achieve optimal health outcomes.
1.5.5 Management of asthma

Currently, there is no definitive way to prevent asthma, and there is no cure. However for the vast majority of people with asthma, the clinical manifestations of the disease can be effectively controlled with appropriate treatments currently available.\textsuperscript{42,139} This was clearly highlighted by the large-scale, international Gaining Optimal Asthma Control (GOAL) study. The GOAL study found that guideline-defined asthma control could be achieved and maintained for patients across a wide range of severities, using salmeterol/fluticasone combination drug therapy.\textsuperscript{139} The high burden of asthma is a contradiction to these findings and demonstrates suboptimal management of this chronic disease.\textsuperscript{137} Asthma management remains a challenge because of its variable nature. It requires a patient-centred, individualised and flexible approach.\textsuperscript{137} Management needs to be ongoing rather than intermittent and involve monitoring and treatment adjustment.\textsuperscript{105,128,137} To achieve this, patients require strong partnerships with health professionals and family or caregivers.\textsuperscript{42,140}

The goals for successful asthma management are to:\textsuperscript{42}

- Achieve and maintain symptom control
- Maintain normal activity levels (including exercise)
- Maintain lung function (as close to normal as possible)
- Prevent asthma exacerbations
- Avoid adverse effects (from medications)
- Prevent asthma mortality

Patients empowered with knowledge, confidence and the skills to undertake guided self-management of their asthma are most likely to attain these goals.\textsuperscript{42} Guided self-management entails patients taking an active part in the management of their condition guided and supported by health professionals. Written asthma action plans
are an invaluable tool in self-management and have proven benefits. The use of written asthma action plans has been demonstrated to increase quality of life, decrease nocturnal symptoms, unscheduled GP visits, ED presentations, hospitalisation and days off work or school. Nevertheless, low levels of patient ownership of written asthma action plans remain an issue. This is despite global and localised asthma guidelines recommending their use and strong evidence that self-management utilising written asthma action plans can improve outcomes. Written asthma action plans have been recommended in guidelines in Australia for over 20 years, yet in a National Survey in 2007-2008 less than a quarter of Australians with current asthma reported possession of one.

The primary measure of asthma management is asthma control; which is a measure of control of the manifestations of the disease. In addition to assessment of clinical symptoms, asthma control assessment requires evaluation of future risk of exacerbations, lung function decline and safety of treatment. A number of tools have been developed and validated to quantify asthma control and thus support clinical decision-making. Utility in clinical practice requires that they are concise and easy to administer to patients. A useful validated tool is the Asthma Control Test (Asthma Score). It is a 5-question tool easily administered and appropriate for people with asthma aged over 12 years. The characteristics of asthma control are described in Table 4.
Table 4: Characteristics of asthma control

<table>
<thead>
<tr>
<th>Good control</th>
<th>Partial control</th>
<th>Poor control (Uncontrolled)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL of the following measures present:</td>
<td>ANY one of the following measures present:</td>
<td>THREE or more of the following measures present:</td>
</tr>
<tr>
<td>• Daytime symptoms ≤ 2 days per week</td>
<td>• Daytime symptoms &gt; 2 days per week</td>
<td>• Daytime symptoms &gt; 2 days per week</td>
</tr>
<tr>
<td>• Need for reliever ≤ 2 days per week *</td>
<td>• Need for reliever &gt; 2 days per week *</td>
<td>• Need for reliever &gt; 2 days per week *</td>
</tr>
<tr>
<td>• No limitation of activities</td>
<td>• Any limitation of activities</td>
<td>• Any limitation of activities</td>
</tr>
<tr>
<td>• No symptoms during the night or on waking</td>
<td>• Any symptoms during the night or on waking</td>
<td>• Any symptoms during the night or on waking</td>
</tr>
</tbody>
</table>

*Does not include SABAs taken prophylactically before exercise

Adapted from the Global Strategy for Asthma Management and Prevention (GINA) and Australian Asthma Handbook[^2][^105]

The asthma-control management cycle shown in *Figure 5* demonstrates the continual assessment, monitoring and therapy adjustments required to maintain symptom control due to the variability of asthma.

![Figure 5 – Control-based asthma management cycle](image)

*Reproduced with permission from the Global Strategy for Asthma Management and Prevention 2015© (GINA)[^2]*
1.5.6 Pharmacological treatment of asthma

Medication is the mainstay of asthma management. Medication administration can be oral, parenteral or inhaled, but inhaled is the preferred delivery method because the localised drug deposition allows for the use of the lowest effective dose for treatment and a reduced risk of systemic side effects. Inhaled medications can be delivered directly into the bronchial tree using pressurised metered-dose inhalers (pMDIs), breath-actuated MDIs, dry powder inhaler (DPIs), soft mist inhalers and nebulised or “wet” aerosols. The advantages of inhaled drug administration from pMDIs can be further enhanced by the use of spacers. There are two main classes of medications used to treat asthma: relievers (also called rescue medication) and preventers (also called controllers).

Reliever medications are used for rapid relief of acute asthma symptoms. They are also used prophylactically to prevent exercise-induced asthma. Relievers include short-acting beta₂ agonists (SABAs), which have a rapid onset of action (5-15 minutes) but a short duration of action (3-6 hours). They relax bronchial smooth muscle by stimulating beta₂ adrenoreceptors and thus ease bronchoconstriction. However, SABAs should not be used regularly as monotherapy, because of the increased risk of asthma exacerbations and asthma-related death. This issue first became apparent in epidemiological studies of the drug isoprenaline and subsequently fenterol, both of which are no longer in use for asthma. It continues to be of concern for salbutamol. Frequent use of a SABA, with or without an inhaled corticosteroid (ICS), is an indication of poorly controlled asthma requiring intervention and therapy adjustment. Rapid-onset long-acting beta₂ agonists (LABAs) can also be used as reliever medications. However, all LABAs (rapid onset or not) are contraindicated as
monotherapy and should only be administered as combination therapy with ICS due to potential patient safety issues.\textsuperscript{42,105,138,152,153}

Preventer medications include inhaled corticosteroids (ICS), which are the first line and most effective maintenance treatment for asthma.\textsuperscript{42,105} ICS reduce airway inflammation and control symptoms, but they also improve longer-term outcomes by reducing lung function decline, the risk of exacerbations and risk of death due to asthma.\textsuperscript{42,105,154} Initiation of ICS for asthma is recommended in adult patients experiencing: asthma symptoms twice a month or more, or night waking once or more in the previous month, or with one or more risk factors for exacerbations.\textsuperscript{42,105} Dose adjustments are based on assessment of control and therapy is stepped up and down as needed.\textsuperscript{42,105,138} LABAs represent an effective adjunct to ICS therapy, where asthma control cannot be achieved with ICS alone. The combination of ICS and LABAs represents gold standard therapy for management of persistent asthma.\textsuperscript{42,105,143} A Cochrane review of 77 RCT studies and 21,248 patients assessed the benefit of the addition of LABA to asthma therapy. The review concluded that the combination reduced the rate of exacerbations requiring oral steroids, improved lung function and symptoms, and marginally decreased the use of SABAs. However, the benefits were less conclusive for children. Concerns about the safety of LABAs were not totally ameliorated by the review, but the absence of between-group differences in serious adverse events and withdrawal rates provided some reassurance.\textsuperscript{155} What is less clear is how to step down from ICS/LABA combination therapy when asthma is stabilised. There is limited research on this subject.\textsuperscript{156} Therefore, before therapy is stepped up it is important that health professionals assess the impact of adherence (including
inhaler technique), trigger exposure and comorbidities. The aim is always to titrate to the lowest effective dose.\textsuperscript{42}

*Figure 6 shows the stepped approach to asthma management in adults. A similar approach is used with children.*\textsuperscript{105}

<table>
<thead>
<tr>
<th>Medication</th>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
<th>Step 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliever</td>
<td>As-needed SABA for symptom relief</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preferred preventer option</td>
<td>Consider low dose ICS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Add low-dose ICS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Continue Low-dose ICS add LABA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Or Start low dose ICS/eflornotrol maintenance/reliever therapy*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Increase to Medium/high-dose ICS and continue LABA</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Or Continue ICS/eflornotrol maintenance/reliever therapy but with higher maintenance dose*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refer to specialist for add-on treatment e.g. IgE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 6 – Stepped approach to medication management of asthma in adults

NB Consider stepping down if symptoms controlled for 3 months and low risk of exacerbation

Ceasing ICS not advised due to an increased risk of flare-up

* SABA not required if using ICS/eflornotrol maintenance plus reliever therapy

Adapted from Global Strategy for Asthma Management and Prevention, Australian Asthma Handbook and Therapeutic Guidelines\textsuperscript{42,105,146}

Despite the benefits of regular ICS, medication adherence remains an issue. A novel solution to poor adherence to ICS and intermittent medication-use that is driven in response to symptoms was the introduction of the Single combination budesonide-eflornotrol inhaler maintenance and reliever therapy (SMART) regimen. The rationale is that the patient in effect titrates the dose of ICS in accordance with beta-agonist dosing.\textsuperscript{157} Two large clinical trials (COMPASS and COSMOS) have investigated the use of maintenance/reliever therapy. They compared SMART with fixed-dose ICS/LABA combinations plus “as required” SABA.\textsuperscript{158,159} Both trials indicated the SMART regimen could achieve similar symptom control and greater reductions in severe exacerbations, compared to medium or high dose fixed therapy.\textsuperscript{160} This was achieved with a lower
overall steroid load from SMART. There remains further scope for research to determine the benefit of the SMART regimen for adults with intermittent and mild asthma.\textsuperscript{157}

Treatment of children with ICS is dependent on age and the persistency of symptoms.\textsuperscript{161} Fluticasone is an ICS that is indicated from 1 year of age if necessary. The majority of children tend to experience infrequent intermittent symptoms (< 4-6 weekly) and do not require preventative therapy.\textsuperscript{161} Where asthma is frequent but intermittent and mildly persistent then a non-steroid preventer may be used as an alternative to low-dose ICS.\textsuperscript{161} Many of the concerns around steroid use in children, relate to growth suppression from ICSs.\textsuperscript{162-164} Confounding the issue is the recognition that asthma, as a chronic disease, can suppress growth independent of drug therapy.\textsuperscript{162} Also fear of ICS and consequent under treatment resulting in poor control and exacerbations can lead to periodic treatment with oral corticosteroids, which may pose a greater risk.\textsuperscript{162} Long-term studies have found that ICS has undetectable effects on adult height, despite detectable slowing of growth in pre-pubescent children.\textsuperscript{162} A more recent meta-analysis indicates a difference in growth effects from different ICS drugs, requiring consideration of the choice of drug and more research on newer drugs. It also found that the most pronounced effects on vertical height occur in the first year of treatment.\textsuperscript{164} Current recommendations are that a minimally effective dose of ICS is appropriate in children with asthma.\textsuperscript{163}

Other medications used as adjuncts in asthma treatment or as steroid-sparing medications include chromones, leukotriene receptor antagonists (LTRAs), anticholinergic agents, methylxanthines and anti-immunoglobulin. One of the newer
treatment options for asthma is omalizumab, which is a humanised monoclonal anti-immunoglobulin (anti-IgE) biologic agent.\textsuperscript{165} In Australia, it is approved for use in moderate to severe allergic asthma in patients who have raised IgE levels and have not managed to control their condition with ICSs.\textsuperscript{105} However, its therapeutic benefit is yet to be fully elucidated regarding which patients are best suited to treatment and the optimal time to initiate the drug.\textsuperscript{166} For instance, there is a lack of understanding of the beneficial effects that have been observed in patients with non-allergic asthma phenotypes when treated with omalizumab. There is also interest in the capacity of this drug class to reduce long-term structural changes in the lung.\textsuperscript{167} It is predicted that more drugs in this class will become available for the treatment of asthma.\textsuperscript{165,168} Meanwhile, further studies are required to indicate the long-term comparative safety and the cost-benefit of omalizumab.\textsuperscript{166} Studies are also required to provide a better understanding of the pathophysiology underlying refractory, severe, persistent asthma to target treatments appropriately.

Table 5 outlines the different medications currently used to treat asthma.
Table 5: Medications to treat asthma

<table>
<thead>
<tr>
<th>Treatment type</th>
<th>Pharmacological class</th>
<th>Drugs available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reliever</td>
<td>Short-acting beta₂ agonists (SABAs)</td>
<td>Salbutamol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Terbutaline</td>
</tr>
<tr>
<td></td>
<td>Rapid onset long-acting beta₂ agonists (LABAs)</td>
<td>Eformoterol *</td>
</tr>
<tr>
<td>Preventer</td>
<td>Inhaled corticosteroids (ICS)</td>
<td>Beclomethasone</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Budesonide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ciclesonide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fluticasone propionate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fluticasone furoate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mometasone</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Triamcinolone</td>
</tr>
<tr>
<td></td>
<td>Long-acting beta₂ agonists (LABAs)*</td>
<td>Eformoterol*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Salmeterol*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vilanterol*</td>
</tr>
<tr>
<td></td>
<td>Cromones</td>
<td>Cromoglycate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nedocromil</td>
</tr>
<tr>
<td></td>
<td>Leukotriene receptor antagonist (LTRA)</td>
<td>Montelukast</td>
</tr>
<tr>
<td>Other preventers used as add-on treatments</td>
<td>Anticholinergic agents</td>
<td>Ipratropium bromide</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tiotropium bromide</td>
</tr>
<tr>
<td></td>
<td>Anti-immunoglobulin E (anti-IgE)</td>
<td>Omalizumab</td>
</tr>
<tr>
<td></td>
<td>Methylxanthines</td>
<td>Aminophylline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Theophylline</td>
</tr>
<tr>
<td>Acute asthma treatments</td>
<td>Oral corticosteroids</td>
<td>Prednisolone</td>
</tr>
<tr>
<td></td>
<td>Short-acting beta₂ agonists (SABAs)</td>
<td>Salbutamol</td>
</tr>
<tr>
<td></td>
<td>Anticholinergic agents</td>
<td>Ipratropium</td>
</tr>
<tr>
<td></td>
<td>Oxygen therapy</td>
<td>Oxygen</td>
</tr>
<tr>
<td></td>
<td>Intravenous medications</td>
<td>Magnesium sulphate</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Salbutamol</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aminophylline</td>
</tr>
</tbody>
</table>

Used in combination with an ICS: (monotherapy contraindicated)

Adapted from *Therapeutic guidelines*¹⁴⁶

1.5.7 Patients at increased risk of asthma exacerbations

There is increasing recognition that management of asthma needs to address more than control of day-to-day symptoms.¹⁶⁹ Chronic disease management involves reducing future risk of negative health outcomes and this approach is important but underutilised in asthma.¹⁶⁹ Patients with asthma are susceptible to subacute or acute, abrupt deteriorations in symptoms and lung function.¹⁶⁹,¹⁷⁰ It is recognised that asthma exacerbations and airway damage are less likely in patients with well-controlled asthma symptoms.¹⁷⁰,¹⁷¹ However, even patients with mild or well-
controlled asthma can experience exacerbations. The burden associated with asthma exacerbations is significant to the patient and health care system, but could be reduced by early identification and intervention of patients at risk. Table 6 shows risk factors that have been associated with poor asthma outcomes and exacerbations.

Table 6: Risk factors for poor asthma outcomes and exacerbations

<table>
<thead>
<tr>
<th>Type of risk factor</th>
<th>Risk factor</th>
</tr>
</thead>
</table>
| Risk factors for exacerbation that are modifiable | • Uncontrolled asthma symptoms  
• High SABA use (> 2 canisters per month)  
• Inadequate ICS (not prescribed, poor adherence, poor inhaler technique)  
• Low FEV₁ (<60% of predicted)  
• Major psychological or socioeconomic issues  
• Exposure to triggers (esp smoking or allergens)  
• Presence of co-morbidities (e.g. obesity, rhinitis, confirmed food allergy)  
• Sputum or blood eosinophilia  
• Pregnancy |
| Risk factors for exacerbation based on previous history | • Intubated or admission to intensive care unit for asthma (ever)  
• Severe exacerbations in the previous 12 months (any)  
• Hospitalisation for asthma in the previous 12 months (2 or more)  
• ED presentations for asthma in the previous 12 months (3 or more)  
• Hospitalisation or ED visit in past month  
• History of delayed presentation to hospital  
• History of sudden-onset acute asthma  
• Presence of comorbidities (other chronic lung diseases, cardiovascular disease) |
| Risk factors for airways remodelling and fixed airflow limitation | • Severe exacerbation in patient not taking ICS  
• Exposure to tobacco smoke, noxious chemicals, occupational exposures  
• Low initial FEV₁  
• Chronic mucous hypersecretion  
• Sputum blood eosinophilia |
| Risk factors for medication side effects | • Systemic side effects  
• Frequent oral corticosteroids  
• High dose and or potent ICS used long term  
• Concomitant use of medications that inhibit P450  
• Local side effects  
• High dose or potent ICS  
• Poor inhaler technique |

Adapted from Global Strategy for Asthma Management and Prevention and Australian Asthma Handbook

1.5.8 Current issues in asthma management

In 1999 “Asthma” was added to a list of National Health Priority Areas (NHPAs) due to the significant burden it represented to the Australian community. The NHPA initiative was developed in response to the World Health Organisation’s global strategy “Health for all by the year 2000”. Currently, nine NHPAs are the subject of targeted
programmes by Commonwealth and State and Territory governments, non-government organisations, health experts, clinicians and patients to reduce disease burden.\textsuperscript{27} Despite the various programmes, initiatives and substantial research designed to improve asthma management, many issues remain unresolved and require further attention.\textsuperscript{109} Asthma management issues relate to the patient, health professionals and the health system and result in poorer health and economic outcomes.\textsuperscript{173}

\textit{Patient-related asthma management issues:}

Patient issues include inappropriate use of asthma medications, poor perceptions, beliefs and behaviours around asthma control, poor knowledge influencing behaviour, and poor engagement with self-management.\textsuperscript{173,174} Inappropriate use of asthma medications encompasses underuse of preventer medications, overuse of reliever medications and inappropriate device technique. Non-adherence to drug treatments can be intentional and unintentional, and it can be difficult to comprehend the issues.\textsuperscript{175,176} Intentional behaviours around poor medication adherence are a complex mix of perceptions, attitudes and beliefs, which are often underpinned by a lack of knowledge: social factors can also play a role.\textsuperscript{173,175,177}

Adherence rates to asthma medication regimens have been found to be as low as 50%, and research has demonstrated the significant challenges associated with improving patient compliance.\textsuperscript{177,178} An Australian cross-sectional web-based survey of 2686 patients with asthma, from 2012, reported that 43\% of patients using a preventer medication were compliant with directions less than five times a week, and 31\% less than once a week. A significant proportion of these patients had uncontrolled asthma.\textsuperscript{30} In a study by Sawyer and Fardy in 2003, 37\% of adults reported using a
reliever medication more than four times in the previous week. While in a pharmacy-based survey of patients considered at risk of poor asthma outcomes, 49% of concession patients, obtaining SABAs on prescription, had quantities dispensed equivalent to daily use. A data-mining study by Bereznicki and colleagues confirmed the suboptimal medication use identified in these self-report studies. The algorithm created for the data-mining programme identified patients who had received 3 or more SABA supplies in the preceding six months. These criteria indicated a suspected usage of 3 or more inhalations per day of reliever medication. In total, 2449 patients were initially identified from 42 pharmacies as potentially meeting the inclusion criteria for guideline-based overuse of SABAs. Clearly there are significant issues around the quality use of medicines in asthma.

Asthma medication adherence issues also include suboptimal dosing due to poor inhaler technique. Inhaler devices provide drug delivery directly into the lumen of the airways. This delivery method has the advantages of reducing the systemic dose, achieving more rapid bronchodilation and providing an enhanced duration and effect compared with oral treatments. However, incorrect delivery of the medication reduces effectiveness of the drug, increases side effects and increases costs associated with wasted treatments. Poor inhaler technique is a significant cause of poor asthma control and has been estimated to be a problem in up to 90% of patients, depending on the device. Contributing to the issue is the inadequate technique of health professionals and suboptimal levels of patient device demonstration. It has been estimated that only 15-69% of health professionals across all disciplines can appropriately demonstrate inhaler devices. In a small intervention study in community pharmacy the statistics were even poorer. Results indicated that 87% of
pharmacists could not correctly demonstrate a turbuhaler device and 94% could not demonstrate a diskhaler device prior to the intervention.\textsuperscript{188} The unwillingness of health professionals to provide device counselling may be associated with the observed lack of skills. It could also be attributed to unsupported remuneration pathways. Regardless of the reason, it remains a major issue in current asthma management. Studies confirm that up to 25% of patients have never received any device technique training, while the vast majority only received instruction upon initiation of therapy.\textsuperscript{189} This is consistent with the community pharmacy research by Schneider and colleagues. They found that in 160 patient presentations requesting a non-prescription SABA, no patients were offered inhaler device counselling.\textsuperscript{40} However, with no additional funding for device demonstration, there is little incentive for community pharmacists to provide the service.

Key to appropriate asthma management is the achievement of good asthma control. However, patient beliefs, perceptions and behaviours can be a significant barrier to achieving optimum control. Patients do not necessarily follow health-professional advice; rather they are guided by their own common-sense beliefs.\textsuperscript{173,190} For instance, patients can have beliefs about the seriousness of asthma; what is normal respiratory function; the necessity of medication; the safety of medications; and their ability to impact on their own health; all of which can undermine management.\textsuperscript{173,175,191-193} A postal survey conducted in Australia found that 65% of participants with asthma considered any form of regular treatment as “bad”.\textsuperscript{194} This is consistent with a review that identified 40-70% of patients were uncomfortable using ICSs long-term. In the same review at least 50% of patients refused to adhere to increased doses of ICS prescribed by their doctors due to concerns about the possibility of side effects.\textsuperscript{193}
Patients are known to display asthma acceptance rather than strive for good asthma control.\textsuperscript{113,126,173,193-197} This can lead to patients under-reporting their symptoms and severity, resulting in inappropriate management.\textsuperscript{193}

It is well documented that patient perceptions of asthma control are incongruent with actual asthma control.\textsuperscript{29,113,126,191,195-200} In an observational study by Laforest in 2007, even patients who were highly symptomatic did not perceive that it was indicative of poor disease control.\textsuperscript{191} These beliefs and perceptions in turn shape patient behaviours. For instance, patients who perceive their asthma to be an intermittent acute condition, rather than a chronic condition, are unlikely to use regular preventer medications. This perception has been called the “no symptoms, no asthma” illness perception.\textsuperscript{201} Understanding and influencing patient perceptions, beliefs and behaviours about asthma represents a challenge for health professionals but is an important aspect of good clinical care.

Lack of patient knowledge can also underpin behaviours that interfere with optimal asthma management and worsen outcomes.\textsuperscript{202} A structured review of patient asthma surveys found that patients had inadequate knowledge about the underlying causes of asthma and treatment options. Particularly, there was a lack of understanding of the inflammatory aetiology of asthma and limited knowledge of correct drug usage.\textsuperscript{193} Patient knowledge is crucial given the high degree of self-management necessary, due to the variability of asthma. Targeting patient education appropriately can be difficult and requires a patient-centred, tailored approach.\textsuperscript{202} Improvements in patient asthma knowledge were achieved as part of an intervention study involving a structured six-month intensive asthma service implemented in community pharmacies in the Eastern
states of Australia. The educational interventions were targeted to individual needs and involved three or four patient visits over the six month period of the research. Encouragingly the knowledge gains achieved over 6 months were retained at 12 months.\textsuperscript{202} Similarly, a review of school-based asthma education programmes demonstrated improvements in knowledge in 7 out of 10 studies. However, improvements in the results of other outcome measures were less compelling. For example, improvements in quality of life (4 of 8 studies) and reduced absenteeism (5 of 17 studies).\textsuperscript{203} This demonstrates the complexities of asthma management and indicates that knowledge is only one of the relevant factors.

There is strong evidence of the benefits to health if asthma patients engage in supported self-management.\textsuperscript{142} This requires patients to take responsibility for their health, make informed decisions, and engage in healthy behaviours. In asthma, this entails adherence to medication regimens, avoidance of trigger factors where possible, monitoring and managing the variability of the condition and managing emotional wellbeing. Essential elements in achieving proactive self-management include the use of a written asthma action plan and regular medical review.\textsuperscript{142,204} A National Review of Asthma Deaths from the UK in 2014 highlighted the importance of improving asthma self-management. It found that 45% of people who died from asthma did not ask for or receive any medical assistance in their final attack. Of those who died, 77% did not have a personal asthma action plan, which would have provided details on how to recognise and respond to worsening asthma. Overall asthma management was found to be unsatisfactory in 84% of patients who died, and 67% had at least one major avoidable factor contributing to death.\textsuperscript{43} However, patients are not always motivated to participate in self-management or attend prearranged appointments for review.\textsuperscript{182}
There are issues around patient acceptability of written asthma action plans and an unwillingness to be autonomous when faced with major health decisions. Despite this, asthma patients have indicated a strong desire to be given information about their condition. Therein lays the opportunity for effective engagement by health professionals to improve asthma management.

**Health-professional related asthma management issues:**

Self-management is not the sole responsibility of the patient; health-professional behaviours are just as relevant to improving outcomes in asthma. Figure 7 shows the relationship between self-management and health professional support and demonstrates the importance of communication.

![Figure 7 – Long-term conditions and self-management](image)

*Reproduced with permission from the National Institute for Health Service Research: December 2014*
Increasingly there is recognition of the importance of partnerships and a tailored approach to patient care.\textsuperscript{137,142,196,206} Evidence of this is seen in the recent updates to the GINA guidelines from 2015 that describe a framework for personalised asthma management.\textsuperscript{207} General practitioners (GPs) are the primary coordinators of healthcare to patients with asthma, but their practice has been found to fall short of the ideals of supported self-management and guideline-based care.\textsuperscript{3,126,195,197,208}

The consultation style and communication skills of the health professional are crucial in developing partnerships that foster effective self-management, but there is evidence that improvements are needed. A systematic review found that the quality of communication impacted on health and economic outcomes.\textsuperscript{209} However, Abramson concluded that GPs in Australia had relatively poor insight into self-management practices, social background and trigger factors, even in high-risk asthma patients.\textsuperscript{210} Qualitative research on patients seeking emergency healthcare for asthma revealed that 35\% had poor relationships with their GPs or didn’t have a GP. Many expressed the view that they wished their doctor had more time to sit and listen. Patients were also critical of the medical care they received if they felt doctors hadn’t listened to them.\textsuperscript{206} A survey from 2003 reported that 21\% of patients agreed with the statement, “I do not always understand what my doctor is telling me,” and 29\% agreed, “My doctor does not always have an answer to my questions.”\textsuperscript{179} Despite the scope to improve there were also positive aspects to the patient-doctor relationship documented. Most patients reported being appreciative of an enquiring approach by doctors and doctors who “really” listened and were pro-active.\textsuperscript{206} Evidence of poor communication by pharmacists is indicated by a lack of patient assessment and counselling,\textsuperscript{211} but the nuances of effective two-way communication have been poorly
studied in pharmacists.\textsuperscript{212} This is despite increasing recognition of the importance of community pharmacists as “communicators” in health care requiring specialised skills.\textsuperscript{213,214}

Self-management education is required to empower patients and improve self-efficacy. Self-management education teaches the patient problem-solving skills and written asthma action plans are a crucial tool. However, lack of ownership of written asthma action plans, despite immense evidence of benefit, continues to be a problem. The Australian National Health Survey from 2007-2008 reported ownership levels of 21.3%.\textsuperscript{215} Other statistics on ownership from different subgroups of patients are variable, but all are low. An Australian nationwide telephone survey from 2007 found that 31% of patients with daily symptoms had a written asthma action plan.\textsuperscript{29} A population survey in South Australia indicated that 18.5% of asthma patients possessed a written asthma action plan. However, ownership was more likely (OR 2.3 95\% CI 1.1-4.7; 27\% ownership) if they rated their GPs as more participatory.\textsuperscript{216} A small qualitative study of 62 asthma patients, presenting to hospital emergency departments, found that more than half did not own a written asthma action plan. The most common reason for not having a plan was that their doctor had not given them one.\textsuperscript{217}

As well as patient surveys, research has been undertaken with GP practices. Researchers interviewed 247 GPs from 97 practices and collected data from practice managers. The outcomes around asthma management were found to be poor, but not related to capacity to provide quality service. Despite 75\% of practices having a spirometer, only 12\% of asthma patients were given spirometry tests. Only 30\% had
their inhaler use reviewed, and only 23% of patients had the severity of their asthma assessed. The study also indicated that only 13% of patients from GP surgeries participating were provided with a written asthma action plan.\textsuperscript{195} One reason for GPs failure to provide written asthma action plans may be related to the attitudes of doctors related to controlling their patients’ therapy. One survey of GPs indicated that 90% of doctors declared they wanted to be consulted before any treatment change by patients.\textsuperscript{218} These attitudes are clearly not conducive to supporting self-management.

Another issue that is problematic with GP asthma management is the lack of medical review. The Living with Asthma Survey found that only 50% of patients had been reviewed by a GP in the previous 12 months,\textsuperscript{179} while in the asthma management survey by Matheson, the figure was less than one-third.\textsuperscript{126} These management issues in the GP setting are not simply confined to the chronic disease of asthma. The large-scale CareTrack study looked at 22 conditions, including asthma, to investigate whether patients received appropriate guideline based care. Overall they found that adult Australians received appropriate care only 57% of the time, and the figure for asthma was even lower at 38%.\textsuperscript{3}

While medication adherence is a significant problem in asthma, inappropriate prescribing is another area for improvement. The stepwise approach to medical management requires continual reassessment of therapy and regular review, which is currently occurring inconsistently.\textsuperscript{126,179} Other research has identified under-prescribing of ICS as a contributor to suboptimal asthma control.\textsuperscript{109} The under-prescribing of ICSs was illustrated by a data-mining intervention by Bereznicki, in community pharmacies in Tasmania. The study achieved a three-fold increase in the
preventer-to-reliever ratio of asthma medications compared to control by screening asthma patients and intervening where appropriate and acceptable. By the conclusion of the intervention, a significantly greater proportion of intervention patients were using ICS to manage their asthma.\(^{180}\)

Misdiagnosis, including over and under-diagnosis, continues to be a problem in asthma because of the lack of objective diagnostic criteria, the difficulties with differential diagnoses, and the possibility of mixed respiratory disease. In clinical practice, it can be difficult to determine if symptoms are related to COPD or asthma. This problem is particularly true for older patients and smokers.\(^{42}\) Children also create diagnostic dilemmas with recurrent wheeze occurring in a significant proportion of children aged five years and younger.\(^{42}\) Results from a prospective cohort study in Canada concluded that, based on guideline criteria, up to one-third of the cohort previously diagnosed with asthma, had no evidence of disease. This finding was despite rigorous testing and withdrawal of asthma medications. This over-diagnosis was greater in the subset of obese patients.\(^{219}\) Some of the conditions that can be misdiagnosed as asthma include: Chronic upper airway cough syndrome, vocal cord dysfunction, bronchiectasis, cystic fibrosis, congenital heart disease, COPD, cardiac failure, medication-related cough, parenchymal lung disease, pulmonary embolism and central airway obstruction.

**Health system related asthma management issues:**

Systemic issues are also relevant to the burden associated with asthma. They include health system organisation and policy development, equity in healthcare, economic management, translating evidence into practice, collection of epidemiological data, and public health promotion. The Global Asthma Report from 2014 indicated that all
countries should have national strategies and guidelines for asthma as part of the effort to reduce the worldwide burden of asthma.\textsuperscript{38} There is evidence of the benefits that can be achieved from a systematic approach to disease management. A National Asthma Programme was implemented in Finland between 1994 and 2004. Elements in the programme included: early diagnosis, prompt treatment with anti-inflammatories, guided self-management and effective networking with GPs and pharmacists. The cost savings from the programme were calculated to be between €300-600 million annually.\textsuperscript{220} Other countries to embark on national asthma programmes with measurable successes are Poland and Brazil. A pilot study in Poland significantly increased asthma diagnoses and reduced hospitalisation due to asthma. The length of hospital stays was also reduced. Preliminary population data from Brazil indicates a 74\% reduction in hospitalisation rates.\textsuperscript{220}

Despite Australia having a developed healthcare system, a national asthma strategy, and national guidelines for asthma, suboptimal asthma management remains an issue. The complexity of the Australian system can create problems for the streamlined organisation of care. Policy and funding for health are shared between federal and state/territory governments. Provision of primary care is generally by private practitioners operating as small businesses (GPs, community pharmacists and allied health professionals) supported by federal government funding.\textsuperscript{221} Government funding is provided via Medicare (Australia’s universal health scheme) and the Pharmaceutical Benefits Scheme (Scheme to subsidise prescription drugs). In an effort to improve chronic disease management of asthma, the federal government has developed a number of GP incentive initiatives in recent years. The Asthma 3+ Visit Plan was implemented in 2001-2002 as a new model for managing patients with moderate to severe asthma and involved Service Incentive Payments (SIPs) for GPs. An
amount of $30 million was committed to implementation. The plan outlined a structured approach to asthma management by GPs over at least three patient consultations, which needed to occur in a period of between four weeks and four months. The structured approach incorporated: diagnosis; patient assessment; lung function testing; development of written asthma action plans; patient education; and review. However, uptake of the 3+ Plan was poor and seen by stakeholders as inadequately researched and developed policy. In response to feedback from respiratory physicians, GPs and patients, the Asthma 3+ Visit Plan was replaced by the Asthma Cycle of Care in 2006. This newer programme still involved elements of assessment, planning and review but only required a minimum of 2 asthma-related consultations in a 12-month period. Provision of a written asthma action plan was maintained as a key component. However, Medicare statistics on SIPs from July 2007 to June 2009 indicated that the change to the Asthma 2+ Visit programme had not resulted in greater patient enrolment. Furthermore statistics continue to reflect low levels of written asthma action plan ownership.

Effective organisational structures are required for the coordinated care of patients. Appropriate referral pathways and strategies for managing patient transitions from primary care to acute care settings are needed. However, an asthma case study on the integration of care from rural South Australia demonstrated systemic deficiencies. It identified a poorly coordinated approach to asthma management. A lack of communication between GPs and other health care providers and poor implementation of EBM. Schneider’s research in community pharmacy measured levels of appropriate referral of patients presenting with a cough. If patients were appropriately assessed, they were found to have poorly controlled asthma. The
indications were that appropriate referral was more likely to occur if a pharmacist was involved in consultations, but that this was not routinely occurring.\textsuperscript{41}

Equity can also be an issue in Australia due to sectors of the community, including indigenous populations, living in rural and remote areas. The National Aboriginal Community Controlled Health Organisation (NACCHO) is the peak body that coordinates specialised primary care health services to indigenous populations. However, the age-standardised mortality rates for asthma remain higher in indigenous populations (2.5 times CI: 1.8-3.4) than among other Australians.\textsuperscript{109} The shortage of specialised, coordinated services in rural areas requires primary healthcare to provide more support for local and rural populations. In the research by Kritikos and colleagues, the aim was to use health promotional activities to improve asthma management in high school students in a rural area. The intervention proved successful and improved asthma knowledge and resulted in greater engagement by students with local pharmacists regarding asthma.\textsuperscript{227}

Substantial resources, effort and research have been directed at improving asthma management for many years, but initiatives are continuing to fail to translate to improved health outcomes. The multifactorial nature of the issues is challenging and new avenues to improve outcomes need to be investigated.

1.6 Background – Community pharmacy and asthma

1.6.1 The role of the community pharmacist in asthma management

The high accessibility and clinical training of community pharmacists\textsuperscript{11,12} determines they are well placed to undertake a significant role in asthma management.\textsuperscript{228,229} This
view is also reflected in guidelines for asthma that outline and endorse their role.\textsuperscript{138}

Asthma particularly provides scope for pharmacist involvement due to the intermittent nature of the condition and the high degree of supported patient self-management required.

Research has demonstrated the capacity and potential of community pharmacists to improve clinical, humanistic and economic outcomes for asthma patients.\textsuperscript{228, 230} In a review by Benavides in 2009, evaluating pharmacist involvement in improving asthma outcomes, data were synthesised from fifteen studies conducted in the community pharmacy setting.\textsuperscript{230} Most of the interventions were based on patient education, drug therapy monitoring and assisting self-management. Positive outcomes were achieved for measures of asthma severity, asthma symptoms, lung function, quality of life, ED visits, hospitalisations and direct and indirect cost savings.\textsuperscript{230} In a later review from 2014, Bollmeier investigated community pharmacy-based asthma services to assess current perspectives and consider future directions.\textsuperscript{228} Thirty-three studies were identified including seven studies based on community-pharmacist-patient encounters for asthma post-2008; 10 studies outlining novel approaches to community pharmacy-based asthma programmes; 10 surveys of pharmacists’, physicians’ or patients’ attitudes and six studies involving training of pharmacists to provide asthma services.\textsuperscript{228} Positive outcomes were observed in patient asthma knowledge scores, inhaler device technique, quality of life, asthma control, symptom scores and lung function. However, positive research outcomes need to be tempered by the knowledge that a greater number of pharmacists are required to provide consistent quality asthma services; that services need to be integrated into community pharmacy workflows as part of routine practice; and assessments are required to determine cost
effectiveness to justify and encourage third party remuneration.\textsuperscript{228,229} Another consideration is that many of the asthma programmes implemented in pharmacy practice research have required considerable commitment by participants. Programmes are often labour intensive requiring dedicated pharmacist-time as well as requiring patients to attend multiple visits. Such factors are a barrier to involvement and would make implementation in a sustainable way challenging.\textsuperscript{228}

Several studies have identified barriers to the provision of optimal asthma management and patient care by pharmacists, including a lack of time, lack of confidence and patient-related factors.\textsuperscript{228,231} Another interesting recommendation in the synopsis by Bollmeier was that pharmacist training to provide asthma services should include communication skills training, such as motivational interviewing.\textsuperscript{228} Improving communication skills could potentially improve confidence and overcome patient engagement issues. Despite these perceived issues, many studies have shown that patients have a high degree of satisfaction with expanded asthma services provided by community pharmacists.\textsuperscript{32,36,180,232-235} This demonstrates patient receptivity and the potential to develop this role in a more sustainable way.

Expanded services that have been identified as opportunities for greater participation by community pharmacists in asthma management\textsuperscript{19,229,236} include: patient screening to facilitate early intervention;\textsuperscript{14,229,232,237,238} patient education;\textsuperscript{202} inhaler technique education and review;\textsuperscript{33,239,240} self-management education and support;\textsuperscript{234,241-243} improving quality use of medication and adherence;\textsuperscript{232,244,245} comprehensive disease state management;\textsuperscript{32,35} health promotion and servicing rural and remote populations
where access to services is limited.\textsuperscript{227,246} Also relevant are contributions to smoking cessation and management of co-morbid conditions.\textsuperscript{247}

Currently, community pharmacists already play an important role in the provision of medications to treat asthma, but there is little evidence about routine clinical practice in the community pharmacy setting.\textsuperscript{230} While there are most certainly examples of excellence and expanded clinical roles in asthma in community pharmacy, generally the indications are that current routine practice is variable, suboptimal and there is a lack of translation of research findings.\textsuperscript{40,41,231,248} In the work by Schneider and colleagues, simulated patient methodology was used to assess pharmacy practice in the sale of asthma reliever medications in 160 community pharmacies in the Perth metropolitan area in Western Australia.\textsuperscript{40} The results of this research indicated deficiencies in patient assessment, inadequate medication counselling, universal lack of demonstration of inhaler technique and lack of pharmacist involvement.\textsuperscript{40} Similarly, a long-term intervention aimed at improving pharmacist instruction of patient inhaler technique in Japan, showed at baseline that few pharmacies had demonstration devices to utilise as counselling aids and more than half of pharmacists provided only a medication leaflet or no instruction at all on how to use inhaler devices.\textsuperscript{240}

In Australia, an educational intervention to improve patient inhaler technique recruited 31 community pharmacists.\textsuperscript{188} Very few of the pharmacists were competent to demonstrate correct technique at the initial assessment (Turbuhaler 13%; Diskus/Accuhaler 6%). However, after receiving training, all pharmacists were proficient (100%). This proficiency was maintained at a high level through active involvement in patient demonstrations over a two-year period (Turbuhaler 83%;
Diskus/Accuhaler 75%). This study speaks to the capacity of pharmacists to be trained to provide quality asthma services.

Another area that requires examination before pharmacists can play a more significant role in improving asthma outcomes is collaborative care. Research has demonstrated the ability of pharmacists to provide effective care to asthma patients, but found that most of the interventions made in pharmacies were not communicated to other members of the primary healthcare team.249 In other research, pharmacists reflecting on their involvement in delivery of a specialist asthma service felt they needed more formalised and proactive communication strategies, to better interact with GPs.250 There are measurable benefits to patients with uncontrolled asthma from collaborative management. Positive outcomes include: reduced asthma-related ED visits and hospitalisations, improved asthma control, and improved quality of life.251

While there is scope to improve pharmacy practice in primary care asthma management, deficiencies have also been identified in the quality of care provided by GPs, such as lack of guideline-compliant practice and suboptimal patient outcomes.3,126,195,197 One issue that impedes optimal asthma management by GPs is the lack of routine asthma visits by patients.197,252 This limits the opportunities for patient education and chronic disease management. A telephone survey of 699 patients with asthma conducted in the Eastern states of Australia ascertained that only 50% of respondents had been reviewed by their GP for asthma in the previous year.179 The accessibility of the community pharmacist provides a solution to these barriers. To unlock the potential of community pharmacists, more effort needs to go into the translation of research through implementation science. It is recognised that
medication management and patient health outcomes in asthma are suboptimal. It remains to be seen whether the potential of community pharmacists can be realised to affect change.

1.6.2 Legislation and guidelines governing supply of asthma medications in Australia

In the supply of medications pharmacists are bound by ethical, professional and legal obligations. The Code of Conduct\(^{253}\) and the Code of Ethics\(^{254}\) support pharmacists to deliver health services within an ethical framework. Professional practice is guided by a National Competency Standards Framework\(^{255}\) and measured via Professional Practice Standards.\(^{256}\) Legislation is enforced via State legislative instruments such as the Medicines and Poisons Act\(^{257}\) and Regulations,\(^{258}\) but guided via a national instrument, The Poisons Standard (SUSMP).\(^{104}\)

Currently in Australia, the SUSMP classifies all asthma preventer medications as Schedule 4 (S4) or “Prescription Only” medications. The legislation requires patients to obtain a prescription from a GP to obtain a supply of the medication from their community pharmacy. Prescriptions for ICS can be written with repeat supplies that allow patients to access enough medication for six months, at standard doses, without the need for review by the GP in the interim. Asthma reliever medications are scheduled as S3 or “Pharmacist Only” medications. Patients can purchase these medications from a community pharmacy without a prescription and without needing to visit a GP. The legislative requirement is slightly different for each of the states and territories, but all require the pharmacist to be directly involved in asthma reliever sales and most states require an assessment of patient therapeutic need and provision of directions for the use of the medication.\(^{104}\) This legislation means that pharmacists
in Australia are in a unique position and may be the only health professional with the opportunity to intervene with patients inappropriately self-managing their asthma, using SABA mono-therapy. In recognition of the importance of this role, and in response to the practice deficits uncovered by Schneider and colleagues,\textsuperscript{40,41} the Guidelines for provision of a \textit{Pharmacist Only} medicine: short-acting beta agonists (SABA guidelines) were developed and subsequently endorsed by stakeholders.\textsuperscript{39}

The initial development of the SABA guidelines was part of PhD research into the provision of non-prescription medication by community pharmacists, undertaken by Carl Schneider. The guidelines were developed by consensus using a modified RAND method.\textsuperscript{259} Consultations were with key multidisciplinary stakeholders including consumers in Western Australia. A four-month collaborative initial guideline implementation programme was then instigated across the state in 2010.\textsuperscript{46} This involved passive dissemination to most stakeholders and academic detailing to community pharmacists. Following the statewide implementation, the Pharmaceutical Society of Australia (PSA) and The National Asthma Council of Australia (NAC) refined the guidelines, after further stakeholder consultation at a national level. The final revision of the guidelines was disseminated nationally to pharmacists in 2011.\textsuperscript{39} Since the first dissemination several updated versions have been developed, with the most recent from 2015. Dissemination was via PSA’s online portal for members and printed in the Australian Pharmaceutical Formulary (APF), which is a compulsory reference for registered pharmacy premises in Australia.\textsuperscript{260} The key referral points in the SABA guidelines (indicating a pharmacist should refer a patient to a medical practitioner) include: poor asthma control, no
medical review within previous 6 months, lack of ownership of a written Asthma Action Plan and experiencing an acute asthma attack.

In conjunction with the pharmacy specific guidelines for supply of non-prescription SABAs, the primary asthma guideline for use by Australian health professionals is the Australian Asthma Handbook, which was last updated in 2015. Resources are available to pharmacists to support guideline-based practice from the NAC (http://www.nationalasthma.org.au) and Asthma Australia, which has foundations in each state (http://www.asthmaaustralia.org.au).

1.7 Background – Guidelines and asthma

1.7.1 Key guidelines for asthma

Australia has been at the forefront of initiatives to improve the assessment and management of asthma. The Thoracic Society of Australia and New Zealand were the first countries to publish guidelines for asthma in 1989. Soon after, guidelines were published in the United Kingdom, Canada and the United States. By the mid-1990s an international task force called the Global Initiative for Asthma (GINA) had been established to tackle the worldwide burden and treatment of asthma.

Early guidelines were based on consensus and expert opinion, although opinions were often formed by knowledge of current research studies. With the rise of evidence-based medicine, these principles were incorporated into guideline development and revision. With research expanding the knowledge base on asthma pathophysiology, diagnosis, management and treatment, asthma guidelines are frequently updated to reflect and convey this knowledge. While it is a laborious process to update evidence-
based guidelines as a complete document, the internet has facilitated web-based updates that can be posted more frequently and allow for faster dissemination of current information.\(^{261}\)

Many guidelines that have been produced worldwide which, while similar in structure and format, are often contextualised to reflect localised issues and differing emphases. Widely referenced guidelines include the Australian Guidelines (the Australian Asthma Handbook);\(^{105}\) GINA guidelines;\(^{42}\) National Asthma Education and Prevention Program (NAEPP) guidelines from the US;\(^{138}\) and British Guideline on the Management of Asthma.\(^{143}\) These guidelines are designed to contain materials and resources for all health professionals (including pharmacists), patients and the general public. However, they differ in their usability for different groups. In comparing the guidelines, Myers noted that the Australian guidelines\(^{105}\) are directed more at primary healthcare physicians, whereas the NAEPP guidelines\(^{138}\) may be better suited to respiratory physicians. The GINA guidelines have the advantage of their global perspective on asthma.\(^{42}\)

All of the guidelines mentioned are freely available on the Internet, however, given the continuing burden of asthma, it is apparent the evidence synthesised in asthma guidelines has not been fully integrated into practice. Producing evidence-based, high-quality guidelines is insufficient in health. This thesis seeks to address the gaps in knowledge translation by focussing on the process of guideline implementation.
1.8 Scope of this research

The research in this thesis is grounded in the knowledge outlined in the preceding background literature. A thorough understanding of current knowledge of clinical guidelines implementation research, community pharmacy practice and asthma were required to address the aim of this thesis. The challenge was to synthesise these broad subject areas and relate them to the specific problem of determining how to ensure that the routine practice of community pharmacists, in their incidental encounters with patients with asthma, occurs in line with the best practice guidelines.

The research journey began by linking the concepts of clinical guideline implementation and community pharmacy. This linkage was achieved by examining the scientific evidence for effective guideline implementation strategies specifically in the community pharmacy setting. What interventions had previously been successful in changing the practice of pharmacists towards guideline compliance? What were the common elements? The research then explored the initial implementation of the guidelines. It also explored issues around guideline adherence and optimal asthma management from a variety of stakeholder perspectives, but particularly in relation to community pharmacy. What helped and what hindered pharmacists’ compliance with guidelines? What effect did the behaviour of other stakeholders have on the practice of pharmacists? What would motivate greater guideline compliance? How could things be done differently? The focus then shifted to obtaining a greater understanding of the patient with asthma that the community pharmacist regularly sees. What are their health and medication issues? Do they need community pharmacist intervention? What are their beliefs and how do they affect self-management of the condition? In what way could a community pharmacist support patients?
Having gathered a deeper understanding of the relationship between all the factors explored, this knowledge was applied to developing and undertaking a translational research implementation-intervention to improve SABA guideline compliant practice by community pharmacies in Perth, Western Australia.

Once the implementation-intervention was complete and the resultant change in pharmacy practice had been assessed, the final stage of the thesis research was a robust and analytical evaluation. What were the successful elements of the intervention? What elements could be refined? What newer research methods could be utilised to improve outcomes? Can the research that was undertaken be used to inform future guideline implementation initiatives in community pharmacy? Were the findings relevant to guidelines not associated with asthma? These questions were addressed through a process evaluation and retrospective application of theory using previously developed tools from the literature.

An on-going issue in health is the failure to translate research into practice and policy. Translational research by its very nature is challenging, and increasingly the argument is being made that EBM should be complemented by evidence-based implementation. This thesis outlines the evidence-based, systematic approach taken in addressing the research question of, “What are the strategies for successful implementation of asthma guidelines in the community pharmacy setting?” The lag time in the health translation process has been calculated to be 17 years. This research seeks to discover more and do better!
“Success will never be a big step in the future: success is a small step taken just now.”

(Jonatan Martensson)
1.9 References


Chapter 1


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Chapter 1


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Chapter 2:

Methodological Summary
2.1 Introduction

The studies of this thesis were designed to address the aim outlined in Chapter 1 and are presented as a series of original, published papers comprising chapters 3 to 7. The studies include a systematic review of the literature, a qualitative research study using focus groups, a cross-sectional study, a controlled pre-post intervention study and an evaluation study. This chapter explains the research and analysis methods applied in the studies, and includes exploratory work and thought processes that guided the direction of this thesis.

2.2 Research setting

This research was conducted in the metropolitan area of Perth, the capital city of Western Australia. The population of Perth at June 2014 was 2.02 million people.¹

2.3 Ethics approvals

Approval was obtained from the Human Research Ethics Committee of the University of Western Australia (approval numbers RA/4/1/1588 and RA/4/1/5000) (Appendix 1) in February 2012, for all research in this thesis. An amendment to the original ethics application was submitted and approved in September 2012 (Appendix 1), in response to difficulties with patient recruitment in the pilot cohort study (Chapter 5).

As per ethics requirements, all participants in the overt research (focus groups and survey) including patients, health professionals and non-professional pharmacy staff provided written informed consent. However, covert simulated patient methodology was used in the intervention study to collect outcomes data on pharmacy practice. Pharmacy staff were unaware of their participation and not identified as part of the
data collection. This method determined the participants to be at low risk of harm and
did not allow for a waiver of the usual ethical requirement of informed consent.

2.4 Research methods

2.4.1 Systematic review of the literature (Published paper – Chapter 3)

A systematic review of the literature was completed as the first undertaking of the
information gathering process, to inform the subsequent intervention design. The
review aimed to understand the literature around implementation of clinical
guidelines to community pharmacy. A protocol for the review was published on
PROSPERO, the International Prospective Register of Systematic Reviews
(CRD42012003019) (Appendix 2).

The methodology used in conducting the review was in accordance with the Preferred
Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).²³ A PICO
framework was developed as a basis for evaluating studies for inclusion.⁴ Key to the
search criteria was defining the terms, community pharmacy and clinical guideline.
Community pharmacy was defined as “a retail business registered for the provision of
pharmaceutical services and from which goods and services relating to the provision of
pharmaceutical services may be available.”⁵ Clinical guidelines were defined as
“systematically developed statements to assist practitioner and patient decisions about
appropriate healthcare for specific clinical circumstances.”⁶⁷ It was also important to
make the distinction between guideline-based programmes administered to patients
in community pharmacy, and implementation-interventions administered to
community pharmacy/pharmacists to change usual (routine) practice. The latter being
the information of interest.
Following article selection, a data abstraction table was created. The abstraction table was piloted, revised and populated. Two researchers completed all phases independently. A Kappa score was calculated to indicate the level of agreement of researchers and consensus was achieved using a third researcher as a moderator where necessary. The abstraction table was based on two existing checklists: the Cochrane data collection form (for intervention reviews of randomised controlled trials and non-randomised controlled trials) and the transparent reporting of evaluations with non-randomised designs (TREND) statement checklist.\textsuperscript{8,9} (Appendix 3)

A narrative synthesis was undertaken due to the methodological and clinical heterogeneity of the included studies, which determined that meta-analysis, was not appropriate.

Analysis involved the iterative categorization of studies (using existing taxonomies where appropriate) based on study design, intervention participants, implementation strategy utilised, the underlying basis for intervention, outcome measures and effectiveness. Interventions were categorised using a modified version of the Cochrane Effective Practice and Organisation Care Review Group (EPOC) taxonomy on implementation strategies.\textsuperscript{6} Outcomes were categorised according to an EPOC classification scheme.\textsuperscript{10}

Three quality assessment tools were utilised in appraising the information from the abstracted studies. The EPOC risk of bias tool for Randomised Controlled trials (RCTSs), Non-Randomised Controlled trials (NRCTs) and Controlled Before and After (CBA) studies\textsuperscript{11} and the Newcastle-Ottowa quality assessment scale for cohort studies\textsuperscript{12} were
used to assess risk of bias, depending on the study design. *(Appendix 4)* The Grading of Recommendations, Assessment, Development and Evaluation working group (GRADE) approach\textsuperscript{13} facilitated appraisal of the quality of evidence for outcomes. *(Appendix 5)* The heterogeneity of the study designs in the review created some difficulties in applying the GRADE criteria. It was unclear whether to pool results of studies with similar outcomes or deal with outcomes discretely using the best quality studies (usually considered to come from RCTs). Thus clarification was sought from the GRADE working group in how to appropriately apply the tool.\textsuperscript{14} Two independent reviewers and a moderator at all stages of the review process ensured methodological rigour.

The systematic review yielded a detailed understanding of the best evidence for different guideline implementation strategies in the community pharmacy setting. This study is presented as an original paper in Chapter 3\textsuperscript{15} of this thesis.

### 2.4.2 Qualitative study (Published paper – Chapter 4)

A qualitative research study underpinned epistemologically by pragmatism and using focus groups, was used to expand on the information gathered from the systematic literature review.\textsuperscript{16,17} The aim was to evaluate the initial implementation of the SABA guidelines and a complementary multidisciplinary support tool, the Asthma Action Plan (AAP) card. However, the overarching objective was to understand the successes and failures of this initiative in influencing health professional practice and patient asthma management, to inform future resource implementation. Key stakeholders in asthma management in the primary healthcare setting were recruited to participate in separate focus group sessions. They included: pharmacists, pharmacy assistants, GPs, practice nurses, asthma educators and patients with asthma. Information was collected pertaining to current awareness and use of the SABA guidelines; awareness
and use of the AAP card; as well as generalised issues around achievement of optimal asthma management. An independent and experienced focus group facilitator conducted all the focus groups and the lead researcher took detailed field notes but did not participate in discussions. Facilitator notes were prepared to provide a structured format for the sessions to ensure minimal variance in the delivery style (Appendix 7). All sessions were audiotaped using three recording devices. Data was collected via audio recording transcription, field notes and written summary sheets, completed by participants at the end of the discussions.

Both qualitative and quantitative data were obtained from the focus group study. Count data provided an indication of awareness of the asthma tools (SABA guidelines and Asthma Action Plan card) previously disseminated. Transcripts of discussions, field notes and written summary sheets were analysed thematically to provide an understanding of the barriers and facilitators to optimal asthma management and resource/tool utilisation.

Thematic analysis involved inductive category development\textsuperscript{17,18} and constant comparison.\textsuperscript{17-19} Two researchers completed the analysis independently, with moderation where necessary. The Knowledge, Attitudes and Behaviour theoretical framework and taxonomy was subsequently applied to categorise the identified themes.\textsuperscript{20} The results provided a greater understanding of the factors relevant in promoting guideline-based practice.

This study is presented as an original paper in Chapter 4\textsuperscript{21} of the thesis.
2.4.3 Patient cohort study (Published paper – Chapter 5)

The focus group study and literature review synthesised information about issues with guideline implementation, asthma management and effective strategies for implementing guidelines in the community pharmacy setting. The next study aimed to understand the health needs of the patient with asthma presenting in community pharmacy and extrapolate that information to consider opportunities for intervention. A needs analysis was conducted by way of a cross-sectional study to gain information about how to appropriately target the implementation intervention.

Six literature searches were undertaken to identify validated tools to characterise patient asthma-management. Searches investigated tools to measure facets of asthma management including asthma control, asthma quality of life, medication adherence, asthma knowledge, patient beliefs and self-management. For each discrete topic search, a variety of tools were identified and considered for incorporation into a final comprehensive composite questionnaire. (Appendix 12) Of primary interest were review articles that provided a comparison and critical appraisal of available tools, or suggested a gold standard.\textsuperscript{22-28} Also of interest were tools that had been used previously in an Australian context.\textsuperscript{29-32} Tools were discounted if they required any clinical measurements such as lung function testing.\textsuperscript{33,34} Two researchers conducted the search independently, and five validated tools were chosen by consensus to be included in the comprehensive “Asthma Questionnaire.”\textsuperscript{29,31,32,35-37} Along with the validated tools, demographic and patient history questions were added. These questions were designed to allow for comparison with epidemiological data from the Australian Centre for Asthma Monitoring (ACAM)\textsuperscript{38} and based on a report by ACAM from 2007; “Survey questions for monitoring national asthma indicators.”\textsuperscript{39} Authors
were contacted to obtain permission to use the tools, and in some instances, it was
necessary to apply for a licence. *(Appendix 13)* This review process ensured content
validity of the final questionnaire.

Having developed the questionnaire it was necessary to format the document to
ensure ease of use by patients and researchers. A professional medical survey
company was employed to develop a scannable, high-quality survey instrument.
*(Appendix 14)*

The questionnaire was piloted in a community pharmacy on 24 asthma patients.
Modifications were made to patient recruitment and the Human Research and Ethics
Office approved the amended methodology (as outlined in section 2.3).

Initially, it was anticipated that it would be possible to recruit 50 asthma patients over
a 4-week period from a single pilot pharmacy. This estimate was based on figures
extrapolated from the Pharmacy Guild Digest indicating that approximately 430
patients with asthma visit the average pharmacy once a month.⁴⁰ The initial ethics
requirement was that only pharmacy staff could approach patients. Passive
recruitment was also possible using brochures and signs in the pharmacy. Pharmacy
staff were instructed to obtain consent from patients for researchers to contact them.
The researchers were then able to phone patients to explain the research, obtain
verbal consent to participate, and negotiate a time to meet at the pharmacy, to obtain
written informed consent and administer the survey. This convoluted process proved
difficult for pharmacy staff and researchers. The result was that only 24 patients were
recruited in a 9-week period, despite the highly motivated community pharmacy staff in the selected pilot pharmacy.

Pharmacy staff related problems with participation fatigue and discussing the project multiple times with patients who visited the pharmacy regularly. Researchers found that patients, who were enthusiastic to participate when initially phoned, failed to present at pre-scheduled appointments or phoned and cancelled due to “being busy”. In order to improve recruitment in the cohort study, amendments to the recruitment process were sought.

The amendments allowed for researchers to set up an interview area in consenting pharmacies, which would be remunerated for their time and involvement. The interview area would be negotiated in each workplace with the criteria to minimise disruption to pharmacy workflows and maximise privacy for patients. Banners were created to advertise the study (Figure 1). While researchers were still unable to approach patients directly, their visible presence meant curious patients could approach researchers. Pharmacy staff were also prompted by researcher presence in-store to direct patients to talk to the researchers. Other options were also included in the application for amended patient recruitment methodology to the Human Research and Ethics Office. These included the option to mail asthma patients identified through prescription data mining; and staff recruitment of patients and scheduling of appointments prior to researcher visits by identifying eligible participants who presented for medication, prescriptions and advice. Unlike the pilot study, patients were remunerated for their time for participating in the cohort study, which was envisaged to enhance recruitment. To reduce fatigue and multiple requests for
patients to participate, researchers were only present in each pharmacy for a 2-week period and for a maximum of 8 days during that time.

![Banner advertising asthma survey and research assistant in an interview area in a community pharmacy](image)

Figure 1 – Banner advertising asthma survey and research assistant in an interview area in a community pharmacy

Modifications were also made to the questionnaire based on patient and researcher feedback. The questionnaire was shortened to improve patient usability and reduce the time required for survey administration. Ultimately the changes to recruitment and the survey instrument improved face validity.

A review article\textsuperscript{26} had recommended the use of the Knowledge, Attitude, and Self-Efficacy Asthma Questionnaire (KASE-AQ).\textsuperscript{32} However this proved to be time-consuming and complicated to administer in the pilot. It was replaced with a more recently developed and shorter tool, the 10-item Consumer Asthma Knowledge Questionnaire (CQ),\textsuperscript{41} after clarifying criticisms of an earlier 12-item version of CQ,\textsuperscript{30} by correspondence with the authors.\textsuperscript{42}
A convenience sample of 30 community pharmacies was used as recruitment sites for the cross-sectional study. The pharmacies selected were varied in size and locality. Based on the pilot study results, the aim was to recruit 300 patients. Logistical considerations such as the time frame and resource availability were the main determinants in selection of the sample size. Six research assistants visited five pharmacies in total, spending two weeks (with a maximum of 8 days) at each pharmacy. Data collection times were also variable and included different weekdays, some nights and weekends to capture a variety of demographics and minimise selection bias. The questionnaire was typically self-administered by patients, but researchers were available to clarify any questions if necessary. Researchers also interviewed patients regarding current medications. The interviews concluded with patients having the opportunity to ask researchers (who were Master of Pharmacy students from the University of Western Australia) any questions they had about their asthma or medication.

Data from the cross-sectional study and intervention study were analysed quantitatively. Data was input into SPSS (version 22) (IBM, New York, United States of America) and Excel spreadsheets and analysis was performed using the R environment for statistical computing. Statistical tests were at the 5% significance level.

Scores were tabulated for each validated tool allowing for assessments of patient asthma control, asthma quality of life, medication adherence, asthma knowledge, patient beliefs and self-management. The medication data was manually entered into an Excel spreadsheet and tabulated.
Summary statistics included: counts, percentages, means, standard deviations, medians, maximums and minimums. Descriptive plots were used to compare variables of interest. Univariate and multivariate logistic regression was used to analyse asthma control, whether the patient had a written asthma action plan, whether patients had a life-threatening asthma attack in the past five years, medical presentations and ICS medication. Data was presented using odds ratios, 95% confidence intervals and $p$-values. General linear regression was used to model (log-transformed) medication adherence and (log-transformed) quality of life. For all analyses, variables that were significant at the 5% level were retained in the final model.

Quantitative analysis of the findings from the questionnaire and medication sheet was used to characterise the patient with asthma visiting community pharmacy. Subsequent qualitative analysis mapped the patient characteristics to opportunities for intervention by the community pharmacist. The opportunity assessment was based on potential roles for pharmacists outlined in the scientific literature.$^{44,45}$

This study is presented as an original paper in Chapter 5$^{46}$ of the thesis.

2.4.4 Assessing barriers and facilitators to guideline implementation

The information gathered from the literature review, focus groups and cross-sectional study were used as the basis for designing a common sense intervention to improve SABA-guideline-based patient care in community pharmacies.

From the literature review, two options were identified as having better quality of evidence for achieving successful uptake of guideline-based practice in community pharmacy: tailoring of interventions to barriers and computerised clinical decision
support systems (CDSS). CDSS were discounted as an intervention due to lack of resources and existing initiatives being developed using pharmacy software. Computer software companies were already working with drug companies and the Pharmacy Guild of Australia, using targeted reminders to improve adherence with certain medications. Instead the approach chosen was to consider the many barriers that had been identified and develop an intervention tailored to address one or more barriers.

It was evident from the focus groups and patient questionnaire that there were significant barriers to optimal management of asthma and guideline-based care. These barriers related to patient and practitioner knowledge, attitudes and behaviours. Various ideas were considered to address these barriers. Mass media health promotion was considered to address patient attitudes and resultant self-management behaviours. The development of smartphone apps for patients and health professionals, to address knowledge gaps was another possibility. Further options included changes to remuneration pathways to support development and use of written asthma action plans, legislative change to up-schedule SABA, and the resolution of the significant but largely undefined role that pharmacy assistants had in asthma management. Some of the barriers were beyond the scope of the research to address, but three were investigated more fully as possible intervention options for this research: smartphone apps, legislative change and the role of the pharmacy assistant. Investigations involved consideration of evidence in the literature, the data already collected, logistical constraints, and discussion with experts.
2.4.5 Selecting a feasible intervention

The smartphone intervention was discounted after a search of the scientific literature revealed the large number of asthma smartphone apps already available, as well as two review articles outlining their limitations. Given that well-resourced organisations had produced many of the available apps, including multinational drug companies and government and non-government organisations, it was considered that the resources of this research were not likely to produce any further benefits, to what was already available.

Legislative change was investigated through a written submission and subsequent meeting with the Chief Pharmacist at the Health Department of Western Australia. (Appendix 19) In the focus groups, pharmacists and general practitioners (GPs) had been particularly strong in their opinion to have SABAs up-scheduled to either “Schedule-3 recordable” (S3R) or “Prescription Only” (S4). Pharmacists believed that the “over-the-counter” availability of SABAs gave patients a sense of entitlement to buy the products without question. Many thought that the extra legislative requirement of having to record the sale would enhance their ability to engage patients in discussion and also help change patient perceptions about reliever medications. In addition, pharmacists and GPs commented that mandatory recording would result in useful records of reliever use that would allow for clinical intervention when medication use was inappropriate. While the Chief Pharmacist viewed the submission favourably, the process for mandating legislative change made it unsuitable for the timelines of this research. The Health Department was following the caretaker convention at the time, and new legislation was not being progressed due to

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an upcoming State government election scheduled for the 9th March 2013. This is an avenue that may be explored further in the future.

The final option considered, and the one eventually chosen as the basis for intervention was consideration of the role of pharmacy assistants in SABA sales. It was evident from the focus group results that pharmacy assistants were highly involved in the provision of asthma reliever medications. This finding was consistent with previous research by Schneider but inconsistent with the legislative requirements for direct involvement of a pharmacist (“Pharmacist Only” Schedule 3). Pharmacy assistants revealed that they were attempting to assess patients and provide the medication. This revelation was concerning not only from a legal perspective but also because of the limited education and training of pharmacy assistants and the universal lack of knowledge of the SABA guidelines, evident from the focus group discussions. The work of Schneider demonstrated that outcomes for asthma patients, in terms of appropriate referral, were poorer when pharmacy assistants conducted asthma reliever sales alone.

In order to address the team dynamics in the community pharmacy, and the significant involvement of pharmacy assistants in these consultations, it was necessary to understand why it was occurring. The finding posed a dilemma because even legislation has not been successful in eliciting compliant professional practice by pharmacists, yet research has found that one of the most powerful ways of achieving guideline adherence in general practice is through legislative compulsion. The scientific literature, focus group data and survey data suggested several possible explanations for current practice behaviours: why pharmacists were not following the
legislative requirement for direct involvement, and why pharmacy assistants were undertaking a significant role in the non-prescription supply of SABAs. Firstly, pharmacists may share the relaxed community attitudes towards asthma. Pharmacist themselves may not perceive that asthma is a serious health issue. The survey undertaken in this thesis and a plethora of international research indicate that patients with uncontrolled asthma have difficulty perceiving their level of control, despite the presence of symptoms. Many patients do not consider asthma to be a chronic disease and manage the condition acutely as an intermittent problem. Improvements in asthma treatments in recent decades, such as the introduction of inhaled corticosteroids, have reduced mortality rates and resulted in a community perception that asthma is no longer a significant health problem. However with nearly 400 deaths in Australia per year (most of which are preventable) and significant morbidity, this is not the case.

It could also be that the subtle legislative change gazetted in 2007, from “direct supervision” by a pharmacist to “direct personal sale” by a pharmacist was not implemented effectively. In Western Australia, changes in Poisons legislation are distributed via newsletters from the Pharmaceutical Society of Western Australia. While the implications are substantial, the change in the wording of the legislation is subtle and may have gone unnoticed.

Another reason for the lack of compliance with the legislation is that pharmacists felt that the requirement to personally undertake every Schedule 3 sale, in the retail setting of community pharmacy, was impossible to achieve. Remuneration pathways instead support workflows, which promote fast and efficient product supply. The Guild
Digest (2012) indicates that the average pharmacy dispenses 54 116 prescriptions per year and services 69 000 customers. The majority of pharmacies operate with only one pharmacist on duty at any one time. Pharmacists do not generally make appointments with patients and thus have very little control over how busy they are. While this affords the patient a highly accessible health professional, it does not allow the pharmacist to easily manage their workflows. The focus group data clearly indicated that pharmacists felt that they could not feasibly do everything and had to “run”, “prioritise” and “make choices about what was most important”. Compounding this issue was the perception that the Health Department do not “police” the legislation.

Pharmacy assistants in turn, faced with the lack of immediate availability of the busy pharmacist and the impatient, insistent asthma patient, related (in focus group discussions) that there was extreme pressure to give patients medication without asking any “annoying” questions. Pharmacy assistants recounted feeling disempowered to do anything even when they were aware of the “Pharmacist Only” legal requirement. Many tried to ask a few questions, which they knew was required, but faced with an annoyed patient and a lack of knowledge of what to do with the answers to questions, quickly gave in to patient demands.

From the work of Schneider and colleagues, it was recognised that the most appropriate outcomes, in terms of guideline appropriate patient referral, resulted from pharmacy assistants referring a patient to a pharmacist. Recognition of the situation occurring was the basis for the development of a common sense intervention
to overcome the barrier of community pharmacy team-dynamics and to formalise the role of the pharmacy assistant in SABA sales and asthma management.

2.4.6 Developing an implementation-intervention

The aim of the intervention was to provide pharmacy assistants a clearly outlined, formal role in non-prescription SABA sales that would support pharmacist involvement and best practice through SABA guideline adherence.

A pre-screening and internal referral tool was developed, “The Asthma Medication Checklist”. (Appendix 20) By using the checklist, pharmacy assistants could collect information in a formal way, from sometimes difficult and resistant patients, but not make the assessment, which requires the clinical training of the pharmacist. It aimed to streamline the process for the pharmacist who could use the basic information collected to tailor further questioning and counselling relevant to the patient. As the questions in the pre-screening tool were based on referral criteria in the guidelines at the very least it could easily be used to identify patients who require referral.

One of the important considerations in developing the checklist was how it would fit in to existing workflows in the pharmacy. The Asthma Medication Checklist was designed to look and operate in the same way as an existing tool in community pharmacy, the Emergency Contraception (EC) Checklist. Previous research indicated that the Emergency Contraception Checklist was routinely used as a pre-screening and internal referral tool. The Asthma Medication Checklist also complied with the documentation required for professional service remuneration negotiated in the Fifth Community Pharmacy Agreement (5CPA), providing a financial incentive for pharmacy staff to use the tool.
Remuneration for clinical services has been an on-going issue for the pharmaceutical profession and key in negotiations between the PGA, the PSA and Federal Government when ratifying the Community Pharmacy Agreements. While remuneration did not come up as a significant discussion point in the focus group sessions, time barriers were mentioned (Chapter 4). In order for staffing levels to be appropriate for labour intensive guideline-based counselling of SABAs, it was important to address the investment cost for the required human resources.

An expert panel provided feedback in the development of the Asthma Medication Checklist and on the overall intervention design and aims. The expert panel comprised ten university tutors teaching in the area of pharmacy practice. The majority of the tutors worked on a casual basis for the UWA Master of Pharmacy Program, with their primary role as practising community or hospital pharmacists. Informal consultations were also held with pharmacy assistants from the pharmacy that piloted the patient survey to obtain their opinion on the checklist tool.

To achieve constructive patient interactions and teamwork within the community pharmacy, communication issues needed to be addressed. There was a sentiment from pharmacy staff (pharmacists and pharmacy assistants) that the patient with asthma did not want to engage. This perception resulted in resentment by pharmacy staff and a loss of motivation to try and communicate. It was decided the best way to address this issue was to provide an understanding of the patient perspective and reasoning behind their perceived ambivalence. Documenting a patient story on video was the tool developed to achieve this aim. (Appendix 20) By giving staff insight into
patient attitudes and beliefs, it was anticipated they would have a more empathetic approach with interactions, which would enhance communication.

As there was no direct intervention with patients, it was necessary for pharmacy staff to recognise that the cultural shifts in patient expectation would not change “overnight”. They would still encounter failure with this new approach, and it was important that such failures didn’t undermine motivation. For this reason, a role-play video acknowledging the difficulties that pharmacy staff faced in interaction with asthma patients was also developed as part of the intervention. (Appendix 20)

In choosing the implementation strategy for the intervention there was acknowledgement of success being reliant on the community pharmacy staff working together as a team. Small group workshops were chosen as the implementation method, to be held in the workplace with all (or as many as possible) members of staff, so that all staff could support the intervention. The resources developed for the intervention included booklets of the Asthma Medication Checklist with “tear-off” sheets that would be easy to use, a copy of the SABA guidelines, a PowerPoint presentation and the two videos. The resources were put on a webpage (www.asthma-pharmacy.org), and also provided to pharmacies as a DVD, to deliver ongoing support. Contact was also made with the Asthma Foundation of WA (AFWA) and the National Asthma Council of Australia (NAC) to provide general educational resources for consumers and health professionals that could be disseminated via the workshops. By providing the resources as a DVD and webpage there would be opportunities to train new pharmacy staff and “revisit” information as an ongoing initiative.
During the study, it became necessary to adapt the intervention and include academic detailing as an implementation strategy, due to low uptake of workshop invitations. Academic detailing is also known as educational outreach.\textsuperscript{64} It involves trained researchers visiting health professionals in the workplace to provide them information on how to change practice. The information and resources provided in the academic detailing visits were consistent with the information provided in the workshop.\textit{(Appendix 20)} The difference was that the information was provided to the pharmacist-in-charge at the time of the visit, rather than the pharmacy staff as a team. This required the pharmacist-in-charge to act as a disseminator of information and driver of practice change. It also did not allow for tailoring of the information via group discussion as was achieved in workshops.

\textbf{2.4.7 Controlled intervention study using simulated patient methodology}

\textit{(Published paper – Chapter 6)}

A pre-post controlled intervention study was undertaken to assess the common sense team-based implementation-intervention developed to improve SABA guideline adherence. The control group included pharmacies in the south metropolitan area of Perth while the intervention group included those in the north metropolitan area. The groupings were based on geographical location and known environmental confounders for asthma control. The purpose of the stratification was to reduce potential cross-contamination of data using the Swan River as a geographical barrier. Pilot testing was undertaken in a random sample of 60 community pharmacies (30 south and 30 north) to assess baseline differences in the primary outcome measure of appropriate medical referral.
Community pharmacies in the intervention area (north metropolitan) were invited to participate in the individualised, small group, asthma-training workshop. Academic detailing of workshop content was provided to pharmacies in the intervention area that did not participate in workshops.

Data collection was via simulated patient methodology. Simulated patients were trained in a one-day workshop, which involved role-play and piloting of the scenario in 8 community pharmacies. (Appendix 18) The scenario developed involved a patient requesting purchase of a SABA. Appropriate assessment would determine that the patient had uncontrolled asthma and poor inhaler technique. The appropriate outcome was inhaler technique training and immediate medical referral in accordance with guidelines.\textsuperscript{65,66} Outcomes relating to legislative compliance were also of interest and included increases in pharmacy assistant-to-pharmacist internal referrals or direct involvement of a pharmacist in consultations. Secondary outcomes included the use of the Asthma Checklist, introduced as part of the intervention, and increases in the number of appropriate assessment questions asked by pharmacy staff. Analysis was undertaken between cohorts and between time points.

Covert simulated patient methodology (also called mystery shopping) was chosen to assess outcomes because of its previous use in pharmacy practice research both internationally and in Western Australia.\textsuperscript{52,53,67-70} It has proven to be a robust methodology if correctly applied\textsuperscript{67,71} and has the advantage of eliminating the Hawthorne effect.\textsuperscript{72} The Hawthorne effect refers to the way research subjects modify their behaviour in response to being studied. The covert nature of the simulated patient methodology eliminates changed practice by pharmacy staff in response to
being observed, giving the method face validity. Further validation of the method could have been achieved by the use of audio recording; however this was not within the scope of the ethics approval.

The information collected by the simulated patients was analysed quantitatively. Data was collected under eight categories at pre and post time points and an extra category in the post time point (related to the implementation intervention). These categories included data collected about the: patient, pharmacy, counsellor, consultation, assessment, device use, counselling, use of the AAP card, and use of the Asthma Medication Request Checklist. Summary statistics included: counts, percentages, means, standard deviations, medians, maximums and minimums calculated for each variable for both intervention and non-intervention pharmacies, separated by pre and post times. Descriptive plots were developed for each variable. Pre-baseline Chi-squared tests or Fisher’s exact tests (depending on sample size) were used to compare variables from intervention and non-intervention areas to assess baseline equivalence and validity of the stratification. Chi-squared tests comparing medical referral outcomes for each simulated patient were completed to investigate any potential bias introduced by data collection. Binary logistic regression was used to investigate differences in whether specific questions were asked between cohorts (intervention and non-intervention) and times (pre and post). Data was presented using odds ratios, 95% confidence intervals and p-values. Linear regression was conducted to analyse differences in continuous outcomes between cohorts and times. Data was presented using mean differences, standard error (SE) of the differences and p-values.

This study is presented as an original paper in Chapter 6 of the thesis.
2.4.8 Evaluation study - retrospective application of theory and taxonomies

(Published paper – Chapter 7)

To complete the investigation by this thesis, of the strategies for effective implementation of clinical guidelines to community pharmacy, it was necessary to evaluate the implementation-intervention designed and tested. A qualitative evaluation of the team-based intervention to improve SABA guideline compliant practice was achieved via retrospective application of the: Behaviour Change Wheel (BCW) framework;\textsuperscript{74} the COM-B system,\textsuperscript{74} which analyses behaviour change in terms of capability, opportunity and motivation; Behaviour Change Techniques Taxonomy (BCTTv1);\textsuperscript{74} and the Intervention Taxonomy (ITAX).\textsuperscript{75} This methodology was chosen based on the increasing interest in the use of theory, frameworks and taxonomies evident in the literature, over the time period of the research in this thesis.

The BCW was chosen because of its specific focus on behavioural modification and the focus group discussions had alluded to perceptions and beliefs being detrimental to optimal patient engagement and optimal asthma management. The other frameworks do not necessarily focus on this aspect of implementation (e.g. The Promoting Action on Research Implementation in Health Services framework (PARiHS)\textsuperscript{76} focuses on organisational issues). ITAX was selected again because of its specific focus on process evaluation. As process issues had hampered the implementation it was felt appropriate to investigate this further. Deconstruction of the common sense intervention and retrospective application of these tools provided insight into issues including the theoretical rationale, logistics, fidelity and mechanism of the intervention.
Retrospective application of the BCW framework, COM-B system and BCTTv1 involved completing a series of worksheets and following eight steps as outlined in a guidebook by Michie, Atkins and West from 2014. Application of ITAX required the completion of a taxonomy checklist to detail the elements of the SABA guideline implementation intervention.

The unique methodology was made more robust through the use of a second researcher to check the application process, with discussion and revision where necessary to achieve consensus.

This evaluation process analysed the logistics and the underlying basis (mapped to formalised theory) of the implementation-intervention to consider how the intervention could be approached differently in a future, larger scale implementation.

This study is presented as an original paper in Chapter 7 of the thesis.

2.5 Analytical methods summary

Triangulation, involving qualitative and quantitative research methods, was used in the analysis of data from the research in this thesis. The advantage of using a variety of research methods is that it facilitates exploration of different perspectives and different issues in approaching the aims of a research project. This research involved:

- A systematic review: analysed qualitatively via a narrative synthesis utilising a variety of taxonomies and risk of bias tools
• Focus group research: analysed quantitatively and qualitatively. Quantitatively, using counts; qualitatively via thematic analysis involving constant comparison. A taxonomy was used to categorise outcomes.

• Survey data: analysed quantitatively and qualitatively. Quantitatively, using scores for validated tools, percentages and counts, summary statistics, binary logistic regression, odds ratios and (log-transformed) general linear regression; qualitatively, by relating the results to opportunities for pharmacist intervention

• Intervention data: analysed quantitatively using percentages and counts, Chi squared and Fisher’s exact tests, binary logistic regression, odds ratios and linear regression

• Evaluation data: analysed qualitatively through deconstruction and retrospective application of a behavioural framework and logistics taxonomy.

*Figure 2 indicates how the methods address the overarching aim of this thesis.*
Figure 2 – Flowchart of triangulation methods used to answer thesis aim
2.6 References


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Chapter 3:

A Systematic Review of the Effectiveness of Implementation Strategies for Clinical Guidelines to Community Pharmacy

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3.1 Background

Clinical guidelines are increasingly being developed specifically for community pharmacists. However, development of guidelines does not necessarily lead to translation into health professional practice.\textsuperscript{1-3} While there is an ever-increasing body of research on implementation of clinical guidelines, the evidence remains inconclusive, and there is a gap in the literature regarding implementation of guidelines to the community pharmacy setting.\textsuperscript{4-7}

This chapter aims to provide an understanding of the strategies that have previously been utilised in the implementation of clinical guidelines to community pharmacy, designed to influence routine practice. Of interest are the implementation strategies employed in the intervention, the underlying basis of the intervention, the outcomes measured and their sustainability. Also key to understanding the effectiveness of different implementation strategies is evaluation of the quality of the research.

This relevance of this study to answering the thesis aim lies in providing a clear and comprehensive understanding of the existing evidence available regarding clinical guideline implementation to community pharmacy. The thesis seeks to understand the gaps and build on this knowledge. The findings of the literature review will inform a subsequent evidenced-based implementation-intervention of the SABA guidelines (Chapter 6).\textsuperscript{8}
3.2 Publication

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SYSTEMATIC REVIEW

Effectiveness of implementation strategies for clinical guidelines to community pharmacy: a systematic review

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Abstract

Background: The clinical role of community pharmacists is expanding, as is the use of clinical guidelines in this setting. However, it is unclear which strategies are successful in implementing clinical guidelines and what outcomes can be achieved. The aim of this systematic review is to synthesise the literature on the implementation of clinical guidelines to community pharmacy. The objectives are to describe the implementation strategies used, describe the resulting outcomes and to assess the effectiveness of the strategies.

Methods: A systematic search was performed in six electronic databases (Medline, EMBASE, CINAHL, Web of Science, Informit, Cochrane Library) for relevant articles. Studies were included if they reported on clinical guidelines implementation strategies in the community pharmacy setting. Two researchers completed the full-search strategy, data abstraction and quality assessments independently. A third researcher acted as a moderator. Quality assessments were completed with three validated tools. A narrative synthesis was performed to analyse results.

Results: A total of 1937 articles were retrieved and the titles and abstracts were screened. Full-text screening was completed for 36 articles resulting in 19 articles (reporting on 22 studies) included for review. Implementation strategies were categorised according to a modified version of the EPOC taxonomy. Educational interventions were the most commonly utilised strategy (n = 20), and computerised decision support systems demonstrated the greatest effect (n = 4). Most studies were multifaceted and used more than one implementation strategy (n = 18). Overall outcomes were moderately positive (n = 17) but focused on process (n = 22) rather than patient (n = 3) or economic outcomes (n = 3). Most studies (n = 20) were rated as being of low methodological quality and having low or very low quality of evidence for outcomes.

Conclusions: Studies in this review did not generally have a well thought-out rationale for the choice of implementation strategy. Most utilised educational strategies, but the greatest effect on outcomes was demonstrated using computerised clinical decision support systems. Poor methodology, in the majority of the research, provided insufficient evidence to be conclusive about the best implementation strategies or the benefit of clinical guidelines in this setting. However, the generally positive outcomes across studies and strategies indicate that implementing clinical guidelines to community pharmacy might be beneficial. Improved methodological rigour in future research is required to strengthen the evidence for this hypothesis.


Keywords: Community pharmacy, Pharmacy, Pharmacists, Implementation, Information dissemination, Guideline, Evidence-based medicine

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Background
In the last 30 years, there has been a major shift in healthcare towards evidence-based medicine and the use of clinical guidelines to facilitate evidence-based practice [1–4]. Clinical guidelines are defined as “systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances” [5]. Their primary aim is to improve patient care and, ultimately, patient health outcomes [4]. They also have many potential benefits for health professionals including improved clinical decision-making and consistency of care [4].

While research has demonstrated that clinical guidelines can achieve improvements in health professional practice and patient outcomes, there is substantial variability in observed effectiveness [2, 6]. A recent study in Australia reported that patients receive appropriate, evidence-based care, on average, only 57% of the time [7]. Despite the proliferation of clinical guidelines, there are still barriers in translating the evidence in clinical guidelines into practice across all healthcare settings [8, 9]. This has resulted in an increase in research attempting to identify the factors that influence successful clinical guideline implementation [10].

Development and dissemination of clinical guidelines does not necessarily translate to health professional uptake and adherence [1, 11]. The impact of clinical guidelines depends on the characteristics of the guidelines themselves as well as the implementation strategies employed [12]. Characteristics such as the complexity of guidelines and the evidence base used in their development are important factors influencing uptake into clinical practice [1]. However, the evidence regarding effective implementation strategies is less clear, and in some instances contradictory, as seen in the conflicting conclusions of research in this field [1, 2, 8, 11, 13]. For example, it is still unclear whether multifaceted implementation strategies, that target multiple barriers to implementation or use multiple strategies, are more effective than single strategies, despite the commonly held assumption that a multifaceted approach is superior [1, 2, 14, 15].

These contradictions have led to the recommendation that implementation strategies should be based around a clear rationale, such as overcoming barriers to change (tailored implementation interventions) [14, 16]. However, methodology on how to determine barriers and how to design strategies to address them, is less clear [17, 18].

Recently, the literature regarding guideline implementation has also advocated the use of theoretical frameworks to inform implementation strategies [19–22]. While theory has not been routinely used in implementation research to date, this approach is gaining momentum [23].

Most of the research into guideline implementation has been conducted with medical practitioners and in the hospital setting [1, 2, 23–26]. In the systematic review of guideline dissemination and implementation by Grimshaw, medical practitioners alone were the target of 74% of interventions [2]. There have been a small number of reviews looking at guideline implementation for allied health practitioners, but only a few studies relate to pharmacists, and many were in the hospital setting [13, 16, 22].

Understanding the impact of clinical guidelines in community pharmacy is important, given the expanding role of community pharmacists in primary healthcare. It is acknowledged that community pharmacists are often a patient’s first point of contact with the health system, and in some instances, the only health professional to see a patient [27]. Worldwide, community pharmacy practice is gradually evolving to incorporate the provision of clinical services and a greater focus on patient care [28]. In response to these practice changes, there has been an increase in the development of clinical guidelines for use in this setting. However, little is known about the implementation of clinical guidelines in community pharmacy.

The aim of this systematic review is to synthesise the literature on implementation of clinical guidelines to community pharmacy. The objectives are to:

- Describe the types of implementation strategies utilised.
- Describe the outcomes resulting from guideline implementation at a:
  - Practitioner level: process outcomes measuring community pharmacy practice
  - Patient level: patient outcomes measuring clinical and/or humanistic outcomes
  - Health system level: economic outcomes
- Assess the effectiveness of the implementation strategies.

Methods
The methodology used in conducting this systematic review was in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and checklist, using the accompanying explanation and elaboration document [29, 30]. The review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 27 September 2012 and updated in May 2015 (registration number CRD42012003019) [31].

Search strategy and study selection
After consulting with a librarian from the Medical and Dental Library at the University of Western Australia, a comprehensive search strategy was devised. Search terms and medical subject headings (MeSH headings) chosen were those relevant to “community pharmacy” AND “clinical guidelines” AND “implementation” (Additional file.
1—Search terms. The search was conducted in six electronic databases (Medline, EMBASE, CINAHL, Web of Science, Informit and Cochrane Library) up to and including the 9 November 2014. No restrictions were placed on the search.

The search results from each of the databases were collated. Articles retrieved that were not printed in English were removed along with duplicate results. The decision to remove articles not written in English was based on resource limitations. There is evidence to suggest this was unlikely to introduce systematic bias into this review [32]. Articles were then screened for eligibility based on the previously devised PICO (participants, interventions, comparators, outcomes) framework [33]. Initial titles and abstracts were screened. Full-text screening was undertaken in articles meeting the inclusion criteria or where the abstract provided insufficient information. A final list of articles was identified for inclusion in the review. Two authors (KW and ITW) independently conducted the full-search strategy and eligibility assessment. Discrepancies in study selection were resolved through discussion, and where consensus could not be achieved, by mediation with a third author (CS).

Eligibility criteria

Studies were not excluded based on research design. Experimental, quasi-experimental, intervention and observational studies were all eligible for inclusion. Studies were selected based on the PICO (participants, interventions, comparators, outcomes) framework [33] outlined below.

Participants

Studies were included if the intervention was in the community pharmacy setting. This included interventions directed to professional staff (pharmacists, interns (unregistered pharmacists) and pharmacy students) and pharmacy support staff (pharmacy assistants, pharmacy technicians). The definition of a community pharmacy used was “a retail business registered for the provision of pharmaceutical services and from which goods and services relating to the provision of pharmaceutical services may be available to the public” [34]. Not included in the review were studies set in hospital pharmacies, multidisciplinary medical clinics run by health funds or other private organisations, outpatient clinics, consultant pharmacist services and Accredited Drug Dispensing Outlets (ADDOs).

Interventions

Of interest were interventions involving the implementation of clinical guidelines. Studies were included if they reported dissemination and implementation strategies directed to community pharmacy which aimed to influence behaviour of pharmacists, and/or other staff, towards uptake and adherence of guideline-based practice. Studies were excluded if they were “patient programmes” and not aimed at influencing practice behaviours in the community pharmacy setting. This included interventions where pharmacists were instructed to provide services for the course of the project, but the aim was not to make this “usual practice” for the pharmacist. For example, the paper by Armour and colleagues in 2007, that described a guideline-based asthma management programme [35].

The description of the intervention strategies was a modified version of the Cochrane Effective Practice and Organisation Care Review Group (EPOC) taxonomy’s section on implementation strategies [36]. This included educational materials, educational meetings, educational outreach visits, mass media campaign, audit and feedback, reminders, practice support and fee for service [36]. Also investigated was the basis for the interventions. Interventions were considered “tailored” if barriers to implementation were initially identified and then addressed in the development of the implementation strategy [36, 37]. “Based on theory” was the term for interventions that used a documented theory, model or framework for the design of the intervention [20]. Interventions addressing “organisational culture” represent those interventions that focus on changing some aspect of the community pharmacy as an organisation [36, 38]. These include many constructs such as leadership effectiveness, workflows within the organisation, staffing and time management issues.

The operational definition of clinical guidelines was “systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances” [5, 36]. This definition was chosen on the basis that it has been included in the updated EPOC taxonomy [36] and also been used in two similar reviews with a similar scope, but in different practice settings [1, 16]. In the application of this definition, it was acknowledged that some studies would be excluded, for example, studies that looked at the implementation of practice standards that did not include guidance on clinical activities [39, 40] and articles that looked at policy documents and frameworks [41, 42]. One of the key determinations from the definition was that the guidelines needed to relate to “specific clinical circumstances.” The use of two reviewers and a moderator provided methodological rigour in application of the definition.

Comparators

For most of the studies in this review, the primary comparator was “usual practice”. Usual practice is indicated by no implementation strategy being directed to the community pharmacy to change current practice.
Outcomes

Outcomes were based on the EPOC classification scheme and included patient outcomes, practitioner outcomes and economic outcomes [43]. Patient health outcome measures of interest included, physical health and treatment outcomes (e.g. mortality, morbidity and surrogate physiological health measures) and psychosocial outcomes (e.g. quality of life) [43]. Practitioner/process outcome measures related to quality of care provided by community pharmacy. This included adherence to recommended practice or guidelines (e.g. extent to which health care providers gave appropriate advice, delivered clinical interventions and followed referral guidelines) [43]. Economic outcomes calculated resource use and measured costs and cost savings associated with guideline implementation (e.g. human resources, consumables and equipment) [43]. Secondary (surrogate) outcomes are those that may indirectly reflect important outcomes, including measures such as knowledge, attitudes and satisfaction of both patients and practitioners [43]. Also of interest was how outcomes were determined. Objective measures involve an impartial measurement and are usually considered more reliable than self-reported measures, which are subjective [44]. Examples of objective data include information from medical or health records, while subjective data may be obtained from a self-report questionnaire.

Data abstraction, synthesis and quality assessment

A comprehensive data abstraction table was developed based on two standard checklists: The Cochrane data collection form (for intervention reviews of randomised controlled trials and non-randomised controlled trials) and the transparent reporting of evaluations with non-randomised designs (TREND) statement checklist (for non-randomised evaluations of behavioural and public health interventions) [45, 46]. The data abstraction table was piloted initially using two articles and revised by consensus (KW and HW). Using the revised table, data abstraction was completed independently by two authors (KW and HW). Discrepancies in data abstraction were resolved through discussion, and where consensus could not be achieved, by mediation with a third author (CS).

A narrative synthesis was undertaken because the methodological and clinical heterogeneity of the studies in this review determined that meta-analysis was not appropriate. A narrative synthesis satisfied the aim by considering different implementation strategies and determining their effectiveness in achieving outcomes reflecting the benefit of clinical guidelines in the community pharmacy setting.

Risk of bias was assessed for all studies included in the review. Studies that were either randomised controlled trials (RCTs), non-randomised controlled trials (NRCTs) or controlled before and after studies (CBAs) were evaluated for bias using the EPOC risk of bias tool [47]. Other studies in this review were cohort or quasi-experimental studies and were evaluated for quality using the Newcastle-Ottawa quality assessment scale for cohort studies [48]. These tools were chosen based on the Cochrane recommendation to use a domain-based evaluation for risk of bias assessments, rather than a tool with a summary score [49]. The Newcastle-Ottawa tool was one of only two tools recommended by Deeks in a review of 182 instruments for measuring risk of bias in cohort studies [50].

The Grading of Recommendations Assessment, Development and Evaluation working group (GRADE) approach [51] was used, in conjunction with the risk of bias tools, to evaluate quality of evidence for outcomes. This is because risk of bias can vary across outcomes, a consideration which is often ignored in systematic reviews [52]. To complete the GRADE assessment, worksheets were used to prepare a summary of findings table [53]. This involved a three-step process of assessing the relative importance of all study outcomes, assessing the certainty of evidence across studies for an outcome and summarising the findings [53].

All quality evaluations including risk of bias and quality of evidence for outcomes were completed independently and then by consensus of two authors, KW and HW, with mediation by CS when required.

A critical appraisal of economic outcomes and economic modelling was not undertaken as it was beyond the scope of this review.

Results

Study selection

Searching the databases resulted in a total of 1937 articles. After adjusting for duplicates and non-English language articles, 1446 remained. Title and abstract screening excluded all but 36 articles. Examining the full-text records and reference lists of the remaining 36 articles resulted in 19 articles reporting on 22 studies, meeting the inclusion criteria. Five articles were discussed with the moderator to achieve consensus (Kappa score 0.86) Fig. 1.

Study characteristics including risk of bias assessments

The 22 studies comprised 10 RCTs [54–63], 3 NRCTs [64–66], 1 CBA trial [67] and 8 quasi-experimental or observational studies [68–75] (Tables 1 and 2). The studies were conducted in Australia (n = 8) [54–56, 60, 64, 65, 68, 69], the USA (n = 4) [57–59, 73], the UK (n = 3) [62, 63, 75], the Netherlands (n = 2) [61, 72], Belgium (n = 1) [67], Canada (n = 1) [71], Finland (n = 1) [74], Germany (n = 1) [70] and Switzerland (n = 1) [66]. The time frame for intervention-duration ranged from 1 day to 2 years. The included studies had sample sizes ranging from a group of 8 pharmacists to an
intervention group of 1222 community pharmacies. Power calculations to determine an appropriate sample size were performed in three studies [62, 66, 70].

The 22 studies included in the review were assessed for risk of bias using separate tools depending on the study design. Consensus was achieved through discussion. Moderation was required for one domain ("comparability domain" in the Newcastle-Ottawa tool), which was the main area of disagreement (Tables 3 and 4).

Fourteen studies were assessed using the EPOC risk of bias tool for RCTs, NRCTs and CBA studies. Of these, 11 studies were evaluated as having a high risk of bias [55–59, 61, 63–67] and three studies assessed as having an unclear risk of bias [54, 60, 62]. Several domains contributed to risk of bias in multiple studies. These included, inadequately addressing incomplete data, lack of similarity in baseline measurements and protection from contamination in the study. It was not clear if these
<table>
<thead>
<tr>
<th>First author year</th>
<th>Country</th>
<th>Sample size</th>
<th>Time frame</th>
<th>Clinical area (guideline(s))</th>
<th>Methodology for collecting outcome data</th>
<th>Key finding(s) for main outcome (+, ++, minimal effect, variable results, no evidence of effect)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Curtain, C. et al, 2011 [54]</td>
<td>Australia</td>
<td>Community Pharmacists, Total (n = 188), Intervention (n = 73), Control (n = 112)</td>
<td>12 weeks</td>
<td>Proton pump inhibitors (National Prescribing Service proton pump inhibitor dosage recommendation)</td>
<td>Clinical intervention software data, Prescription data, Patient survey, Economic data</td>
<td>++</td>
</tr>
<tr>
<td>De Almeida Neto, A.C. et al, 2000 [55]</td>
<td>Australia</td>
<td>Pharmacists, Total (n = 43) from community pharmacies, Total (n = 238), Intervention (n = 15 pharmacists, Control (n = 19 pharmacies)</td>
<td>Three-week baseline data collection followed by a 6-week intervention period, immediately after the workshop</td>
<td>Non-prescription drugs—analgesics</td>
<td>Simulated patient methodology, Pharmacist survey</td>
<td>+</td>
</tr>
<tr>
<td>De Almeida Neto, A.C. et al, 2001 Study 1 [56]</td>
<td>Australia</td>
<td>Community Pharmacists, Total (n = 24), Intervention group (n = 16), Control group (n = 8)</td>
<td>Three 4-week periods before and immediately after a 3-h training workshop, and after a further interval of 14 weeks</td>
<td>Non-prescription drugs—analgesics</td>
<td>Simulated patient methodology</td>
<td>++</td>
</tr>
<tr>
<td>De Almeida Neto, A.C. et al, 2001 Study 3 [64]</td>
<td>Australia</td>
<td>Not stated</td>
<td>Three 2-week periods (baseline, post workshop 1 and post workshop 2)</td>
<td>Non-prescription drugs—cough and cold medicines</td>
<td>Simulated patient methodology</td>
<td>++</td>
</tr>
<tr>
<td>De Almeida Neto, A.C. et al, 2001 Study 5 [68]</td>
<td>Australia</td>
<td>Pharmacists and pharmacy assistants from community pharmacies, total (n = 99)</td>
<td>12 weeks of pseudo-random and feedback visits, post a training visit</td>
<td>Non-prescription drugs—heartburn and indigestion treatments (protocol or heartburn management)</td>
<td>Simulated patient methodology</td>
<td>++</td>
</tr>
<tr>
<td>Egen, Y. et al, 2003 [70]</td>
<td>Germany</td>
<td>Gynaecologists, total (n = 111), intervened baseline (n = 24), post intervention (n = 27), pharmacists, total (n = 416), baseline (n = 21), post (n = 27), women in childbearing age (n = 131), post (n = 118)</td>
<td>16 months intervention with interviews pre and post</td>
<td>Folic acid [The Societies of Nutrition, Gynaecology and Obstetrics, Human Genetics, Paediatrics, and Neuroendocrinology jointly issued corresponding recommendations]</td>
<td>Simulated patient methodology, Pharmacist interview, Gynaecologist telephone interview</td>
<td>No evidence of effect</td>
</tr>
<tr>
<td>Source</td>
<td>Country</td>
<td>Practice Setting</td>
<td>Participants</td>
<td>Diabetes Measure</td>
<td>Eligibility Criteria</td>
<td>Findings</td>
</tr>
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<tr>
<td>Guiguis, L.A. et al. 2007</td>
<td>Canada</td>
<td>Practicing pharmacists, Total (n = 8)</td>
<td>Tested the diabetes tool</td>
<td>Participants were introduced to the tools, and their experience was evaluated after 2 weeks. One year later a survey was faxed to investigate any sustained use/change in practice</td>
<td>(Canadian Diabetic Guidelines)</td>
<td>Pharmacist self-report forms, Pharmacists survey, Focus group discussion</td>
</tr>
<tr>
<td>Koester, E.S. et al. 2014</td>
<td>The Netherlands</td>
<td>Community pharmacies, Total (n = 20), Pharmacists, (n = 50)</td>
<td>Dispensing data was collected for the period between 1 Jan, 2008 to 10 May, 2011.</td>
<td>Methotrexate (Safe Methotrexate Dispensing Recommendations published by the Royal Dutch Pharmaceutical Society in accordance with the Dutch Health Care Inspectorate)</td>
<td>Pharmacist-structured interviews, Electronic dispensing records</td>
<td></td>
</tr>
<tr>
<td>Kadian, W.A. et al. 1999</td>
<td>USA</td>
<td>Community pharmacies, Total (n = 90)</td>
<td>Intervention (n = 44)</td>
<td>March 1996 to 30th June 1996</td>
<td>Asthma (Current asthma treatment guideline)</td>
<td>Patient survey No evidence of effect</td>
</tr>
<tr>
<td>Legrand, S.A. et al. 2012</td>
<td>Belgium</td>
<td>Pharmacists, Total (n = 100)</td>
<td>Intervention group (n = 68), Control group (n = 32)</td>
<td>Intervention pharmacists completed a baseline questionnaire, and after a 6-month intervention period participants (including controls) were asked to complete a post-questionnaire</td>
<td>(DRUID (driving under the influence of drugs, alcohol and medicine) project dispensing guidelines)</td>
<td>Medication and driving Pharmacist survey</td>
</tr>
<tr>
<td>Martin, B.A. et al. 2010</td>
<td>USA</td>
<td>Pharmacists, Total (n = 25)</td>
<td>The study was conducted during 2002–2003</td>
<td>Smoking cessation</td>
<td>Pharmacists telephone interviews Invoices submitted—(remuneration claims)</td>
<td></td>
</tr>
<tr>
<td>Naunton, M. et al. 2004</td>
<td>Australia</td>
<td>GPs, Total (n = 200—74% visited)</td>
<td>Baseline data collection</td>
<td>Osteoporosis</td>
<td>Pharmacist survey</td>
<td></td>
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</tbody>
</table>

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The Implementation of Asthma Guidelines to Community Pharmacy: 174
<p>| Table 1 Summary of included studies evaluating implementation of clinical guidelines in community pharmacy (Continued) |
|---|---|---|---|
| Patwarthar, P.D. et al. 2012 [58] USA | Intervention group | Community pharmacies, total (n = 88), Pharmacists (n = 16), Technicians (n = 24), Control group | Smoking cessation |
| | | | Pharmacist self-report forms |
| | | Community pharmacies (n = 88), Pharmacists (n = 16), Technicians (n = 24), | |
| | | | (Treating tobacco use and dependor: Clinical practice guideline re 2008 update) |
| | | | The specific recommendation to use AAR is situations in which the | |
| | | | SA’s approach may not be feasible |
| Poomarlainen, L et al. 2009 [74] Finland | Pharmacists, Total (n = 734) | TIPPA implementation, 4 years (2002-2006). Data collection for this research, 1 month-June 2002 | Guideline-based counselling |
| | | | Pharmacist survey |
| | | | Minimal effect |
| Reisch, D. et al. 1998 [59] USA (New Mexico) Community pharmacies, Total (n = 301) | Keterolac claims were reviewed for 3 months before intervention (Aug - Oct 1995) and for 2 months after intervention (Dec - Feb 1996) | Keterolac |
| | | | Dispersing data |
| | | Intervention (n = 150), Control (n = 151) | (Manufacturers prescribing guidelines for keterolac) |
| | | Data obtained from: Community pharmacies (n = 162), Intervention (n = 90), Control (n = 72) | Economic data |
| | | | Diabetes |
| | | Australia | |</p>
<table>
<thead>
<tr>
<th>Reference</th>
<th>Country</th>
<th>Population</th>
<th>Intervention Details</th>
<th>Control Details</th>
<th>Study Design</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revie, J. F. et al. 2006 [66]</td>
<td>Switzerland</td>
<td>Community pharmacies, total (n = 52), Pharmacists, total (n = 150) recruited to attend training</td>
<td>6-week study period where the computer-generated prompt was active plus another 3-week period where interventions were recorded but the prompt was deactivated</td>
<td>Clinical intervention software data, prescription data, Pharmacist survey</td>
<td>American Diabetes Association Clinical Practice Recommendations, Aspirin therapy in diabetes, Recommendation for the addition of low-dose aspirin therapy to medication regimen of high-risk patients with diabetes</td>
<td></td>
</tr>
<tr>
<td>Sigrist, T. et al. 2003 [66]</td>
<td>Switzerland</td>
<td>Community pharmacies, total (n = 27)</td>
<td>Control (n = 21) pharmacies</td>
<td>2 months</td>
<td>Non-prescription drugs</td>
<td>Simulated patient methodology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention (n = 14)</td>
<td>Control (n = 13), Intervention participants to attend workshops, Pharmacists (n = 30), Pharmacy assistants (n = 63)</td>
<td></td>
<td></td>
<td>Variable results</td>
</tr>
<tr>
<td>Thorley, T. et al. 2009 [76]</td>
<td>UK</td>
<td>Community pharmacies, total (n = 123)</td>
<td>March 2003 (111) implementation communication, mystery shopping data collected over 4 months (May-Aug 2003)</td>
<td>Asthma</td>
<td>Simulated patient methodology</td>
<td>Evidence-based questions (23) from Royal College of Physicians (RCP) to determine patient asthma control and to direct response based on answer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention (n = 37) (18 clusters), Control (n = 34) (18 clusters)</td>
<td></td>
<td>(Protocol for Education at First Dispensing of a Statin (EAFD) and Pharmacist self-report forms</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>Population</td>
<td>Intervention</td>
<td>Comparator</td>
<td>Protocol</td>
<td>Methodology</td>
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<td>EO intervention (n = 15), CPE intervention (n = 15), IOC and CPE intervention (n = 15), Control (n = 15)</td>
<td>July–Nov 2000 post intervention data collection</td>
<td>Drugs—vaginal candidiasis</td>
<td></td>
<td></td>
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<tr>
<td>Watson, M. et al, UK 2007 (63)</td>
<td>Community pharmacies, Total (n = 20)</td>
<td>The Intervention comprised two training sessions 1 month apart (Sept and Oct 2005)</td>
<td>Good pharmacy practice</td>
<td>Pharmacist survey</td>
<td>No evidence of effect</td>
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<tr>
<td></td>
<td>Medication care assistants (n = 20)</td>
<td></td>
<td>Simulated patient methodology</td>
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<tr>
<td></td>
<td>Intervention (n = 20 MCA), Control (n = 10 MCA)</td>
<td></td>
<td>[Royal Pharmaceutical Society of Great Britain (RPSGB) guidelines and WHO-AM guideline: Professionals and good practice guideline for the supply of non-prescription medicine]</td>
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</tbody>
</table>

Key:
- Simulated patient methodology: this involves data collection using covert patients (mystery shoppers) to assess pharmacy practice (95).
<table>
<thead>
<tr>
<th>Table 2: Comparison of studies</th>
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<tr>
<td>Study design</td>
</tr>
<tr>
<td>Randomised controlled trial (RCT)</td>
</tr>
<tr>
<td>Non-randomised controlled trial</td>
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<tr>
<td>Controlled before and after studies</td>
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<tr>
<td>Other</td>
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<tr>
<td>Participants self-selected</td>
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<tr>
<td>Pharmacists</td>
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<tr>
<td>Pharmacy support staff (technicians and assistants)</td>
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<tr>
<td>Other health professionals</td>
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<tr>
<td>Patients/Public</td>
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<tr>
<td>Intervention type</td>
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<tr>
<td>EHRCC taxonomy</td>
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<tr>
<td>Educational materials</td>
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<tr>
<td>Educational meetings</td>
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<tr>
<td>Educational outreach visits</td>
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<td>Mass media campaigns</td>
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<td>Audit and feedback</td>
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<tr>
<td>Reminders</td>
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<td>Practice support</td>
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<td>Fee for service</td>
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<tr>
<td>Basis for intervention</td>
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<tr>
<td>Improve clinical knowledge</td>
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<tr>
<td>Improve communication skills</td>
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<tr>
<td>Based on addressing organisational culture</td>
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<tr>
<td>Based on a specified theory of behaviour change</td>
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<tr>
<td>Based on addressing identified barriers (all three)</td>
</tr>
<tr>
<td>Outcome measures</td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td>Study design</td>
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<tr>
<td>Participants</td>
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<td></td>
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<tr>
<td>Pharmacists</td>
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<tr>
<td>Pharmacy support</td>
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<td>Other health</td>
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<td>Professionals</td>
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<tr>
<td>Patients/Public</td>
</tr>
<tr>
<td>Intervention type (EPDC taxonomy)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Basis for intervention</th>
<th>Reminders</th>
<th>Practice support</th>
<th>Fee for service</th>
<th>Improve clinical knowledge</th>
<th>Improve communication skills</th>
<th>Based on addressing organisational culture</th>
<th>Based on a specified theory of behaviour change</th>
<th>Based on addressing identified barriers (behaviour)</th>
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<td>Practitioner outcomes—subjective measures</td>
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<td>✓</td>
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<td>Overall effective in achieving main outcomes</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Key:**
- Educational materials: distribution of educational materials to support guideline-based practice (paper-based, electronic, patient focused, practice tools), disseminated by mail, email or in-person. Educational meetings: conferences, lectures or workshops.
- Educational outreach visits: use of a trained person to meet with health professionals to give information with the intent of changing the professional’s practice. Includes academic detailing.
- Mass media: use of communication that reaches a large number of people including television, radio, newspapers etc. targeted at a population level. Audits and feedbacks: any summary of clinical performance, which may also include recommendations for clinical action.
- Reminders: interventions involving computer prompts to support practice.
- Practice support: follow-up contact (e.g., visits or phone calls) to provide motivation and support to practitioners post education.
Table 3: Results of risk of bias assessment using the EPOC risk of bias tool for RCTs, NRCs, CBA studies.

<table>
<thead>
<tr>
<th>Reference (DPD risk of bias tool)</th>
<th>Low risk of bias</th>
<th>High risk of bias</th>
<th>Overall assessment within a study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenny et al., 2013</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>De Almeida et al., 2012</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>De Almeida et al., 2013</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>Knudsen et al., 2014</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>Leung et al., 2015</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>Neumann et al., 2016</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>Penna et al., 2017</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>Reich et al., 2018</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>Sigit et al., 2021</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>Van den Boogaard et al., 2022</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>Watson et al., 2022</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
<tr>
<td>Watson et al., 2023</td>
<td>+ +</td>
<td>+ +</td>
<td>+ +</td>
</tr>
</tbody>
</table>

Key: + Assessed as "low risk" of bias; $+$ Assessed as "unclear risk" of bias; ++ Assessed as "high risk" of bias.

Inadequacies were due to lack of reporting or flaws in research design. Two of the studies evaluated as having an overall unclear risk of bias used implementation strategies involving a computer prompt [54, 60]. The Newcastle-Ottawa tool for cohort studies was used to evaluate eight studies [68–75]. The study by Egen showed the least risk of bias with the domains around selection of study groups and outcomes deemed low risk [70]. However, like all of the cohort studies, in this review, the study design or analysis meant the comparability of cohorts could be a source of bias. There was little to suggest that studies had used measures to correct for confounding variables in any of the eight studies evaluated.

Use of the two risk of bias tools lead to the observation that many of the studies in this review were subject to selection bias and performance bias. Selection bias was inherent in the self-selection of study participants. Self-selection of participants occurred in 18 of the 22 studies, even if randomisation methods were subsequently used [54–58, 60–64, 66–69, 71–74]. Performance bias relates to the propensity for the studies to be threatened by the Hawthorne effect, which is the tendency to modify behaviour when being observed [76, 77]. Simulated patient
methodology is one method that has been used in pharmacy-practice research to avoid the Hawthorne effect [78]. In this review, simulated patient methodology was used in two studies [55, 56, 62–64, 66, 68–70, 75]. However, in most instances, the studies used the simulated patients overly rather than covertly, which while ethically sound, does not eliminate the risk of bias.

**Implementation strategies and their effectiveness**

The areas of clinical practice that guideline implementation were designed to impact were varied. They involved chronic disease states [57, 60, 65, 71, 73], guidelines for the supply of particular classes of medications [55, 56, 59, 61, 64, 66, 69–70, 72], community pharmacy’s role in preventative health [58, 67, 73] and guidelines for appropriate pharmacy practice [63, 74]. The variation did not allow for any conclusions to be made about the effectiveness of implementation based on guideline characteristics.

Implementation activities were targeted to community pharmacy and, in particular to pharmacists in 20 studies [54–62, 66–75] and pharmacy support staff in 11 studies [56, 58, 61–64, 66, 68, 69, 72, 75]. In two studies, implementation activities were directed exclusively to pharmacy support staff, while three studies involved implementation activities to other health professionals and/or patients as well as community pharmacy staff [58, 65, 70]. Both the studies in this review involving comparisons between professional and support staff demonstrated that better outcomes were achieved when the patient encountered a pharmacist [62, 75].

Eighteen studies involved multifaceted interventions [54–58, 60, 62–70, 73–75], and single intervention strategies were used in four studies [59, 63, 71, 72]. The multifaceted nature of the majority of implementation strategies did not allow for a clear understanding of the effectiveness of individual strategies. Overall, eight different implementation strategies were reported in studies in the review including, use of educational materials, educational meetings, educational outreach visits, mass media campaigns, audit and feedback, reminders (including CDSS), practice support and fee for service.

The most commonly used implementation strategies were educational interventions. All but two of the studies in the review had an educational component in their intervention including provision of educational materials, educational meetings or educational outreach visits [54–59, 61–70, 72–75]. Seven studies used educational strategies exclusively [59, 63, 65, 72–75]. Of these, two studies used behaviour change theory to inform the intervention [63, 73] resulting in variable outcomes. The

### Table 4 Results of risk of bias assessment using the Newcastle-Ottawa risk of bias tool for cohort studies

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection</td>
<td>Representativeness of the exposed cohort</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Selection of the non-exposed cohort</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Ascertainment of the exposure</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Demonstration of outcome</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>was not present at start of the study</td>
<td>-</td>
<td>-</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>-</td>
</tr>
<tr>
<td>Composability</td>
<td>Comparability of cohorts on the basis of the design or analysis</td>
<td>-</td>
<td>-</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td>Outcome</td>
<td>Assessment of outcome</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Was follow-up long enough for outcomes to occur</td>
<td>-</td>
<td>-</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Adequacy of follow-up cohorts</td>
<td>-</td>
<td>-</td>
<td></td>
<td>*</td>
<td>*</td>
<td>*</td>
<td>*</td>
</tr>
</tbody>
</table>

Reference: Newcastle Ottawa Quality Assessment Scale

NB. Where interventions were directed to more than one group analysis was only for the component that related to community pharmacy.

Key:
- Selection of study groups (1 to 3 stars allowed for each item)
- Comparability of the groups (up to 2 stars allowed)
- Outcome (up to 2 stars allowed for each item)
remaining five studies achieved modest positive outcomes. Educational outreach visits (sometimes called academic detailing) were undertaken in three studies [62, 65, 70]. One of the studies by Watson compared educational outreach and education meetings, individually and in combination, against a control [62]. This study did not demonstrate effectiveness for either strategy.

In six studies, educational interventions were combined with audit and feedback [55, 56, 64, 66, 68, 69]. Bennett and colleagues authored all of these studies. Five of the studies (from two papers) were in collaboration with De Almeida Neto [55, 56, 64, 68, 69] as the primary author, and one study was in collaboration with Sigrist [66] as the primary author. The studies using audit and feedback were generally effective. All reported positive outcomes except one, which had variable outcomes [66].

Practice support, in the form of follow-up visits, phone calls or provision of practice tools (e.g. checklists, patient handouts, documentation forms), was used in seven studies [55, 56, 58, 60–62]. Only one study used practice support as a single intervention [71]. The study was a pilot study that provided pharmacists with practice tools for diabetes management. The proposed method was to implement the tools in conjunction with an education programme; however, the education programme was not available for the pilot study. The use of the practice support tools alone resulted in a modest positive outcome.

Computer prompts, as reminders to support practice change, were the used in four studies [54, 57, 60, 67, 71]. The studies using this implementation strategy in the community pharmacy setting produced variable outcomes. The sub-studies by Curtain and Reeve [54, 60], which were both part of the larger Pharmacy Recording of Medication and Services (PROMIS) project [79], demonstrated very strong evidence of effect, whereas the study by Krijan [57] demonstrated no effect. The strongly positive outcomes and comparatively robust methodology, seen in the Curtain [54] and Reeve [60] studies, indicate the best evidence for effectiveness of an implementation strategy in the community pharmacy setting.

The study by Egen used an intensive mass media campaign along with specific educational interventions directed to pharmacists and gynaecologists [70]. This multifaceted approach did not demonstrate evidence of effect in pharmacist- or patient-outcome measures.

A monetary incentive (fee for service) was only used in one study as an implementation strategy [57]. However, it was part of a multifaceted implementation, which also involved educational interventions and reminders. There was no evidence of effectiveness demonstrated.

**Basis for implementation strategies**
Most implementation strategies were educational and designed to improve knowledge and/or communication skills. However, this choice of implementation strategy was, in almost all instances, not based on an identified deficit in these areas. Tailored implementation strategies, based on addressing identified barriers to successful guideline implementation, were only evident in two studies [61, 63]. The barriers identified included, organisational barriers, knowledge deficits, social factors such as patient indifference and suboptimal communication by non-professional pharmacy staff. Both the studies, which used tailored strategies, were ineffective in producing positive primary outcomes. Two other studies also addressed organisational factors (including workflow and time constraints), but without mentioning that the choice of strategy was tailored [58, 71]. Both proved to be moderately effective. Studies were based on specific behaviour theories or frameworks in six instances [55, 56, 58, 63, 66, 73]. The behavioural theories, frameworks and strategies used included "Motivational Interviewing" techniques [55], "Stages of Change Model" [55, 56, 66], "Trans-theoretical Model for Change" [73], "Social Cognitive Theory" [58], "Health Beliefs Model" [66], "Theory of Planned Behaviour" [63], "Calgary-Cambridge Model of Communication Skills" [63] and "Cognitive Behavioural Therapy" [63] techniques. Despite most of the studies in this review reporting positive outcomes, two out of six studies based on behaviour change models did not [63, 66].

**Characteristics of outcome measures including quality of evidence assessments**
Fifteen studies [54–56, 58–60, 64, 65, 67–69, 71–73, 75] reported positive outcomes as a result of clinical guideline implementation. Five studies indicated no significant improvement in primary outcomes measures as a result of the implementation strategy [57, 61–63, 70] and two studies reported minimal or variable results [66, 74]. Almost all studies reported multiple outcomes making assessment of primary outcomes difficult. Objective measures were used to report outcomes in 18 studies [54–56, 59–69, 71, 73–75]. Self-reported outcomes, both patient and practitioner outcomes, were included in 15 studies [54, 55, 57, 58, 60–63, 65, 67, 70–74]. In many instances, these outcomes were assessed via novel un-validated tools, modified validated tools or the reporting was inadequate to ascertain validity and reliability of the tool. Such measures are of limited benefit in evaluating successful guideline implementation. Surrogate measures were used in nine studies and included assessments of attitudes, self-efficacy, and patient and practitioner satisfaction/acceptability of interventions [55, 57, 60, 61, 65, 67, 71, 73, 74]. Four studies did not use any objective measures and relied upon self-reported (subjective) measures [57, 67, 71, 74].
All studies in the review measured process outcomes related to changes in the practice of community pharmacy staff. Patient outcomes were only measured in three studies and all relied upon self-reported outcomes using patient surveys [54, 57, 70]. Only one of the patient outcomes measured was based on a health outcome, but it was a surrogate measure for perceived asthma control [57]. The lack of measurement of robust (objective) patient outcomes determines that few conclusions can be made about the evidence of effectiveness for implementation of guidelines to community pharmacy.

Most studies did not comment on sustainability of outcomes or mentioned it as a limitation of the research. Sustainable practice change was noted in two studies, but the sample sizes were small [71, 73]. Four studies indicated a decline in outcomes over the course of data collection [54, 60, 61, 71]. One study indicated that ongoing communication was required for sustainability [75]. Thus there is little evidence that the positive outcomes generated by implementation of clinical guidelines in most of the studies, are sustainable effects.

Economic outcomes were determined in three studies [54, 59, 62]. All the economic evaluations looked at different measurements. These included the cost of implementing guidelines [62], cost savings to the health system due to improved guideline adherence [54] and an attempt at a more thorough cost-benefit analysis [59]. No analysis was undertaken to assess the quality of the economic modelling undertaken.

Six primary outcome measures were agreed upon and assessed using the GRADE approach [51]. Five outcomes were assessed as having very low quality of evidence. One outcome was assessed as having low quality of evidence. The main reasons for this were the heterogeneity of the studies, variability of outcomes and the potential for bias in studies. None of the outcomes were considered to have moderate or high quality of evidence. Thus, even though the studies demonstrated positive outcomes from clinical guideline implementation, these outcomes are generally not a reliable indication of the likely effect. The likelihood that the effect will be substantially different is very high (Table 5).

Discussion
This systematic review expands on the limited research into guideline implementation to allied health practitioners [13, 16] and the extensive research on guideline implementation to medical practitioners in hospitals and the primary healthcare setting [1, 2, 25, 26]. The findings of this review indicate that there is a growing body of evidence on clinical guideline implementation to community pharmacy, but conclusions that can be drawn from this evidence are limited. Many studies lack rigour in their methodology and are at risk of substantial bias.

There is also a great deal of variability in the studies in this field making analysis challenging. The studies to date generally do not provide evidence of a grounded approach to the development of their implementation strategies. The strategies employed are mostly multifaceted, with an over-reliance on educational interventions. Reporting of multiple outcomes complicates assessment of the effectiveness of clinical guidelines implementation. The focus for outcomes is on process and surrogate outcomes, rather than patient outcomes, and the quality of evidence for outcomes is low. However, despite the limitations in the research to date, there are indications that clinical guideline implementation may be of benefit and that CDSS may be an effective implementation strategy in this setting.

In this review, variability was seen in the types of guidelines and areas of clinical practice, the intervention strategies utilised and the resultant outcomes, despite remaining focused in the community pharmacy setting. Other reviewers in implementation science have found similar variability. A recent systematic review, which only looked at the implementation of asthma protocols, noted inconsistent results in practitioner and patient outcomes within the one disease state [80].

The lack of rationale in intervention design and over-reliance on educational implementation strategies are also not unique to research in community pharmacy. There is a similar over-reliance on educational interventions in the literature [17, 18, 22]. This is surprising because educational interventions have been demonstrated to be minimally effective, particularly if they simply involve passive dissemination of information [2, 18, 22, 81]. This review demonstrated a similar minimal effectiveness of educational strategies, although it was hard to determine due to the multifaceted nature of most interventions. As the evidence in the literature for a multifaceted approach remains inconclusive, it would seem sensible, wherever possible, to use less complex interventions [14]. Potentially, less complicated interventions would be more cost effective, easier to sustain and better able to inform future practice [14].

A clear rationale involves using a tailored approach or theoretical framework to inform the implementation strategy.

Current consensus in the literature is that implementation strategies should consider the barriers and facilitators (determinants) of change [2, 16–18, 25, 82]. Although researchers agree on the use of a tailored approach, there are currently no recommended, reliable ways to identify and overcome barriers to successful implementation [22, 82]. Krause et al. demonstrated the complexity of tailoring implementation strategies in the area of chronic disease management [82]. The complexity of devising a tailored strategy is what may have resulted in the small number of studies assessing barriers to implementation in this review. It may also explain the lack of effectiveness of tailored implementation strategies.
Table 5: Summary of outcomes and quality of evidence using GRADE

<table>
<thead>
<tr>
<th>Implementation of guidelines in to community pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population:</strong> Staff in community pharmacies</td>
</tr>
<tr>
<td><strong>Settings:</strong> Australia (n=7), The UK (n=3), The USA (n=5), The Netherlands (n=2), Belgium (n=1), Canada (n=1), Finland (n=1), Germany (n=1), Laos (n=1), New Mexico (n=1), Switzerland (n=1).</td>
</tr>
<tr>
<td><strong>Intervention:</strong> Implementation of clinical guidelines: Comparison: Usual practice</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Impact</th>
<th>No of studies (n)</th>
<th>Quality of the evidence [GRADE]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient outcome measures — health outcomes [57]</strong></td>
<td>The only study to measure health outcomes looked at self-reported asthma control. There was no clear indication of any change to asthma control identified.</td>
<td>1</td>
<td>Very low</td>
</tr>
<tr>
<td><strong>Patient outcome measures — behavoury knowledge [54, 70]</strong></td>
<td>Patient behaviour change was measured in two studies and included patients visiting GPs in response to a clinical intervention and patients initiating a medication in response to a mass media campaign. The results were mixed and overall inconclusive. Patient knowledge measures did not necessarily correlate with their behaviour.</td>
<td>2</td>
<td>Very low</td>
</tr>
<tr>
<td><strong>Preclinical outcome measures — shifts in behaviour (including knowledge, communication skills, social skills, self-efficacy) [53, 56, 58, 61-64, 67-69, 73, 75]</strong></td>
<td>Most of the preclinical outcome measures from the twelve studies demonstrated positive outcomes; however, there was still a degree of variability for some measures limiting strong conclusions. Practitioners were found to ask more questions, including open-ended questions and were more likely to initiate conversations with patients. Patient assessment scores were another positive outcome measure that assessed communication with patients. Variable results were seen in measurement of: knowledge; skills; two studies demonstrated no change in knowledge while another indicated improved practitioners knowledge as a result of the intervention. Patient counselling: Two studies demonstrated improvements in provision of advice, one demonstrated no differences between the intervention and control groups and one indicated a decline in rate of clinical information provision in the intervention group. Self-efficacy: no change and positive outcomes were seen in different studies.</td>
<td>12</td>
<td>Very low</td>
</tr>
<tr>
<td><strong>Process (practice change) outcome measures — guideline adherence, legislation adherence, guideline appropriate referral use of support tools. [53, 56, 58, 59, 62-66, 68-72, 75]</strong></td>
<td>There were variable results in process outcome measures from fourteen studies. Eight of the studies looked at guideline adherence/implementation. There was some variability related to the interpretation of guideline compliance and differences in the way it was measured. No studies had no evidence of effect or minimal improvements to guideline compliance due to interventions. A study by Wiltzen et al. 2012 used two differing methods of intervention with neither demonstrating improved guideline compliance. While, in a study by Lipton, compliance was variable and found to be correlated with the legislative requirements [drug schedule] of the medication requested. Patient referral in accordance with guidelines was another key outcome measure in three studies. All demonstrated improvements in referrals. A study by Lipton looked at use of support tools after one year. The sample size was insufficient for reliable conclusions to be drawn.</td>
<td>54</td>
<td>Very low</td>
</tr>
<tr>
<td><strong>Process (practice change) outcome measures - clinical interventions, drug therapy changes, clinical services [54, 57, 60, 61, 70, 73, 75]</strong></td>
<td>Six out of the seven studies that looked at clinical service provision, clinical intervention rates and medication changes/ improved medication compliance were positive. However, in the study by Spoon the intervention was multi-disciplinary and multifaceted and usual health professional educational interventions along with a mass media intervention. This was only partially successful and it was uncertain if any changes to drug therapy were due to community pharmacy involvement. One study showed no improvements in provision of asthma services but this study consisted of a small sample size and a single intervention.</td>
<td>7</td>
<td>Very low</td>
</tr>
<tr>
<td><strong>Health service delivery [economic or labelled outcome measures — cost savings or cost of intervention [54, 59, 62]</strong></td>
<td>Only three studies looked at economic outcomes, each employing different analysis methods. Only one study attempted a cost/benefit analysis, requiring multiple assumptions. The other two studies looked at the cost of the intervention or the cost savings expected from undertaking an intervention. The number of assumptions did not allow reliable conclusions to be drawn.</td>
<td>8</td>
<td>Very low</td>
</tr>
</tbody>
</table>

Reference: GRADE working group guide to evidence table

**Key**

- **High**: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different is low.
- **Moderate**: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different is moderate.
- **Low**: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different is high.
- **Very low**: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different is very high.

**NB:** Substantially different = a large enough difference that it might affect a decision.
observed, which seems to challenge the recommendations in the literature. Community pharmacy is a complex, retail environment with many staff and possibly many barriers to clinical guideline implementation. A greater understanding of the barriers unique to the community pharmacy setting may improve outcomes.

The current literature also promotes the use of theory to underpin study design, but with little knowledge of how to choose between the many behaviour change theories and how to successfully translate their constructs into an intervention [20, 21, 23, 83]. It is these challenges that may have resulted in very few studies in this review using a theory-based approach to implementation. Furthermore, the studies in this review that did use theory to guide implementation produced variable results. This is also consistent with the literature. While there are strong advocates for the use of theory in implementation science, interventions based on theory are not necessarily more effective [84]. However, there are potential advantages to the generalisability and replicability of theory-based implementation interventions [26], which would be useful to improve the evidence for guideline implementation in community pharmacy.

The implementation strategy to show the most promise in the community pharmacy setting was CDSS. Two studies using this strategy measured objective outcomes and demonstrated a strong effect, as well as being comparatively rigorous in their methodology. This observation holds logical appeal because CDSS has the potential to integrate with the existing workflows of pharmacists [85]. As pharmacists routinely use computers in the dispensing process, CDSS reminders possibly have fewer barriers to overcome in terms of integration into practice. Legrand et al. demonstrated the superiority of computer-integrated reminders compared to non-integrated information in their study on medicines and driving [67]. However, further research is required to truly understand the potential of computer prompts in community pharmacy what types of prompts are effective, what variables influence effectiveness, the sustainability of such interventions and ultimately their effect on patient health outcomes. Supporting the evidence of benefit for CDSS in the community pharmacy setting is the fact that reminders have improved outcomes in other settings [2, 25, 86].

While the majority of studies in this review reported positive outcomes, there was variability in the types of outcome measures used and the magnitude of the effect, both between and within studies. These findings are consistent with the current literature for both allied health and the medical profession [2, 6, 13, 16, 20]. Multiple outcome measures in studies were common, and this added to the challenge of interpreting the results. Interpretation of these results also requires consideration of the quality of evidence and whether the research outcomes are valid measures of clinically significant changes in practice and patient care.

Detection of patient health outcomes can be difficult in the time frames seen for most studies in this review. Also, many of the studies implemented guidelines for the treatment of minor ailments using non-prescription medications. The expected clinical benefit in such instances would be small and challenging to measure. Worrall and colleagues support this notion with their review, which found little evidence to suggest that clinical practice guidelines produce significant changes in clinical outcomes in primary care [26].

Understandably, very few of the studies in this review looked at patient outcomes, and only one study measured a patient health outcome, which was a surrogate measure about perceptions of asthma control using a non-validated tool [57]. Consequently, no objective health outcomes were measured in this review. Given that improving patient health outcomes is the main objective in the development and implementation of clinical guidelines, the current research in community pharmacy is failing to provide substantive evidence of effect. Researchers have noted a similar lack of patient outcome data regarding clinical guideline implementation in other settings and professions [2, 16, 26, 87]. The main outcome measures seen in the literature [87] and in this review were process measures, at the level of the practitioner.

All the studies in this review assessed practitioner behaviour change, and most used objective measures to assess practice. While such measures may indicate behaviour change on the part of the practitioner, they do not necessarily indicate successful guideline implementation, translation of evidence into practice and may not correspond with patient outcomes.

One of the more interesting observations from this review was the importance of considering the role of support staff in the community pharmacy setting when implementing guidelines. Two studies in this review measured outcomes achieved when strategies were directed at professional pharmacy compared to support staff. Both studies demonstrated that better outcomes were achieved when the patient encountered a pharmacist [62, 75]. This observation has also been substantiated in other pharmacy practice research [88, 89]. The implications of this surrogate outcome measure lie more in the consideration of study design in the community pharmacy setting. It is possible that lack of acknowledgement of the influence of pharmacy support staff, in designing an implementation intervention, could be responsible for some of the variability in outcomes observed.

Another major problem that limits the ability of researchers to make firm conclusions about guideline implementation is the poor methodological quality of studies and the poor reporting of interventions [2, 10, 13, 22, 26, 76, 90]. Unfortunately, this review is no different. Many studies used self-selection in the recruitment process.
Self-selection results in samples that are unlikely to be representative of the wider population [91]. This selection bias leads to recruitment of participants who are motivated and more likely to adopt practice changes [91]. Performance bias was also inherent in many studies in this review. Unfortunately, by its very nature, practice-based research is vulnerable to participant–behaviour change due to the consent and awareness created by the research [13]. For controlled trials, selection and performance bias occur in both intervention and control groups. This can lead to small differences in effect between groups, which perhaps underestimates the value of the implementation strategy, but it may also overestimate the absolute effect of an intervention [91]. The concern is that findings do not necessarily translate to the “real world” [98, 87, 90].

**Strengths**

The strength of this review is that it focuses on the single organisational setting of community pharmacy, which is unique. A criticism of implementation science has been that it can be hard to decipher the components of an intervention and the basis for using a strategy [92]. This review has managed to detail these characteristics for each study, providing a greater understanding of the gaps in research. A comprehensive assessment of the quality of all included studies and primary outcomes, using three validated tools, also allowed for insight into the strength of evidence from the studies.

**Limitations**

A limitation of this narrative synthesis is that of the 22 studies synthesised, half were from Australia or the UK, and there were multiple studies by only three research groups (Brimbrough, The PROMISE researchers and Watson) [54–56, 60, 62–64, 66, 68, 69]. When the weighting of evidence is clustered in such a way, there is a reduced ability to make generalised conclusions. Conclusions were also limited by the determination that most of the studies were at a high risk of bias. However, the authors of the papers in this review were not contacted for further information. Such information may have helped to better discern methodological quality and provided stronger evidence. Another concern is that the majority of positive outcomes were the result of publication bias. There are also limitations in a narrative synthesis compared to meta-analysis.

**Practice implications**

The findings of this review make an important contribution to the evidence base for the role of clinical guidelines in the community pharmacy setting. The review has the potential to guide pharmacy practice research and inform successful implementation, of clinical guidelines, in community pharmacy in the future. As highly accessible primary healthcare practitioners, the scope of practice of community pharmacists is increasingly important in influencing patient health outcomes. In recent years, there has been a focus by governments and non-government organisations on primary healthcare due to the recognised benefits to patients and society that a strong primary healthcare system generates [28, 93, 94]. Improving the effectiveness of pharmacists to provide evidence-based care through the use of clinical guidelines can strengthen primary healthcare.

**Conclusion**

While this review points to the potential of clinical guidelines to influence practice in community pharmacy, at present, there is little to suggest that they positively affect patient outcomes. There is also little evidence on the best strategies for implementation. This lack of evidence is not surprising due to the complexity of implementation science, the heterogeneity of studies and the poor methodological quality of research in this setting. In the future, study design should focus on using a more systematic approach. More attention should be given to the rationale of an implementation intervention and the choice of outcome measures. The community pharmacy setting is unique in the influence that pharmacy support staff can have on outcomes achieved by guideline implementation. As a result, careful consideration should be given to their role in any study design. Improved methodological rigour in future research will strengthen the evidence of the benefits of clinical guidelines and the best strategies to implement them in community pharmacy.

**Additional file**

**Abbreviations**

AODCs: Accredited Drug Dispensing Outlets; CBA: controlled before-and-after trial; CDSS: computerised clinical decision support system; EPIC: Effective Practice and Organisation Care (Reviewer Group); GRADE: Grading of Recommendations Assessment, Development and Evaluation; MCAs: medicine counter assistant; NBT: non-randomised controlled trial; PICO: participants, intervention, comparator, outcome framework; PRISMA: preferred reporting for systematic reviews and meta-analyses; RCT: randomised controlled trial; TREAD: transparent reporting of evaluations with non-randomised designs.

**Competing interests**

KW is the proprietor of a community pharmacy in Perth, Western Australia and thus has a financial interest in community pharmacy.

**Authors' contributions**

KW conceptualised and designed this review as part of her PhD studies, guided and supervised by CS, and RC. KW and RC secured funding for the research from the Health Department of Western Australia. HW was the second reviewer in the team and CS acted as moderator. KW prepared an initial draft paper with all authors contributing to subsequent drafts and approving the final manuscript.
Chapter 3


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3.3 Key findings from systematic review

This systematic review was the first comprehensive review of the literature on strategies for implementation of clinical guidelines to community pharmacy.⁹ Previous reviews regarding clinical guideline implementation have focused on other settings and other health professionals.⁴,⁵,¹⁰,¹¹ There is an abundance of research in community pharmacy that investigates guideline-based programmes and interventions administered to patients.¹²⁻¹⁹ While these studies indicate the potential of pharmacists to provide guideline-based care to produce positive outcomes, they do not represent the translational research of interest in this thesis. For instance, The Pharmacy Asthma Care Program (PACP) was a guideline-based programme developed by researchers at the University of Sydney.¹² The research produced impressive results such as improving patient asthma control, medication adherence, quality of life, asthma knowledge and perceptions. However, researchers prescribed the programme administered to patients. Pharmacists were directed what to do and at what intervals to conduct services, over a six month period. Patients were recruited especially for the programme. This research was not attempting to change routine practice, but rather understand the benefits pharmacists could potentially offer to patients with future expanded practice. Conversely, the research of interest in this thesis was research that aims to change the way pharmacists routinely interact with patients presenting in store.

Key findings included:

• The studies were heterogeneous in terms of the areas of clinical practice they aimed to influence through guideline implementation. Practice areas included a
variety of chronic diseases, different classes of medications, preventative health initiatives and appropriate pharmacy practice. This heterogeneity limited conclusions from the review.

- The majority of studies were undertaken in Australia, The United States of America (USA) and The United Kingdom (UK), with a paucity of research in less developed health systems.
- Most studies involved interventions directed at pharmacists with little regard shown for the possibility that other stakeholders in community pharmacy guideline-based care might have an influence on practice. (e.g. pharmacy assistants, GPs or patients)
- Interventions were primarily multifaceted educational implementations of highly variable design. Few studies had a clear basis or rationale for the intervention undertaken, such as tailoring to overcome identified barriers or grounding in formalised behavioural theory.
- Interventions based on computerised clinical decision support systems (CDSS) showed the greatest promise for achieving practice change based on outcomes and quality of evidence.
- Outcome measures were heterogeneous, but only one study measured a patient health outcome, which was a subjective measure of perceived asthma control. The lack of objective patient outcome measures is an issue because the ultimate aim of improving guideline compliant practice is to improve patient health outcomes. However, it is understandable given the timeframes required for translational practice change and subsequent extrapolation into patient outcomes. Economic outcomes were also infrequently studied.
• Most studies used self-selection as part of the methodology, which was one of the key reasons for the significant number assessed as having a high risk of bias. Many studies were also subject to bias from the Hawthorne effect, which can be problematic in practice research.

• There was little evidence that the interventions to implement guidelines produced sustainable practice change although the majority did produce positive outcomes.

• Ultimately the body of research at present on clinical guideline implementation to community pharmacy provides little information about optimal strategies to achieve outcomes and little evidence of beneficial patient outcomes.

• Further research should use a more systematic approach to intervention design and consider novel methods to overcome bias inherent in the naturalistic setting.

   Consideration of other stakeholders in patient care and more collaborative implementation initiatives are required. Ideally longer time frames for research, which incorporate objective patient health outcomes and economic evaluations, will substantiate the hypothesised benefits of guideline-adherent practice by community pharmacists.

3.4 Relevance of findings to the thesis

The low quality of evidence and the heterogeneity of the studies of the review revealed a significant gap in knowledge about clinical guidelines implementation to community pharmacy. It also provided little guidance for the proposed evidence-based implementation-intervention (Chapter 6). However findings of potential interest in informing the thesis were:

• The lack of studies that considered stakeholders other than pharmacists
Chapter 3

- The lack of a systematic approach in implementation-intervention design (either via tailoring or theory-based)
- The potential benefits of CDSS in the community pharmacy setting
- The lack of patient outcomes

The use of CDSS was eventually discounted as an implementation strategy, due to ongoing initiatives by the Pharmacy Guild of Australia in partnership with various drug companies using CDSS to improve medication adherence. The achievement of patient outcomes within the timeframes of the research was also deemed unrealistic and not pursued.

Ultimately, the knowledge gleaned from the systematic review, which was utilised in developing the implementation-intervention, and addressing the thesis aims were: consideration of other stakeholders (in particular pharmacy assistants) and use of a tailored approach to intervention design.
3.5 References


Chapter 3


Chapter 4:

A Focus Group Study to Investigate the Determinants of Optimal Asthma Management and Guideline-Based Care in Community Pharmacy

Presented as published in the BioMed Central publication:

*Asthma Research and Practice*

4.1 Background

The SABA guidelines and AAP card were implemented in Perth Western Australia commencing in November 2010. While a multidisciplinary and multifaceted approach was used, ultimately the implementation involved passive dissemination methods to the majority of stakeholders, and academic detailing and other educational opportunities for pharmacists.¹ The education offered was an explanation of the guidelines, card and legislation around SABAs. The scientific literature on guideline implementation indicates that passive dissemination methods are ineffective in generating guideline-based practice.²⁻⁴ The evidence for educational interventions is variable but more promising via academic detailing (educational outreach).²,⁵,⁶

This chapter aims to use qualitative research methods to understand the successes and failures of the initial SABA guidelines and AAP card implementation. In doing so, it provides an opportunity to learn more about clinical guideline implementation in community pharmacy, from the perspective of all stakeholders. Qualitative methodology also provides rich data that can result in a greater understanding of the barriers and facilitators of asthma management, in the primary care setting and how to improve current management.

As part of this thesis, the research from this chapter supplements the findings of the systematic literature review, reported in Chapter 3.⁷ Together, the information from the review and this focus group research provides the grounding for developing and testing an evidence-based implementation-intervention of the SABA guidelines (Chapter 6).⁸
4.2 Publication

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Asthma Research and Practice

RESEARCH

A qualitative evaluation of the implementation of guidelines and a support tool for asthma management in primary care

Kim Watkins, Colleen Fisher, Jila Misaghian, Carl R. Schneider and Rhonda Clifford

Abstract

Background: Asthma management in Australia is suboptimal. The "Guidelines for provision of a Pharmacist Only medicine: short acting beta agonists" (SABA guidelines) and a novel West Australian "Asthma Action Plan card" (AAP card) were concurrently developed to improve asthma management. The aim of this qualitative research was to evaluate the collaborative, multidisciplinary and multifaceted implementation of these asthma resources and identify the lessons learnt to inform future initiatives.

Methods: Feedback was sought about the implementation of the SABA guidelines and the AAP card using focus groups with key stakeholders including pharmacists (>2), pharmacy assistants, asthma educators, general practitioners, practice nurses and people with asthma (patients). Audio recordings were transcribed verbatim. Data were analysed thematically using constant comparison. The common themes identified from the focus groups were categorised according to a taxonomy of barriers including barriers related to knowledge, attitudes and behaviour.

Results: Seven focus group sessions were held with 57 participants. Knowledge barriers were identified including a lack of awareness and lack of familiarity of the resources. There was a significant lack of awareness of the AAP card where passive implementation methods had been utilised. Pharmacists had good awareness of the SABA guidelines but pharmacy assistants were unaware of the guidelines despite significant involvement in the sale of SABAs. Environmental barriers included time and workflow issues and the role of the pharmacy assistant in the organisation workflows of the pharmacy. The attitudes and behaviours of health professionals and patients with asthma were discordant and this undermined optimal asthma management. Suggestions to improve asthma management included the use of legislation, the use of electronic resources integrated into workflows and training pharmacists or practice nurses to provide patients with written asthma action plans.

Conclusions: Greater consideration needs to be given to implementation of resources to improve awareness and overcome barriers to utilization. Attitudes and behaviours of both health professionals and patients with asthma need to be addressed. Interventions directed toward health professionals should focus on skills needs related to achieving improved communication and patient behaviour change.

Keywords: Focus groups, Asthma, Guidelines, Resources, Stakeholders, Community pharmacy

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Background

Asthma remains a significant health problem in Australia and is associated with significant morbidity, mortality and decreased quality of life [1, 2]. Patients with asthma are required to make day-to-day decisions about how to manage their health. Effective self-management requires the collaboration of all the members of the primary health care team, including general practitioners, community pharmacists, asthma educators and practice nurses, in collaboration with the patient. Effective self-management should also involve the use of a written asthma action plan and appropriate use of "preventer" and "reliever" medications [1]. Written asthma action plans have been proven to reduce mortality, hospitalisations and urgent GP visits [1]. Regular use of "preventer" medications, in appropriate patients, controls the disease and prevents exacerbations [3]. The drug class that is primarily used for this purpose is inhaled corticosteroids. Asthma "reliever" medications are short-acting bronchodilators medicines that provide rapid symptom relief. However it is also acknowledged that regular or excessive reliance on these medications can contribute to poor asthma control and can put the patient at risk of a severe, possibly life-threatening, exacerbation of the disease [1, 4].

Despite the availability of effective evidence-based management strategies, asthma management in Australia remains suboptimal. Ownership of written asthma action plans remains low, at under 25% nationally, even though they have been recommended in national guidelines for more than 20 years [1, 3, 4]. Analysis of dispensing data indicates that most inhaled corticosteroids are neither prescribed nor used according to current asthma guidelines and there is an over-reliance on "reliever" medications [1].

In Australia, community pharmacists are the most frequently accessed primary health care provider [5]. They also play a key role by supplying the medications used to treat asthma. This responsibility is even more critical due to legislation that allows patients to access "reliever" medications without a prescription from their general practitioner (Schedule 3 - "Pharmacist Only Medication") [6]. The sale of reliever medications must be under the direct supervision of a pharmacist, which means, pharmacists may often be the only health care professional in a position to regularly assess the patient with asthma. Despite the importance of this role, previous research demonstrated patient assessment, in non-prescription asthma reliever purchases in community pharmacy in Western Australia, to be inadequate [7]. Subsequently the "Guidelines for provision of a Pharmacist Only medicine: short acting beta agonists (SABA guidelines)" (Fig 1) were developed to outline best practice for pharmacists. In 2011 the Pharmaceutical Society of Australia (PSA) adopted the SABA guidelines nationally [8]. Concurrently the Health Department of Western Australia's Respiratory Health Network developed another novel multidisciplinary resource, the Asthma Action Plan (AAP) card (Figs 2a, b). The AAP card is a portable credit card sized tool that contains a written asthma action plan and includes a section to record medication purchases. It was designed to complement the guidelines, streamline the referral process, encourage patient self-management, improve collaboration and communication and increase the ownership of written asthma action plans [9, 10].

The implementation of the SABA guidelines and The AAP card, was undertaken by the University of Western Australia (UWA), the Respiratory Health Network of the Health Department of Western Australia (HDWA), the Asthma Foundation of Western Australia (AFWA) and the Pharmaceutical Society of Western Australia (PSWA) [10]. The intervention was unique because of its collaborative, multifaceted and multidisciplinary approach. The multifaceted implementation involved targeting pharmacists, patients and general practitioners and used strategies including lectures, educational outreach (academic detailing), educational information packs and media releases via professional networks [10]. The 4-month implementation resulted in the distribution of more than 47,000 AAP cards and provision of academic detailing and/or information packs to more than 500 pharmacies (including all pharmacies in the Perth metropolitan area) [10].

The aim of this research was to evaluate the implementation of the “Guidelines for provision of a Pharmacist Only medicine: short acting beta agonists (SABA guidelines)” and "Asthma Action Plan (AAP) card". The specific objective was to understand the successes and failures of this initiative in influencing health professional practice and patient asthma management to inform future resource implementation.

Methods

Ethics approval

Ethics approval was obtained from the UWA Human Research and Ethics Committee (HREC RA/4/1/5000). In accordance with the approval requirements written informed consent was obtained from all participants in this research.

PICOT framework for initial implementation

Table 1 outlines the details of the initial implementation of the asthma resources using the PICOT framework.

Evaluation methods

A qualitative approach underpinned epistemologically by pragmatism and utilising focus groups, was used for this research [11, 12]. The advantage of a qualitative approach is that it provides an understanding of the perspective of stakeholders and the barriers that exist to
Fig. 1 SABA guidelines in PDF format.

Fig. 2 a Asthma action plan card (front) in JPEG format. b Asthma Action Plan Card (back) in JPEG format.
practice change [13]. Implementation research has demonstrated that identification of barriers and tailoring implementation strategies to overcome barriers, may lead to improved patient care [14].

Seven focus group sessions were held with key stakeholders in asthma management in the primary care setting and those targeted in the SABA guideline and AAP card implementation. Including a range of stakeholder groups from care pathways facilitated a greater understanding of the barriers resulting from a lack of collaboration and barriers associated with perceptions of individuals about their role. As such, focus groups were conducted separately with pharmacists (≥2), pharmacy assistants, asthma educators, general practitioners, practice nurses and people with asthma (patients). Having groups of participants with similarities allowed for exploration of shared experiences to gain an understanding of the issues around asthma management. This approach is consistent with the views of Krueger and Casey who noted there was a decrease in the quality of data from groups composed of highly diverse participants [15].

Participant recruitment

Purposeful sampling was used to recruit focus group participants [16]. Initial recruitment was via professional organisations and patient networks. Additional methods included the use of letters and direct emailing of individual pharmacies, medical practices and contacts from the primary author’s professional network. Strategies were triangulated where necessary to ensure adequate recruitment numbers. The aim was to recruit between four and 12 participants as was consistent with optimal idea exchange within focus groups [15, 17, 18]. Written informed consent was obtained for participation and for audio recording. Participants from all groups received a retail gift voucher of nominal value to compensate for their time and travel costs, except for the asthma educators who attended the session as part of their normal working hours.

Focus group format

The quality of data generated from focus groups depends on the skill and impartiality of the facilitator [11, 15]. An experienced focus group facilitator, who was not a stakeholder, was recruited from the School of Population Health at the University of Western Australia to facilitate discussions. She was subsequently invited to collaborate with the research team as a co-author. A researcher (KWW) and the facilitator (CF) attended each focus group session. The researcher did not participate in discussions but took detailed field notes of the session. Krueger noted that it was important for the person responsible for analysis to be present in focus groups due to the subtleties of mood, energy and enthusiasm that convey rich information that cannot be determined via transcripts alone [15]. ‘Immersion’ in the data provided a deeper understanding and enhanced interpretation [13, 15]. Engaging the same facilitator allowed for minimal variation in delivery style between focus groups. The facilitator was provided with a structured format to ensure uniformity in the way focus groups were conducted. This included: An introduction, explanation of the ground rules (e.g. manners, confidentiality), explanation of procedural issues (e.g. audio recording) and information about participation and consent. This structured approach provided reassurance to participants that they were in a safe and non-threatening environment [16]. The focus groups were timed to last for approximately 1 hour. The priority in holding focus groups was to get a broad perspective from a variety of stakeholders. While there was stakeholder heterogeneity between groups repetition of common themes was evident providing confidence that saturation of the main themes was achieved [12, 15].

As the SABA guidelines are clinical guidelines specifically for pharmacists, only pharmacy staff (pharmacists & assistants) discussed the guidelines in focus group sessions. The AAP card is a multidisciplinary resource and as such was discussed in all of the focus group sessions. Where participants were unaware of the card they were given a sample of the resource along with a brief explanation of its purpose and asked to speak hypothetically about their impressions of the tool.

Topics for discussion included participants’ knowledge of the guidelines and card, opinions about usefulness and usability of the resources, barriers inhibiting their use and ideas to improve the resource and/or asthma management (Additional file 1).

Data collection

Data were collected in three ways from the focus group sessions:

1. Researcher observations and field notes
2. Audio recordings
3. Participant demographics and written summary of key opinions.

Field notes, which have been argued to play an important role in accurately representing discussions [11] included detailed participant responses, descriptive information and numerical data about resource awareness, as has been described by Krueger and Casey [15]. The field notes were utilised in the analysis in conjunction with the transcripts and provided context and emotion not always conveyed by the written quotes alone.

Participants were asked at the end of the focus group discussion to independently fill out a summary sheet of perspectives. Summarising critical points in this way was a method of confirming the accuracy of findings (Additional file 2).

Data analysis
Having the primary researcher (KW) present at all focus group sessions provided opportunities for the analytical process to begin during data collection [15, 19]. Audio recordings were transcribed verbatim. To ensure methodological rigour, transcripts were thematically analysed independently by two researchers (KW, JM) [11, 15]. Inter-coder agreement was checked and a moderator was available (CS) where necessary to achieve consensus [12, 13]. The analysis included inductive category development to allocate the categories to be informed by the data rather than using a pre-conceived framework approach [13, 16]. The process of analysis involved:

Step 1: Immersion in the data through reading and re-reading transcripts
Step 2: Highlighting words or phrases that capture key thoughts and making notes of first impressions on analysis
Step 3: Labelling similar thoughts with a code (development of coding scheme)
Step 4: Codes grouped into broader categories based on similarities
Step 5: Themes identified based on a greater understanding of the relationships between categories and the identification of patterns in the data.

The technique used was consistent with constant comparison [11, 15, 19]. This process was reflective and iterative and involved continual refinement and revision of codes and broader categories over the course of the analytical process. It also involved concurrent development of an understanding of the relationships between codes and categories through not only the use of transcripts but also field notes. This conceptual understanding led to the identification of themes from the data.

Thematic analysis involved comparison of similarities and differences across stakeholder groups [15]. It also provided clarity about the barriers and facilitators to the use of the resources and asthma management in general. An inductive approach was taken with the thematic analysis and subsequent application of the knowledge, attitudes and behaviour theoretical framework and taxonomy allowed for interpretation of what influences guideline-based practice [20, 21]. Briefly, the taxonomy comprises 7 general categories relating to knowledge (lack of awareness or lack of familiarity), attitudes (lack of agreement, lack of self-efficacy, lack of outcome expectancy, or the inertia of previous practice), and behavior (external barriers) [20]. Use of a taxonomy allows for greater applicability of the results of this research.

Summary sheet data was analysed in conjunction with the focus group transcripts.

Results
Focus group participation and demographics
A total of seven focus group sessions were held with 57 participants. Nine and ten participants attended the two pharmacist focus groups respectively. Other groups included: pharmacy assistants (11 participants), practice nurses (six participants), asthma educators (five participants), general practitioners (six participants) and patients (ten participants). The patient group had an even gender spread (four male and six female) and an age range of 21 to 80 years with a mean age of 51.8 years. The participant demographics are shown in Table 2.

Benefits of resources
Community pharmacists displayed a positive attitude towards the SABA guidelines. In this study they articulated clear benefits in having formal clinical guidelines for the non-prescription supply of short acting beta agonists. They saw the guidelines as a useful education, clinical and communication resource that enhanced professionalism.

I have been using them [the guidelines] as a teaching technique for new staff. Students, more as a training guide than anything. (PHARMACIST)

It’s a good starting point and you might just tease out something from them [patients] by working through the guidelines...something they hadn’t been doing right. (PHARMACIST)

It’s a way of getting information from patients and finding if things are working as they’re supposed to be. (PHARMACIST)

If we’re trying to project an image of being professional rather than competing with supermarkets then it is a
Table 2 Focus group demographics & knowledge of the asthma resources

<table>
<thead>
<tr>
<th>Focus group participants</th>
<th>Pharmacist group 1</th>
<th>Pharmacist group 2</th>
<th>Pharmacy assistant group</th>
<th>Practice nurse group</th>
<th>Asthma educator group</th>
<th>General practitioner group</th>
<th>Patients with asthma (patient) group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant numbers</td>
<td>9 (35)</td>
<td>10 (40)</td>
<td>11 (40)</td>
<td>6 (26)</td>
<td>5 (20)</td>
<td>6 (25)</td>
<td>10 (40)</td>
</tr>
<tr>
<td>Age (average) (Range)</td>
<td>41.5 (26–57)</td>
<td>31 (23–60)</td>
<td>27.6 (19–49)</td>
<td>61.7 (50–72)</td>
<td>42.6 (33–60)</td>
<td>49 (41–57)</td>
<td>51.8 (21–80)</td>
</tr>
<tr>
<td>Hours of work</td>
<td>3</td>
<td>9</td>
<td>6</td>
<td>0</td>
<td>3</td>
<td>3</td>
<td>N/A</td>
</tr>
<tr>
<td>Awareness of Asthma Action Plan card</td>
<td>8 (89%)</td>
<td>10 (100%)</td>
<td>10 (91%)</td>
<td>2 (33%)</td>
<td>5 (100%)</td>
<td>1 (17%)</td>
<td>2 (20%)</td>
</tr>
<tr>
<td>Use of Asthma Action Plan card (current or previous)</td>
<td>5 (56%)</td>
<td>5 (50%)</td>
<td>5 (45%)</td>
<td>0 (0%)</td>
<td>2 (40%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Awareness of SABA guidelines</td>
<td>8 (89%)</td>
<td>10 (100%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>5 (100%)</td>
<td>0 (0%)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

A good idea for all pharmacies to adopt.
(PHARMACIST)

There was also recognition that having formal guidelines for non-prescription supply of SABAs improved medication accessibility for patients.

Without these sort of guidelines it is not likely a lot of these medicines would be available over the counter... It’s probably reducing the workload on doctors as well.
(PHARMACIST)

While all participants in the groups could hypothetically acknowledge the potential benefits of the AAP card, the focus and enthusiasm for discussion related to negative aspects of the AAP card. Many of the barriers mentioned challenged the realisation of the hypothetical benefits in practical application. Furthermore barriers often related to development and use of written asthma action plans and asthma management in general rather than specifically the AAP card.

Barriers to resource use
The barriers identified to the use of the SABA guidelines and AAP card are shown in Fig. 3. The barriers were classified according to an existing taxonomy [20].

Knowledge barriers

**Lack of awareness**
There was high awareness of the SABA guidelines among pharmacists (group 1 89%, group 2 100%) and similarly a high awareness of the AAP card (group 1 89%, group 2 100%). In contrast the participants in the pharmacy assistant group were completely unaware of the SABA guidelines (0%) but had a good awareness of the AAP card (91%). The only other group with participants who had much familiarity of the asthma resources was the asthma educator focus group. All of the asthma educator participants (100%) were aware of both the SABA guidelines and the AAP card. Participants in the general practitioner and practice nurse group were completely unaware of the SABA guidelines and had minimal awareness of the AAP card (33 and 17% respectively). Only 20% of patient group participants were aware of the AAP card, despite the card being marketed as a patient resource.

![Fig. 3 Barriers to use of asthma resources](image-url)
**Lack of familiarity**

Although the majority of pharmacists, pharmacy assistants and asthma educators were aware of the AAP card only 49% had previously used the cards in practice and no participants had continued to use them. No patient reported using the AAP card to assist in self-management of his or her asthma. This lack of experience with use of the AAP card meant that in many instances the focus group participants were speaking about initial impressions of the tool and its hypothetical use. As a consequence our focus changed and the discussion broadened towards a more general conversation about issues in asthma management and written asthma action plans.

**Attitudinal barriers**

**Lack of self-efficacy-the need to prioritise work**

Pharmacists mentioned that with the time constraints they often faced in daily practice they had to prioritise their work. They felt that they couldn’t do all the tasks for ideal patient management.

> Sometimes in the pharmacy there’s usually only a single pharmacist on duty... and you have to run... that’s part of working, isn’t it, sometimes you just keep on doing what’s most important, and it’s time. (PHARMACIST)

**Lack of self-efficacy-inability to engage patients**

While patient behaviors were considered to be obstructive to guidelines-based care there was also evidence that the attitude of pharmacists was that there was little they could do to alter the situation. There was a feeling that they were disempowered to practice according to the SABA guidelines.

> The main problem with the guidelines is that the people who need the discussion to happen the most are the ones who are least likely to talk to you in a lot of instances. (PHARMACIST)

> So they [the patients] seem to think it is their god-given right to be handed their Ventiolin and just resent being asked questions. (PHARMACIST)

**Lack of outcome expectancy**

When it came to the discussion about the AAP card the views of pharmacists and pharmacy assistants were particularly important, as they were essentially the only group that included participants that had attempted to use the resource.

Pharmacists felt unsupported in their attempts to use the card. This included lack of stakeholder support from patients, general practitioners and even the health system (in terms of legislative support to encourage better self-management by patients with asthma). All pharmacists indicated they had “given” up using the card.

> If [the patients] are not interested... I [the pharmacist] am not. (PHARMACIST)

> I still give [the card] out, and everyone in my drop still gives it out, but we never see, we rarely see anyone bringing it in a second time. (PHARMACY ASSISTANT)

Pharmacy assistants had a negative view of patients with asthma and little understanding of the reasoning behind their behaviour and resistance to engage.

> They were also more likely than pharmacists to view the AAP card as a punitive monitoring tool than as a referral tool or a way of improving asthma action plan ownership.

> If customers are using these [cards] you know they are genuine. You don’t have to be suspicious of them just coming in and buying reliever medications. (PHARMACY ASSISTANT)

Pharmacists were more likely to see the reluctance for patients to engage in conversation as a result of lack of understanding, however, pharmacy assistants tended to focus on negative perceived patient attributes, such as laziness.

> Vagueness... people might start off with [the card] the first time and then they can’t be bothered. (PHARMACY ASSISTANT)

> Waste of time as people get too lazy to bring in card (PHARMACY ASSISTANT: Summary Sheet)

While there was much malignation of patient unwillingness to engage, it would seem that attitudes of pharmacists and pharmacy assistants in the community pharmacy were not conducive to improving the situation. Although these attitudes were conveyed in relation to the resources, it was clear that they applied to engaging with asthma patients in all instances. Not just in specific circumstances.

**Behavioural barriers**

**Patient-related barriers**

There was much discussion surrounding resistance of patients to interactions with health professionals and the view that patients preferred to self-manage their asthma. Patient behaviour and engagement difficulties were seen as a significant barrier to the success of the card and also as a barrier to optimal management of asthma. Health professionals believed that patients with asthma did not want their help and would “do their own thing” regardless of the advice they were given. Some found patients became aggressive in response to attempts to intervene.
There was little acknowledgement of the patient perspective or reflective thinking about the motivations behind patient behaviour.

People get, even with the pharmacist, really antsy. They say I’ve been using this for a while, why do you need to ask me all these questions. (PHARMACIST)

Since they are the customer and they are going to get [the reliever medication] anyway they just go...yeah, yeah, yeah, yeah [to your questions]. (PHARMACY ASSISTANT)

I did try once to get people to come back for the asthma education plan and come the next week, nope, it’s really dispiriting. (PRACTICE NURSE)

Patient unwilling—capability (PRACTICE NURSE—Summary Sheet)

I’ve never had a card handed over to me to fill out...I’ve never had a client bring one in...never. [Chorus of agreement] (ASTHMA EDUCATOR)

The majority of asthmatics I see rely purely on Ventolin* or similar, and the reason’s because the preventers are cartoons based and there’s enormous prejudice against them. They won’t use them, particularly parents. (GENERAL PRACTITIONER)

Even the patient group acknowledged that they themselves were often ambivalent and “part of the problem” in achieving optimal asthma management.

I wouldn’t be bothered, couldn’t be bothered carrying [the card] around...You’d have to be just about dying not to be able to tell somebody to dial 000, you’ve got asthma. (PATIENT)

It’s probably only a matter of time before I have another severe attack. But at this stage, if it’s not happening, you don’t think about it. (PATIENT)

I’d been wheezing all day and hadn’t paid attention to it [my asthma]...my husband’s a GP but he was out and by the time he came home then I passed out and he had to resuscitate me. (PATIENT)

Environmental barriers—collaborative care difficulties

Although patient engagement was considered the major barrier to use of written asthma action plans (including the AAP card) and optimal asthma management, the general practitioner was also seen by other stakeholder groups to be unsupportive of collaborative care initiatives. There was frustration in the fact that general practitioners had the ultimate responsibility to provide patients a written asthma action plan and were seen not to be fulfilling that role.

At the end of the day [written asthma action plans] have to be done by a GP. We can’t give this information...we can refer...I don’t think GPs are being proactive enough in making sure patients actually have one. (PHARMACIST)

Doctors just don’t seem to follow up and do it [fill in the card with an action plan]...Patients come back and say their doctor didn’t want to know about it. (PHARMACIST)

I’ll sometimes write it out [a written asthma action plan] and the doctor will sign it...but it’s still up to them actually...that’s the biggest problem. (PRACTICE NURSE)

It is just not going to happen [GPs writing asthma action plans]; I think GPs are as complacent about asthma as the general community. (ASTHMA EDUCATOR)

The attitudes of many health professionals showed little understanding of the GP perspective and the difficulties they faced in managing patients with asthma.

General practitioners acknowledged that there were barriers in their practice that prevented them from managing patients with asthma and providing patients with written asthma action plans. They particularly felt frustrated that patients would only present when unwell, which did not allow for chronic disease management, only the provision of acute care.

People will present when they get a flare up, get some treatment, but they don’t come back to discuss a plan for next time. (GENERAL PRACTITIONER)

You’re just dealing with the acute flare up and managing that...They don’t really want to come in afterwards and do...longer term planning when they’re well, because they’re well and they don’t feel like attending them, to do that, they’ve got too many other things to do. (GENERAL PRACTITIONER)

It’s usually just; oh they need a script along with all the other stuff. They don’t always have the time to deal with asthma...and it’s down the bottom of their list. (GENERAL PRACTITIONER)
Time in general practice (GENERAL PRACTITIONER-Summary Sheet)

Practice nurses echoed this sentiment.

You give them opportunistic education...not a formal clinic thing, because it’s just impossible. (PRACTICE NURSE)

We do really get more acute people...they arrive to us, having an acute asthma attack. (PRACTICE NURSE)

The asthma two-step plan...we're not really doing that. (PRACTICE NURSE)

Environmental-related barriers—time and workflow

Time barriers were another issue identified by health professionals and pharmacy assistants as hampering their ability to use the card and effectively support optimal asthma management.

Even in the quietest pharmacies you’re always battling for time. Either you’re in a rush or they’re in a rush...so there is a time factor. (PHARMACIST)

There’s a time factor as well. They [patients] are going to be too hostile, and they don’t want to stand around waiting for us to fill in the card. (PHARMACY ASSISTANT)

I don’t have time to sit down and really do [education]...how you’re supposed to...then get them back later [for a written asthma action plan]. (PRACTICE NURSE)

You’ve got to actually fit in the spirometry checks as well...you’ve got to work out if you’ve got time...so it just gets a bit difficult to provide longer term management advice to patients. (GENERAL PRACTITIONER)

Time consuming—should be more faster process so that customer would be inclined to use the AAP card. (PHARMACY ASSISTANT—Summary Sheet)

Environmental-related barriers—the role of the pharmacy assistant

Of particular interest in the pharmacy assistant focus group discussion was the description of their role in SABA sales. Currently the scheduling of salbutamol and terbutaline inhaler medications (SABAS) in Western Australia is according to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) [22]. This recommends a classification for these medications as Schedule 3 or “Pharmacist Only” medications. The West Australian Poisons Regulations of 1965 indicate that, “a Schedule 3 substance should only be sold by way of direct personal sale by a pharmacist or an intern pharmacist under the direct personal supervision of a pharmacist” [6]. They also state that, “the pharmacist must take all reasonable steps to ensure there is a therapeutic need for the product” [6]. Despite the legislative requirements for pharmacist involvement and a universal lack of knowledge of the SABA guidelines, pharmacy assistants indicated that they were highly involved in the provision of SABAS. This involvement represents an environmental barrier to optimal asthma management.

Guideline/resource-related barriers—the format of the Asthma Action Plan card

There was a great deal of discussion surrounding the format of the card. Most stakeholders commented that patients had overloaded wallets and were not likely to carry around a card that didn’t really serve a purpose from the patient’s perspective.

I think people think it’s too bulky...they don’t want to carry it around in their purse. (PHARMACY ASSISTANT)

The customer is not going to carry this around purely to record when they buy their Ventolin*. That’s really the issue. They don’t see any value in that. (PHARMACIST)

Bulky/annoying: could get tatty (ASTHMA EDUCATOR—Summary Sheet)

There was criticism of the paper-based format when most health records are being converted to an electronic format.

A card of this size is just another barrier and so much of our recording and things we do is electronic. I think it has become almost a little bit old fashioned. (PHARMACIST)

The recording of Ventolin* is something that either has to be electronic or it’s not going to happen. (PHARMACIST)

I think all of us would agree that a computer based template would be the format we’re likely to use, more than a card, because we’re not filling out a card. (ASTHMA EDUCATOR)

The paper-based format was also seen as problematic due to its lack of durability.
I think guys put it [the AAP card] in their back pockets... and it just gets really tattered. (PHARMACIST)

Guideline/resource-related barriers—the content of the Asthma Action Plan card

There was also criticism of the content of the card. Pharmacists particularly felt the dual purpose of a written asthma action plan and beta-agonist record was confusing.

Do we want to highlight that they need an asthma management plan, get them to a GP? Or do we actually want a mechanism for recording? ...We're trying to do two things here at cross-purposes. (PHARMACIST)

Many indicated that the language of the card was inappropriate for patients.

I'd like to see the wording re-done so it's more patient friendly. (PRACTICE NURSE)

[The card] is not really culturally appropriate for the indigenous population...will probably a number of groups...English as a second language. (ASTHMA EDUCATOR)

It was felt that important information such as asthma first aid and definition of beta-agonist over-use was missing.

[The card contains] emergency action but it is not really first aid. It wouldn't be useful... (PRACTICE NURSE)

I don't think that [the card] would get the message across that you should only be using one (Ventolin) a month. (PATIENT)

There's got to be some sort of awareness that there is a problem if you're using [reliever medications] "x" amount of times per week...basically our guidelines need to be exploded out to everyone else, so that way everyone is aware...I'm using [my medications] five times a week so I'd better go and talk to my doctor, or talk to my pharmacist. (PHARMACIST)

Information such as peak flow and oxygen use was seen as irrelevant for a generalised tool.

I mean, worsening asthma, peak flow 50 to 75 per cent. Hardly anyone does peak flow now. (PRACTICE NURSE)

Peak flow used to be popular 15 years ago but... now we never use it...It seems to have died a death. I occasionally use peak flow but it's not really helpful. (GENERAL PRACTITIONER)

When I have given [the cards] out, people have gone to the emergency part and [said] oxygen, so where do I get that? You could read it as; will I need to have oxygen at home? (ASTHMA EDUCATOR)

Discussions in the asthma educator and general practitioner groups particularly focused on suggesting specific and practical ideas to improve the card content, that addressed many of the issues mentioned above, which they found unacceptable.

Inadequate detail on front page regarding when asthma is under control (GENERAL PRACTITIONER—Summary Sheet)

Instructions to patients need to be clearer (PRACTICE NURSE—Summary Sheet)

These issues with format and content all constitute a barrier to resource utilisation.

Solutions for improvements

There were a variety of solutions offered by all stakeholders in all focus groups regarding the SABA guidelines, the AAP card and asthma management in general. However, most of the discussion about improvements in all groups veered towards three main themes: mandatory recording of beta-agonist purchases, development of electronic resources to improve asthma management and using pharmacists and practice nurses to develop written asthma action plans.

Mandating of SABA recording

Interestingly there was much interest by pharmacists in strengthening the legislation around non-prescription supply of beta agonists. The view of pharmacists in the group was that mandating the recording of beta-agonists would assist patient engagement and SABA guideline compliance.

If it's mandated, and every pharmacy has to do it [recording patient details], then they [the patient] can't skip a pharmacy and go down the road where nobody asks questions because it's mandated and they are going to get asked wherever they go. And it forces...forces them to engage and forces them to actually have a conversation with the pharmacist. (PHARMACIST)

That mandating would be a good way of changing expectations...It's not that they [patients] don't have
time, it's that they expect when they go into a retail
shop that they're not going to be asked questions. That
they come in get what they want in a second and walk
out. (PHARMACIST)

I think the only way that it [the guidelines] is actually
going to produce dramatically improved outcomes is if
it's mandated. (PHARMACY ASSISTANT)

People could sign a consent form [when purchasing
asthma relievers] ...they could get phone calls from
education nurses and information sent out... stuff
like that. You could record [asthma relievers], if
they did that... it would actually help. (PHARMACIST)

The fact that the AAP card included a beta-agonist re-
cording function was seen as pointless without legisla-
tion enforcing the recording function.

It's not mandatory so you just sort of lose momentum.
(PHARMACIST)

[ Mandatory use of the card] could make my life
harder. Well more work for us to do, but at least
you know then that they have to use it and they
have to record it, because they can't buy it
otherwise. (PHARMACY ASSISTANT)

Despite the popularity of the notion of mandatory
recording of SABA sales there were some concerns
raised about the importance of maintaining patient
accessibility to medication and the potential unaccept-
able for patients of legislative change.

In certain places you have to have an asthma
card or have come from the doctor [to obtain a
beta-agonist] ... there is a danger there, because if you
have someone who is having an asthma attack what
are you going to do? (PHARMACIST)

The backlash [from mandatory recording of
reliever medications] would be huge.
(ASTM A EDUCATOR)

Electronic resources

The criticism of the AAP card being a paper-based re-
source was matched by enthusiasm for the development
of electronic resources to improve asthma management.

I don't know whether there's something electronic that
could be done these days, an App on the phone or
something... So much of our recording and things we
do is electronic. (PHARMACIST)

Electronic... something that you can scan on a
program... something that the [medication] history
comes up, how many [reliever medications], starting it
that way. (PHARMACY ASSISTANT)

[Electronic action plans] are good because you can
see exactly what they've had. If you're just writing
one [an action plan] out they [patients] tend to
lose it or never bring it back when you have the
next appointment. (PRACTICE NURSE)

I think keeping an electronic record of your
preventatives; your Ventolin and so forth would be
valuable in this day and age. (PATIENT)

However there was also recognition that electronic
formats would not necessarily suit all demographics.

Not everybody has computer, especially older
patients. (PHARMACY ASSISTANT)

I think a lot of my patients... depends on age... 80 year
olds wouldn't use electronics. (GENERAL
PRACTITIONER)

Overall most health professionals felt disempowered
to intervene in asthma patient's inappropriate self-management
and reliance on asthma reliever medications and felt that the
card did not offer solutions to this issue with its imperfect
paper-based recording function.

Improving written asthma action plan ownership

In terms of addressing the issue of lack of patient owners-
cepthip of written asthma action plans, again the card was
not seen as the solution. Asthma educators particularly
felt that currently existing written asthma action plan
templates were superior to the card.

You only have to look at [these other plans] and
you see, they look a lot more colourful and maybe
more likely to stick in people's minds I think...
(ASTM A EDUCATOR)

When explaining asthma action plans to clients, I find
these [other plans are] really simple... they're all on one
to page at whereas [with the AAP card] you're
flapping. (ASTHMA EDUCATOR)

Pharmacists felt that they could play a role in writing
plans for patients.

What would be the consequences if we [pharmacists] did
actually set out an action plan? The doctors would get
upset but the patients would get one. (PHARMACIST)
We could do an asthma educator course and become the person who does the plan instead. (PHARMACIST)

However there was also discussion about the need to up-skill pharmacists to take on the role of preparing written asthma action plans for patients.

I think pharmacists do need up-skill ing though to provide this service. [Written asthma action plans] (PHARMACIST)

Additionally there was some concern about the need to address time and remuneration barriers before pharmacists could undertake this expanded clinical role.

I think it comes back to the time and remuneration factor, you know that if you are going to employ, or have pharmacists, and have the time to do that [write asthma plans]. There needs to be balance. I think it is a great thing to do and a great service but we need to be able to get the pharmacist out of the dispensary and to do that you obviously need to be getting paid for it. (PHARMACIST)

Similarly some general practitioners felt that a solution to improve written asthma plan ownership could be utilisation of practice nurses to undertake the task.

Where I would probably end up using that [AAP card] within the context of my practice would be if they came to see the nurse to actually get the action plan done, because that’s when we put aside a bit of time for them to sit with the nurse and have discussions. (GENERAL PRACTITIONER)

Do it all themselves, let [practice nurses] get on with [writing asthma action plans]. (GENERAL PRACTITIONER)

However some were cautious about this proposition and questioned the capability of practice nurses to undertake the role.

"I’m not sure [about nurses writing asthma action plans]...we have practice nurses but I don’t know that asthma is their strongest area, I think they’d be happy showing people how to use their inhalers but I’m not sure about going through it all." (GENERAL PRACTITIONER)

Discussion

This research explored the views of stakeholders of asthma resources produced and implemented to improve asthma management. Utilising focus groups allowed for an in-depth understanding of the barriers that undermine successful implementation of resources to achieve practice change and improved patient health outcomes. While this research focussed on specific resources, the information gleaned from these focus groups provides insight into key issues of asthma management and effective use of resources to improve health-professional practice and patient engagement.

The lack of awareness and use of the asthma resources was initially surprising given the comprehensive, multifaceted implementation plan used by the collaborative team which included personnel and resources from a university research team, the government Health Department, a professional pharmacy organisation and an asthma organisation [10]. However it is not unexpected given the evidence in the scientific literature on clinical guideline implementation [23–26]. Despite the seemingly thorough approach essentially all of the implementation activities involved educational interventions using passive dissemination, to most professionals, and educational outreach to pharmacists. The difference in awareness of the asthma resources found between groups may be due to the differing dissemination strategies employed. Educational interventions have been demonstrated to be minimally effective, particularly if they simply involve passive dissemination [23–26]. Educational outreach has been found to be effective in medical settings [25], however, in the community pharmacy setting, Watson and colleagues demonstrated no evidence of practice change using this intervention method [27]. Clearly the first step to successful implementation of guidelines and other resources is to ensure that there is not only widespread knowledge of the resource but also a willingness to incorporate it into practice. More consideration needs to be given to the implementation strategies employed to achieve this and there should be less reliance on passive implementation.

Sustained practice change will not result if too many barriers are encountered during initial attempts of practitioners to use a resource. In the case of the SABA guidelines and the AAP card the barriers encountered were many and not just related to the resources themselves. It was evident that attitudes of all stakeholders were influencing behaviours that were detrimental to optimal asthma management. There was a misalignment of asthma management goals and behavioural expectations between patients and health professionals and this discordance seemed to be central to the issue.

Overwhelmingly the perceived difficulties with patient engagement resulted in pharmacists and pharmacy assistants having a pessimistic view of their ability to influence patients to appropriately self-manage their condition. Asthma educators, general practitioners and practice nurses were equally pessimistic and felt they had limited opportunities to provide chronic disease management and patient education. Apathy to engage was even acknowledged by patients themselves. In many
instances patients were unaware of poor asthma control or were resigned to having asthma exacerbations and limitations put on their lives by this chronic condition. Patients only focussed on current symptoms and did not have expectations of interventions by health professionals aimed at chronic disease management. These patient attitudes are consistent with much of the literature in asthma [28, 29]. What is also known from the literature is that illness perceptions determine the way in which asthma patients cope and self-manage this condition [30]. The focus group results convey that effective self-management, with the support of health professionals, cannot be achieved without addressing patient attitudes, beliefs and perceptions about asthma. The extent of the issue warrants a community level intervention directed at the patient. Resources such as the AAP card are unlikely to have an impact without patient acceptance and more widespread consultation should be undertaken in resource development.

Equally health practitioner attitudes require addressing. There was little evidence of a patient-centred focus by health professionals or reflection on changes that could be made to allow for more effective patient engagement. Negative perceptions had reduced the motivation of health professionals. In this study there were indications of lack of self-efficacy and poor impressions of outcome expectancy hampering patient engagement. Motivation to change practice needs consideration in any implementation of guidelines and/or resources. Remuneration opportunities may change prioritisation of activities but ultimately improving outcome expectancy is critical. In order to do this, health professionals require not only motivation but also the skills to achieve outcomes. Capability must be addressed. As health professionals saw patient engagement and patient attitudes as a barrier, any asthma management intervention should tackle their skills needs in this area and not just clinical education needs. Health professionals require advanced communication skills and experience with techniques such as motivational interviewing in order to effectively adjust practice and explore and guide patient perceptions [31].

Environmental barriers were also a key concern. It was not surprising that many of the health practitioners mentioned time and remuneration as barriers to practice [21, 32]. This has been well documented. However the most interesting finding related to how organisational factors, in particular the role of the pharmacy assistants, impacted on practice. What became evident, from the focus groups, was that pharmacy-assistant involvement was a barrier to the provision of guideline-based care in the community pharmacy setting. Pharmacy assistants had no knowledge of the SABA guidelines but articulated being highly involved in the provision of non-prescription asthma reliever medications and in some cases saw it as “their responsibility”. This is consistent with prior research in this region that observed in 47% of non-prescription sales of beta-agonists there was no obvious involvement of a pharmacist [7]. The participation of pharmacy assistants is despite the current legislative requirements for direct pharmacist involvement and despite the fact they are not qualified or trained to undertake this role. Surprisingly, even though current legislative requirements are not being met, both pharmacists and pharmacy assistants wanted the legislative requirements strengthened to include mandatory recording of non-prescription beta-agonist purchases. While this may seem pointless, given current lack of adherence to legislative requirements, mandatory recording may have an impact because it may change the workflows around the supply of SABAs. Current workflows in community pharmacy dictate that pharmacy assistants lacking formal training are often the first and only point of contact for asthma patients who are often resistant to engagement. Mandatory recording may facilitate improvement in asthma management because it may increase the involvement of pharmacists by moving the interaction into the dispensary for recording purposes. This would be desirable because increased pharmacist involvement has previously been found to result in more appropriate medical referral of asthma patients [33]. Mandatory recording would also provide easier opportunities for auditing legislative compliance by pharmacists. Currently the Schedule 3 legislative requirements are not routinely policed and statutory bodies rarely prosecute breaches [34].

Discussions in focus groups about the AAP card evolved into discussions about written asthma action plans in general. While the AAP card had merit in the hypothetical it was a flawed resource that was not going to be accepted and utilised by stakeholders. The stakeholders noted there were other preferable resources but these resources were also underutilised and not serving the purpose of improving asthma management [1–4].

The sole authority of general practitioners to provide written asthma action plans was seen as a barrier to patient ownership of written asthma action plans. General practitioners lamented the lack of opportunity to manage asthma as a chronic illness. Practice nurses talked about the remuneration pathways for writing asthma action plans. In Australia, a general practitioner is eligible to receive a Service Incentive Payment (SIP) for each Asthma Cycle of Care completed [35]. However a minimum of two asthma related consultations must be completed within 12 months and at least one of the consultations needs to be a review consultation planned at a previous consult [35]. Both the general practitioners and practice nurses noted that this 2-step process was difficult to achieve with patients not returning for their review consultations. The observations of this barrier are
interesting given that the Asthma Cycle of Care in Australia has previously been modified from a 3-step process (the Asthma 3+ Visit Plan) in response to feedback from respiratory physicians, general practitioners and patients. It would seem that the simplified 2-step Asthma Cycle of Care has not achieved its aims of ensuring patients with asthma are provided on-going monitoring. Non-attendance at asthma disease management consultations is not an issue unique to Australia. Audit data from the UK on avoidable deaths in asthma indicated that 22% of patients who died had missed routine asthma appointments in the year before death [36].

Suggestions to address the inability of general practitioners to ensure all patients with asthma have a written asthma action plan included practice nurses writing plans and pharmacists being trained to write asthma action plans. Practice nurses may have fewer time barriers than general practitioners but the fact that patients are still required to present at a general practice surgery does not address the issue of opportunity. Community pharmacists, alternatively, are highly accessible and as medication experts could possibly undertake this role with some up-skilling. This may be an avenue worth exploring to increase patient asthma action plan ownership given the on-going difficulties over the last 20 years in addressing the issue. Time barriers are likely to be a problem for pharmacists in undertaking this role, given current time pressures articulated in focus group discussions. Appropriate remuneration would allow for employment of extra staff and may increase pharmacist motivation to engage in clinical service delivery [37].

There was much discussion about the AAP card being a paper-based resource. What became evident is that most stakeholders across all demographics prefer electronic resources. This included patient-based resources in the format of smartphone Apps, along with written asthma action plans and medication records compatible with the software that general practitioners and pharmacists already use. A review by Huckvale and colleagues in 2012 assessed the content of apps designed to assist patient asthma self-management [38]. Of the 103 apps assessed the conclusion was that none provided a combination of reliable, comprehensive information and useful self-management functions [38]. While there are plenty of electronic resources available, more consideration needs to be given to the production of unbiased, high quality, evidence-based and simple-to-use resources that health professionals can confidently recommend to patients to promote self-management. Organisational barriers relate to characteristics of the work setting such as staff workload, management issues, financial considerations and structural arrangements that govern workflows [39]. These barriers need to be overcome for resource implementation to successfully achieve its intended outcomes. It makes sense to link resources to existing software used by health professionals rather than using extraneous paper-based resources. Pharmacists, and general practitioners frequently spoke about organisational barriers, such as time pressures, as an issue to optimal practice. Resources that fit into existing workflows (e.g. using existing software such as dispensing software or prescribing software) are likely to be more efficient [40].

**Strengths**

A key strength of this research was the triangulation of data sources. Engagement with a range of stakeholders enabled multiple perspectives on the topic. The inclusion of pharmacy assistants, who are not health professionals and do not necessarily receive any formal training in medicines and healthcare, provided rich information about their influence on asthma management. The initial implementation strategy of the SABA guidelines involved pharmacists only and did not acknowledge the workflows in this setting that have pharmacy assistants on the frontline of patient interaction. Running a pharmacy assistant focus group proved valuable in allowing for unconstrained discussion by assistants who may have felt intimidated by a structured interview or in a situation where pharmacists were present [11, 18]. Member checking was undertaken in the form of a written questionnaire.

**Limitations**

It is acknowledged that in qualitative research the researchers bring personal values, assumptions and biases to the study. The primary researcher in this study was KW. As a research assistant for the initial SABA guideline collaborative implementation, member of the Health Department of Western Australia's Respiratory Health Network Executive Advisory Committee and community pharmacist proprietor, KW had a thorough knowledge of the background of the SABA guidelines, AAP card and community pharmacy profession. Awareness of this potential for bias meant that every effort was made to ensure objectivity in the data collection and analysis. This included using a "non-stakeholder" as a moderator; verbatim transcripts of focus group discussions, multi-modal data collection (via field notes, transcripts and summary data) and independent thematic analysis conducted by a second researcher. Member checking did not involve verbal confirmations or access of medical records.

The findings of qualitative research are not generalisable and the ideas generated by these focus group discussions would need quantitative research to assess their applicability [15–17]. Additionally the poor awareness of the resources resulted in many of the discussions being hypothetical, which was an unexpected limitation of the research. Focus groups as a method have inherent limitations and can only explore the barriers and facilitators...
that participants can articulate. There may be unrecognised barriers and facilitators that were not uncovered by the research methods utilised. While the use of homogeneous focus groups allowed for frank and free discussion it would be useful in future research to attempt focus groups with heterogeneous groups of stakeholders. This would allow for exploration of the issues around lack of collaborative care in asthma, which were evident in the results.

Conclusions

Using guidelines and resources to improve asthma management requires an effective implementation strategy and consideration of knowledge, attitudinal and behavioural barriers to practice change. The discordant views of patients and health professionals regarding asthma management are a significant barrier to resource implementation and optimal patient health outcomes and this needs to be addressed. Interventions directed toward health professionals should focus on skills needs related to achieving improved communication and patient behaviour change.

Environmental barriers such as workflows need to be understood for effective incorporation of resources into practice.

Additional files

Additional file 1: Sample facilitator notes. (DOCX 67 kb)

Additional file 2: Patients with asthma at risk: Tools for implementation evaluation study. (PDF 84 kb)

Abbreviations

AFAP, Asthma Action Plan card; APFA: The Asthma Foundation of Western Australia; HDWA: Health Department of Western Australia; HREC: Human Research Ethics Committee; PSI: The Pharmaceutical Society of Australia; PSWA: The Pharmaceutical Society of Western Australia; SABA guidelines: Guidelines for provision of a Pharmacist Only medicine; short acting beta agonists: SABA; standard for the Uniform Scheduling of Medicines and Poisons (USMP): Standard for the Uniform Scheduling of Medicines and Poisons; UWA: University of Western Australia.

Competing interests

Ms Kim Watkins is the proprietor of a community pharmacy in Perth, Western Australia and this has a financial interest in community pharmacy.

Authors’ contributions

KW conceptualised and designed this qualitative research as part of her PhD studies, guided and supervised by CS, and RC. KW and RC secured funding for the research from the Health Department of Western Australia. CS was the facilitator of focus group sessions with KW present as an observer. Transcripts were thematically analysed independently by KW and JM. KW prepared an initial draft paper with all authors contributing to subsequent drafts and approving the final manuscript.

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4.3 Key findings from focus group study

Key findings included:

- There was poor awareness of the AAP card by stakeholders where passive dissemination methods had been used. This was not unexpected due to evidence in the scientific literature.

- Academic detailing provided high awareness of the SABA guidelines and AAP card by pharmacists. Conversely, pharmacy assistants were universally unaware of the SABA guidelines but highly involved in asthma medication sales and were attempting to assess and counsel asthma patients.

- Awareness, theoretical benefits and positive attitudes about the guidelines and resources did not extrapolate to behaviour change by patients, or practice change by health professionals. Barriers to implementation need to be addressed.

- Many barriers to guideline-based practice and use of the resources were identified and could be categorised according to a taxonomy of knowledge, attitudes and behaviours.

- Behavioural barriers related to the resources themselves, the working environment and the patient. Engaging with the patient was seen as a significant issue for all health professionals and resulted in a loss of self-efficacy to positively influence patient asthma management. Patients had views about asthma management that were discordant to the views of health professionals. To overcome barriers related to patient engagement and attitudes, health professionals require enhanced skills to improve communication and promote patient behaviour change.

- Environmental barriers related to lack of collaboration between health professionals, time and workflow issues. In particular, the role of non-professional
staff (pharmacy assistants) as the first patient encounter was one of the factors limiting the involvement of pharmacists in patient consultations. Such barriers need to be addressed before practice change can be achieved.

- Many suggestions were made about initiatives to improve asthma management. Main themes included up-regulation of legislation for non-prescription SABA purchases to include the mandatory recording of sales; development of electronic resources rather than paper-based resources; and training pharmacists or practice nurses to develop written asthma action plans for patients.

- To improve asthma guideline-based practice more consideration of the barriers to practice is required during implementation.

4.4 Relevance of findings to the thesis

It was evident from the focus groups that the initial academic detailing initiative had created good awareness by pharmacists of the SABA guidelines and AAP card. However, the education provided had not addressed barriers to the uptake of these tools into practice. It is useful to consider these results in terms of the Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework. RE-AIM can be used to assess the impact of translational research in health. The initial implementation demonstrated good “reach” to pharmacists but poor “reach” to other stakeholders. It also demonstrated poor “adoption” of the guidelines and card into practice. These findings directed the development of the implementation-intervention for this thesis (Chapter 6). The implementation-intervention devised was tailored to overcome identified barriers to SABA guideline-based practice. Stakeholders indicated
many problems inherent with the AAP card as a useable resource and thus it was
decided not to persist with this tool in implementation activities.

Many substantial barriers were identified to the use of the guidelines and also asthma
management in general. The challenge was to identify barriers that could be addressed
within the time frame and with the resources available for this thesis research. The
focus group research directed the thesis towards contemplating three main
intervention options.

1. Defining the role of the pharmacy assistant in SABA requests
2. Legislative change to support guideline-based practice
3. Smartphone Apps as a tool to support guideline-based practice

Ultimately, the insights from the qualitative focus group research directed an
implementation-intervention that was tailored to consider the role of the pharmacy
assistant, as part of the community pharmacy team, in the provision of SABA guideline-
based care to patients with asthma (Chapter 6).
4.5 References


Chapter 5:

A Cross Sectional Study to Characterise the Patient with Asthma Presenting to Community Pharmacy and Understand the Opportunities to Develop the Role of Pharmacists

Presented as published in the Nature Partner Journal (NPJ):

*Primary Care Respiratory Medicine*

*Impact factor 2015: 2.909*

5.1 Background

There have been many surveys conducted in Australia and around the world that characterise the patient with asthma.\textsuperscript{1-8} They indicate the significant issues with asthma management that exist, despite the availability of therapies that can control the symptoms of the disease for the majority of patients.\textsuperscript{9,10} The burden of this disease remains unacceptably high, notwithstanding substantial resource allocation to correct the situation.\textsuperscript{11,12} Community pharmacists represent an opportunity for intervention that is under-utilised but increasingly viable. The viability relates to high accessibility,\textsuperscript{13} policy support to strengthen primary healthcare,\textsuperscript{14} and the expanding clinical role of community pharmacists.\textsuperscript{15} However, to appropriately understand the opportunities to develop the role of pharmacists it is necessary to characterise the patients with asthma that they routinely encounter.

This chapter aims to assess the needs of patients with asthma who routinely present in community pharmacies. Through the analysis of the results, the study extrapolates patient need to opportunities for pharmacists to intervene.

This study informs the thesis in two ways. It answers the question, “Do patients with asthma need health professional intervention?” This provides an understanding of the relevance of the thesis. The study results also contribute to the design of the implementation-intervention (Chapter 6),\textsuperscript{16} in conjunction with the systematic review (Chapter 3)\textsuperscript{17} and focus group research (Chapter 4).\textsuperscript{18} It contributes by considering the many options for community pharmacist involvement in improving patient care.
5.2 Publication

Opportunities to develop the professional role of community pharmacists in the care of patients with asthma: a cross-sectional study

Kim Watkins¹, Aline Boudrin², Michelle Treveson¹, Kevin Murray³, Peter A Kendall¹, Carl R Schneider¹ and Rhonda Clifford¹

There are many indications in Australia and globally that asthma management is suboptimal. Ideally, patients need to proactively self-manage the condition with the support of health professionals. Community pharmacists are a highly accessible resource for patients but currently provide inconsistent services. General practitioners also face many barriers to the provision of chronic disease management for asthma patients. The aim of this research was to characterise patients with asthma who present to community pharmacy. The objective was to identify opportunities to develop the role of pharmacists in the context of the primary healthcare setting and in view of the needs of the patients they routinely encounter. The results of a comprehensive survey of 248 patients recruited from community pharmacies indicated there was discordance between patient perceptions of asthma control and actual asthma control. Almost half the patients surveyed had poorly controlled asthma, whereas almost three quarters perceived their asthma to be well or completely controlled. Fewer than 20% of patients were utilising written asthma action plans, and issues around quality use of medicines were identified. The significance of the incongruent perceptions regarding asthma control is that patients are unlikely to proactively seek intervention and support from healthcare professionals. Community pharmacists provide a significant opportunity to address these issues by direct intervention. There is scope to investigate pharmacists preparing written asthma action plans for patients, using software to monitor medication adherence and prescribe on-going medication. To maximise the potential of pharmacists, barriers to practice need to be identified and addressed.

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INTRODUCTION

Despite the important advances made in the past 30 years in the medical management of asthma, the condition remains suboptimally controlled and constitutes a significant health burden. Asthma has impacts at an individual and societal level, and has been a National Health Priority Area in Australia since 1990.¹

Currently, asthma is routinely managed in the primary-care setting by general practitioners (GPs). GPs are responsible for writing asthma action plans for patients and prescribing preventive medications (inhaled corticosteroids (ICSs)) to control the condition. However, deficiencies in the quality of care provided by GPs have been observed including, inadequate provision of written asthma action plans, lack of guideline compliant practice and suboptimal patient outcomes.²⁻⁴ One issue that impedes optimal asthma management by GPs is the lack of routine asthma visits by patients.⁵⁻⁷ Limiting the opportunities for patient education and chronic disease management. GPs observe that patients present only at times of acute exacerbations of asthma.⁸ Meanwhile, community pharmacists are the most highly accessible primary-care health professionals,⁹ yet are an under-utilised resource.¹⁰⁻¹²

Increasingly, there is evidence that indicates the potentially beneficial role that community pharmacists can have in reducing the burden of asthma.¹³⁻¹⁵ However, most of the research to date has been on guided screening and management programmes, undertaken as relatively short-term research interventions.¹⁶⁻²⁴ These programmes often require specialised training and resources. There is a paucity of translational research in asthma that develops sustainable roles for community pharmacists that are widely implemented as part of ‘routine practice’ and embraced by the broader healthcare system. On the contrary, there is evidence to indicate that in ‘routine practice’, community pharmacists are not assessing, intervening or referring patients appropriately and are falling well short of their potential.¹⁷⁻²⁰ Many barriers are impeding GPs and community pharmacists in the provision of quality, evidence-based care for asthma patients.²¹⁻²³

In Australia, the unrealised potential and suboptimal practice by community pharmacists is particularly relevant because of legislation that permits asthma reliever medications to be provided by pharmacists without a prescription. Legally, pharmacists have the responsibility to assess patient therapeutic need and directly supervise the sale of asthma reliever medications under Schedule 3 ‘Pharmacist-Only’ legislation.²⁴ The effect of this legislation is that community pharmacists may be the only health professional in a position to regularly assess patients with asthma relying on reliever medications. Even patients using ICSS and/or other prescription medication have prescriptions dispensed by pharmacists on a monthly basis, whereas GPs and medical
specialists are able to write a prescription for a 6-month supply and thus may only see the patient twice per year or less, depending upon medical adherence.

In recognition of the unique role that community pharmacists have in asthma management in Australia, the Pharmaceutical Society of Australia endorsed Guidelines for the provision of short-acting β₂-agonist as Pharmacist-Only medications (SABA) guidelines.21 However, to develop sustainable roles for pharmacists and identify opportunities for screening, intervention or referral within the scope of routine practice, it is important to understand more about the needs of patients with asthma routinely presenting in community pharmacy. This includes patients obtaining prescriptions as well as those who may be self-managing with reliever medications. There is a need to understand the issues of patients seeking help and advice as well as those who do not acknowledge they have any issues with asthma and simply visit pharmacies as a retail destination. What are the characteristics of the asthmatic patient that the pharmacist encounters on a daily basis?

The aim of this research was to characterize patients with asthma who present to community pharmacy. The objective was to identify opportunities to develop the role of pharmacists in the context of the primary healthcare setting and in view of the needs of the patients they routinely encounter.

RESULTS
Pharmacy and patient numbers
A convenience sample of 50 community pharmacies were invited to participate in the research and 39 agreed to act as patient recruitment sites. Comparisons based on pharmacy location and pharmacy type did not suggest any non-response bias (Table 1). Six Master of Pharmacy students surveyed a total of 249 patients over the 2-month data collection period. The number of questionnaires completed in each pharmacy ranged between 9 and 17 with a mean of 8.3 surveys collected per pharmacy. One survey was excluded due to incomplete data leaving a total of 248 surveys.

Demographics
Sixty-seven percent of patients surveyed were females, and 72% of patients were born in Australia (Table 2). The survey included an age range of 18.5–94.9 years with a median age of 48.8 years. Data on current employment status were pooled into employed (employed for wages and self-employed) and not employed (out of work and looking, out of work but not looking, homemaker, student, retired, unable to work).

Participant demographics—counts and percentages of categorical patient demographic variables

<table>
<thead>
<tr>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>82</td>
</tr>
<tr>
<td>Female</td>
<td>106</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
</tr>
<tr>
<td>18–49</td>
<td>127</td>
</tr>
<tr>
<td>≥50</td>
<td>121</td>
</tr>
<tr>
<td>Country of birth</td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>179</td>
</tr>
<tr>
<td>Other</td>
<td>69</td>
</tr>
<tr>
<td>Highest level of education</td>
<td></td>
</tr>
<tr>
<td>Up to year 12</td>
<td>130</td>
</tr>
<tr>
<td>Technical college/Bachelor/Post Graduate</td>
<td>118</td>
</tr>
<tr>
<td>Current employment status</td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>121</td>
</tr>
<tr>
<td>Not employed</td>
<td>127</td>
</tr>
<tr>
<td>Language primarily spoken at home</td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>239</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
</tr>
<tr>
<td>Household size</td>
<td></td>
</tr>
<tr>
<td>Small household (&lt;4 occupants)</td>
<td>186</td>
</tr>
<tr>
<td>Large household (4 or more occupants)</td>
<td>62</td>
</tr>
<tr>
<td>Income</td>
<td></td>
</tr>
<tr>
<td>Less than $80,000</td>
<td>135</td>
</tr>
<tr>
<td>$80,000 or more</td>
<td>93</td>
</tr>
</tbody>
</table>

Patient history and medication use
Of the 248 patients' surveys, 31 (12.5%) perceived that they had a life-threatening attack in the past 5 years. Thirty-nine patients (15.7%) owned a written asthma action plan to assist in management of their asthma (Table 3).

One hundred and eighty-one patients surveyed (73.0%) were using a 'preventer' medication to treat their asthma. Fifty-five patients (22.2%) were managing their asthma with a SABA alone and two patients (0.8%) were using a SABA and long-acting β₂-agonist (LABA) as their only therapy (Table 4).

Of the 181 patients using ICS, 98 (54.14%) had poorly controlled asthma. There were 148 patients using combination ICS and LABA, and 73 (52.2%) of these had poorly controlled asthma (Table 5). Patients using their asthma reliever inhaler more than once a week were significantly more likely to be using ICSs than patients not using their reliever that frequently (odds ratio (OR) = 1.85; 95% confidence interval (CI) = 1.01–3.38; P = 0.0449).

Table 6 gives a summary of the key results from each of the validated tools incorporated into the Asthma Questionnaire.25 Using the ACT, patients with a score of 20 or more are considered to have well-controlled asthma, whereas patients with a score of 19 or less are classified as having poor overall asthma control. In this survey, 120 patients (48.4%) had poorly controlled asthma.

Factors influencing asthma control
Table 7 shows the regression analysis of factors affecting asthma control. Univariate analysis indicated that poor asthma control was significantly related to older age (P = 0.0068), poor quality of life (P < 0.0001), poor beliefs about ability to control asthma (P < 0.0001), use of ICS (P = 0.0033), smoking (P = 0.0189) and sinusitis (P = 0.0005). No relationships were demonstrated...
between asthma control and knowledge scores or medication adherence scores. Ownership of a written asthma action plan, gender of the patient and concomitant hay fever were also not shown to be predictors of poor asthma control. Multivariate analysis demonstrated that the only significant relationship was between asthma quality of life and asthma control ($P = 0.0001$) where patients with higher scores in the AQOLS (indicating asthma has a greater negative impact on their quality of life) were significantly more likely to have poorly controlled asthma (for a one-point increase in AQOLS score: OR = 2.24, 95% CI = 1.93–2.59).

Factors influencing written asthma action plan ownership
A significant positive relationship was found between use of ICS and ownership of a written asthma action plan (ICS use versus no ICS use: $OR = 2.07$, 95% CI = 1.07–4.06, $P = 0.030$). Variables such as age, sex and asthma knowledge had no relationship with written asthma action plan ownership.

### Table 3. Selected responses to patient history questions—counts and percentages of categorical patient history variables

<table>
<thead>
<tr>
<th>Question</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms or treatment for asthma in the past 12 months? Yes</td>
<td>252, 93.55</td>
</tr>
<tr>
<td>No</td>
<td>165, 6.45</td>
</tr>
<tr>
<td>Asthma worse or out of control in the past 12 months? Yes</td>
<td>96, 38.71</td>
</tr>
<tr>
<td>No</td>
<td>152, 61.29</td>
</tr>
<tr>
<td>Hospital admissions in the last 12 months? Yes</td>
<td>7, 2.82</td>
</tr>
<tr>
<td>No</td>
<td>241, 97.18</td>
</tr>
<tr>
<td>Life-threatening asthma attack in past 5 years? Yes</td>
<td>31, 12.50</td>
</tr>
<tr>
<td>No</td>
<td>210, 87.50</td>
</tr>
<tr>
<td>Not sure</td>
<td>7, 2.82</td>
</tr>
<tr>
<td>Days off work, study or usual activities because of asthma? Yes</td>
<td>52, 20.97</td>
</tr>
<tr>
<td>No</td>
<td>195, 79.03</td>
</tr>
<tr>
<td>Lifestyle modifications due to asthma? Yes</td>
<td>110, 44.45</td>
</tr>
<tr>
<td>No</td>
<td>125, 55.55</td>
</tr>
<tr>
<td>Not sure</td>
<td>12, 4.44</td>
</tr>
<tr>
<td>Written asthma action plan ownership? Yes</td>
<td>99, 40.37</td>
</tr>
<tr>
<td>No</td>
<td>204, 59.63</td>
</tr>
<tr>
<td>Currently smokes? Yes</td>
<td>45, 18.15</td>
</tr>
<tr>
<td>No</td>
<td>203, 81.85</td>
</tr>
<tr>
<td>Co-morbidities—hay fever? Yes</td>
<td>106, 42.74</td>
</tr>
<tr>
<td>No</td>
<td>142, 57.26</td>
</tr>
<tr>
<td>Smokes? Yes</td>
<td>41, 16.58</td>
</tr>
<tr>
<td>No</td>
<td>207, 83.42</td>
</tr>
<tr>
<td>Depression? Yes</td>
<td>51, 20.56</td>
</tr>
<tr>
<td>No</td>
<td>197, 79.44</td>
</tr>
</tbody>
</table>

### Table 4. Patients current asthma medications

<table>
<thead>
<tr>
<th>Medication Type</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients not currently using any medication to control asthma</td>
<td>10, 4.05</td>
</tr>
<tr>
<td>SABA as only therapy</td>
<td>56, 22.58</td>
</tr>
<tr>
<td>SABA and LABA as only therapy (without any ICS)</td>
<td>2, 0.81</td>
</tr>
<tr>
<td>Patients using ICS (with or without other medications)</td>
<td>161, 67.75</td>
</tr>
<tr>
<td>Combination LABA/ICS (with or without other medications)</td>
<td>149, 59.65</td>
</tr>
<tr>
<td>Cromoglycate*</td>
<td>3, 1.21</td>
</tr>
<tr>
<td>Montelukast*</td>
<td>1, 0.40</td>
</tr>
<tr>
<td>Theophylline*</td>
<td>3, 1.21</td>
</tr>
</tbody>
</table>

*Abbreviations: ICS: Inhaled corticosteroids; LABA: Long-acting β2-agonists; SABA: Short-acting β2-agonists.*

All patients using these medications were also using an inhaler containing ICS.

### Table 5. Asthma control and medication use

<table>
<thead>
<tr>
<th>Medication Type</th>
<th>Poorly controlled</th>
<th>Well controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>N (%)</td>
<td>N</td>
</tr>
<tr>
<td>On ICS</td>
<td>22, 96</td>
<td>30, 84</td>
</tr>
<tr>
<td>Yes</td>
<td>96, 54.14</td>
<td>67, 45.86</td>
</tr>
<tr>
<td>No</td>
<td>58, 42.00</td>
<td>50, 58.00</td>
</tr>
<tr>
<td>On ICS/LABA combination</td>
<td>78, 52.70</td>
<td>70, 47.30</td>
</tr>
</tbody>
</table>

*Abbreviations: ICS: Inhaled corticosteroids; LABA: Long-acting β2-agonists.*

Factors influencing asthma attacks and emergency medical presentations
Patients with poor asthma control were significantly more likely to have had a ‘life-threatening asthma attack’ in the previous five years compared with those with good asthma control (OR = 2.58, 95% CI = 1.07–6.22, $P = 0.031$). Patients with a greater perceived ability to control asthma were significantly less likely to have had a ‘life-threatening attack’ in the previous 5 years compared with those with poorer perceived ability to control asthma (for a one-point increase in Perceived Control of Asthma Questionnaire score: OR = 0.90, 95% CI = 0.83–0.97, $P = 0.0039$).

Emergency presentations included urgent visits to a GP, Emergency Department (ED) or hospital admission, due to asthma getting worse or out of control or having a life-threatening attack. Patients with poor asthma control were significantly more likely to have had an emergency medical presentation compared with those with good control (OR = 2.74, 95% CI = 1.99–4.27, $P = 0.0003$). Patients with greater perceived ability to control asthma were significantly less likely to have had an emergency medical presentation compared with those with poorer perceptions about the ability to control asthma (for a one-point increase in Perceived Control of Asthma Questionnaire score: OR = 0.93, 95% CI = 0.88–0.98, $P = 0.0055$).

### Discussion

**Main findings**
This study achieved its aim to provide an understanding of the needs of patients with asthma in the community. It accomplished...
Table 6. Key results of individual validated tools from the Asthma Questionnaire

<table>
<thead>
<tr>
<th>Asthma control (ACT—Asthma Control Test)12,13</th>
<th>19.1 (sd. = 4.45, range: 5–25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median score of ACT</td>
<td>20</td>
</tr>
<tr>
<td>Number of patients with poor asthma control</td>
<td>120 (40.4%)</td>
</tr>
<tr>
<td>Number of patients who rated their asthma as being well controlled or completely controlled in the previous 4 weeks</td>
<td>175 (70.6%)</td>
</tr>
<tr>
<td>Number of patients who thought their asthma was well or completely controlled who were assessed as having good asthma control</td>
<td>119 (48.0% of the 175 patients)</td>
</tr>
<tr>
<td>Patients experiencing shortness of breath at least once in the previous 4 weeks</td>
<td>109 (44.0%)</td>
</tr>
<tr>
<td>Patients experiencing shortness of breath at least once in the previous 4 weeks</td>
<td>182 (73.4%)</td>
</tr>
<tr>
<td>Asthma quality of life (AQoL-5—Asthma Quality of Life Questionnaire—Sydney)14</td>
<td>1.32 (sd. = 1.54, range: 0.00–8.57)</td>
</tr>
<tr>
<td>Domain indicating greatest negative impact on quality of life due to asthma</td>
<td>Social disruption domain mean score 2.10 (sd. = 1.95, range: 0.00–10.00)</td>
</tr>
<tr>
<td>Domain indicating least negative impact on quality of life due to asthma</td>
<td>Concerns for health domain mean score 1.16 (sd. = 1.01, range: 0.00–9.04)</td>
</tr>
<tr>
<td>Patients who were troubled by shortness of breath in the previous 4 weeks</td>
<td>122 (59.4%)</td>
</tr>
<tr>
<td>Shortness of breath that was mildly troubling</td>
<td>102 (48.1%)</td>
</tr>
<tr>
<td>Shortness of breath that was severely or very severely troubling</td>
<td>17 (7.9%)</td>
</tr>
<tr>
<td>Patient medication adherence (NSU12—Adherence Starts with Knowledge Questionnaire)17</td>
<td>23.4 (sd. = 7.16, range: 12–41)</td>
</tr>
<tr>
<td>Mean score of ASK12</td>
<td>23.4 (sd. = 7.16, range: 12–41)</td>
</tr>
<tr>
<td>Mean subscale score for inaccuracy/forgetfulness</td>
<td>0.92 (sd. = 3.19, range: 3–15)</td>
</tr>
<tr>
<td>Mean subscale score for treatment beliefs</td>
<td>7.96 (sd. = 7.06, range: 1–17)</td>
</tr>
<tr>
<td>Mean subscale score for behaviour</td>
<td>8.49 (sd. = 3.50, range: 3–22)</td>
</tr>
<tr>
<td>Patients who did not disagree with the statement that they forgot to take their medication sometimes</td>
<td>112 (45.2%)</td>
</tr>
<tr>
<td>Asthma knowledge (CO—Consumer Asthma Knowledge Questionnaire)18,19</td>
<td>7.29 (sd. = 1.65, range: 2–10)</td>
</tr>
<tr>
<td>Mean score of CO</td>
<td>7.29 (sd. = 1.65, range: 2–10)</td>
</tr>
<tr>
<td>Mean domain score for management knowledge</td>
<td>4.13 (sd. = 1.17, range: 1–6)</td>
</tr>
<tr>
<td>Mean domain score for medication knowledge</td>
<td>3.16 (sd. = 0.92, range: 0–4)</td>
</tr>
<tr>
<td>Patients who knew that written asthma action plans could prevent hospitalisations</td>
<td>216 (87.1%)</td>
</tr>
<tr>
<td>Patients with a lack of understanding about medication side effects</td>
<td>139 (50.1%)</td>
</tr>
<tr>
<td>Patient beliefs about asthma control (PCAQ—The Perceived Control of Asthma Questionnaire)20</td>
<td>4.80 (sd. = 1.63, range: 2–6)</td>
</tr>
<tr>
<td>Mean score of PCAQ</td>
<td>4.80 (sd. = 1.63, range: 2–6)</td>
</tr>
<tr>
<td>Patients who did not disagree with the statement ‘It seems as though fate and factors beyond my control affect my asthma’</td>
<td>102 (41.1%)</td>
</tr>
<tr>
<td>Patients who agreed or strongly agreed with the statement ‘If I do all the right things, I can successfully manage my asthma’</td>
<td>221 (89.1%)</td>
</tr>
</tbody>
</table>

This through surveying patients in the community pharmacy setting but not targeting any particular subset of patients. In understanding patient need, it was possible to explore how the role of pharmacists can be developed to enhance patient asthma management. A key finding that warrants further investigation was the discordance between patient perceptions of asthma control and actual asthma control across the cohort. The significance of these perceptions is that patients are unlikely to proactively seek intervention and support from healthcare professionals in chronic disease management of asthma. They may only access services when experiencing acute exacerbations. Another interesting observation highlighted by the data was that patients had a good understanding of the benefits of written asthma action plans, yet there were low levels of ownership. There was little indication that patients were being proactive in obtaining and using written asthma action plans, despite understanding their importance. Medication issues were also evident from this survey. There were a significant number of patients with poor asthma control who were using anICS and, in most instances, also a LABA. Guidelines indicate that most patients can control their asthma symptoms with low-dose ICS.24 The combination of ICS/LABA is not first-line therapy and is only recommended when medium doses of ICS treatment fail. Given that under-treatment does not seem to be a significant issue related to poor asthma control observed in this cohort, other issues need to be addressed. These could include poor medication adherence, exposure to triggers, symptoms based on co-morbidities, smoking and/or poor inhaler technique.22

Although there were a large number of patients being prescribed ICS, there were still over a quarter of patients not using a preventative medication to control their asthma. An explanation for the better control seen in this cohort could be that these patients have less severe disease and hence are able to maintain better control. Nevertheless, there is evidence that patients with persistent asthma but only mild symptoms can benefit from daily ICS treatment.23 Meanwhile, the one-third patients not using preventative medication and with poor asthma control are at risk. Excessive use of SABAs has been clearly identified as a risk factor for serious asthma exacerbations and death.21

A surprising result from this survey was the relatively high proportion of patients who reported having a ‘life-threatening’ asthma attack in the previous 5 years. Life-threatening attacks refer to an ICU admission or the requirement for mechanical ventilation.25 Serious sequelae such as these are rare and in Australia in 2008–2009 the overall age-adjusted rate of invasive mechanical ventilation for asthma was just 18.5 per 1,000 hospital separations for asthma.26 The statistic measured could be
Table 7. Univariate regression analysis of factors affecting asthma control

<table>
<thead>
<tr>
<th>Variables</th>
<th>Odds ratio</th>
<th>95% Confidence interval</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>1.41</td>
<td>0.83-2.40</td>
<td>0.2072</td>
</tr>
<tr>
<td>Age</td>
<td>1.43</td>
<td>1.10-1.84</td>
<td>0.0066</td>
</tr>
<tr>
<td>RSAD2 1st d. increase (39.55 years)</td>
<td>1.16</td>
<td>0.91-1.50</td>
<td>0.2338</td>
</tr>
<tr>
<td>White asthma action plan</td>
<td>Yes versus no</td>
<td>1.02</td>
<td>0.51-2.01</td>
</tr>
<tr>
<td>Overall quality of life</td>
<td>One-point increase</td>
<td>22.35</td>
<td>9.27-53.88</td>
</tr>
<tr>
<td>Overall medication adherence</td>
<td>One-point increase</td>
<td>1.00</td>
<td>0.96-1.03</td>
</tr>
<tr>
<td>Overall knowledge</td>
<td>One-point increase</td>
<td>0.98</td>
<td>0.84-1.14</td>
</tr>
<tr>
<td>Patient beliefs score</td>
<td>One-point increase</td>
<td>0.69</td>
<td>0.84-0.94</td>
</tr>
<tr>
<td>On ICS medication</td>
<td>Yes versus no</td>
<td>2.42</td>
<td>1.34-4.35</td>
</tr>
<tr>
<td>Current smoker</td>
<td>Yes versus no</td>
<td>2.23</td>
<td>1.14-4.36</td>
</tr>
<tr>
<td>Hay fever</td>
<td>Yes versus no</td>
<td>1.28</td>
<td>0.72-2.12</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>Yes versus no</td>
<td>2.59</td>
<td>1.82-5.49</td>
</tr>
<tr>
<td>Combination ICS/LABA</td>
<td>Yes versus no</td>
<td>1.54</td>
<td>0.92-2.57</td>
</tr>
</tbody>
</table>

Abbreviations: RSAD2, Relative Socio-economic Advantage and Disadvantage; LABA, long-acting β2 agonist.

observed in a cross-sectional study in community pharmacy by Armour and colleagues.11 The main difference between the studies is that they were targeting patients for recruitment who were at risk of poor asthma outcomes. The discordance observed in actual asthma control versus perceptions of asthma control was also consistent with much of the literature in Australia.12,13 and around the world.14,15

The accepted issues associated with poorly controlled asthma were also evident from this survey. Patients with poorly controlled asthma were at greater risk of life-threatening attacks, having emergency medical presentations and suffering a reduced quality of life. Contrary to other surveys of asthma patients, no relationships were detected between asthma control and medication adherence and asthma control and rhinitis. However, this may have been due to a lack of power to detect such relationships. The lack of correlation with medication adherence may also have been related to limitations associated with ASK-12 tool, as it is recognised that adherence is difficult to measure.16

The ASK-12 is a subjective tool that is reliant on patient memory and willingness to report poor adherence.17 Objective measures are the gold standard, and subjective measures are considered less reliable. Problems with reliability were confirmed in validation studies of the ASK-12. The three subscales of the tool were slightly below the accepted cut-offs for reliability (test-retest reliability and internal consistency reliability). It was also noted that reliability might be impacted on in larger samples, because reliability is associated with an upper limit on a scale’s validity.17 These factors may all have been relevant to the unexpected results.

Despite the lack of correlation in the overall scores, there were indications from the ASK-12 subscale scores that adherence was not ideal. In one question almost half the patients conceded that they forgot to take their medications sometimes. This is consistent with literature reports that around 50% of patients on long-term therapy fail to take their medication at least some of the time.8 It is also well accepted that rhinitis is a comorbidity that can exacerbate asthma, is frequently under-diagnosed and increasing in prevalence.10 The fact that a correlation was not identified in this cohort may also relate to the timing of the survey. Rhinitis is a seasonal condition, and the data collection period for this survey was short and did not coincide with ‘hay fever season’. Conversely, the correlations observed in this cohort between rhinitis and sinusitis and asthma control and current smoking were consistent with the literature.10,11

The use of written asthma action plans has been recommended in Australian asthma guidelines for more than 20 years, and initiatives have failed to lift ownership levels that remain unacceptably low. The low levels of ownership seen in this cohort were consistent with Australian data from 2007 to 2008. This data reported 14.4% ownership in persons aged 15 years and over.18 In 2013, changes were made to remuneration pathways for GPs, designed to improve chronic disease management and increase levels of written asthma action plan ownership.19 However, there is a lack of evidence in this study to demonstrate improvements resulting from these changes.

The medication issues highlighted in this cohort are similar to those in other Australian surveys. In this survey 60% of patients were using ICS/LABA combination therapy, which implies an overuse of expensive and possibly unnecessary medication. High use has been observed in other Australian studies, albeit at variable levels of 59%20 and 65%.21 More disturbing was that this survey and others uncovered a small incidence of LABA use without concomitant ICS treatment. This is contraindicated because of increased risks to morbidity and mortality. The incidence was 0.8% for this cohort with 0.6%20 and 0.4%19 in other Australian studies. This high level of ICS in this and other surveys is in contrast to the results from a telephone survey of asthma patients conducted in 2007.22 They found the majority (33%) of

high because it represents the patients’ interpretation of ‘life-threatening attack’. If this were the case, it demonstrates how clinically important these symptoms are to patients. This cohort also indicated high rates of emergency visits to GPs but relatively low rates of ED presentations and hospitalisation. A possible interpretation is that patients have a poor understanding of the symptoms of asthma and when to seek medical help. Another interesting observation, that should be explored further, was the contradictory nature of the relatively high numbers reporting experience of a ‘life-threatening attack’ compared with the overall low concerns for health, indicated by the quality of life assessments. This observation could support the hypothesis that patients are not concerned and do not ‘pay attention to their asthma’, but panic and are scared when experiencing acute exacerbations.

Interpretation of findings in relation to previously published work. In this cohort of community pharmacy patients nearly half of the participants (48.4%) were assessed as having poorly controlled asthma, which is consistent with other studies in Australia and overseas.22,23 It is lower than the 77% with suboptimal control published in partnership with Primary Care Respiratory Society UK.
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adult participants were not currently using ICSs, and the figures were even lower in symptomatic patients. The survey also noted that 34% were managing their asthma with SABAs only, which was notably higher than the result of 22% for this survey.19

In terms of the treatment options, the figures from this survey were inconsistent with those from other Australian surveys. Hospitalisation due to asthma has been reported at levels of around 2.7% in children and 2.8% in adults, but in this survey the level was 2.8%. Similarly, ED presentations were 10% in a web-based survey but lower in this cohort at 7.7%. In contrast, a high proportion of patients (47%) in this survey reported that they had consulted their GP because their asthma was worse or out of control in the previous 12 months, compared with 28% for the web-based survey. It is likely that these variable results are due to patient interpretation of the question being asked. In the same web-based survey, 51% reported having a non-urgent visit to a GP for review of asthma, which correlates with this survey result of 47%. It may be that people in the web-based survey understood the term 'review' as not being related to chronic disease management, but a 'review' of their treatment due to an exacerbation.20 Interpretation of survey questions is also known to be a factor in patient reports of 'life-threatening exacerbations'.

Strengths and limitations of this study
A strength of this study is that it was a survey of community-based patients with asthma, visiting a pharmacy but not necessarily seeking advice or assistance with asthma management. Another strength is the comprehensive nature of the survey, utilising five variables to provide a complete picture of patient asthma management. Characterisation of patient attributes and needs permits consideration of the current and potential role community pharmacists have in intervening to improve supported self-management by patients. It also allows for consideration of the appropriateness of current referral pathways. This research will assist in the development of future research interventions being targeted to patient need and the development of formalised roles for pharmacists in asthma management.

A limitation of the study was the low statistical power for some of the subset analyses. However, given the gaps in the literature, this study was regarded as hypothesis-generating research to provide a greater understanding of the needs of patients presenting in community pharmacy. Subsequent research will be fully powered to investigate significant findings. Another limitation was the potential for bias in the recruitment of pharmacies and patients for this study. With a convenience sample, generalisability of the results may be limited. The busy retail environment of community pharmacy meant that staff may not have given all patients with asthma presenting in the pharmacy the chance to participate, resulting in staff-selection bias. There was also the possibility of self-selection bias in the sample. Time-poor patients or those working may not have been well represented. Patients who were concerned about their asthma may have been more willing to participate and over-represented. However, it was notable that the demographics were comparable to larger population studies. Another limitation is one associated with many asthma surveys,26 the issue that the diagnosis of asthma was self-reported and not confirmed by medical records. Assessments were only made using self-reported data; inhaler technique of patients was not assessed, which may have an impact on asthma control, even when medication adherence is high.

Implications for future research, policy and practice
Based on the Pharmacy Guild of Australia figures, the average community pharmacy encounters about 430 patients a month with asthma.27 Extrapolating from the results of the questionnaire, community pharmacies on average would encounter 200 patients with poor asthma control per month or 7 per day. The significant cost of these patients to the community in terms of lost productivity and healthcare utilisation is a burden that community pharmacists have the opportunity to reduce. Recent figures for 2015 indicate a total cost for asthma being $288m a year in Australia.28 Hospital admissions, ED presentations and emergency GP presentations could all be reduced by early intervention and referral of patients with poor control by community pharmacists. In the financial year 2008–2009, AstraZeneca costs alone for asthma totalled AUD $128 million and out of hospital medical services (primary services provided by registered medical practitioners) totalled AUD $198 million.29 Indirect costs associated with lost days off work and study could also be substantially reduced. In 2015, productivity losses due to asthma were estimated to be AUD $1.1 billion.30

Currently, health service provision in community pharmacy is inconsistent, and prescription dispensing directs the workflow in most community pharmacies. Guidelines indicate that pharmacists should refer asthma patients to a GP if they are fulfilling the following: experiencing an acute exacerbation; do not own a written asthma action plan; have not had a medical review in the past 6 months; or have been assessed as having poor asthma control.22 From our survey results, these criteria would require pharmacists to refer almost every patient with asthma that they encounter. Clearly, this strategy is not achieving the desired results in terms of asthma control, appropriate use of medicines and written asthma action plan ownership. One way to address the issue is to implement programmes to improve guideline compliant referral by pharmacists; however, this does not tackle the barriers faced at the level of the GP. Another option may be to expand the role of pharmacists. Greater recognition and formalisation of the clinical role of pharmacists may facilitate optimisation of the intervention opportunities for pharmacists as primary healthcare professionals. However, there are many barriers to clinical service provision by pharmacists including low patient receptivity, lack of established inter-professional collaborative pathways, time pressures, organisational issues and remuneration pathways that emphasise the sale of product and efficient dispensing, rather than supporting patient-centred health care.27 Nevertheless, this option seems reasonable to pursue based on pharmacists proven ability to positively have an impact on health outcomes of asthma patients, their high degree of patient accessibility and the demonstrated patient need.

There are several possibilities for expanded practice by pharmacists. Pharmacists could have a role in the development of written asthma action plans for patients. This addresses the current situation whereby patients are not presenting to doctors for written asthma action plans, despite having a sound understanding of their benefit. For pharmacists to undertake this role, further education and training would be required, but given their expertise in medication, it is within their scope of practice. Trials would need to consider how pharmacists could effectively collaborate with the patient's doctor to ensure appropriate medical review for patients.

As medication experts, pharmacists are also well placed to monitor the step-up and step-down medication regimen recommended for asthma to optimise therapy. Asthma, as a variable lung condition, requires continual monitoring and reassessment of dosage and this may not be occurring, especially given the low level of written asthma action plan ownership and the high incidence of LABA prescribing observed. Although pharmacists can identify medication issues, to be truly effective at improving outcomes they need to have the capacity to support guideline-based treatment and appropriate patient behaviours. This could possibly occur with an expanded prescribing role.

Under-treatment does not seem to be an issue for many patients in this cohort given the high proportion on combination LABA/ICS. Thus, the poor asthma control observed is likely to be
partly attributed to adherence issues including not using the prescribed medications appropriately or poor device technique, despite not being substantiated by this survey. Along with adherence issues, other explanations for poor control include misdiagnosis and difficulty-to-treat asthma. It is likely that only a small proportion would fall into these categories in which case the pharmacist could identify and refer these patients. Conventional access and cost of medication can influence ICS use in asthma patients. Patients may be prescribed ICS initially, but choose to medicate with cheaper and more accessible SABAs, particularly when required to see GP to obtain ongoing ICS prescriptions. They may have a poor understanding of the concept of preventative treatments and preferentially choose the treatment that provides obvious and immediate symptomatic relief. ‘Continued Dispensing’ is a novel way that pharmacists could contribute to solving these barriers. The Pharmaceutical Society of Australia released ‘Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists V1.0’ in January 2012. This new legislation allows pharmacists to use their professional judgement to maintain supply of certain medications and ensure continuity of therapy. In this way, pharmacists may intervene when patients seek to self-medicate with SABAs by offering education and a continued supply of ICS. A trial of Continued Dispensing of ICS could be considered given the results of this survey indicating high levels of ICS prescribing but still inadequate asthma control. However, any such trial would need to consider potential detrimental effects to the recommended 6-monthly medical review of patients.

Medication adherence issues are also a key area that pharmacists could have an impact on. Community pharmacists can easily monitor medication adherence via dispensing software. Studies have demonstrated the potential of computer-generated prompts in facilitating pharmacist intervention. The regular contact pharmacists have with patients provides the opportunity for discussion of the complexities that underlie non-adherent behaviour. However, deciphering patient beliefs requires time and advanced communication skills, using patient-centred counselling techniques. Pharmacists may require skills training to undertake more in-depth motivational style interviewing. Such activities are also labour intensive, and time and resources can also be allocated given appropriate remuneration.

Non-medication-related important barrier is not the only determinant in pharmacist participation in clinical services, and remuneration alone will not ensure successful uptake. Inhaler device technique checks are an example that demonstrates this issue. Remuneration has recently become available for pharmacists in Australia for inhaler technique checking, and this may improve uptake into practice, although other significant barriers to practice change have not been addressed. Workflows based around dispensing and pharmacy layouts possibly contribute to the difficulties in re-organisation of practice to accommodate clinical services and longer patient consultations.

Patient perceptions and receptivity may also be relevant. A lack of expectation of a service may lead to resistance by patients to participate or lack of motivation by pharmacists to provide the service. Multiple expanded services and remuneration options in asthma could provide the necessary incentive to undertake the organisational and capacity changes required. It could also expedite changes in patient perceptions and expectations from a pharmacy consultation. Currently, one of the issues pharmacists have with the non-prescription supply of SABAs are the patient barriers encountered. In a retail environment, patients have a sense of entitlement; they perceive that the medication is safe and do not expect to be asked questions. These communication issues are further exacerbated and problematic if patients have poor perceptions around asthma control. There are many areas in asthma management and patient care that pharmacists already participate in or could expand their practice to incorporate.

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These include improving inhaler technique, facilitating smoking cessation and providing holistic patient care by addressing comorbidities that influence asthma such as rhinitis, sinusitis and depression. The key may be expanding and formalising the pharmacists’ role in asthma to improve the viability of services and ensure consistency of care.

Conclusions

Pharmacists have the potential to optimise asthma management in the community by direct intervention. Nearly, half of the participants surveyed were assessed as having poorly controlled asthma, yet a proportion of patients displayed a lack of awareness of the issue and were thus unlikely to be seeking support from a health professional. Their poor control had them at risk of life-threatening attacks, requiring emergency medical care and experiencing a reduced quality of life. There is scope to investigate pharmacists preparing written asthma action plans for patients, using software to monitor medication adherence and prescribing on-going medications for asthma, to improve guideline-based management. To maximise the potential of pharmacists, barriers to practice need to be identified and addressed.

MATERIALS AND METHODS

Ethics

Ethics approval was obtained from the University of Western Australia’s Human Research and Ethics Committee (HREC, 1/4/1/150/009) for both the pilot and cross-sectional study. Written informed consent was obtained from all participants in this research.

Questionnaire development

A questionnaire was designed by the research team to comprehensively characterise patients and their asthma management in the primary healthcare setting. Demographic and patient history questions were based on epidemiological data available in Australia. A review of the literature was undertaken to investigate current, validated tools available. Of primary interest were review articles that provided a comprehensive and critical appraisal of available tools or recommended a gold standard. Additional areas of interest were tools previously used in an Australian setting. Several tools were selected for incorporation into a composite Asthma Questionnaire (Supplementary Appendix 1—Final composite asthma questionnaire—Validated tools included and scoring). Where necessary, licence to use the selected tools were obtained before commencement of study. The finalised Asthma Questionnaire was formatted into a user-friendly document to improve readability and simplify data entry (Supplementary Appendix 2—Questionnaire). A medication sheet was devised to complement the Asthma Questionnaire and record patients’ current medications. Endorsers of the questionnaire were sought and obtained from the National Secretariat of the Pharmacy Guild of Australia. The questionnaire was given an A1 rating as part of the Survey Accreditation Program of the Pharmacy Guild of Australia (Certificate Number 819).64

Pilot study

A pilot study was conducted in a community pharmacy in Perth, Western Australia, between March and May 2012. The aim was to assess the ease of recruiting participants with asthma from community pharmacies and the utility of the new composite Asthma Questionnaire. The pilot identified that patient recruitment was a challenge. Feedback from pharmacy staff and researchers indicated that the length of the questionnaire was a barrier to patient involvement. Researcher assistants administering the questionnaire reported that patients had difficulties in completing the 50-item knowledge section (BASE-AQ: Knowledge, Attitude, and Self-Efficacy Asthma Quassel) and that it substantially added to the time to complete the Asthma Questionnaire.

Modifications based on pilot study

Changes were made to patient recruitment methodology and to the composite Asthma Questionnaire based on the results of the pilot study. A more modular method of recruitment was devised to reduce the burden of
recruitment on pharmacy staff and to increase the speed of recruitment. Patients were recruited for their time. The 20 item KASE-AQ knowledge tool was initially selected for the composite questionnaire based on recommendations in a review article. It was changed to a more recently developed and shorter tool, the 10 item Consumer Asthma Knowledge Questionnaire (CQ). The CQ was not originally chosen for the pilot questionnaire due to criticisms raised about an earlier 12 item version. The authors of the CQ were contacted to obtain more information about the refined 10 item CQ and to respond to the review criticisms that were satisfactorily addressed. Apart from its brevity, another advantage of the CQ over the KASE-AQ was that it was developed by researchers at the University of Sydney and thus highly applicable to the Australian context.

Cross-sectional survey
The refined composite Asthma Questionnaire was administered as a semi-structured, cross-sectional survey, to patients with asthma, recruited from community pharmacies. The survey was administered to patients between March and May 2013.

Sample size
The feasibility of patient recruitment was based on information from the Pharmacy Guild Digest that each community pharmacy serves on average a population of 4,390 people. With 10% of the population currently reported to suffer from asthma in Australia that means that each pharmacy provided service to ~430 people with asthma. On average patients visited their community pharmacy about once per month. Thus, in a 2-week period, an estimate of 215 patients with asthma attended their community pharmacy. Assuming 5% recruitment resulted in a feasibility of 10 patients interviewed per pharmacy over the study period. This number was deemed appropriate and achievable given the resources available for the study. However, it should be noted that no formal prior sample size calculation was carried out.

Research assistant training
Master of Pharmacy students from the University of Western Australia acted as research assistants to administer questionnaires. They were provided initial training on ethics requirements, background information about asthma, guidelines and validated tools and how to administer the questionnaire. Weekly meetings were held throughout the data collection period to discuss any issues encountered. Research assistants sat with patients as they filled in the questionnaire and could clarify questions but only when patients asked for assistance. For instance, patients were only given definitions of ‘life-threatening asthma’ and ‘written asthma action plan’ if they specifically asked, thus their perception of these concepts was the basis for answers. Research assistants completed the medication sheet with information provided by patients. Following completion of the questionnaire, patients were asked if they had any questions. The research assistants were permitted to offer clinical advice within their capabilities as final year Masters students or could refer the patients back to the pharmacist in store.

Pharmacy recruitment and training
A convenience sample of community pharmacies, in the north metropolitan area of Perth, Western Australia, was invited to participate in the research as patient recruitment sites. Comparisons based on pharmacy type and pharmacy location were undertaken to check for potential non-response bias. A researcher visited each pharmacy to explain the methodology prior to commencement of the study. A PowerPoint presentation and instruction sheet was used as part of the training. Flyers and brochures were also developed to facilitate recruitment and promote the research in store. Research assistants were individually allocated to a pharmacy at set times over a 2-week period for patient interviews and data collection.

Patient recruitment and inclusion criteria
In response to the pilot study, three different recruitment methods were offered to pharmacists to encourage pharmacy participation. These were designed to maximise patient interview numbers as per Figure 1. Only one pharmacy decided to send out letters. Most recruitment was by provision of information brochures and incidentally when researchers were in store, where the banners attracted attention. Ethics requirements determined that researchers could not approach patients directly, which added to the challenge of recruitment. Pharmacy staff were instructed to offer interviews to any patient with asthma presenting to the pharmacy. The aim was to schedule interview appointments for at least 10 asthma patients over the 2-week researcher visit. Patient eligibility was based on the following three inclusion criteria: People diagnosed with asthma who were over 18 years of age and able to speak and read English.

Data analysis
Demographics and medical history were collated and tabulated. Each of the validated tools was scored individually. Summary statistics, including means, s.d., medians, maximums, minimums as well as percentages and counts were calculated for each question and for each tools summary score. Binary logistic regression was used to analyse relationships between questionnaire responses and poor asthma control, ICS use, ownership of an asthma action plan as well as medical presentation and life-threatening attack in the past 5 years (ever−yes and never−no). ORs and 95% CIs are provided. General linear regression was used to model (log transformed) quality of life and (log transformed) medication adherence and their relationships with patient demographics. Using participants’ postcodes, an index of Relative Socio-economic Advantage and Disadvantage (IRSD) value was assigned to each participant. The IRSD was collected in the 2011 Census of Population and Housing, and is one of the Social Indexes for Areas. Patient age, sex and IRSD score were adjusted for in all analyses. For all analyses, variables that were significant at the 5% level were retained in the final model. All data were analysed using the R environment for statistical computing.

ACKNOWLEDGEMENTS
We are grateful to the community pharmacies and their patients with asthma who agreed to participate in this research, along with the Master of Pharmacy students from the University of Western Australia who administered the questionnaires. We would also like to acknowledge Jennifer McQueen and the staff at SAVANT surveys for their assistance in formatting and scanning the questionnaires.

CONTRIBUTIONS
KW conceptualised and designed this research as part of her PhD studies, guided and supervised by CS, KM, PH and RC. KW and RC secured funding for the research from the Health Department of Western Australia. All assisted KW with literature searches for appropriate validated tools for the development of the questionnaire. KW developed the questionnaire. MTK and KM completed the statistical analysis with input from KW. KW prepared an initial draft paper with all authors contributing to subsequent drafts and approving the final manuscript.

COMPETING INTERESTS
KW is the proprietor of a community pharmacy in Perth, Western Australia, and thus has a financial interest in community pharmacy. The remaining authors declare no conflict of interest.

FUNDING
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REFERENCES

Supplementary Information accompanies the paper on the npj Primary Care Respiratory Medicine website [http://www.nature.com/npjpcrm/].
5.3 Key findings from patient survey

Key findings included:

- Approximately half the patients with asthma presenting to community pharmacy had poorly controlled asthma and were at increased risk of exacerbations and morbidity from their asthma.

- Patients with poor asthma control were significantly more likely to experience a reduced quality of life.

- Patient perceptions of asthma control did not align well with clinical control of asthma. For instance patients with poor asthma control perceived they had good control. The importance of this is that patients may not be proactively seeking health professional support.

- There were low levels of written asthma action plan ownership despite an acknowledgement by patients of their benefit. Patients were not proactive in ensuring written asthma action plan ownership and use in self-management.

- A large proportion of patients were prescribed optimal treatments (including ICS and ICS/LABA combinations) but still had uncontrolled asthma, as measured by the ACT. This meant that issues other than suboptimal treatment were possibly contributing to poor control. These could include issues such as medication adherence, exposure to triggers, symptoms based on co-morbidities, smoking and/or poor inhaler technique.

- About a quarter of patients were self-managing their asthma with reliever medications only. The majority of these patients had well-controlled asthma indicating mild and/or intermittent disease, but one-third had poor control and were consequently at significant risk of serious consequences and even death.
• There were indications that patients ignored their asthma most of the time but felt vulnerable and scared when experiencing exacerbations. This inference was related to the relatively high proportion of patients reporting a perceived "life-threatening attack", but overall the cohort surveyed reporting "low concerns" for their health.

• Patients in this cohort were likely to seek urgent medical care (usually from their GP) when they perceived they were experiencing exacerbations. This was indicated by the relatively high rates of emergency visits to GPs, but low rates of ED presentations and hospitalisation compared to national statistics.

• The lack of proactive asthma management by patients, detailed in this survey, indicate that opportunistic interventions by community pharmacists may be beneficial. The accessibility of community pharmacists is advantageous in this regard.

• Pharmacists could play an expanded role in asthma management through the preparation of written asthma action plans, using software to monitor medication adherence, and prescribing on-going medications for asthma.

• Further research is required to investigate expanded roles for pharmacists in asthma management and how to successfully implement them.

5.4 Relevance of findings to the thesis

It was evident from this study that a large proportion of patients with asthma routinely presenting in community pharmacies had issues managing their asthma. Furthermore, the one-quarter of patients managing their asthma with SABAs alone could do so without contact with any other health professional. This signified the need for the
work in this thesis. However, poor patient perceptions around issues with asthma management meant that patients were unlikely to be proactively seeking help from pharmacists or other health professionals. This finding directed that the implementation-intervention devised for this thesis (Chapter 6)\textsuperscript{16} addressed engagement and communication issues with patients, who were not necessarily seeking help with their asthma. It also reinforced the importance of community pharmacists as the focus for this thesis, being the frontline in primary healthcare due to their accessibility and incidental interactions with patients, who are not regularly presenting to GPs for assistance. The study identified areas for future research, not pursued by this thesis for logistical reasons; such as pharmacists preparing written asthma action plans and continued prescribing of ICS.
5.5 References


Chapter 6:

An Intervention Study to Implement Asthma Guidelines to Community Pharmacists to Improve Guideline-Based Practice

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6.1 Background

The preliminary research completed in this thesis provided rich information about clinical guideline implementation in community pharmacy (Chapter 3).\(^1\) It also identified barriers and facilitators to asthma management and guideline adherence in the primary healthcare setting (Chapter 4).\(^2\) Finally, it determined the needs of community-based patients with asthma and the opportunities for pharmacists to contribute to improved healthcare (Chapter 5).\(^3\)

This chapter represents the next phase of the research. It used all of the information gathered to develop, execute and evaluate the effectiveness of an implementation-intervention of the SABA guidelines to community pharmacy. By trialling an implementation-intervention based on the best available evidence, the aim was to facilitate a greater understanding of the strategies that influence the effectiveness of asthma guideline implementation in the community pharmacy.

The chosen intervention was tailored to address an identified barrier.\(^4-6\) The aim of the research from the outset was to influence routine practice and the “normal” patient experience in community pharmacies. The many barriers to clinical guideline implementation\(^7,8\) and issues in asthma management\(^9,10\) required careful consideration of all intervention options. While the patient survey (Chapter 5)\(^3\) had identified opportunities for enhanced roles for pharmacists such as the provision of written asthma action plans and prescribing of on-going medications, these were discounted as intervention options. Although worthwhile opportunities for future research, they were not developed and ready for translation to routine pharmacy practice. The need
for further research, pilot studies and possibly legislative changes determined that
time frames were not suitable for investigation in this thesis.

Ultimately, consideration of evidence in the literature, the data collected, logistical
constraints, and discussion with experts in the field, determined the selection of an
implementation-intervention. The implementation-intervention selected was designed
to address the unique and undefined role of the pharmacy assistant in guideline-based
SABA sales. It recognised the team environment of the community pharmacy setting,
which had not been accounted for in the initial implementation of the SABA guidelines,
as tools for pharmacists.

The systematic review (Chapter 3) identified that pharmacy assistants were often not
considered in guideline implementation to community pharmacy.¹ Focus group data
(Chapter 4) demonstrated the significant, but undefined and poorly equipped role
pharmacy assistants were playing in patient interactions.² Furthermore the patient
survey data (Chapter 5)³ emphasised that a high proportion of patients managing with
SABAs alone, and presenting in community pharmacy, may not encounter any other
health professionals. One-third of this cohort was found to have poor control, and
consequently patients were at risk of serious exacerbations and even death.

The implementation-intervention aimed to improve the knowledge, communication
skills and self-efficacy of pharmacy assistants in their interactions with patients with
asthma. It also provided a mechanism for pharmacy assistants to collect preliminary
patient assessment information to improve workflows, facilitate internal referral (from
the pharmacy assistant to the pharmacist) and enhance pharmacist involvement with
patients. Increasing the involvement of pharmacists in patient interactions was key and has been shown to improve outcomes.\textsuperscript{11,12} Additionally the implementation-intervention provided a motivation for practice change by demonstrating the financial viability of guideline-based practice. Motivation was addressed by educating pharmacists/owners on how to access current service-based remuneration pathways. Consideration of the optimal delivery method for the intervention involved how to educate staff members as a team, rather than just as individuals. The need to develop skills and tailor information to individual community pharmacies ultimately lead to the decision to deliver the implementation-intervention via small group workshops. This approach was supported in the literature where it was noted that interactive workshops had the potential to target knowledge, attitudes and skills at the level of the individual and the peer group.\textsuperscript{5}
BMJ Open Implementation of asthma guidelines to West Australian community pharmacies: an exploratory, quasi-experimental study

Kim Watkins,¹ Michelle Travlos,² Kevin Murray,² Peter A Kendall,¹ Carl R Schneider,² Rhonda Clifford¹

ABSTRACT

Objectives: Pharmacy assistants are often the first point of contact for patients presenting in community pharmacies. The current role of pharmacy assistants in the supply of asthma reliever medications (short-acting β₂-agonists) was identified as a barrier to appropriate guideline-based care. The aim of this research was to devise and evaluate a team-based intervention to formalise the role of pharmacy assistants and to improve asthma guideline-based care in community pharmacy.

Design: A controlled pre-post intervention study was conducted in 336 metropolitan pharmacies located in Perth, Western Australia. Pharmacies were stratified into 2 groups (167 intervention and 149 control) based on known confounders for asthma control. The intervention was designed using a common-sense approach and resources developed included a checklist, videos and two page. Delivery was via workshops (25 pharmacies) or academic detailing (162 pharmacies). Pharmacy practice was assessed preintervention and postintervention via covert simulated patient methodology. Primary outcome measures included patient medical referral, device use demonstration and counselling, internal referral and direct involvement of a pharmacist in consultations.

Results: There was a significant increase in patient medical referral in intervention pharmacies from 32% to 47% (p=0.0007) from preintervention to postintervention, while control pharmacies showed no significant decrease from 50% to 44% (p=0.22). Device counselling was not routinely carried out at any stage or in any cohort of this research and no significant changes in internal referral were observed.

Conclusions: Increases in medical referral indicate that asthma guideline compliance can be improved in community pharmacy if implementation employs a team-based approach and involves pharmacy assistants. However, results were variable and the intervention did not improve practice related to device counselling or internal referral pharmacist involvement. Undertaking more workshops may have improved results. Guideline implementation in community pharmacy should consider the role of pharmacy assistants and how to overcome logistical barriers to pharmacy participation in implementation activities.

Strengths and limitations of this study:
- This research used a thorough methodological approach to designing a ‘common-sense’ intervention to improve asthma guideline compliance.
- The intervention was typical because it recognised the impact of pharmacy assistants on the professional practice of community pharmacists, which is often not considered, but is pivotal, in this setting.
- The intervention was unique in its team-based approach to community pharmacy practice to improve guideline compliance.
- Conclusions were limited by the lack of baseline equivalence of groups for the primary outcome of medical referral.
- Generalisability of the findings was reduced due to self-selection of workshop pharmacies. Self-selection can introduce bias, as participants are likely to be more motivated to improve professional practice.

BACKGROUND

Asthma is a chronic respiratory disease characterised by recurrent episodes of wheezing, breathlessness, chest tightness and coughing. Although there is no cure for asthma, symptom control can be achieved in most patients with appropriate treatment. However, poor asthma control and inappropriate patient self-management remain an issue in Australia and throughout the world, despite the availability of effective therapies.

In Australia, a national classification system exists, called scheduling, which controls how medicines and chemicals are made available to the public. S4 ‘Prescription Only’, S3 ‘Pharmacist Only’
and S2 ‘Pharmacy Only’. Asthma-reliever medications (short-acting β2agonists or SABAs) are classified as S3 and thus can be purchased without a prescription and without seeing a doctor, but under the direct supervision of a pharmacist. The community pharmacist is required to intervene and refer patients who may be inappropriately managing their condition. The term ‘medical referral’ is used to denote when the community pharmacy staff instruct a patient to seek medical advice from a general practitioner (also called a physician or doctor).

Research by Schneider et al. demonstrated that community pharmacists were not adequately fulfilling their role in appropriate referral. In response to the identified practice deficits, the Guidelines for provision of a Pharmacist Only medicine: short-acting β2 agonists (SABA guidelines) were endorsed by stakeholders and distributed to pharmacists by the Pharmaceutical Society of Australia (PSA) and The National Asthma Council of Australia (NAC) in 2011.15

In recent years, there has been a proliferation of clinical guidelines as a method to promote evidence-based healthcare. However, research suggests that clinicians frequently do not follow guidelines, resulting in an evidence-practice gap.15 16 In the community pharmacy setting, research on clinical guidelines implementation is relatively new and there is little evidence on how to improve evidence-based practice.17 Most of the research to date has focused on the potential of pharmacists to achieve positive patient health outcomes through enrolling non-service-users.18 19 While this can indicate some of the issues relevant to suboptimal evidence-based practice, it does not fully explain the barriers to research translation and effecting change on the routine practice of community pharmacists.

The standards accreditation process (Quality Care Pharmacy Program) for community pharmacies in Australia requires pharmacy assistants, involved in handling non-prescription, scheduled medicine sales (including SABAs), to complete an online training unit by the Pharmacy Guild of Australia, while under supervision in the workplace.15 16 Pharmacy assistants not working in accredited pharmacies and/or not servicing patients with non-prescription, scheduled medicines are not required to complete the Guild courses and may not receive any formalised training. However, with 90% of pharmacies across Australia currently accredited,17 the majority of pharmacy assistants should receive some basic training.

Focus groups conducted with pharmacists and pharmacy assistants in 2012, regarding the utility of the SABA guidelines, indicated that there were many barriers to guideline-based practice.15 Particularly remarkable was the observation that pharmacy assistants who participated in the study were universally unaware of the guidelines, but were highly involved in the non-prescription supply of SABAs, rather than internally referring patients to the pharmacist.18 This lack of knowledge and high participation in supply was unexpected because of the mandatory training requirements for pharmacy assistants (in accredited pharmacies) and the legislation requiring pharmacists to be directly involved in patient assessment and supply of SABAs (S3 ‘Pharmacist Only’ legislation).15 19 20

The initial implementation strategy of the SABA guidelines had not addressed the issue of pharmacy assistant involvement and the barriers to internal referral of patients from pharmacy assistants by pharmacists.21 There was no acknowledgment of the workflows that exist in community pharmacy whereby the pharmacy assistant is often the first person to encounter patients requesting non-prescription asthma-reliever medications. There was only recognition of the legislation requiring pharmacist involvement; thus, the focus was to disseminate information about the guidelines to pharmacists.21 The focus group observations indicated that this was a significant oversight, particularly in light of previous research by Schneider et al.22 Schneider et al.22 ascertained that outcomes for asthma patients, in terms of appropriate medical referral, were poorer when pharmacy assistants alone were involved in asthma-reliever medication sales.

Another barrier identified in non-prescription SABA supply was the difficulties pharmacy assistants encountered trying to engage with asthma patients, who they found resistant to questioning and impatient.18 Research shows that there is discordance between perceived asthma control and actual symptomatic control,23 24 so it is not unexpected that patients with asthma are resistant to engagement as they do not perceive they need support. Unfortunately, poor patient disclosure of health information in community pharmacy is an issue, which can influence appropriateness of outcomes.25 26 Where such barriers exist, the recommendation is for interventions that promote better communication between patients and pharmacy staff.27

It was evident that workflows supporting the involvement of pharmacy assistants, unaware of the SABA guidelines and experiencing difficulties with engagement of patients with asthma, were creating a barrier to pharmacist participation, appropriate guideline-based assessment and patient medical referral. Therefore, the aim of this research was to devise and evaluate a team-based intervention to formalise the role of pharmacy assistants in order to improve asthma guideline-based care in community pharmacy.

METHODS

Design of a ‘common-sense’ intervention to overcome an identified barrier

‘Common-sense’ interventions are designed using a pragmatic and logical approach based on empiric evidence and past experience.29 The design of this intervention was undertaken by researchers with experience and knowledge of community pharmacy practice, based on evidence obtained from the scientific literature and information from focus groups. Researchers, from their
experience in community pharmacy, recognised that activities undertaken in the pharmacy required \textit{team} effort and \textit{team} support. Evidence from the literature was gleaned by undertaking a systematic review to examine the effectiveness of implementation strategies for \textit{clinical guidelines} to community pharmacy.\textsuperscript{12} There was little evidence that was conclusive about the best approach to implementation of guidelines in community pharmacy, but there was an observation that it was important to consider the role of non-professional staff (pharmacy assistants), due to the influence they can have on the practice of pharmacists. This observation is consistent with the findings of Schmee et al\textsuperscript{23} who demonstrated improved patient outcomes associated with patient referral from assistants to pharmacists. However, few implementation interventions had previously included pharmacy assistants. Also there were few studies based on and demonstrating the benefit of behavioural theory in intervention design. Reviews on guideline implementation from other settings were also considered and there was a general consensus that it was important to identify barriers and tailor interventions to overcome them.\textsuperscript{30, 31} Focus groups were used to map barriers and facilitators of guideline implementation and asthma management.\textsuperscript{30} Many barriers were identified, but two key issues were used in developing the intervention. Communication issues were problematic due to the discordant views of patients and health professionals on asthma management. It was also evident from the focus group discussions that pharmacy assistants played a significant role in assessing and counselling patients but had problems engaging with patients. A variety of intervention options were considered, including smartphone apps, legislative changes, and patient health promotional activities. Ultimately formulating an \textit{appropriate} role for pharmacy assistants to support pharmacists was chosen. This option was practical, relatively simple, unique and supported by the evidence and preliminary research.

\textbf{Design logistics}

Small group workshops were chosen as the delivery mode for the 'common-sense' intervention. Poor uptake of workshop invitations required adaptation of the intervention and subsequently academic detailing was undertaken in pharmacies in the intervention group that did not participate in workshops. Academic detailing was a reasonable adaptation based on evidence of effectiveness of this strategy from the literature.\textsuperscript{49, 53} and the fact that it uses face-to-face interaction in the practice setting, as did the workshops. Workshops and academic detailing were completed between October 2013 and March 2014.

The primary author (KW) conducted the workshops. As a community pharmacist and pharmacy proprietor, the primary author had a good understanding of the workshop material and of pharmacy staff and their working environment. A background of teaching pharmacy practice and communication skills provided the necessary skill set to conduct workshops. Workshops were conducted in each pharmacy and all staff members of that pharmacy were encouraged to participate. Workshops ran for between 1 and 2 hours depending on the level of group discussion. Conducting training in-store allowed for tailoring of information based on the observed environment, current workflows and staff relating previous experiences with patient engagement. The components of the intervention included group education and communication skills training. Information was provided about asthma, the patient perspective, improving communication, legislative requirements, the SABA guidelines and reimbursement opportunities in practice. A Microsoft PowerPoint presentation, two videos and checklist tool were developed specifically for the workshop. Educational materials from the NAC and Asthma Foundation of Western Australia, as well as copies of the SABA guidelines from the PSA, were provided to pharmacists. Workshops were interactive and group discussion was used to motivate staff and give them 'ownership' of the optimum way to use the resources. It was important to include pharmacists in the intervention and not just pharmacy assistants. During the intervention design process, recognition was given to the fact that the community pharmacy functions as a whole system and pharmacy assistants and pharmacists needed to support each other to achieve the desired outcomes. To maintain practice-change post workshop, pharmacies were provided a DVD of all workshop content (including the video material), notepads of checklists ready to implement and a link to a web page containing PDF documents of the guidelines and checklist that could be printed (http://www.asthma-pharmacy.org). They were also encouraged to contact the research team if they had any issues or successes.

Academic detailing is also known as educational outreach. It involves trained researchers visiting health professionals in the workplace to provide them information on how to change practice. Three pharmacists were trained by the primary author (KW) to conduct detailing visits. Each academic detailing visit took \textasciitilde{}15 min. The trained academic detailers were given a standardised protocol to ensure uniformity in the information provided to the community pharmacies. The information and resources provided in the academic detailing visits were consistent with the information provided in the workshop. The difference was that the information was provided to the pharmacist-in-charge at the time of the visit, rather than the pharmacy staff as a team. This required the pharmacist-in-charge to act as a disseminator of information and driver of practice change. It also did not allow for tailoring of the information via group discussion as was achieved in workshops. Pharmacies received, as part of the academic detailing visit, a copy of the SABA guidelines, a DVD of all workshop content (including the video material), notepads of checklists ready to implement and a link to the asthma-pharmacy web page (http://www.asthma-pharmacy.org).
Resources
Checklist development
A tool was devised centred on the assessment information outlined in the SABA guidelines (see online supplementary material). The concept was based on an existing "Emergency contraception checklist" that is accepted and widely used by pharmacies in Western Australia. It was anticipated that an equivalent tool for provision of SABAs would be relatively easy to incorporate into practice. The Asthma Medication Request Checklist is a 7-item simple tick-box tool, which can be completed by patients alone or with the support of a pharmacy assistant within a couple of minutes.

It aimed to influence all of the target outcomes by acting as a pre-screening tool, an internal referral tool and time-management tool. An incentive to using the checklist was that it complied with documentation requirements to access remuneration pathways for clinical service provision and meet accreditation standards. An expert panel of pharmacists was used to refine the tool and it was formatted in a way consistent with other tools promoted by PSA. As a communication tool/patient engagement tool, the checklist allowed pharmacy assistants to collect information from patients not receptive to answering questions. It achieved this in a few ways. The form added formality to the interaction making patients feel it was important to answer the questions. It overcame patient frustration with the inadequate communication skills of pharmacy assistants. Pharmacy assistants were empowered to collect information where previously they had been reluctant to ask questions for fear of "upsetting patients". It also avoided a situation whereby patients were asked the same questions by assistants and then again by pharmacists. Collecting the information was time effective, which was important in situations where impatience was undermining interactions. It also allowed pharmacists to have more in-depth and personalised discussions based on the information already gathered. Such tailored conversations were more relevant, meaningful and interesting to patients. The checklist was an alternative way of engaging with patients who had become accustomed to pharmacy staff asking "annoying" questions in an unimaginative way, or not making any assessments at all. Staff were reminded that filling in the checklist was not the goal. The checklist was simply a tool to help them engage and achieve appropriate guideline-based care of the patient.

Training videos
Two videos were produced for the training workshops.

The first video was a patient story describing a near death experience with asthma. Understanding the patient perspective was also used as a method of enhancing communication and a more empathic approach by pharmacy staff. The second video was a role-play video used to demonstrate the difficulties with patient engagement and also to model the desired behaviour and use of resources. Humour in the video was used to facilitate discussion. By sharing stories of problematic patient encounters, staff were able to reflect on how to improve patient engagement in the future.

Trial design
The study was a controlled trial with a control group (no intervention) and an intervention group conducted in community pharmacies in Perth, Western Australia. The groupings were based on geographical location. Perth is an urban centre with development extending along the coastline of the Indian Ocean and divided by the Swan River. To the east of the city is a steep escarpment known as the Darling Scarp. The areas chosen were the south and north metropolitan areas of Perth, Western Australia. Eastern suburbs were excluded due to possibility of environmental and socioeconomic factors influencing results, as indicated by a report on geographic distribution of asthma hospitalisations from Australia. The purpose of the stratification was to reduce potential cross-contamination of data using the Swan River as a geographical dividing line. A baseline assessment was used to demonstrate that the selected north/south groups were equivalent. Assessments were performed at baseline and post intervention. The study was performed between September 2012 and June 2014. The sample size was determined by including all pharmacies in the south and north metropolitan area of Perth, Western Australia, listed on the Pharmacy Registration Board of Western Australia Premises Register. Hospital pharmacies were excluded from the study. The primary author performed all group allocations.

Prebaseline pilot testing
Simulated shoppers visited a random sample of 60 pharmacies in the non-intervention and intervention groups (30 south and 30 north) in September 2012. This pilot testing was undertaken before baseline data collection started, to validate the stratification method chosen. There were no significant differences in the cohorts for the primary outcome of appropriate medical referral (63.3% referral south vs 56.7% referral north, p=0.60).

Implementation of the intervention
Each community pharmacy in the intervention area (north metropolitan) was invited to participate in an individual, in-store, small group, asthma-training workshop. An initial invitation letter was sent with follow-up via phone call and email. The invitation encouraged all pharmacy staff to attend, including professional and non-professional staff; full-time, part-time and casual staff. The primary author enrolled all workshop
participants. Academic detailing of workshop content was provided to pharmacies in the intervention area that did not participate in workshops. Academic detailing was performed using a ‘cold calling’ method with no prior appointment. This method was selected after consultation with researchers with previous experience in academic detailing in community pharmacy. With visits being conducted during normal working hours, interruptions to conversations were inevitable. To minimise the disruptions, detailing visits were scheduled between 10:00 and 16:00. Detailers were limited to a maximum of eight detailing visits in 1 day to avoid fatigue.

Data collection
Data collection was via covert simulated patient methodology. As per ethics approval, pharmacies were not informed that they would receive simulated patient visits. This methodology has been widely and successfully used in the community pharmacy setting by pharmacy practice researchers at the Centre for Optimisation of Medicines at the University of Western Australia. A 1-day training session was held for four research assistants who were provided information about the scenario, data collection and data entry. The training session provided opportunities for role-play and refinement of tools where necessary. Following the training day, the research assistants piloted the methodology in eight pharmacies to ensure fluency in the scenario and to test for unforeseen issues. The research assistants included a female pharmacist aged 25–30 years, two university students aged 20–25 years (man and woman) and a woman aged 45–50 years. Simulated patients were blinded to the group allocation.

Scenario
The scenario involved a simulated patient presenting to a community pharmacy asking ‘Could I buy a Ventolin please?’ Ventolin is a common brand of asthma reliever medication used in Australia. Although the simulated patients could provide more information upon request, they were instructed not to volunteer information. Table 1 outlines the scenario description. If pharmacy staff sought further information, patient assessment would reveal a patient with poorly controlled asthma and poor inhaler technique. This required inhaler technique training and immediate medical referral in accordance with guidelines. Simulated patients were provided an empty Ventolin inhaler if asked to demonstrate inhaler technique.

Outcomes
The primary outcomes of interest related to guideline and legislative compliance. These included patient medical referral to a doctor for uncontrolled asthma, inhaler device demonstration and increases in pharmacist internal referrals or direct

<table>
<thead>
<tr>
<th>Table 1 Simulated patient scenario description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient request</strong></td>
</tr>
<tr>
<td><strong>Possible questions and answers based on WWHAM guidelines</strong></td>
</tr>
<tr>
<td>Who is the patient?</td>
</tr>
<tr>
<td>What are the symptoms?</td>
</tr>
<tr>
<td>How is your asthma?</td>
</tr>
<tr>
<td>How long have you had asthma/symptoms?</td>
</tr>
<tr>
<td>What treatments have you tried for these symptoms?</td>
</tr>
<tr>
<td>Do you have any other medical conditions/medications?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma has been getting worse over last month</td>
<td></td>
</tr>
<tr>
<td>For the last month has been using Ventolin 2 puffs once every day to relieve symptoms</td>
<td></td>
</tr>
<tr>
<td>Has been using Seretide regularly at a dose of 2 puffs twice a day for 2 years</td>
<td></td>
</tr>
<tr>
<td>The last time they saw a physician/doctor was ‘ages ago’</td>
<td></td>
</tr>
<tr>
<td>Has not ever been admitted to hospital with asthma before</td>
<td></td>
</tr>
<tr>
<td>Does not have a written asthma action plan</td>
<td></td>
</tr>
<tr>
<td>Does not know the rule of 4s—what to do in an emergency</td>
<td></td>
</tr>
<tr>
<td>Trigger factors for asthma include pet hair and pollen</td>
<td></td>
</tr>
<tr>
<td>Ventolin=salbutamol 100 µg per actuation (blue inhaler)</td>
<td></td>
</tr>
<tr>
<td>Seretide=fluticasone/salmeterol 250 µg/25 µg per actuation (purple inhaler)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inhaler technique</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>If inhaler technique is assessed, the inhaler is not shown before use and the breath is not held after inhalation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Appropriate outcome</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Medical referral for poor asthma control</td>
<td></td>
</tr>
<tr>
<td>B. Correction of poor inhaler technique</td>
<td></td>
</tr>
</tbody>
</table>


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involvement of a pharmacist in consultations. Secondary outcomes included use of the Asthma Medication Request Checklist introduced in the intervention and increases in the number of appropriate assessment questions asked by pharmacy staff (pharmacists and pharmacy assistants).

Statistical analysis
Percentages and counts (N) were calculated for each of the categorical variables for the intervention and non-intervention pharmacies at pre-post intervention time points. To investigate whether north and south pharmacies were equivalent, prebaseline $\chi^2$ tests (or Fisher's exact tests where appropriate) were conducted to compare whether specific questions were asked. To investigate bias between simulated patients, a $\chi^2$ test was conducted comparing the primary outcome of patient medical referral. Binary logistic regression was used to investigate differences in whether specific questions were asked (events="Yes") between cohorts (intervention and non-intervention) and times (each model also contained their respective interaction). ORs, 95% CIs and p values are provided. Linear regression was conducted to analyse differences in continuous outcomes between cohorts and times. Mean differences, SE of the differences and p values are provided. Data were analysed using the R (Version 3.1.3) environment for statistical computing (R Core Team, R: a language and environment for statistical computing, 2015, http://www.r-project.org).

RESULTS
Participant flow
Simulated patient visits were conducted in 336 pharmacies at two time points (pre-intervention (January 2013–March 2013) and post-intervention (April 2014–June 2014)). Of these, 187 pharmacies received an intervention (north metropolitan) and the remaining 149 pharmacies (south metropolitan) did not. Workshop interventions were conducted in 25 pharmacies with 137 staff members. Academic detailing was undertaken in 162 pharmacies. A total of three pharmacies were excluded from the analyses due to incomplete data. Figure 1 shows the flow of participants through the intervention.

Figure 1 CONSORT flow chart of participants.

<table>
<thead>
<tr>
<th>Intervention cohorts</th>
<th>North metropolitan (intervention cohort)</th>
<th>South metropolitan (control)</th>
<th>Cohort comparisons</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre, count (%)</td>
<td>Post, count (%)</td>
<td>Pre, count (%)</td>
</tr>
<tr>
<td><strong>Time of simulated patient assessment (preintervention or postintervention)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Counsellor demographics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Position of first counsellor*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>55 (29.4)</td>
<td>55 (29.4)</td>
<td>NS</td>
</tr>
<tr>
<td>Pharmacy assistant</td>
<td>31 (16.6)</td>
<td>36 (20.3)</td>
<td>NS</td>
</tr>
<tr>
<td>Other</td>
<td>10 (5.3)</td>
<td>7 (3.7)</td>
<td>NS</td>
</tr>
<tr>
<td>Unsure</td>
<td>91 (48.7)</td>
<td>87 (46.5)</td>
<td>NS</td>
</tr>
<tr>
<td>Change in counsellor (when first consultant was a pharmacy assistant at both time points)*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No change</td>
<td>5 (83.3)</td>
<td>4 (66.7)</td>
<td>NS</td>
</tr>
<tr>
<td>Assistant to pharmacist</td>
<td>0 (0.0)</td>
<td>1 (16.7)</td>
<td>NS</td>
</tr>
<tr>
<td>Pharmacist consulted</td>
<td>1 (16.7)</td>
<td>1 (16.7)</td>
<td>NS</td>
</tr>
<tr>
<td>Consultation details</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waiting time (busyness measure)†</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>155 (82.9)</td>
<td>170 (90.9)</td>
<td>0.0236</td>
</tr>
<tr>
<td>1-5 min</td>
<td>31 (16.6)</td>
<td>16 (8.6)</td>
<td>NS</td>
</tr>
<tr>
<td>Over 5 min</td>
<td>1 (0.6)</td>
<td>1 (0.5)</td>
<td>NS</td>
</tr>
<tr>
<td>Patient assessment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questions (frequently asked)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is this product for you?</td>
<td>125 (68.8)</td>
<td>124 (66.3)</td>
<td>NS</td>
</tr>
<tr>
<td>Have you used this product before?</td>
<td>77 (40.1)</td>
<td>58 (31.0)</td>
<td>NS</td>
</tr>
<tr>
<td>How often are you using your reliever?</td>
<td>60 (32.1)</td>
<td>71 (38.0)</td>
<td>NS</td>
</tr>
<tr>
<td>Have you had a review by a doctor?</td>
<td>48 (25.7)</td>
<td>45 (24.1)</td>
<td>NS</td>
</tr>
<tr>
<td>Are you using a preventer?</td>
<td>24 (12.8)</td>
<td>92 (49.2)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td><strong>Inhaler technique questions asked</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>When did you last have your device technique checked?</td>
<td>1 (0.6)</td>
<td>0 (0.0)</td>
<td>Not performed</td>
</tr>
<tr>
<td>Can you show me your technique?</td>
<td>1 (0.6)</td>
<td>2 (1.1)</td>
<td>Not performed</td>
</tr>
<tr>
<td>Demonstration of technique</td>
<td>2 (1.1)</td>
<td>1 (0.5)</td>
<td>Not performed</td>
</tr>
<tr>
<td>Device technique demonstrated (NS; Demonstrated technique in all instances was incorrect)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication counselling information provided</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information given (most frequently)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information given on dosage</td>
<td>20 (10.7)</td>
<td>25 (13.3)</td>
<td>NS</td>
</tr>
<tr>
<td>Information given on duration/frequency of use</td>
<td>13 (7.0)</td>
<td>34 (18.1)</td>
<td>0.0013</td>
</tr>
<tr>
<td>Discussions about medical referral</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referral to a healthcare professional</td>
<td>59 (31.6)</td>
<td>0.0007</td>
<td>75 (50.3)</td>
</tr>
<tr>
<td>Immediate referral recommended (when referred)</td>
<td>5 (8.5)</td>
<td>NS</td>
<td>6 (8.0)</td>
</tr>
</tbody>
</table>

* Denotes a categorical variable with a null hypothesis of no difference between the intervention and control group. **NS** denotes not significant.
<table>
<thead>
<tr>
<th>Intervention cohorts</th>
<th>North metropolitan (intervention cohort)</th>
<th>South metropolitan (control cohort)</th>
<th>Cohort comparisons</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=187</td>
<td>n=149</td>
<td></td>
</tr>
<tr>
<td>Time of simulated patient</td>
<td>Pre, count (%)</td>
<td>Post, count (%)</td>
<td>Pre, count (%)</td>
</tr>
<tr>
<td>assessment (preintervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>or postintervention)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reason for referral given</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(when referred)*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncontrolled asthma</td>
<td>17 (28.8)</td>
<td>21 (24.1)</td>
<td>NS</td>
</tr>
<tr>
<td>Overuse of reliever medication</td>
<td>36 (44.1)</td>
<td>37 (42.5)</td>
<td>NS</td>
</tr>
<tr>
<td>No medical assessment &lt;6 months</td>
<td>4 (6.8)</td>
<td>6 (6.9)</td>
<td>NS</td>
</tr>
<tr>
<td>Lack of written asthma action plan</td>
<td>0 (0.0)</td>
<td>2 (2.3)</td>
<td>NS</td>
</tr>
<tr>
<td>Use of Asthma Medication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Request Checklist introduced as part of intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient asked to fill in checklist</td>
<td>NA</td>
<td>2 (1.1)</td>
<td>Not performed</td>
</tr>
<tr>
<td>Explanation of checklist purpose was offered</td>
<td>NA</td>
<td>2 (1.1)</td>
<td>Not performed</td>
</tr>
</tbody>
</table>

\( *\) "Counselor" refers to the pharmacy staff member interacting with the patient.

\( *\) Each analysis with this variable was performed as the individual category versus the rest.

This analysis was performed as: no waiting time versus waiting time due to limited numbers in the 'over 5 min' category.

NS, not significant; pre, preintervention; post, postintervention.
similar at both time points and in all pharmacies. The exceptions were patient medical referral and information provided about medication duration/frequency of use. Non-intervention pharmacies showed a non-significant decrease in patient medical referral from 50% to 44% (p=0.22). In comparison, intervention pharmacies showed a significant increase in patient medical referral from 32% to 47% (p=0.0007). Baseline medical referral was significantly different between cohorts. The non-intervention cohort was significantly more likely to refer at baseline (intervention vs control at preintervention: OR 0.45, 95% CI 0.29 to 0.71, p=0.0005). Postintervention, there was no significant difference in medical referral between the intervention and control cohort (intervention vs control at postintervention: OR 1.13, 95% CI 0.74 to 1.75, p=0.56). Pharmacies in the intervention cohort were significantly more likely to discuss duration/frequency of reliever medication usage postintervention than preintervention (OR 2.97, 95% CI 1.58 to 5.77, p=0.0013). This was significantly different to the observations in the non-intervention group where discussions about duration/frequency of reliever use in this cohort remained the same over the two time periods (p=0.0201).

Figure 3 illustrates some of the significant outcomes across the cohorts and over time.

**Resource use**

Of the 187 pharmacies that received the intervention, 2 pharmacies (1%) used the Asthma Medication Request Checklist introduced. One pharmacy was from the workshop cohort and one pharmacy was from the academic detailing cohort. Correspondence with the primary author indicated that more pharmacies were using the resource, but this was not evident in the simulated shopping results. Two workshop pharmacies sent emails providing feedback about successful patient interactions using the checklist and another workshop pharmacy requested delivery of more checklists to use. None of these pharmacies were noted as using the checklist during simulated patient visits.

**DISCUSSION**

The aim of this research was to devise and evaluate a team-based intervention to formalise the role of
pharmacy assistants in order to improve SABA guideline-based care in community pharmacy.

A key primary outcome of interest was increased patient medical referral due to identification of poor asthma control. The significant increase in medical referral observed in the intervention group indicates the potential effectiveness of this intervention. Another positive outcome observed was the increased incidence of discussions with patients about reliever duration and frequency of use. However, outcomes were variable and these positive results were not supported by results for other primary and secondary outcomes such as internal referral of patients from pharmacy assistants to pharmacists (indicating greater legislative compliance), increased device counselling or use of the 'Asthma Medication Request Checklist' tool.

Some of the variability in the results may have been due to the workshop content and emphasis on particular elements of the guidelines. Inhaler device counselling was not an element of the guidelines specifically addressed in the workshop and only one question in the checklist related to previous device demonstration. In contrast, there was a greater focus on appropriate assessment of asthma control and medical referral criteria. This emphasis was borne out in the results and demonstrates that the content of a workshop can have an influence on outcomes. Furthermore, in this research, one person undertook all workshops, but the flexible, tailored approach could potentially lead to variable outcomes from multiple presenters who provide different emphases in a wider implementation programme. It is possible that constructing the workshop differently to focus on areas of poor practice related to the guidelines could have achieved better results.

Another reason for the variations in the success of this intervention may lie in the adaptations applied to the intervention during the course of the research. A thorough 'common-sense' approach was used in the design of the intervention. There was recognition, in choosing small group workshops, that community pharmacies are complex healthcare organisations requiring a team approach to implementation of new practice. However, in a naturalistic research setting, there are complexities that cannot always be predicted and controlled. Community pharmacies operate in a retail environment with long hours and are subject to seasonal fluctuations in workload. The workshops were initially offered in October and the poor uptake was attributed to the 'busy Christmas retailing period'. Another issue was the difficulty in holding staff gatherings with extended trading hours and the large number of part-time and casual employees in the retail sector. Holding training outside of working hours also required investment on the part of business owners in terms of wages for staff. All these logistical issues inhibited uptake of the workshop intervention. This necessitated an adaptation of the workshop intervention that could be delivered via academic detailing.

Academic detailing was achievable on a much larger scale, but it did not facilitate team support for the initiative and relied on internal communications within the pharmacy to disseminate information and promote
practice change. It also did not provide the opportunity to tailor the information to individual pharmacies. It is possible that the intervention could have achieved stronger positive outcomes if more workshops had been completed. Unfortunately, this study was not powered to detect a statistically significant difference between the academic detailing and workshop strategies. However, some trends were noticed that suggest the superiority of workshops compared to academic detailing. Both intervention groups were more likely to ask patients about preventative use at the postintervention time point, but there was a greater increase in the odds of this occurring in workshop pharmacies. Also workshop pharmacies asked significantly more assessment questions than academic detailing pharmacies. It is important that future research and intervention design should consider logistical issues to ensure successful implementation of guidelines. There are several taxonomies and frameworks available that may assist and provide a more systematic approach to intervention design and consideration of logistical issues.12–41

Despite the logistical problems encountered, the rationale in choosing small group workshops for interventions in community pharmacy seems to have merit, due to acknowledgement of the team-based environment that community pharmacists practice in. It is recognised that team-based change is likely to be slower and more incremental than changing the practice of an individual healthcare practitioner42 and hence the difficulty in achieving practice change in the community pharmacy setting, regardless of logistical issues. Results indicated some improvements in individual counselling and medical referral but not in system-level process improvements. Improvement in the outcomes of internal referral, device counselling and use of the new checklist necessitates workflow changes and this was not evident. Examples of partial or individual implementation success can be seen in the three pharmacies that either provided qualitative feedback about using the checklists or requested more checklists. Despite these self-reported indications of implementation success, none of the pharmacies were noted using the checklist tool when visited by a simulated patient.

Historically, translating evidence into practice has been an incredibly slow and unpredictable process and it can take decades for empirical research to be implemented in routine medical practice.43–45 With practice change being a slower process for teams rather than individuals, it may have been that the dose and duration of this intervention were not substantial enough to achieve strongly significant outcomes and allow time for process adjustments. Reinforcement of the intervention was by way of resources, including access to a web page. Multiple workshops or detailing visits over a longer time frame may have provided stronger reinforcement of messages; opportunities to refine modified workflows and possibly could have improved outcomes. It is recognised that when new behaviours are attempted in the workplace, but routines are yet to be fully established, reinforcement can play a crucial role in maintenance and entrenchment of new practice.46 Given the team environment of community pharmacy, a substantial reinforcement programme should be factored into future interventions or guideline implementation initiatives.

Not only was team-based change required for intervention success but the intervention also needed to influence mutual engagement between pharmacy staff and patients. Patient engagement issues were addressed in a number of ways. Strategies such as communication skills training47–50 and providing insight into the patient perspective51 were based on evidence from the scientific literature. Other measures included recognition of the problems faced by pharmacy staff and the introduction of the Asthma Medication Request Checklist tool to assist with information gathering. However, it is possible that without an intervention directed specifically at patients, these measures were not sufficient to achieve the required change in patient beliefs and behaviours to achieve mutual engagement and information exchange. The work of Watson et al.52 found that the willingness of patients to provide information to pharmacy assistants was correlated with behavioural intentions and subjective norms. Without addressing the complexities underlying patient behaviour, substantive changes in asthma management may be unachievable. This suggests that there may be benefits in using a behavioural theory-based approach in intervention design, which is increasingly being recommended in the scientific literature.49, 51–52 However, a similar study, using the Theory of Planned Behaviour in intervention design and targeting pharmacy assistants, ultimately did not improve guideline compliance.53 At present, there is limited evidence of the benefits of the use of theory in the implementation of guidelines, particularly in the community pharmacy setting.

Direct pharmacist involvement and internal referral of patients from pharmacy assistants to pharmacists were considered important measures of legislative compliance. Legislation in Australia requires pharmacists to be directly involved in SABA sales. The results demonstrated no impact on either direct pharmacist involvement or internal referral due to the intervention. However, the large number of simulated patient visits for which the counsellor position could not be identified confounds interpretation of the true incidence of pharmacist involvement in consultations or of internal referral. The practical issue this identifies is that patients do not know whom they are talking to in almost half their visits to a community pharmacy. This situation is not conducive to optimal communication where patients can confidently seek and receive advice from a highly trained health professional: the community pharmacist. While no changes in internal referral were observed, both groups had an increase in the percentage of pharmacy assistants “consulting” with a pharmacist, and this
increase was significant in the control cohort. Consultation with a pharmacist means that the pharmacy assistant handles the entire patient interaction but refers to the pharmacist for advice or permission to conduct the sale. Such “consultation” does not meet the requirements for legislative compliance and has been shown to worsen outcomes in previous research. Best outcomes are observed when successful internal referral occurs. The final significant observation from this research relates to the poor practice surrounding device counselling and demonstration of asthma inhalers. Despite being an inherent component of the SABA guidelines, device counselling was not routinely carried out at any stage or in any cohort of this research. Correct inhaler technique is crucial in optimising asthma treatment and minimising side effects. International guidelines recommend that pharmacists should contribute to patient education about inhalers and this is not occurring. The importance of this area, and the deficits in current practice, warrants specific guidelines. The results in this study are not unique and deficiencies in patient education on inhaler technique have been observed in other studies. Therefore, barriers to the provision of this service need further investigation.

CONCLUSION

Increases in medical referral indicate that asthma guideline compliance potentially can be improved in community pharmacy if implementation employs a team-based approach and involves pharmacy assistants, giving them a more defined and formalised role. However, the implementation intervention did not improve practice related to device counselling or internal referral/pharmacist involvement. These variable results may have been improved if more workshops had been undertaken. Logistical barriers to using workshops as an intervention strategy in this setting need to be overcome to test this hypothesis. Future research on guideline implementation to community pharmacy should consider the role of the pharmacy assistant and how to overcome logistical barriers to pharmacy participation in implementation activities. Consideration also needs to be given to the duration of an intervention and incorporation of reinforcement messages.

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Contributors KW conceptualised and designed this research as part of her PhD study, guided and supervised by GR, KM, PAK and RC. KW and RC secured funding for the research from the Health Department of Western Australia. KW expanded and ran the pharmacy asthma workshops, produced all workshop materials, participated in academic detailing, was an actor in the role-play videos, KW developed resources and conducted training sessions for simulated patients and academic detailers. MT and KM compiled the statistical analysis with input from KW. KW prepared an initial draft paper with all authors contributing to subsequent drafts and approving the final manuscript.

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Competing interests KW is the proprietor of a community pharmacy in Perth, Western Australia, and thus has a financial interest in community pharmacy.

Ethics approval Ethics approval was obtained from the University of Western Australia’s Human Research and Ethics Committee (HREC 08/04/11558) to conduct mystery shopping and for the intervention (HREC 10/RA/4/15006).

Provenance and peer review Not commissioned; externally peer reviewed.

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Implementation of asthma guidelines to West Australian community pharmacies: an exploratory, quasi-experimental study

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6.3 Key findings from intervention study

Key findings included:

- The intervention achieved a significant increase in the key outcome of appropriate medical referral, concordant with the SABA guidelines.
- Referral within the pharmacy (internal referral) from pharmacy assistants to pharmacists remained unchanged from baseline.
- Asthma device demonstration is not routinely occurring in community pharmacies and the intervention did not impact on this practice deficit.
- The positive outcomes indicate that the role of pharmacy assistants should be considered in any implementation of clinical guidelines to community pharmacy. Pharmacy assistants currently play an integral function in patient interactions and they are usually the first point of contact for patients.
- The almost universal lack of device demonstration by pharmacists requires more specific emphasis on this practice deficit as part of any future interventions. It demonstrates that the content of a workshop is important to outcomes.
- The low participation rates in workshops indicate barriers to delivering interventions in community pharmacy via this method. These barriers may include seasonal variations in retailing priorities, the long opening hours of community pharmacies, the large proportion of part-time and casual employees, cost of paying employees to attend training sessions outside of normal working hours. Further research is required to understand the best delivery mode for interventions to community pharmacy.
- The implementation-intervention was able to be adapted for delivery via academic detailing. Academic detailing was achievable on a wide scale to community
pharmacy, but it was uncertain how much this alternate delivery method affected outcomes.

- Academic detailing required the individual receiving the information to disseminate the messages to other staff members. The conjecture was that the team-based workshop could have improved practice change outcomes by having a greater impact on teamwork, skills and motivation.

- Another consideration in the success of the intervention was whether multiple workshops or detailing visits were required to reinforce guideline-based practice change. More research is required to understand the optimal dose and duration of an intervention.

- The intervention was designed using a common sense approach to overcome identified barriers. Recent literature has promoted the use of behavioural theories in intervention design. It is unclear if this methodology would have changed the components of the intervention or improved intervention success.

### 6.4 Relevance of findings to the thesis

This study involved devising and testing an implementation-intervention based on evidence from the scientific literature, data from preliminary research and expert consultation. This was relevant in addressing the overall thesis aim to investigate and evaluate strategies for successful implementation of clinical guidelines to community pharmacy. The results indicated that:

- Consideration of pharmacy assistants was important when implementing guidelines in community pharmacy.
• Academic detailing and small group workshops were useful strategies in community pharmacy (although the relative benefits of each remained unclear).

• Issues that required more consideration included logistical issues and whether taxonomies and formal theories could be used to improve the results of a pragmatically designed intervention.
6.5 References


Chapter 7:

Evaluation of an Intervention Study to Implement Asthma Guidelines to Community Pharmacy

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*BMJ Open*

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7.1 Background

Evaluation is an important part of the process of implementing guidelines and translating evidence into practice.\(^1\) There are many components to an effective and comprehensive evaluation of guideline implementation, and generally, multiple evaluations are required.\(^2\) Ultimately the evaluation process provides information regarding the value of a guideline in achieving its aims. Evaluations may necessitate revisions in the implementation strategy or even the guideline itself.\(^2\)

An initial implementation of the SABA guidelines in 2010\(^3\) had failed to translate and improve routine clinical practice in community pharmacies.\(^4\) This chapter aims to retrospectively understand the individual elements of a subsequent evidenced-based, tailored implementation-intervention of the SABA guidelines (Chapter 6)\(^4\) that may have influenced the variable outcomes achieved. A greater understanding could be used to refine and improve the implementation-intervention devised in this thesis, for future wider application in addressing the evidence-practice gaps identified by this research. The evaluation considers the elements in intervention design that are essential to achieving improved guideline-based practice in community pharmacy.

The focus of this evaluation was on the process of implementation, given the overarching aim of this thesis was to understand how to implement guidelines effectively, to the community pharmacy setting. Two methods were chosen for this evaluation. The first method examined the technical and functional aspects of the implementation process.\(^5\) The second method aimed to understand the theoretical rationale behind the common sense intervention design.\(^6\) This evaluation involved the retrospective application of a variety of existing tools including the Intervention
Taxonomy (ITAX), the Behaviour Change Wheel (BCW), the Capability, Opportunity, Motivation and Behaviour Model (COM-B) and Behaviour Change Techniques Taxonomy (BCTTv1).

ITAX was selected because it was designed to identify key features in intervention delivery and content that can influence outcomes. There was recognition that logistical problems associated with conducting small group workshops may have influenced outcomes. A greater understanding of logistics of the implementation-intervention was required. The BCW and its associated tools (the COM-B system and BCTTv1) were selected because of the current interest in formalised theory to improve implementation. A criticism of the use of theory is that there is little guidance on how to select or apply the many behavioural theories available. The BCW overcomes this disadvantage by synthesising information from 19 frameworks of behaviour change to overcome the limitations of each. A comprehensive guidebook provides a systematic approach to the application of the tools. (Appendix 21)

The retrospective application of these tools represented a novel evaluation approach.
7.2 Publication

BMJ Open

Post hoc evaluation of a common-sense intervention for asthma management in community pharmacy

Kim Watkins, Liza Seubert, Carl R Schneider, Rhonda Clifford

ABSTRACT

OBJECTIVES: The aim was to evaluate a common-sense, behavioural change intervention to implement clinical guidelines for asthma management in the community pharmacy setting.

DESIGN: The components of the common-sense intervention were described in terms of categories and dimensions using the Intervention Taxonomy (ITAX) and Behaviour Change Techniques (BCTs) using the Behaviour Change Wheel (BCW). Capability, Opportunity and Motivation Behaviour (COM-B) System and Behaviour Change Techniques Taxonomy (BCTTv1). The retrospective application of these existing tools facilitated evaluation of the mechanism, fidelity, logistics and rationale of the common-sense intervention.

INTERVENTION: The initial intervention study was conducted in 336 community pharmacies in the metropolitan area of Perth, Western Australia. Small group workshops were conducted in 25 pharmacies; 162 received academic detailing and 149 acted as controls. The intervention was designed to improve pharmacy compliance with guidelines for a non-prescription supply of asthma reliever medications.

RESULTS: Retrospective application of ITAX identified mechanisms for the short-acting β agonists intervention including improving knowledge, behavioural skills, problem-solving skills, motivation and self-efficacy. All the logistical elements were considered in the intervention design but the duration and intensity of the intervention was minimal. The intervention was delivered as intended (as a workshop) to 13.4% of participants indicating compromised fidelity and significant adaptation. Retrospective application of the BCW, COM-B system and BCTTv1 identified 9 different behaviour change techniques as the rationale for promoting guideline-based practice change.

CONCLUSIONS: There was a sound rationale and clear mechanism for all the components of the intervention but issues related to logistics, adaptability and fidelity might have affected outcomes. Small group workshops could be a useful implementation strategy in community pharmacy. If logistical issues can be overcome and less adaptation occurs, duration, intensity and reinforcement need consideration for successful wider implementation.

Strengths and limitations of this study

- This research used a cutting-edge approach to implementation science innovation by demonstrating a successful and practical application of the Behaviour Change Wheel framework and Intervention Taxonomy in the complex setting of community pharmacy, where heterogeneous studies and small effects from interventions provide little information on how to best improve practice.
- The method for this research was strengthened by the involvement of two researchers in the coding of the behavioural components in all steps.
- A limitation of the research was that the choice of tools used in the evaluation might not have been optimal for deciphering the intervention. There are many evaluation tools in the literature and other tools may have yielded different information or results more useful to informing future implementation.
- There are inherent disadvantages in methodology involving post-hoc evaluation. There was also a lack of participant feedback and perception data that could have been useful in retrospective application. For instance, to understand the dose of the intervention achieved with the shared implementation strategy.

BACKGROUND

Evaluation of Interventions

Evaluation is a crucial component of implementation science. Evaluations may look at process, outcome, impact and economics of an intervention, and ideally the choice of evaluation method should suit the purpose of the evaluation. A variety of tools including frameworks, taxonomies and models have been developed to assist in the evaluation of interventions, all with their own strengths and limitations.

There is no single ideal evaluation tool or method and more work is needed to understand the comparative benefits of the many tools already developed. Thorough evaluation is an...
ongoing process and multiple analyses are often required to inform key decision makers and policy directives. Process evaluation considers all aspects of delivering an intervention; this encompasses the concepts of logistics and fidelity. Logistics refers to the detailed organisation and implementation of a complex operation. Logistics in implementation science considers the ability to operationalise the research: how to plan and manage the intervention including resources and personnel. Fidelity is defined as the extent to which interventions are delivered as planned. When an intervention is not delivered as intended (e.g., low participant responsiveness, low intervention dose), then the effect size and statistical power of the research can be diminished. Analogous to fidelity is the concept of adaptability. If an intervention has adaptive elements, it can be modified without compromising the integrity or results of the intervention.

One of the many frameworks identified in a scoping review of classification schemes (including taxonomies, lists and frameworks) was the Intervention Taxonomy (ITAX). The taxonomy outlines the delivery characteristics and goals of an intervention and is relevant to the concepts of logistics, fidelity and understanding the implementation process. ITAX has the ability to characterise complex, multicomponent behavioural studies. The taxonomy has previously demonstrated its validity and acceptability; it was developed using literature review as the methodological basis and has been peer reviewed and pilot tested. Although it is a relatively simple to use checklist, it is comprehensive and focuses on elements that might be applicable to understanding outcomes. The aim of creating the taxonomy was to improve intervention design and execution and allow for comparison across studies. It was used in this way by the Resources Enhancing Alzheimer’s Caregiver Health consortium to evaluate multiple intervention studies. These characteristics make ITAX an appropriate tool for process evaluation in post hoc analysis, rather than simply a checklist for use at the intervention design stage. The taxonomy provides greater insight than just the intervention process. In detailing goals of an intervention, it distinguishes between the strategies used and also considers the mechanisms of action or underlying rationale of the intervention.

An understanding of these concepts is important in deciphering outcomes. Were outcome failures attributable to poor implementation process or to a failure in the theory of intervention design, be it implicit (common-sense approach) or explicit (formal theory-based approach)?

Interventions in healthcare have traditionally been designed using a pragmatic approach. However, the healthcare system is complex and interventions to improve practice tend to be equally complex. They often achieve only variable or modest results. Furthermore, even when interventions are successful, they can be difficult to document, sustain, reproduce in new settings and implement on a larger scale. There are concerns that common-sense interventions have poorly developed rationales for achieving outcomes. These challenges have led to increasing support for the use of a systematic approach and behavioural theory in the design of clinical guideline implementation interventions. However, not all scientists believe that the complexities of a theory-based approach are superior to a pragmatic, logical, ‘common sense’ approach, based on empiric evidence. Their argument is that all interventions are based on ‘theory’ but some are explicit, informal and use a common-sense rationale, while others are formalised. This formalised theoretical approach does not necessarily improve outcomes.

In advocating the use of theory in intervention design, the approach becomes a question of which theory to use. The antagonists would argue that this is one of the key flaws and that many theories overlap or contradict each other. The Behaviour Change Wheel (BCW) addresses this problem by synthesising 19 behaviour change frameworks identified in the literature into one comprehensive framework. The BCW framework is the Capabilities, Opportunity and Motivations-Behavioural (COM-B) model which analyses behaviour change in terms of capability, opportunity and motivation. Complementing the BCW framework is the Behaviour Change Techniques Taxonomy (BCTTv1). The taxonomy describes 93 specific behaviour change techniques and allows for standardised reporting of interventions. These tools are novel and their usefulness has not been fully established. Proponents of a ‘common-sense’ approach believe that until the use of theory has been demonstrated to be superior, it should remain a personal choice whether researchers adopt this method or not.

An alternative, newer application of the use of theory is to deconstruct and reassemble common-sense interventions to evaluate and improve on preliminary research. This provides an understanding of the theoretical underpinning of the intervention, described in terms of the techniques used to change behaviour. It can be a useful method in determining whether poor outcomes of a common-sense intervention were due to a deficiency in the rationale. It can also assist in determining unnecessary elements that add to the cost or complexity of an intervention.

A community pharmacy intervention to implement asthma guidelines

Guidelines specific to community pharmacists are relatively new but under increasing development as pharmacists expand their clinical role in this setting. However, there is very little understanding of how the existing research on implementation science relates to community pharmacy, with most studies undertaken in hospital settings or in general medical practice. A systematic review of clinical guideline implementation to
community pharmacy has determined that interventions in this setting have only yielded mixed and moderately effective results until now. 12 Despite many in the scientific community now advocating for the use of theoretical frameworks, very few studies in this setting are grounded by the use of theory, and thus there is little evidence of the benefit of this approach. 12 Also, no studies have used the BCM framework in community pharmacy research at this point in time.

In 2011, new guidelines for the provision of a Pharmacist Only medicine: short-acting β agonists (SABA guidelines) were endorsed by stakeholders and distributed to pharmacists by the Pharmaceutical Society of Australia and The National Asthma Council of Australia. SABAs are inhaled 'reliever' medications used to alleviate the symptoms of asthma, such as wheezing and breathlessness. However, inappropriate reliance on SABAs can put patients at risk of severe asthma exacerbations and even death. 25, 26 In Australia, legislation allows patients to purchase SABAs under the supervision of a pharmacist, without a prescription and without necessarily seeing a doctor. Thus, compliance with these guidelines and the role of community pharmacists in Australia is particularly significant. They may be the only health professional with a chance to intervene when patients inappropriately self-manage their asthma with non-prescription 'reliever' medications. Despite this crucial role, research indicates that there are many barriers to SABA guideline-based practice and optimal asthma management. 27, 28 This practice deficit was addressed by a common-sense intervention in 2013. The intervention aimed to formalise the role of pharmacy assistants, improve internal referral from pharmacy assistants to pharmacists and improve medical referral of patients with poorly controlled asthma, in the supply of non-prescription SABAs. 29 The results of the intervention were positive but variable and require consideration on how they can be improved before wider implementation is appropriate. 29

The aim of this research was to evaluate a common-sense intervention to implement asthma guidelines in the community pharmacy setting.

The objectives were to:
1. Perform a prospective evaluation using a taxonomy to evaluate the mechanisms for producing outcomes, fidelity and logistics
2. Deconstruct the common-sense intervention into behavioural change techniques to evaluate the implicit theory (rationale) of the intervention
3. Comment on the ability of these methods to refine a common-sense intervention to improve outcomes and improve suitability for wider implementation.

METHODS
Evaluation tools
Triangulation methods involving two different approaches, using formalised tools, were chosen for evaluation of the common-sense SABA guideline implementation intervention designed by Watkins et al. 25

1. The ITAX was retrospectively applied to evaluate the mechanism (how the intervention was designed to achieve outcomes), fidelity (how well the intervention was delivered as planned) and logistics (how the intervention was delivered). 25

2. The theoretical rationale of the common-sense intervention was examined through retrospective application of the BCM framework, the COM-B model and BCTTv1 described in the work by Michie et al. 31

Generally, these taxonomies, frameworks and models are used prospectively to ensure that all the important elements are considered in the intervention design process. The novel retrospective use of these tools involved the same process by considering each component of the SABA guideline intervention. Authors were required to consider the characteristics of the SABA guideline intervention in terms of the terminology and elements detailed in the checklists and worksheets relevant for each tool. The outcomes resulting from the retrospective application of the tools included categories consisting of dimensions (ITAX) and behaviour change techniques (BCM, COM-B & BCTTv1).

Retrospective application of ITAX
Application of ITAX involved completion of a taxonomy checklist 9 to detail the SABA guideline intervention. The taxonomy considers various dimensions of an intervention organised into two broad categories: delivery characteristics and intervention characteristics. The dimensions were used to consider: the mechanism, fidelity and logistics of the SABA intervention, with a view to investigate possible future improvements. The checklist was completed by the primary author (KW) and checked by a second author (CS). Consensus was reached by discussion.

Retrospective application of the BCM framework, the COM-B model and BCTTv1
Application of the BCM framework is outlined in a guidebook that contains a series of worksheets based on eight steps. 31 The process involved three stages encompassing the eight distinct steps (figure 1). 31

Stage 1 included steps 1–4 in the guidebook and involved understanding the behaviours to be influenced. Retrospective application required identifying and analysing the specific behaviours that needed to change to enhance SABA guideline compliance and facilitate internal referral of patients from pharmacy assistants to pharmacists. Stage 2 included steps 5 and 6 from the guidebook and looked at the possible options for intervention. Stage 3 included steps 7 and 8 from the guidebook and decided on the content and implementation possibilities. Undertaking these steps provided an understanding of whether the chosen intervention was sensible and feasible to address the
relevant behaviours identified and whether the implementation strategy chosen was reasonable with a sound basis for success.

The COM-B model\(^1\) is used to assess capability, opportunity and motivation (Figure 2). This model was applied as part of step 4. After identifying a number of behaviours that would improve SABA guideline compliance (steps 1–3), COM-B was applied to each one as part of a behavioural analysis, to determine what needed to change for the behaviours to be supported. Step 5 identifies intervention functions, which are the broad categories of methods designed to address behaviour change (e.g., education, persuasion). Retrospective application involved looking at each element of the SABA intervention to ascertain its function in changing behaviour. The Affordability, Practicality, Effectiveness and cost-effectiveness, Acceptability, Side-effects/safety and Equity (APEASE) criteria\(^2\) were considered at this stage to check the utility of each function. The APEASE criteria were also used at steps 6, 7 and 8, which considered utility of policy categories, behaviour change techniques and the delivery mode for the intervention.

![Figure 1](image)

**Figure 1** Application of a theoretical framework to intervention design: THE BCW and COM-B system. BCW, Behaviour Change Wheel.

All worksheets were completed by the primary author (KW) and checked by a second author (LS) with previous experience using the tools. Disagreements in coding were resolved by discussion and consensus.

**Results**

**Retrospective application of ITAX**

The ITAX Checklist was populated with information regarding the common-sense SABA guideline intervention. A summary of the deconstruction into categories and dimensions is shown in Table 1.

**Mechanism of the SABA intervention**

The mechanism of the SABA intervention was detailed in the ‘intervention characteristics’ category of the ITAX checklist, which included the dimensions of treatment content, strategy and mechanism of action. Retrospective application of the ITAX described mechanism in general terms such as knowledge, behavioural skills, problem-solving skills, motivation and self-efficacy. The retrospective application of the BCW framework also considered mechanism but described in terms of behaviour change techniques. Both tools demonstrated that there was a clear mechanism and sound rationale for the SABA intervention.

**Fidelity of the SABA intervention**

Dimensions relevant to the fidelity of the SABA intervention included: adaptability, schedule, scripting, treatment implementation, treatment content strategies, interventionist characteristics and sensitivity to participant characteristics. Of interest in considering the fidelity of the SABA intervention was the recognition that the intervention had been substantially adapted. The content was delivered as intended (as a workshop) to 13.3% of participants. While ITAX considered the level of adaptation, it did not measure the effectiveness of the adaptation.

**Logistics of the SABA intervention**

The logistics of the SABA intervention were detailed in the ‘intervention delivery’ category of the ITAX checklist. These included dimensions of mode, material, location, schedule, scripting and treatment implementation. All the logistical elements were considered in the SABA intervention design but the duration and intensity (schedule) of the intervention was minimal. The intervention consisted of one workshop of ~1.5 hours or a detailed visit of 15 min. Resources were provided to reinforce messages from the intervention.

**Retrospective application of the BCW framework, the COM-B model and BCTTv1**

All components of the common-sense SABA guidelines intervention could be categorised according to their effect on behaviour change, using the BCTTv1 by following the eight steps of the BCW framework and

![Figure 2](image)

**Figure 2** COM-B Model. COM-B, Capability, Opportunity and Motivation-Behaviour.\(^2\)

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Kim Watkins
<table>
<thead>
<tr>
<th>Dimension</th>
<th>Definition</th>
<th>Options checklist</th>
<th>Intervention logistics and characteristics of the SABA implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Delivery characteristics</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mode</strong></td>
<td>Method of contact between interventionist and participant</td>
<td>▶ Face to face (individual or group)</td>
<td>▶ Face to face (workshop or academic detailing visit)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Telephone (individual or group)</td>
<td>▶ Video—motivational videos</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Internet (individual or group)</td>
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<tr>
<td></td>
<td></td>
<td>▶ Video/CD instruction</td>
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</tr>
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<td></td>
<td></td>
<td>▶ Telephone contact with computer</td>
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<td></td>
<td></td>
<td>▶ Mailing of written material</td>
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<tr>
<td></td>
<td></td>
<td>▶ Personal digital assistant, mobile phone</td>
<td></td>
</tr>
<tr>
<td><strong>Materials</strong></td>
<td>Materials used in the delivery of the intervention</td>
<td>▶ Manuals/workbooks</td>
<td>▶ Information sheets/checklist—Guidelines from PSWA, Asthma Medication Request Checklist (developed specifically for the research)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Information sheets/checklists</td>
<td>▶ Pamphlets—From NAC and AFWA—general information on asthma</td>
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<td></td>
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<td>▶ Pamphlets</td>
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<td></td>
<td></td>
<td>▶ Videocassettes</td>
<td>▶ DVD—reference materials including two videos</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Audiocassettes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ CDs/DVDs</td>
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<td></td>
<td></td>
<td>▶ Assistive devices</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Internet</td>
<td></td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td>Where the intervention is delivered</td>
<td>▶ Participant’s home</td>
<td>Workplace (community pharmacy)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Classroom</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>▶ Healthcare provider’s office</td>
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<td></td>
<td></td>
<td>▶ Hospital, clinic, operating room</td>
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<td></td>
<td></td>
<td>▶ Work site</td>
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<td></td>
<td></td>
<td>▶ Community centre</td>
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<td></td>
<td></td>
<td>▶ Nursing home</td>
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<td></td>
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<td>▶ Group residence facility</td>
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<tr>
<td></td>
<td></td>
<td>▶ Research facility</td>
<td></td>
</tr>
<tr>
<td><strong>Schedule</strong></td>
<td>Duration and intensity of intervention</td>
<td>▶ Overall duration of the intervention</td>
<td>▶ 1 workshop of approx 1.5 hours or academic detailing visit about 15 min</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Number of sessions</td>
<td></td>
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<td></td>
<td></td>
<td>▶ Minutes of contact per session</td>
<td>▶ Reinforcement via resources provided</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Distribution of sessions over time</td>
<td></td>
</tr>
<tr>
<td><strong>Scripting</strong></td>
<td>Level of detail guiding interaction between the interventionist and the participant</td>
<td>▶ Exact script/protocol provided</td>
<td>Specific language provided via power point with elaboration allowed in interactive discussion—all workshops undertaken by one interventionist to maintain consistency of message</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Specific language provided with elaboration allowed/not allowed</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>▶ Goals/tasks specified but no further scripting</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ General guidelines provided</td>
<td></td>
</tr>
<tr>
<td><strong>Sensitivity to participant characteristics</strong></td>
<td>Extent to which participant background, experience and abilities are incorporated in the delivery of intervention</td>
<td>▶ Intervention materials and delivery in language preferred by participant</td>
<td>Intervention materials and delivery in language preferred by participant—recognition of the level of understanding and perspective of both non-professional and professional staff</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Materials written for specific reading or health literacy level</td>
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<tr>
<td></td>
<td></td>
<td>▶ Visual supplements, augmentative communication devices for hearing impaired</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>▶ Oral supplements and visual enhancements for vision impaired</td>
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</tbody>
</table>

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<table>
<thead>
<tr>
<th>Dimension</th>
<th>Definition</th>
<th>Options checklist</th>
<th>Intervention logistics and characteristics of the SABA implementation</th>
</tr>
</thead>
</table>
| Interventionist characteristics | Qualifications and training, concordance with participant characteristics | - Required disciplinary/ professional expertise for interventionists  
- Licensing/certification requirements  
- Type and quantity of training provided  
- Proficiency tests passed  
- Race/ethnicity/age/gender matching of interventionist to participant  
- Intervention staff recruited from participant community  
- Interventionist knowledgeable of cultural views and values of participants | - Intervention staff* recruited from participant community  
- Training for academic detailers— one-on-one training of 1 hour length Workshops undertaken by trainer of academic detailers  
- Interventionist knowledgeable of cultural views and values of participants |

| Adaptability | Extent to which intervention can be modified.  
- What can be modified?  
- On what basis are modifications made?  
- When in the course of the study can modifications be made? | What:  
- Number/schedule/duration of sessions  
- Location  
- Mode of delivery  
- Content/target  
- Dosage  
On what basis:  
- Participant assessment  
- Participant progress  
- Spontaneous request  
- Stated event  
- Clinical judgement  
- Checklist/laboratory test results, performance outcomes  
When:  
- Intake  
- Baseline  
- Specified intervals during intervention | What:  
- Could increase number of sessions if a pharmacy could not get all staff to attend the one session  
- Could change the location to training room of a professional organisation  
- Could change mode of delivery—changes were made to incorporate academic detailing. Could also use a large multipharmacy lecture.  
On what basis:  
- Spontaneous request (eg, participant request to hold multiple workshops or change location)  
- Based on participant progress—low recruitment numbers required adapting the intervention to academic detailing  
When:  
- At intake (being adaptable during recruitment may increase participation)  
- Specified intervals—throughout the recruitment adapting to recruitment numbers required a change in delivery mode  
- Documentation of number of sessions and duration—25 workshops and 162 academic detailing visits  
- The content was delivered as intended (via workshop) to 13.4% of participants. It was delivered in a modified version (academic detailing) to 8.6% |

| Treatment implementation | Treatment Delivery: Documentation of interventionist compliance to intended treatment and modifications  
Treatment Receipt: Extent to which processes are implemented by participant and/or goals are met | Number and duration of sessions  
- Content delivered  
- Knowledge, skills, motivation, self-efficacy, social support/ integration, changes in pathophysiology assessed in participant |
### Table 1 Continued

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Definition</th>
<th>Options checklist</th>
<th>Intervention logistics and characteristics of the SABA implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Content and goals of intervention (intervention characteristics)</strong></td>
<td>Treatment content strategies: Specific strategies aimed at improving outcomes</td>
<td>▶ Provision of feedback to participant through tracking and monitoring</td>
<td>▶ Treatment receipt (knowledge, skills, motivation, self-efficacy, etc) was not specifically assessed, although the format which was interactive provided an opportunity for participants to clarify the information</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▶ Provision of information</td>
<td>▶ Treatment enactment was assessed by way of direct observation</td>
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<td></td>
<td></td>
<td>▶ Behavioural incentives/reinforcements</td>
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<td>▶ Didactic instruction</td>
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<td></td>
<td></td>
<td>▶ Skill-building techniques</td>
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<td></td>
<td></td>
<td>▶ Problem-solving techniques</td>
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<td></td>
<td>▶ Stress-management techniques</td>
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<td></td>
<td></td>
<td>▶ Facilitation of social support</td>
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<td></td>
<td></td>
<td>▶ Biological interventions (surgery, medications, radiation)</td>
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<td></td>
<td></td>
<td>▶ Structure/process modifications (eg, staffing, scheduling, communications)</td>
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</tbody>
</table>

**Mechanisms of action**

<table>
<thead>
<tr>
<th>Key processes, goals or mediators of desired treatment outcomes</th>
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</tr>
</thead>
<tbody>
<tr>
<td>▶ Ability to assess risks/goals</td>
<td>▶ Knowledge</td>
<td>▶ Knowledge—of guidelines, legal requirements</td>
</tr>
<tr>
<td>▶ Behavioural skills</td>
<td>▶ Problem-solving skills</td>
<td>▶ Behavioural skills—how to engage and communicate more effectively with patients</td>
</tr>
<tr>
<td>▶ Motivation</td>
<td>▶ Self-efficacy</td>
<td>▶ Problem-solving skills—how to engage with reluctant patients</td>
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<td></td>
<td>▶ Social support</td>
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<td></td>
<td>▶ Social engagement</td>
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<td></td>
<td>▶ Environmental motivation</td>
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<td></td>
<td>▶ Change in policies/regulations</td>
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<tr>
<td></td>
<td>▶ Biological pathways</td>
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</tr>
</tbody>
</table>

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Table 1. Continued

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Definition</th>
<th>Options checklist</th>
<th>Intervention logistics and characteristics of the SABA implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>how to be remunerated for service provision</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>▶ Self-efficacy—checklist improves belief and ability to collect</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>appropriate patient assessment information</td>
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</tbody>
</table>

In the context of the SABA guideline intervention, the following definitions apply:
Interventionist/Intervention staff: These were the personnel who conducted the intervention. This included researchers who conducted the workshops and/or academic detailing visits.
Participants: These were the pharmacy staff who received the intervention including pharmacists and non-professional staff (pharmacy assistants).
AFWA, Asthma Foundation of Western Australia; ITAX, Intervention Taxonomy; NAC, National Asthma Council of Australia; PSWA, Pharmaceutical Society of Western Australia; SABA, short-acting β-agonists.

applying the COM-B model. A summary of the deconstruction into behavioural change techniques is shown in table 2. The stages and steps undertaken in the identification of the behaviour changes techniques were as follows:

Stage 1: Understand the behaviour
Step 1: Define the problem in behavioural terms
The defined problem behaviours were related to the provision of non-prescription asthma reliever medications in community pharmacies to patients in accordance with the SABA guidelines and legislation.

Stage 2: Select the target behaviours
Step 2: A total of 28 potential target behaviours were identified. These were then analysed and prioritised according to impact on desired outcome, likelihood of being able to change the behaviour, likelihood that the behaviour will have a positive or negative impact on other related behaviours (spillover score), how easy it will be to measure the behaviour (measurement score), Target behaviours were rated as very promising (VP), promising (P), unpromising but worth considering (UP) or unacceptable (U). The SABA intervention aimed to target behaviours related to pharmacy assistants and these were determined to be very promising.

Stage 3: Specify the target behaviours
The specific target behaviours involving pharmacy assistants included:
A. Asking patients appropriate questions
B. Referring patients to the pharmacist to meet legislative requirements (internal referral)
C. Managing the workload/workflow of the pharmacists to facilitate pharmacist involvement

Step 4: Identify what needs to change
Application of the COM-B model for each of the three target behaviours identified physical capability, psychological capability, physical opportunity, social opportunity, reflective motivation and automatic motivation all needed to be addressed for all the target behaviours to occur.

Stage 2: Identify intervention options
Step 5: Identify intervention functions
Applying the APEASE criteria resulted in selection of the following intervention functions appropriate to the aim: education; persuasion; incentivisation; training; environmental restructuring; modelling.

Stage 3: Identify content and implementation options
Step 5: Identify behaviour change techniques
Using the identified intervention functions, the active components (Behaviour Change Techniques—BCTs) were determined using the taxonomy (BCT1v1) and included:
▶ Information about social and environmental consequences
▶ Information about health consequences
▶ Prompts/cues
▶ Self-monitoring of behaviour
▶ Verbal persuasion about capability
▶ Identity associated with changed behaviour
▶ Incentive
▶ Demonstration of the behaviour
▶ Instruction on how to perform a behaviour

Stage 4: Identify mode of delivery
Options for delivery of the intervention included face-to-face delivery either at an individual or group level and at a distance using phones and computers. Population level interventions using broadcast, outdoor, print and digital media were considered cost prohibitive.

DISCUSSION
This evaluation and deconstruction resulted in a greater understanding of the complex elements of a behaviour change intervention to implement clinical guidelines for asthma management, in the community pharmacy setting. It demonstrated that the common-sense
<table>
<thead>
<tr>
<th>ASHMA INTERVENTION SUMMARY OF CONTENT USING THE BCW, BCT AND COM-B</th>
<th>Capability</th>
<th>Psychological</th>
<th>Opportunity</th>
<th>Motivation</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCT</td>
<td>Physical</td>
<td>Social</td>
<td>Physical</td>
<td>Reflective</td>
</tr>
<tr>
<td>Information about social and environmental consequences</td>
<td>Education</td>
<td>Persuasion</td>
<td>Information was given about asthma management and current information about the gaps in practice. Explanations were provided about why patients may not recognise the need for assistance in asthma management. Information was also provided about legislative requirements and guidelines for practice.</td>
<td>√</td>
</tr>
<tr>
<td>Information about health consequences</td>
<td>Education</td>
<td>Persuasion</td>
<td>Information and statistics about the serious consequences of asthma including a patient's story about a near-death experience.</td>
<td>√</td>
</tr>
<tr>
<td>Prompts/cues</td>
<td>Education</td>
<td>Persuasion</td>
<td>A checklist was introduced as a way of asking appropriate questions to support internal referral and pharmacist decision-making based on the guidelines.</td>
<td>√</td>
</tr>
<tr>
<td>Self-monitoring of behaviour</td>
<td>Education</td>
<td>Incentivisation</td>
<td>The use of a checklist helped to provide a quantifiable measure of service provision. Encouragement was given that patients may still be resistant at first but that the process could become habitual.</td>
<td>√</td>
</tr>
<tr>
<td>Soft-monitoring of behaviour</td>
<td>Education</td>
<td>Training</td>
<td>Pharmacy assistants were encouraged that patients with asthma would engage if approached in the right way. The difficulties were acknowledged and then strategies were provided to enhance communication.</td>
<td>√</td>
</tr>
<tr>
<td>Verbal persuasion about capability</td>
<td>Persuasion</td>
<td>Persuasion</td>
<td>Pharmacy assistants were encouraged about the importance of their role in the process of managing patients with asthma and given clear guidance on what their role was in the context of the legislative requirements.</td>
<td>√</td>
</tr>
<tr>
<td>Identity associated with changed behaviour</td>
<td>Persuasion</td>
<td>Incentivisation</td>
<td>Information was provided about how to access remuneration for professional services resulting from guideline-based practice.</td>
<td>√</td>
</tr>
<tr>
<td>Incentive</td>
<td>Training</td>
<td>Modelling</td>
<td>A role play video was used to demonstrate difficulties with patient engagement and then a discussion was based on the video. Another patient story video was used to demonstrate the patient perspective to enhance communication and motivation.</td>
<td>√</td>
</tr>
<tr>
<td>Instruction on how to perform a behaviour</td>
<td>Training</td>
<td>Modelling</td>
<td>A checklist was introduced as a way of collecting appropriate information and as a way of facilitating internal referral of patients within the pharmacy.</td>
<td>√</td>
</tr>
</tbody>
</table>

intervention was comprehensive and comparable to an approach using theory and a logistics taxonomy. This supports the notion that the use of taxonomies, frameworks and a theory-based approach in intervention design is not necessarily going to make interventions more successful.\(^5\)

However, the evaluation involving a retrospective application of ITAX did highlight some issues that may have influenced the success of the intervention. The intervention design process was based on workshops as the implementation strategy. It became clear that significant adaptation had occurred which may have affected the fidelity of the original team-based approach to the intervention. The theoretical basis for the intervention might have been compromised in the adaptation, which replaced workshops with academic detailing. Academic detailing involved delivery of the information to an individual and required the individual to disseminate the information, as well as galvanising and modifying the ‘pharmacy team’ to change behaviour. This involved a different approach to the researcher interacting and tailoring information to the ‘pharmacy team’ as a whole, in a workshop situation. What was unclear from the use of the taxonomy was to what extent the adaptation had affected outcomes. Further process evaluations, using qualitative research methods, are required to understand to what extent fidelity had been maintained by the change in intervention delivery and what improvement in the outcomes could be expected, if more workshops were delivered.

The necessity to adapt the intervention was related to logistical issues of recruitment and reach,\(^29\) and these barriers need to be understood before considering the intervention for wider health system implementation. Again, further qualitative research could potentially provide insight into the logistical barriers encountered.\(^5\) Nevertheless, despite the significant adaptation, positive outcomes were achieved.\(^5\) The intervention resulted in increased medical referral of patients with poorly controlled asthma as per the SABA guidelines. This leads to the conjecture that if the barriers to participation in small group education in community pharmacy could be overcome, this may prove to be a successful implementation strategy for this setting. There is some evidence in the literature to support this hypothesis. Schneider et al.\(^28\) used intern pharmacists to deliver asthma interventions in the workplace, as part of their training. Their interventions included delivery of an educational session for pharmacy staff and a health promotion activity directed at patients.\(^28\) The results were an impressive doubling of the rate of medical referral.\(^28\) Similarly, Kritikos et al.\(^25\) conducted a pilot study, using small group asthma education sessions in the community pharmacy setting, which resulted in improvements in clinical and humanistic outcomes.

The deconstruction process into behaviour change techniques demonstrated that there was a sound rationale for all the components of the common-sense intervention to achieve SABA guideline compliant practice. This is important, as a criticism of complex common-sense interventions is that there can be a tendency to simply add elements without necessarily having a clear purpose or enhancing effectiveness.\(^24\) The fact that all the elements of this common-sense intervention were for a specific purpose indicates that explicit theory is not essential in the intervention design process and may not be the panacea to implementation science it claims to be. It is possible that the use of formalised theory just adds unnecessary complexity and distracts from the ultimate goal of improving health outcomes. Common-sense interventions, designed by researchers who understand the participants, their behaviours and the research setting, can be just as viable a method. Perhaps it is the preliminary research and formative evaluations that provide an entrenched understanding of the issues that are most crucial in intervention design. Supporting this view is the research by Presseau et al.\(^22\) who undertook a similar deconstruction process to code a random sample of 29 diabetes implementation interventions. The majority of the implementation interventions in the study targeted evidence-based care processes and outcomes.\(^22\) When deconstructed, they were found to influence multiple behaviours, in a similar way to the common-sense SABA intervention.\(^23\) The methodology involved initially coding the intervention strategies in terms of the Effective Care Delivery of Care taxonomy and then using the BCITF\(^1\) to detail the ‘active elements’.\(^22\) Presseau et al.\(^22\) found that many of the interventions coded had good scope, detail and rigour, supporting the value of well-thought-out common-sense interventions. This is in contrast to other literature that criticise the poor methodology and reporting of intervention studies.\(^35\)\(^36\)

Regardless of the benefits or not of a theory-based approach, what was evident from the deconstruction process was that theory alone is not enough in intervention design or understanding outcomes. The logistics and fidelity of an intervention are equally important considerations and need to be given more attention. Logics can be challenging in naturalistic settings. Therefore, it may be advantageous to use a more structured approach when planning interventions. One that considers content as well as delivery mode and resources. ITAX or similar logistics frameworks and taxonomies remain vital for process evaluation. Apart from the significant adaptation required, other issues highlighted by deconstruction using ITAX included the duration and intensity of the intervention. Only one session was held to convey the information of the SABA guideline implementation intervention, and reinforcement was by way of resources but no further contact with researchers. The relatively short duration and intensity were appropriate for the exploratory nature of the research, but demonstrate that implementation on a wider scale requires more resource allocation to these elements. It also points to the importance of pilot/feasibility/exploratory studies before large-scale health system implementation.\(^22\) What
was not clear was how long and how intense the reinforcement needed to be to substantially improve outcomes or ensure effectiveness of wider implementation.

Other issues the evaluation process did not address were the concepts of context, climate and sustainability. Further qualitative evaluations are needed to consider these issues, to understand outcomes and to ensure the success of wider implementation. The taxonomies do not replace the requirement for evaluations based on participant and stakeholder feedback. At present, these concepts are hard to define and measure, but are highly relevant to implementation effectiveness. Context considers the physical and social environment and relates to the generalisability of the research findings. However, the important elements that constitute 'context' are yet to be fully elucidated, making assessment challenging. The implementation climate is the extent to which use of a specific innovation is rewarded, supported and expected within an organisation. The climate could vary between individual community pharmacies and its effect on overall outcomes could be significant. Thus, it could also impact on results of a wider implementation. Sustainability refers to the ability to maintain intervention effects. This becomes an important consideration in the allocation of limited resources available for health system implementation. These unresolved issues indicate the complexity of implementation science; the difficulty in understanding all the factors affecting intervention outcomes and the difficulty in predicting the effectiveness of interventions. Change techniques used in achieving outcomes. Neither of these approaches provided information about which elements were important or had the greatest impact on outcomes. This duplication of information, using different terminologies to essentially describe the same element, highlights an emerging issue in implementation science. The growing interest in the use of taxonomies, frameworks and theories has seen an explosion in their development and use, creating some confusion in how to choose and use tools appropriately.\textsuperscript{14} Consolidation of the available tools and consensus about their application are required to maximise benefits of a formalised approach to research.

Despite the unresolved issues, there are several potential advantages to undertaking the evaluations completed in this paper. The evaluation of the SABA guideline intervention indicated at well-thought-out mechanism and rationale for achieving outcomes, high degree of adaptation and short duration and intensity of the intervention. However, it did not provide a comprehensive solution to improving outcomes or understanding the suitability of the intervention for wider implementation. The value of retrospective deconstruction may be in using the methodology across a number of studies for comparative purposes. There are a few examples in the literature, but this approach is yet to be rigorously tested.\textsuperscript{15} Deconstruction into individual elements such as BCTs and using a common language (taxonomy) has the potential to simplify the comparison of studies, improve replication and link BCTs to outcomes.\textsuperscript{16} This process may be especially relevant in the community pharmacy setting, due to the heterogeneity of research involving implementation of clinical guidelines.\textsuperscript{17} However, successful deconstruction is dependent on the quality of reporting of studies. Without effective descriptions, interventions cannot be replicated, evaluated and compared and researchers cannot build on research findings.\textsuperscript{18} This is where taxonomies, frameworks and checkpoints do become important in the standardisation of reporting. There are numerous examples in the literature of tools for reporting interventions, including the tools used in this evaluation and their use is becoming more widespread.\textsuperscript{19}

While formalised approaches to implementation interventions, either at the design stage or in a subsequent evaluation, have benefits, they are not the complete answer. Implementation science is complex and there will always be intangible human influences that confound deciphering interventions and understanding outcomes. Generally, triangulation in evaluation looks at a single phenomenon but uses multiple data sources or methods or theories.\textsuperscript{20} The objectives are to find and uncover new information to provide a greater understanding of a complex problem. Evaluations can use both quantitative and qualitative methods. Employment of both methods can be helpful in addressing research questions in a more comprehensive way.\textsuperscript{21} Triangulation research methods are required to build up a picture of what is required for successful implementation in any single context. Multiple evaluations are required and more emphasis on evaluation of interventions is needed in implementation science.

Conclusion

It was possible to conduct a process evaluation and deconstruction based on theory to appraise an existing common-sense, clinical guidelines implementation intervention in community pharmacy. The deconstruction of the intervention, into behaviour change techniques, demonstrated that a common-sense approach to intervention design could be equivalent to a theoretical approach. The common-sense intervention was comprehensive and had a sound rationale and theoretical underpinning. However, the deconstruction of a single intervention did not provide insight into how to improve outcomes. The application of ITAX highlighted issues related to logistics, adaptability and fidelity but additional evaluations of context, climate and sustainability
are required. Duration, intensity and reinforcement of the intervention need consideration for successful wider implementation. Small-group workshops may prove to be a useful implementation strategy in community pharmacy if logistical issues can be overcome and less adaptation occurs. The assessments completed and the frameworks and taxonomies used provided some answers to improving implementation of guidelines, but further qualitative evaluations, triangulation of research and evaluations across interventions are required.

Contributors KW conceived and designed this research as part of her PhD studies, guided and supervised by CR and RG. KW and RG sought funding for the research from the Health Department of Western Australia. LS assisted KW with the application of behavioural change theory using the COM-B model and Behaviour Change Wheel. KW prepared an initial draft paper with all contributing authors to subsequent drafts and approved the final manuscript.

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Competing Interests KW is the proprietor of a community pharmacy in Perth, Western Australia and thus has a financial interest in community pharmacy. Ethics approval Approval for this research was obtained from the Human Research Ethics Committee of the University of Western Australia (approval numbers RA4/11/068 and RA4/11/5060).

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Post hoc evaluation of a common-sense intervention for asthma management in community pharmacy
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7.3 Key findings from evaluation study

Key findings included:

- The novel methodology used in evaluating the SABA implementation-intervention, involving the retrospective application of taxonomies and frameworks, was successful in achieving an understanding of the elements of the intervention. However, it did not provide definitive answers on how to improve outcomes.

- The common-sense approach to intervention design, based on addressing an identified practice barrier, was found to be comprehensive with a sound rationale. This demonstrates the use of explicit theory in intervention design is not essential. A theory-based approach can have benefits (e.g. improved reporting and replicability of interventions), but it does not necessarily address all the issues (e.g. logistical barriers) that may influence intervention outcomes.

- Issues identified that might have impacted on the SABA implementation-intervention outcomes related to logistics, adaptability, fidelity, duration, intensity and reinforcement. More research is also required to understand the generalisability and sustainability of the outcomes.

- Small group workshops as a mode of implementation for community pharmacy had a sound rationale, but logistical issues impeded participation and necessitated adaptation of the intervention. More research is required to investigate how to overcome logistical barriers.

- Academic detailing was achievable on a much larger scale than small group workshops but lacked the team-based approach to overcoming practice barriers because the information was provided to one staff member only (the pharmacist-in-charge). Given that influencing the role of the pharmacy assistant was key,
academic detailing was heavily reliant on internal communication and diffusion of information in the community pharmacy setting to achieve outcomes.

- Triangulation research methods are required in evaluation to understand the important elements for successful implementation in any single context. This was demonstrated by the different knowledge gleaned using both ITAX and the BCW. The retrospective application of these tools indicated that both the rationale and logistical/process considerations could impact on the ultimate effectiveness of an implementation strategy.

### 7.4 Relevance of findings to the thesis

There is little point in developing guidelines if they are not successfully implemented into practice and the success of implementation cannot be determined without evaluation. This thesis started with research to confirm the hypothesis that an initial implementation of the SABA guidelines and AAP card³ had been largely unsuccessful in translation to practice. The subsequent evidence-based, tailored, implementation-intervention (Chapter 6)⁴ demonstrated variable outcomes related to practice change by community pharmacists. Variable outcomes included increased medical referral of patients, unchanged internal referral of patients (from pharmacy assistants to pharmacists) and poor practice around device demonstration. In moving forward to improving future implementation initiatives and addressing the aim of this thesis, it was necessary to comprehend the elements of the implementation-intervention that were successful in promoting guideline-based practice, by community pharmacy. The systematic review (Chapter 3) identified that a diverse range of implementation strategies have been utilised in community pharmacy, but there is a poor
understanding of which ones work in what instances. It is unclear when strategies are successful and when they are not. Dissecting the SABA implementation-intervention into individual elements (based on the rationale of intervention design and the process of implementation) resulted in an advanced understanding of the key components for successful implementation of guidelines in the community pharmacy setting.
7.5 References


Chapter 8:

Thesis Discussion
8.1 Background

The preliminary studies in this thesis provided an understanding of current knowledge regarding implementation of clinical guidelines in community pharmacy (Chapter 3);\(^1\) issues in asthma management from the perspective of stakeholders in the primary healthcare setting (Chapter 4);\(^2\) and clinical issues of patients with asthma (Chapter 5).\(^3\) The information gathered was then used to design and conduct an implementation-intervention study, designed to improve SABA guideline-based practice in community pharmacy (Chapter 6).\(^4\) The implementation-intervention was tailored to address the role of pharmacy assistants in non-prescription SABA requests, which had been identified as a practice barrier (Chapters 3 and 4).\(^1,2\) The variable outcomes produced by the SABA implementation-intervention were subsequently evaluated using a retrospective deconstruction of the intervention into individual elements, including logistical and behaviour change elements (Chapter 7).\(^5\) The systematic process followed in the research for this thesis provided the information necessary to address the thesis aim:

“To investigate and evaluate the strategies for successful implementation of clinical guidelines to community pharmacy.”

This chapter brings together the logic of the process and the findings of the individual studies to discuss the overarching thesis aim. It demonstrates the significant contribution to knowledge, of this thesis, while being cognizant of the key strengths and limitations. The chapter concludes by considering the implications of this research for policy and practice, including current interest in the implementation-intervention.
8.2 Key findings and contribution to knowledge

The research completed in this thesis demonstrated, the complexity of the issues around asthma management, and the numerous methodological considerations required in designing and undertaking an intervention to successfully implement clinical guidelines to the community pharmacy setting. However, it also indicated the potential of community pharmacists to play a significant role in asthma management, and that implementation of clinical guidelines can improve evidence-based practice, as was the hypothesis for this thesis.

8.2.1 Current literature on guideline implementation to community pharmacy

The first area of enquiry was to examine the literature determining the effectiveness of clinical guideline implementation to community pharmacy. The systematic review in Chapter 3 identified the significant evidence gaps in the evidence in this field.¹ Few studies had a clear, systematic approach to intervention design or an underlying rationale. Most achieved positive outcomes but few looked at patient health outcomes or the sustainability of practice change. The variable results and lack of studies based on formalised theory determined the evidence for using a theory-based approach in intervention design were inconclusive. Finally, the high risk of bias and poor quality of evidence for outcomes in most studies in the review also limited conclusions. The best evidence was for CDSS as part of the implementation strategy, although this was only used in a small number of studies.⁶,⁷ Another notable finding was the lack of consideration of stakeholders in guideline implementation, other than pharmacists (e.g. pharmacy assistants, patients and GPs).¹
The conclusions from this review contributed to the intervention study of this thesis (Chapter 6). It directed a pragmatic, systematic approach, based on a clear rationale, to the design of the SABA guideline implementation-intervention. The decision was made to tailor an implementation-intervention to address barriers to guideline-based practice and optimal asthma management. The review also led to the consideration of the role of pharmacy assistants, as key stakeholders, in guideline-based practice.

The literature review indicated that implementation-interventions should address patient outcomes, economic outcomes and sustainability. These aspects will be important future studies following on from work in this thesis. However, the focus of this implementation-intervention was on the achievement of practice change, as the first step to the translation of the guidelines. Refining an implementation strategy was a priority, given the lack of evidence for optimal strategies as identified in the systematic literature review. Refinement of a successful strategy would facilitate the development of a larger scale implementation-intervention, over a longer time-period, which could be evaluated based on patient health outcomes. In making these decisions, there was recognition of the time frames quoted in the literature for translation research to achieve sustained outcomes and also the substantial barriers identified in asthma management in the literature and by this thesis (Chapter 4).

### 8.2.2 Understanding the barriers to guideline-based practice and asthma management

The second area of enquiry was to understand the barriers and facilitators to clinical guideline implementation and asthma management. Qualitative research, using focus groups with key stakeholders in primary healthcare (including health professionals,
pharmacy assistants and patients), provided rich data that helped to inform the thesis research direction further (Chapter 4). Key points were identified related to implementation strategies. In the stakeholder groups (e.g. GPs, practice nurses, patients) where passive dissemination methods had been used for the initial implementation of the SABA guidelines and AAP card, there was poor awareness of the tools, but the academic detailing to pharmacists had resulted in good awareness. These results were not surprising given that evidence on clinical guideline implementation from other settings confirms passive dissemination as unsuccessful as an implementation strategy. However, while academic detailing provided awareness, it was also clear from the focus groups (Chapter 4) that awareness of a resource did not necessarily change health professional practice or patient self-management of asthma. The initial implementation included academic detailing focused on informing pharmacists of the guidelines. It had not addressed the barriers to behaviour change required for uptake of the resources into routine practice or considered what influences optimal asthma management. These barriers and issues needed to be considered for successful implementation.

A variety of barriers to optimal guideline-based asthma management were identified and grouped according to whether they related to knowledge deficits, stakeholder attitudes or existing behaviours of stakeholders (as per a previously published taxonomy). Patient attitudes and behaviours were considered to be a significant barrier by health professionals that led to challenges with patient engagement. The discordant attitudes of health professionals and patients further exacerbated these challenges. The work environment also contributed to behaviours that undermined patient care. Environmental barriers included time and workflows. These factors
limited the involvement of pharmacists in patient consultations and determined that non-professional staff (pharmacy assistants) were usually the first to encounter patients.²

The results of the qualitative research informed the implementation-intervention study (Chapter 6) in several ways. Patient engagement issues and discordance were tackled in the implementation-intervention by including elements that improved communication skills and provided an understanding of the patient perspective. The patient perspective was illustrated through a video of a patient story developed specifically for the intervention. Time, workflow issues and the role of the pharmacy assistant were addressed through the development of a written checklist tool. The Asthma Medication Request Checklist provided a means of internal referral from pharmacy assistant to pharmacist. The checklist gave pharmacy assistants a defined role, allowed them to collect preliminary patient information relevant to the SABA guidelines, and manage the workflows for pharmacists. Pharmacists could use the assessment information gathered to enable more tailored and succinct patient conversations. Another advantage of the checklist was that it met the criteria for documentation of clinical activities regarding chronic disease management. This provided a financial incentive to allocate time and support guideline-based practice.

8.2.3 The needs of the patient with asthma and the opportunities for community pharmacists to improve asthma management

The third area of enquiry undertaken in this thesis was to investigate the characteristics of the patients with asthma that a community pharmacist routinely encounters. This was achieved through a patient survey (Chapter 5).³ This research
was particularly relevant given the unique situation that exists in Australia with the legislation for SABAs.\textsuperscript{19,20} Legislation determines that patients can access SABAs without a prescription and without necessarily seeing a doctor. Understanding the needs of patients with asthma routinely presenting in community pharmacies was crucial to understanding the importance and the relevance of the proposed intervention. The survey was also useful in demonstrating the need for pharmacists to play a proactive clinical role in asthma management based on guidelines. Furthermore, it indicated the scope for future enhanced clinical roles for pharmacists that moved beyond the current translational research in this thesis (summarised in the section below on future research).

A questionnaire was devised to conduct the survey of asthma patients. It was comprised of a number of validated tools investigating different facets of asthma management including asthma control,\textsuperscript{21,22} quality of life,\textsuperscript{23} medication adherence,\textsuperscript{24} asthma knowledge,\textsuperscript{25,26} beliefs about asthma control.\textsuperscript{27} It also considered demographic information and patient history. The results of the survey clearly indicated that half the patients with asthma that present to pharmacies required health professional intervention to: optimise their asthma self-management, promote Quality Use of Medicines and improve their quality of life. A small but significant proportion of these patients were found to be at imminent risk of life-threatening attacks and requiring emergency medical care. However, it was also evident that addressing these health concerns would be a challenge due to the lack of awareness by patients of their suboptimal self-management and the health risks. The discordance between actual clinical control of asthma and patient perceptions of asthma control explained some of the patient engagement issues identified from the focus group study.\textsuperscript{2} Furthermore,
the low levels of written asthma action plan ownership observed, indicated that patients were not empowered to appropriately self-manage their asthma. Based on the referral criteria from the SABA guidelines the majority of patients with asthma encountered by community pharmacists would require referral. Referral criteria include poor asthma control, lack of written asthma action plan ownership, medical review not within previous six months, or current acute asthma exacerbation.\(^{28}\)

### 8.2.4 Design and evaluation of an intervention to improve SABA guideline-based practice in community pharmacy

The fourth area of enquiry began by investigating current (baseline) pharmacy practice, which was achieved using simulated patient methodology. The results indicated that pharmacists were not assessing, referring or counselling patients in accordance with the SABA guidelines.\(^{4}\) These findings concurred with focus group results (Chapter 4)\(^{2}\) that the initial implementation had not resulted in guideline-based practice change due to a variety of barriers. The poor guideline-adherent practice identified, confirmed the appropriateness of an intervention to improve practice, based on patient need (Chapter 5)\(^{3}\) and practice deficits (Chapter 6).\(^{4}\) Having considered the evidence, barriers, and need for an intervention to implement the SABA guidelines, the next phase was to devise and undertake an implementation-intervention (Chapter 6).\(^{4}\)

Due to the limited evidence on successful implementation strategies, for clinical guideline implementation in community pharmacy, from the systematic literature review, (Chapter 3)\(^{1}\) a pragmatic and flexible approach was necessary. Key considerations in the development of the implementation-intervention were to: use a common sense pragmatic approach; be translational with the aim of impacting on
routine clinical practice; and be within the scope of the resources of this thesis research. A variety of intervention options were considered and investigated (Chapter 2). The minimal evidence from the systematic review required a strategy that also included the best evidence for implementation from other settings.\textsuperscript{13,29,30} The information gathered was then contextualised and supplemented with stakeholder expertise and experience via, focus group data, survey data, expert panel consultation, and researcher experience as a community pharmacist and proprietor.

Several reviews from other settings indicated that a tailored approach to overcome identified barriers was important to effecting change on professional practice and health care outcomes.\textsuperscript{15,29,31-33} As mentioned in the Cochrane review by Baker and colleagues, the issue was then one of how to identify and choose the barriers (determinants) to address, and how to tailor the intervention.\textsuperscript{31,32} There is sparse knowledge on how to approach these issues, particularly in the community pharmacy setting. The research of Krause and colleagues demonstrated the complexities of a tailored approach by identifying a large number of determinants that may be relevant in intervention design. In their conclusion, they suggested the use of multiple methods for understanding determinants and also suggested brainstorming could be useful.\textsuperscript{34}

Brainstorming of ideas to improve asthma management was included as part of the focus group discussions in this thesis research (Chapter 4).\textsuperscript{2} Brainstorming led to the consideration of legislative change and the use of smartphone applications as possible intervention options. However, they were discounted after further investigation. Legislative change was logistically not feasible within the time frame of the research, due to an impending government election resulting in the Health Department of WA following caretaker conventions at that time.\textsuperscript{35} Smartphone Apps were not pursued
when a literature revealed a significant number of asthma apps already in existence.\textsuperscript{36,37} The ultimate intervention chosen was to formalise the role of the pharmacy assistant in SABA guideline-based practice. This was identified as a key issue both in the systematic review (Chapter 3)\textsuperscript{1} and focus group study (Chapter 4).\textsuperscript{2} Further confirming this strategy for intervention were the results of the patient survey (Chapter 5) which indicated patients had poor awareness of their suboptimal asthma control and were unlikely to be seeking assistance.\textsuperscript{3} Patients who did not perceive the need for intervention were unlikely to be receptive to answering questions or waiting for a pharmacist, during initial encounters with pharmacy assistants.

The role of the pharmacy assistant was significant due to existing workflows in community pharmacy. To impact on workflows, a whole team-based approach was logical. Thus small group workshops were chosen as the implementation mode. Small group workshops are included in the definition of “educational meetings” in the EPOC taxonomy of implementation strategies.\textsuperscript{38} This choice of strategy was also supported by evidence in the literature that educational meetings can improve both professional practice and healthcare outcomes.\textsuperscript{39} Grimshaw noted that educational meetings were a feasible strategy in most settings.\textsuperscript{15}

However, upon implementation of the workshop strategy, it became evident that logistical issues were hindering pharmacy uptake resulting in low participation rates. In response, the decision was made to adapt the intervention for delivery via academic detailing (educational outreach). Academic detailing has been demonstrated in research to change practice behaviours.\textsuperscript{13,15,16} However, much of the research pertains to prescribing practices and relatively simple behaviour change patterns, such as
influencing choice of drugs in prescribing.⁴ In the systematic review (Chapter 3),¹ academic detailing was undertaken in three guideline implementation studies in community pharmacy, with variable success.⁴⁰-⁴² Also, the initial implementation of the SABA guidelines had unsuccessfully used academic detailing to pharmacists. While the initial implementation had impacted on awareness it had not achieved guideline-based practice change. Despite this failure, the decision was made to adapt the implementation-intervention for delivery via academic detailing due to the content being tailored to address barriers. The tailoring set it apart from the content of the initial implementation, which had simply provided education via academic detailing about the existence of the SABA guidelines.

Key differences between the workshop strategy and academic detailing strategy included: the opportunity to treat the staff in community pharmacies as a team, tailor the information to the individual community pharmacy and deliver the information to all staff rather than one member. The contact time of the intervention was also substantially diminished with workshops taking between one and two hours (depending on staff participation) and academic detailing visits only lasting 15 minutes. The outcomes post-intervention were measured using covert simulated patient methodology, and comparisons were made with baseline practice.

The implementation-intervention delivered via both small-group workshops and academic detailing resulted in a significant and positive outcome for appropriate guideline-based patient medical referral.⁴ Medical referral was a key primary outcome of interest. The intervention group showed a significant increase in referral from
baseline to post-intervention. Conversely, there were no significant differences from baseline to post-intervention for the control group.

Using the EPOC classification of outcomes, measures of guideline adherence (such as guideline-based patient medical referral) are considered to be a primary process outcome measuring quality of care.⁴³ Thus, the positive results achieved for this outcome (following the implementation-intervention) should be indicative of improvements in patient care. However, other process outcomes measured including internal referral from a pharmacy assistant to a pharmacist and device counseling did not change as a result of the intervention. These variable results may have been attributed to the workshop content placing more emphasis on patient referral than other elements of the SABA guidelines and/or the adaptation of the workshop delivery mode to academic detailing. There were some statistically significant differences in outcomes between “workshop pharmacies” and “academic detailing pharmacies” that indicated the intervention outcomes might have been strengthened if more pharmacies had participated in workshops.⁴ However, the small sample size of the “workshop pharmacies” determined that the research was not powered to make these conclusions.

8.2.5 Post-hoc evaluation of a team-based intervention to implement the SABA guidelines to community pharmacy

The fifth area of enquiry involved post hoc analysis of the implementation intervention (Chapter 7).⁵ Given the variable results of the intervention the evaluations conducted provided an opportunity to understand the elements that may have been relevant in achieving practice change. The methodology was unique and involved the
retrospective deconstruction of the intervention using ITAX,\textsuperscript{44} to examine logistical issues and, the BCW,\textsuperscript{45} to understand the underlying mechanisms or rationale for the intervention. Evaluation also provided an opportunity to consider the differences between a common sense, pragmatic approach, compared to an approach grounded in formalised behavioural theory, when designing interventions. There is currently strong advocacy for the latter approach in the scientific literature.\textsuperscript{46-50}

Given the novel methodology, the first finding was that it was feasible to use the tools in a retrospective evaluation. The application of ITAX highlighted that success of the intervention might have been hindered by issues associated with logistics, adaptability fidelity, duration and intensity. However, ITAX did not consider the effects of context, climate and sustainability, which would require further evaluation. The use of the BCW illustrated that the common sense, pragmatic intervention design was comprehensive and all the elements had a clear rationale for changing behaviour. However, as a single study, it did not necessarily provide insight into how to improve outcomes. The value in the retrospective application of the BCW may be in pooling deconstruction data from multiple studies and identifying individual BCTs that are successful in achieving positive outcomes.\textsuperscript{51,52}

It remains unclear whether the tailored, pragmatic approach to intervention design could have been improved by using formalised behaviour change theories. Studies have indicated that tailored interventions are more likely to improve professional practice than dissemination alone of guidelines\textsuperscript{31,32} and there is merit in this method.\textsuperscript{53} However, the optimum method for identifying determinants and tailoring interventions remains unresolved.\textsuperscript{34,54} At this stage the evidence supporting the use of
theory in the community pharmacy setting is somewhat deficient, primarily due to the lack of studies.\textsuperscript{1} However, a recent systematic review of 58 interventions to enhance adherence in chronic respiratory disease concluded that interventions were more effective if developed using behaviour change theory.\textsuperscript{55} Other recognised benefits inherent in using theory are the systematic approach, lack of implicit assumptions and uniformity of documentation, which could prove advantageous in future research.\textsuperscript{48,50} While the evaluation methods highlighted many issues to consider in future implementation-interventions they did not provide comprehensive and definitive answers. This is in contrast to the work of Steinmo and colleagues who took this methodology a step further. Qualitative research based on the results of a post hoc retrospective application of the BCW, Theoretical Domains Framework (TDF) and BCTTv1 provided the information necessary to modify and improve a pragmatic implementation intervention to decrease the mortality rate due to sepsis.\textsuperscript{49,56}

8.2.6 Overall thesis findings

\begin{quote}
\textit{``Writing a guideline may be difficult, but determining how to best implement the guideline is more difficult.\textsuperscript{57}''}
\end{quote}

The overarching aim of this thesis was to understand more about the strategies for successful implementation of clinical guidelines for asthma to community pharmacy. The challenge of addressing this thesis aim is not to be under-estimated given that one of the most consistent findings in clinical and health services research is the failure to translate findings into health professional practice.\textsuperscript{15} Furthermore, there is a plethora of research in implementation science, but many unanswered questions and
conflicting evidence on how to successfully implement clinical guidelines.\textsuperscript{13,29,30,58} The final challenge related to the relatively short timelines available for this thesis compared with the timelines required for translation research quoted in the scientific literature.\textsuperscript{8}

Despite these significant and recognised challenges, the tailored implementation-intervention (determined by thorough preliminary research) produced practice change in the form of improved guideline-based patient medical referral (Chapter 6).\textsuperscript{4} This is evidence that the pragmatic approach, using triangulated research methods in devising a tailored intervention to overcome barriers to SABA guideline-based practice in community pharmacy, had merit. Furthermore, much was learned about the unique concerns of implementing guidelines in the community pharmacy setting. For instance considering the role of the pharmacy assistant and the logistics of how to engage staff in educational workshops. The greater understanding of asthma achieved by this research highlighted that asthma remains a significant health issue and that community pharmacists have the potential to play a role in improving health care and patient outcomes.

Understandably, not all outcome measures were improved by the intervention. There were no significant changes to internal referral from pharmacy assistants to pharmacists and inhaler device checks were not occurring at any stage of the research.

The improvements in guideline-based referral of asthma patients indicated that strategies based on small group workshops and academic detailing could be successful in achieving practice change in the community pharmacy setting.\textsuperscript{4} The relative benefits
of each remain unclear. Regardless of the benefits or otherwise, logistical and cost issues associated with engaging community pharmacies in small group workshops need to be overcome for this to be an effective option in larger scale implementations. The positive outcome also points to the importance of tailoring an intervention to overcome barriers that may undermine practice change. This is consistent with the literature from other settings.\textsuperscript{13,15,29,31,34,58,59}

In tailoring the guideline implementation intervention to the community pharmacy setting there was acknowledgement of the role of the pharmacy assistant. This is an important consideration due to the existing workflows that result in the pharmacy assistant being the first point of contact for most patients. In any intervention in community pharmacy, their role should be considered.\textsuperscript{1} Also relevant to the context was the fact that the guidelines tested in the intervention were for asthma management. The patient study indicated some of the unique barriers associated with managing the chronic condition, asthma. In particular the unique issues with patient engagement due to patients having poor recognition of what constitutes good asthma control. These contextual issues were identified in the preliminary research (Chapters 3,4 and 5)\textsuperscript{1-3} and indicate the benefit of triangulation methods and tailoring of interventions for guideline implementation.

The retrospective application of taxonomies and frameworks in the evaluation study (Chapter 7)\textsuperscript{5} indicated the benefits and limitations these tools can have in contemplating all facets of an intervention; that may impact on behaviours and outcomes. Prospective use of these tools may have focused more attention on factors such as dose, duration and reinforcement of the intervention, which were likely to be
inadequate, and potentially resulted in more moderate outcome effects. Although the tailoring process in this intervention design resulted in a clear rationale for achieving behaviour change, many interventions in community pharmacy do not.\textsuperscript{1} Greater use of theory could be beneficial to ensure a sound basis for interventions, however it would not necessarily achieve better outcomes than a tailored, pragmatic intervention.

The popularity of taxonomies, frameworks and checklists are increasing in an effort to provide a more systematic approach to guideline implementation and improve translation. Recently, Mazza and colleagues have produced a draft taxonomy to classify the nature and content of guideline implementation strategies.\textsuperscript{60} The work of Gagliardi has been on developing a checklist for guideline implementation planning through review of existing resources.\textsuperscript{61,62} Interestingly, the checklist by Gagliardi has listed as one of its planning considerations to: “Consider or assess barriers to guideline implementation and use, and stakeholder needs and preferences through literature review, observation, focus groups, interviews or survey.” The research in this thesis has met these criteria in full. However, until consensus on a uniform approach to guideline implementation is achieved, the development of the vast array of tools may simply add to heterogeneity and confusion in the literature.

\textbf{8.3 Strengths and limitations of research}

This thesis consists of five published studies (systematic review, focus group study, patient survey, intervention study and evaluation study).\textsuperscript{1-5} The strengths and limitations inherent in each study are discussed in Chapters 3-7. This chapter focuses on the strengths and limitations of the work in this thesis in considering the
overarching aim: to investigate and evaluate the strategies for successful implementation of clinical guidelines to community pharmacy.

8.3.1 Strengths

The work in this thesis is the first in the world to explore clinical guideline implementation strategies specifically in the community pharmacy setting. It answers the question: What are the characteristics of an implementation intervention that make it successful in reducing an evidence-practice gap? This work is fundamental to informing future implementation initiatives to maximise the benefit derived from guidelines in terms of pharmacy practice and patient health. The work is timely due to the recent increase in the number of guidelines specifically for community pharmacy and the expanding clinical role of pharmacists.

This thesis is characterised by a strong methodological approach. Triangulation of methods and thorough preliminary research were undertaken before embarking on the implementation-intervention. The systematic literature review made a detailed assessment of the current research employing three quality-assessment tools, including the EPOC risk of bias tool, the Newcastle-Ottowa risk of bias tool and GRADE approach. The focus group consulted widely by including all stakeholders in primary care asthma management, collected data using three methods and reported outcomes using the Knowledge, Attitudes and Behaviour taxonomy. The patient study provided a thorough understanding of the issues pertaining to patients with asthma routinely encountered in the community pharmacy setting and considered possible roles for pharmacists in improving asthma management. In the intervention study, use of a control cohort and covert simulated patient methodology (to minimise the Hawthorne effect) improved the quality of the evidence for outcomes. The robust post-hoc
evaluation process, using ITAX and the BCW, provided the next step towards improving the intervention for the future. The evaluation study also reflected current trends in the literature by applying a theoretical framework.

Another strength is that the work addressed a health priority area in asthma management. It explored the potential benefits associated with improved utilisation of the accessibility and clinical skills of community pharmacists at a time when government is seeking to strengthen the primary health care sector. With support staff (e.g. pharmacy assistants, dental assistants, community health workers) expanding their scope of practice in health service provision, this research may also be relevant in informing implementation initiatives beyond community pharmacy.

8.3.2 Limitations
In terms of methodology, there are several limitations regarding the design of this thesis research. The focus groups (Chapter 4) were initially based on discussing the AAP card as a way of facilitating guideline-based patient care. However it became evident that there was limited uptake of this resource. This required a focus on more general issues around asthma management. While it was appropriate to engage with all stakeholders, in retrospect more focus group discussions with pharmacists regarding the SABA guidelines would have been informative in directing the research.

The focus group study (Chapter 4) provided an indication of stakeholder familiarity with the SABA guidelines. However, there were no measurements of knowledge of guideline content or asthma management in general. While this is a limitation of the research there was the opportunity to raise lack of knowledge as a barrier to
engagement and optimum patient care. Pharmacy assistants revealed that lack-of-knowledge was a reason for not asking patients too many questions and strengthened the decision to formalise their role as part of the implementation-intervention (Chapter 6).\(^4\) Overwhelmingly though, the main barrier to asthma management (mentioned by all health professionals and ancillary staff) was the patient’s resistance to answering questions. Although knowledge deficits were not specifically addressed in the intervention, resources were provided to participants in workshops to facilitate professional development. Useful further research would be to evaluate practitioner knowledge of guideline-based care.

There are several limitations in making conclusions based on cross-sectional data (Chapter 5).\(^3\) These include an inability to analyse behaviour over time, an inability to determine cause and effect and the fact that the data is not guaranteed to be representative as it only indicates a snapshot in time.

The implementation-intervention (Chapter 6)\(^4\) could have been improved in a number of ways. Rather than post-hoc analysis with the BCW and ITAX (Chapter 7),\(^5\) this analysis could have been done prospectively to refine the intervention before implementation. This may have pre-empted some of the process issues encountered. Ideally the implementation-intervention should have been piloted as recommended in the Medical Research Council (MRC) guidelines for the development of a complex intervention.\(^6\) However, the implementation-intervention could be seen as a pilot study and as such it included the key elements of the MRC development-evaluation-implementation process. \(\text{Figure 1}\)
Figure 1: Key elements of the development and evaluation process in complex interventions
*Reproduced with permission from the MRC.*

Post-intervention evaluations, such as feedback from pharmacists and staff participating in workshops or academic detailing, could have been incorporated into the research. These would have provided valuable insight into the effective and non-effective elements of the implementation-intervention (Chapter 6). For instance, there was a very high participation rate in academic detailing but this may have been due to the method of "cold-calling" participants. The decision was made (due to time constraints and previous experience in making appointments with pharmacists) to cold call pharmacies and wait until the pharmacist was available. The times were chosen to minimise disruption and maximise pharmacist availability to participate. Nevertheless this may have resulted in interactions that were “unwelcome” and not received in a positive way.

Selection bias was a limitation of several of the studies in this thesis and often intrinsic to practice research undertaken in the community pharmacy setting. Focus group (Chapter 4), survey (Chapter 5) and workshop participants (Chapter 6) were all self-selected and thus at risk of not being representative of the wider populations from which they were drawn. In the focus groups, saturation of themes was sought to
minimise the influence of bias. Minimising bias was more problematic in the patient survey. However, the results of the survey were consistent with larger population studies from Australia lending weight to their validity. A randomised controlled trial (RCT) was not possible in the intervention study due to the possibility of contamination. This resulted in a quasi-experimental study using a cluster design with a control cohort. Despite efforts to ensure the consistency of practice at baseline between cohorts, there were unexplained differences. It was postulated that these baseline practice discrepancies might reflect the many intervention activities occurring around asthma at any point in time in the health system. It is also likely that there is a significant variation in the practice of individuals within a single community pharmacy, which may confound results. Contributing to bias in the intervention study was the self-selection of pharmacies to participate in workshops. This may have indicated greater motivation towards professional practice and guideline adherence. It also limits the comparisons that can be made between the strategies of small group workshops and academic detailing. However, comparisons were already limited by sample size.

Another factor that may have contributed to the variable results is the degree of influence that this research team had in eliciting behaviour change. Put in simpler terms: “Did the intervention messengers (workshop facilitators and academic detailers) have the standing to influence the participants?” “Were they perceived as thought leaders and experts in the field?” If the intervention had been provided by a key opinion leader or under endorsement of a respected professional organisation with traction in the industry, the response to workshop invitations and the practice change outcomes might have been greater. While the guideline themselves were from PSA, pharmacy’s peak professional body in Australia, the education was under the
banner of UWA researchers. Efforts were taken to minimise this limitation through professionalism. For instance, the Asthma Medication Checklist tool was formatted in the same way as other PSA checklists.

While the intervention design process was thorough and tailored to overcome barriers to guideline-based practice there are clearly many barriers to optimal management of asthma. For instance, patient barriers may not have been completely overcome given there was no direct intervention to that stakeholder group. More research is required to determine whether the tailored implementation-intervention designed, had an impact on patient-related barriers. Personality traits have been demonstrated to influence patient behaviour and self-management of chronic diseases, including asthma. While evidence of the potential of pharmacist counselling to impact on complex health behavioural issues is emerging, further research is required.

Recognition of the many factors that can influence asthma management lead to the decision not to include patient outcomes in the analysis. The focus instead was on practice outcomes. This is a limitation of the research because patient health outcomes represent the ultimate goal of guideline implementation. However, it can be difficult to attribute patient health outcomes directly to guidelines. For this reason, practice or process outcomes, which are more sensitive measures, are frequently used as indicators of quality of care. Unfortunately, these surrogate measures do not necessarily extrapolate to improved patient health outcomes. Further research is required to demonstrate this link. Therefore no conclusions about the impact on patient health can be made from this research. A similar lack of patient health outcomes was also evident from the systematic review of interventions to implement
clinical guidelines in community pharmacy, (Chapter 3)\(^1\) and future research should seek to address this gap.

Grimshaw observed in his large review of the effectiveness of guideline dissemination and implementation strategies from 2004 a similar lack of patient outcomes.\(^{13}\) He noted the extensive use of process measures as the primary end-point for determining intervention effectiveness, as well as a lack of economic evaluations. This thesis did not include any economic evaluations, which was recognised as a limitation from the outset. It is an area for further research, in the acknowledgement that a comprehensive assessment of the effectiveness of any implementation strategies requires an economic evaluation. The costs and likely benefits of introducing a guideline should always be considered in determining the most appropriate implementation strategy.\(^{13,70}\)

The final limitations relate to the concepts of generalisability, transferability and sustainability of the SABA guideline implementation-intervention. This research was examining the setting of community pharmacy. However, the unique legislation for SABAs in Australia may mean that the results cannot be generalised to community pharmacy in other countries. Furthermore, the results may not be transferable to other guidelines or other disease states. There is a unique set of barriers associated with patient behaviour around asthma management and use of SABAs, which may not apply to other disease states. Nevertheless, some of the findings of this thesis are transferable, such as consideration of the role of pharmacy assistants and the benefits of tailoring interventions to barriers when implementing clinical guidelines in the community pharmacy setting. More research is required to understand the
sustainability of the intervention, which is also a limitation of this thesis. Typically in the time frames of this research, practice change is observed in “early adopters”. Later-stage research translation in a sustainable way is unclear and requires longer observation times.\textsuperscript{73}

8.4 Implications for policy, practice and future research

The work in this thesis explored far more than the explicit aim. This research has the potential to influence future health policy, community pharmacy practice, and research in a variety of ways.

8.4.1 Demonstrating the need to consider implementation

Significant effort and resources are utilised in the development of guidelines, but the same consideration is often not provided to the implementation strategy. By highlighting the failure of the initial dissemination/implementation of the SABA guidelines to promote evidence-based practice, this thesis provides evidence of the need to allocate more resources to implementation activities. In the future, implementation plans would be developed simultaneously with guidelines.\textsuperscript{70}

8.4.2 Improving the evidence base for clinical guideline implementation in community pharmacy

The evidence base for optimum strategies for clinical guideline implementation remains incomplete despite 30 years of research. Greater insights are required to understand which strategies work for different evidence in different settings and what are the important processes and elements of successful change.\textsuperscript{74} This thesis
addressed a gap in the existing knowledge by synthesising evidence for effective clinical guideline implementation to the community pharmacy setting.

There was no definitive answer to, "What are the effective strategies for guideline implementation to community pharmacy?" More work needs to be done, to understand the barriers to community pharmacy staff participation in education, and particularly small group workshops. A comparison of small group workshops and academic detailing would be useful in determining the difference in the effectiveness of these two strategies, and the benefit of including pharmacy assistants in educational activities. Further research on the benefits and limitations of CDSS are also necessary. The review (Chapter 3)¹ indicated the possible advantages of CDSS in guideline implementation in community pharmacy, but further investigation of this strategy was not pursued for this thesis.

The review in this thesis (Chapter 3)¹ highlighted the issues of poor methodology, low quality of evidence and poor rationale for interventions. Future pharmacy practice research should aim to use a more systematic approach to the design of interventions. Greater use of taxonomies and behavioural theories may assist with some of these concerns and improve research reporting. However, as demonstrated in the post hoc evaluation (Chapter 7),⁵ there is no “one size fits all” gold standard method or tool for intervention design at this point. The work to date seems to indicate that the benefits of theory do not necessarily extrapolate to improved outcomes, although this hypothesis is unresolved at present and requires an answer. The review (Chapter 3)¹ also highlighted a lack of patient outcomes and economic outcomes, and future research should aim to incorporate these measures.
8.4.3 Improving the intervention and implementation

Given the variable success of the SABA guideline implementation-intervention it is necessary to investigate what improvements could be made to enhance outcomes.

It is possible that the quality of the SABA guidelines themselves may have influenced the success of implementation. While no such barriers were identified from the focus group research (Chapter 4),\textsuperscript{2} future research could include a critical appraisal of the guidelines. The Appraisal of Guidelines for Research and Evaluation (AGREE 11) Instrument\textsuperscript{25} is a newly updated, validated tool comprising of 23 items in 6 domains, which would be an appropriate instrument for appraisal.

The evaluation (Chapter 7)\textsuperscript{5} included deconstruction of the implementation-intervention elements into BCTs. It would be useful to have a greater understanding of the relative effectiveness of the individual elements to ascertain their contribution to improved practice. Further analysis would provide an opportunity to incorporate elements that focus on practice deficits that are not impacted upon via the implementation-intervention, such as inhaler technique demonstration. It would also allow for the removal of elements that do not contribute to outcomes but add to complexity and cost.

For instance, the SABA guideline implementation intervention contained elements to improve communication skills and patient engagement. Pharmacy staff were introduced to concepts such as motivational interviewing and provided insight into the patient perspective through a patient-story video. Insight into the patient perspective aimed to give staff empathy, an understanding of the issues underlying patient
behaviours, and consequently improve communication. This would provide a basis for pharmacy staff to influence patient behaviours around asthma self-management. What was unclear was the effectiveness of these elements in achieving their aims. More evaluations are required to understand if there were improvements in the communication style of staff and changes in patient behaviours/attitudes to asthma.

Evaluations of the communication style of pharmacy staff are challenging due to bias introduced via the Hawthorne effect. However, it would be useful to conduct evaluations that measure the effects of the SABA implementation-intervention on pharmacy staff communication and extrapolate the information to changes in patient behaviours. There are several examples of qualitative research using audio recording of pharmacy staff to analyse communication with patients. They demonstrate methodology that could prove useful in evaluating communication skills of pharmacy staff in SABA requests. Audio recordings of the covert simulated patient visits, conducted as part of this thesis, could also have provided richer, qualitative information, compared to the quantitative data collected via the data collection form (Appendix 18). However, covert audio recording is fraught with ethical constraints and was not permissible in this research.

Extrapolating changes in pharmacy staff communication skills to patient health behaviours is more challenging but could possibly be achieved by follow-up of patients involved in SABA-request interactions. Pharmacists have demonstrated their ability to produce meaningful improvements to patient health behaviours, in self-management of chronic diseases, with more intensive, longer-term interventions. It remains to
be investigated whether a translational intervention such as the SABA implementation-intervention can achieve patient behaviour change.

Another element of the SABA guideline implementation-intervention designed to influence pharmacy staff behaviour was the role-play video. A systematic review of video-assisted patient education to modify behaviour found that the presentation format could influence outcomes.\textsuperscript{80} It is unclear if the videos developed as part of the SABA intervention achieved their objectives, and this requires further research. However, the review, which assessed twenty primary studies, provides evidence to support the notion that the videos may have been successful as educational and behaviour change tools.\textsuperscript{80} It was noted that video formats using real people are more effective than graphical illustrations of health information and that improving skills is best achieved by enacting the behaviour.\textsuperscript{80} The videos developed for this thesis used both of these formats. Other research analysing videos (YouTube) as health professional educational tools, noted that deeper learning results from group discussion and critical thinking stimulated by watching videos.\textsuperscript{81} The workshop format facilitated this possibility.

It is likely that more evaluation studies are required to improve and maximise the benefit of the SABA implementation-intervention for future use. In considering what was achieved with the research in this thesis it would be useful to employ a recently devised heuristic taxonomy by Proctor and colleagues, to evaluate the process of implementation.\textsuperscript{82} The taxonomy outlines eight distinct outcomes of implementation research. These include acceptability, adoption, appropriateness, feasibility, fidelity, cost, penetration and sustainability. Using this taxonomy would advance
understanding of the process of implementation rather than just the outcomes achieved in terms of practitioner behaviour change (Figure 2).

![Implementation outcomes diagram]

Figure 2: Summary of outcomes in implementation research: Outcomes of the process of implementation detailed in red
Adapted from Proctor and colleagues.82

 Acceptability refers to whether the intervention was agreeable, palatable or satisfactory, including the content, complexity, comfort, delivery and credibility.82 For this thesis research, this could be measured at the level of the pharmacy staff and the level of the patient. Did the pharmacy staff agree with the messages conveyed in the workshop or via academic detailing? Did they think that using a checklist was a good idea? Did they have reservations asking patients with asthma questions when they seemed reluctant to engage? At the level of the patient, it would be important to understand their perspective of the intervention. Did patients find the new communication style of pharmacy staff, or filling in the checklist, acceptable changes to practice? Constructs such as these could be assessed using qualitative research methods.
Adoption is defined as the intention or decision to employ the practice change associated with the intervention. The concept of adoption can be considered at various levels: at the level of the individual (pharmacy staff member) or the level of the setting or organisation (whole pharmacy practice change initiative). For instance in this research how many pharmacies/individuals were willing to use the Asthma Medication Checklist introduced as part of the SABA implementation-intervention? Measuring adoption at both levels is challenging with the simulated patient methodology used in this thesis. Individuals may have adopted changes to their practice, but the simulated patients may have encountered individuals who hadn't adopted the changes within the setting. In the SABA guidelines implementation-intervention, focus group discussions with stakeholders (Chapter 4) were utilised to try and pre-empt issues with “adoption” by ascertaining barriers to practice change.

Appropriateness refers to the relevance of the intervention for the setting and how well it fits in addressing a particular health problem; its compatibility, suitability, usefulness and practicability. Appropriateness addresses issues such as whether the new practice is consistent with the missions of the healthcare setting (pharmacy), skillset of staff and job expectations. Outcomes can be measured at different levels including the level of the individual (pharmacy staff member), the organisation (the pharmacy) and the patient. Regarding the SABA guideline implementation-intervention appropriateness raises many potential questions that warrant further investigation and may have lessened outcomes. For instance, in the focus group discussions (Chapter 4), pharmacists and other stakeholders recounted feeling frustrated at GPs not providing patients with written asthma action plans. Given a
referral point for the SABA guidelines, is lack of ownership of a written asthma action plan; pharmacists may have perceived it was pointless referring patients if GPs were unresponsive. Another example where appropriateness comes into question is the universal lack of device demonstration observed in this research (Chapter 6), despite being outlined in the SABA guidelines. Do pharmacists perceive that it is their role to offer this service? Do they perceive that it is not appropriately remunerated to warrant time allocation? Do they perceive that they don’t have the skills to demonstrate devices? Other issues around appropriateness are at the level of the pharmacy. Clearly, the low uptake to participate in workshops indicated a lack of appropriateness of this delivery method. Workshops required Pharmacy Managers to prioritise asthma education over other professional activities. They needed to find a time that all staff could attend after hours and be willing to pay staff to attend. At patient level, the patient questionnaire conducted in this thesis (Chapter 5) clearly demonstrated that it was appropriate for pharmacists to intervene and provide guideline based care due to the observed poor asthma control and other medication and management issues.

**Feasibility** relates to the ability to successfully adopt the practice changes associated with the intervention. This looks at the resources, skills and training requirements to change practice and considers the individual. The concept of feasibility relates to “capability and opportunity” as assessed in retrospective behavioural analysis achieved through application of the COM-B model, undertaken in Chapter 7. The focus group research (Chapter 4) had alluded to time barriers impeding SABA guideline-based care and this was considered in the intervention design process. The implementation-intervention streamlined information gathering and workflows through formalising the
role of the pharmacy assistant and development of the Asthma Medication Checklist. Further research needs to confirm the success of these initiatives designed to address feasibility issues.

*Fidelity* is defined as the level to which an intervention was delivered as intended. Was the integrity of the intervention maintained as planned? The SABA implementation-intervention had issues with fidelity, which may have impacted on outcomes. The low level of uptake of pharmacies to participate in small-group workshops required adaptation of the intervention for delivery via academic detailing. These issues with fidelity were highlighted via retrospective application of ITAX (Chapter 7). Future research is required to understand the barriers to the delivery of interventions via small group workshops to community pharmacy staff.

A further consideration is the fidelity of the academic detailing as an intervention strategy. One researcher conducted the workshops to maintain consistency in delivery of information, but four research assistants undertook the academic detailing. It is possible that intervention messages were not delivered consistently with the different detailers or in different pharmacies. Messages may have been rushed or interrupted due to pharmacy busyness, as academic detailing visits were unscheduled and during pharmacy opening hours. Attempts were made to pre-empt the effect of fidelity issues on the adapted SABA implementation-intervention study (Chapter 6). Academic detailers were provided a script and resources to ensure detailing messages were as consistent as possible. Statistical analysis was also undertaken to investigate if there were significant differences in the outcomes achieved between different detailers and
different strategies (workshops vs detailing). However sample sizes limited the ability to make strong conclusions about the comparisons between the different strategies.

Another interesting observation related to fidelity revolves around the issue of internal communication within the pharmacy setting. Previous research has noted that internal communication and teamwork in community pharmacies influences quality of service and practice change.\textsuperscript{83-85} The difficulties in holding small-group workshops and getting pharmacy staff together emphasised the communication issues between staff members within the setting. These communication barriers are understandable given the long opening hours and many casual and part-time staff employed in community pharmacies. Recognition of the need for a unified team approach, better communication and improved internal referral workflows was one of the initial reasons for choosing workshops as a delivery method. However, adaptation of the intervention to academic detailing meant that messages were not directly delivered to pharmacy assistants. As one of the main objectives was to formalise and define the role of pharmacy assistants in non-prescription SABA sales, internal communication and diffusion of messages was crucial to progress the intervention, and ensure uptake of the initiative by all pharmacy staff. Given that communication within the pharmacy was already an issue, academic detailing was likely to be less effective at promoting practice change at the level of the organisation, even if successful at the level of the individual. Issues with internal communication may account for the variable success encountered with academic detailing in the community pharmacy setting.\textsuperscript{1,40-42} These observations warrant further pharmacy practice research that considers how to improve internal communication and teamwork in the community pharmacies. This knowledge could enhance the success of future guideline implementation initiatives.
Cost refers to the cost-benefit or cost-effectiveness of an implementation intervention. The research in this thesis did not undertake an economic evaluation but recognises the importance of future research of this nature. The systematic review (Chapter 3)\(^1\) also indicated that there is a scarcity of such evaluations currently in the literature. The chosen strategies of small group workshops and academic detailing are relatively labour intensive and costly implementation strategies. However, these high cost strategies may prove cost-effective if they can achieve measurable changes in patient asthma management and reductions in the utilisation of expensive health services. Given that a recent report from 2015 on the economic costs of asthma in Australia indicated direct healthcare costs at AUD $1.2 billion and total costs at AUD $27.9 billion,\(^8\) is scope to achieve substantial improvements through improved asthma management. In the longer term, investment in seemingly more expensive implementation initiatives such as the SABA guideline implementation-intervention will require the research to demonstrate their cost-effectiveness.

Penetration refers to the level of institutionalisation of practice change observed from implementation.\(^8\) What proportion of pharmacies receiving the intervention is expected to provide SABA guideline-based care to patients post-intervention? In considering expected penetration with larger scale implementation, it becomes necessary to consider the representativeness of the cohort tested. It is possible that pharmacies willing to participate in workshops were more motivated to change practice. However, the outcomes achieved in this subset may not extrapolate to all community pharmacies. Academic detailing had the advantage of being able to be provided to all pharmacies and thus not influenced by self-selection bias. It may be that academic detailing produced more moderate outcomes but had a higher
penetration and is preferable for future implementation-interventions. These determinations could not be made due to the lack of statistical power in comparing workshops and detailing pharmacies (Chapter 6). Future research focused on comparison of these strategies could be useful in understanding the potential penetration of the implementation-intervention.

*Sustainability* is defined as the extent to which practice change is maintained, incorporated and integrated as part of routine clinical practice. It is notable that penetration and sustainability are related, and that higher penetration can lead to improved sustainability. This concept was evident from the focus group research (Chapter 4). Pharmacy staff commented that mandated practice was required in dealing with SABA requests so that patients could not “skip a pharmacy and go down the road (to another pharmacy) where nobody asks questions.” The impression was that they didn’t want to potentially upset patients with questions when other pharmacies weren’t practicing in a similar manner. This may be a function of community pharmacists operating in a retail environment and the expectations of patients in that environment. Another comment from focus group discussions by a pharmacist was, "It’s not that patients don’t have time, it’s that they expect when they go into a retail shop they are not going to be asked questions. That they come in, get what they want in a second, and walk out.” Community pharmacists are unique as health professionals operating in a retail environment. This produces advantages in accessibility but also disadvantages related to remuneration and patient expectations. These issues need to be considered when studying successful implementation strategies in the community pharmacy setting. It is possible that strategies delivering high penetration may be important to sustaining changes to routine practice and this
concept requires further investigation. Regarding the potential for sustainability of the SABA implementation–intervention, the level of interest indicated by professional organisations since completion of the research provides an avenue to maintain the initiative and increase penetration.

8.4.4 Progressing the intervention

A number of pharmacy organisations have already expressed an interest in progressing the intervention from this thesis and/or using the resources developed. Now that the post-implementation-intervention data has been collected and the research finalised, there have been opportunities to pursue these enquiries. The following organisations have expressed an interest in the intervention as part of professional asthma service training:

1. The Pharmacy 777 Group88 – A group of 26 pharmacies in metropolitan and rural Western Australia.
2. Chemmart Pharmacy National Group89 – A franchise of over 300 pharmacies across Australia.
4. The Asthma Foundation of Western Australia91 – A not-for-profit organisation, which aims to reduce the burden of asthma in WA through training and research.

Consulting with PSA National also provided an opportunity to discuss their procedures for guideline implementation, as the primary disseminators of clinical guidelines for pharmacists. Discussions were held with the Executive Director or Practice Support
and Education and the National Training Manager at PSA.\textsuperscript{90} This potentially is the first step to using the research in this thesis to promote investment in evidence-based implementation of guidelines, rather than passive dissemination through mail distribution of written materials and publication on their website.\textsuperscript{92}

### 8.4.5 Legislative change

In the focus group study (Chapter 4)\textsuperscript{2} there was strong support from many stakeholders for up-regulation of SABAs.\textsuperscript{2} Pharmacists felt that the expectation from patients was that if SABAs were available from a retail outlet, without a prescription, then they did not have to answer questions. The solution suggested was up-regulation to Schedule 3 Recordable (S3R), which would require pharmacist involvement and mandatory recording of the supply. It was felt that mandatory recording of SABA purchases would solve many issues by adding formality and a sense of importance to SABAs, facilitating opportunities for pharmacists to engage patients, and producing medical records to more effectively monitor medication use.

GPs were also strongly in support of up-regulation but indicated SABAs should be S4 (“Prescription Only”). They felt that the current S3 legislation distanced them from assisting patients with asthma management. Interestingly, in countries such as the UK where SABAs are only available on prescription, the problems of excessive reliance and overuse of these medications remain.\textsuperscript{93} In the UK, a review into asthma deaths found that inappropriate prescribing in primary care was implicated in almost half the cases. Of the 195 deaths, almost 40% of patients had been prescribed more than 12 SABAs (more than one a month) in the previous year. Similarly, a recent population study
from the UK of nearly 36 000 medical records indicated that 13.6% of adults were prescribed more than twelve SABAs a year.⁹⁴

It is feasible that up-regulation to S3R is a good compromise between patient accessibility and health professional involvement and could impact on inappropriate patient self-management of SABAs. This proposal for legislative change was investigated as an intervention option for this research. A submission was made to the Government of Western Australia, Department of Health (Pharmaceutical Services Branch). (Appendix 19) The legislative change was not pursued at the time of the submission due to an upcoming state election and a caretaker period of government in operation. However, this proposed legislative change warrants revisiting.

### 8.4.6 Expanded clinical roles for pharmacists in asthma management

The focus group study (Chapter 4)² and the patient study (Chapter 5)³ provided support and evidence for potential expanded roles for pharmacists in asthma management beyond SABA guideline-based referral. These included preparation of written asthma action plans by pharmacists, use of software to monitor medication adherence, and pharmacist prescribing of on-going medications.

Low ownership of written asthma action plans continues to be a significant issue, despite being recommended in medical guidelines for more than 20 years.⁹⁵ The accessibility of pharmacists is advantageous in addressing this issue, and they could potentially play a role in preparing written asthma action plans for patients. A careful assessment of the training requirements and barriers to practice would be required for
this service to be implemented in community pharmacy. It would also be necessary to develop guidelines of practice and appropriate remuneration pathways.

Pharmacists in Australia are already successfully using software to monitor medication adherence, albeit in a somewhat inconsistent way.\textsuperscript{96} The data mining work of Berezni\l{}cki and colleagues demonstrated the potential for pharmacists to expand this role in a more systematic way.\textsuperscript{97} They were able to target patients with suboptimal asthma who required health professional intervention to manage their medications and their health better. Another conceivable way to use the dispensing software in community pharmacy is via CDSS. The systematic review (Chapter 3)\textsuperscript{1} pointed to CDSS as being an effective strategy for implementation of clinical guidelines in community pharmacy.\textsuperscript{7,98} However, the evidence was based on a small number of studies, and there is limited information about the sustainability and generalisability of the effects. Alert fatigue and clinical inertia are recognised issues with CDSS.\textsuperscript{6} Further research may create a greater understanding of how to optimally use software to enhance the clinical offering of pharmacists to improve patient health outcomes.

Much of the research in clinical guideline implementation in pharmacy, including this thesis, has focused on the role that community pharmacists play in triage of patients and appropriate referral. A report commissioned by the Pharmacy Guild of Australia by Chapman and colleagues explored the nature, extent and impact of triage provided by community pharmacies in Victoria, Australia.\textsuperscript{99} Key findings included, “most pharmacists are capable of providing primary healthcare, including triage, for a wide range of common ailments, not just minor ones.”\textsuperscript{99} It was also noted that “community pharmacies appear to missing opportunities to play a much more central role
providing primary health care. Estimates of referrals from community pharmacists in Australia, ascertained from National database research in 2002, indicated that 4.19 million patients annually were referred to GPs and 1.77 million were referred to other health workers. However, patients do not necessarily follow through with referral advice, and significant barriers still exist to collaborative care in the primary health setting. There is scope for pharmacists to play a more direct role in clinical care through continued prescribing which requires investigation. The relative ease of access of SABAs compared to ICSs reinforces patient behaviours that undermine their management of asthma. The potential for pharmacists to maintain supply of ICSs appears to be a logical solution. Development of this expanded role would require, further research; training of pharmacists; development of clinical guidelines; legislative change and new remuneration pathways.

8.5 Conclusion

This thesis confirms the hypothesis that implementation of clinical guidelines can improve evidence-based practice by community pharmacists. However, there remains an imperfect evidence base on which to make strong conclusions about the optimum strategies for effective implementation, to achieve sustainable changes to routine pharmacy practice. Nevertheless, several issues have been identified as areas for future focus, and further investigation to more completely address the knowledge gaps related to clinical guideline implementation in the community pharmacy setting.

A key issue highlighted by the research in this thesis is the need to contemplate how workflows in community pharmacy can influence guideline-based practice. Specifically,
there has been a lack of acknowledgement of the role of pharmacy assistants as the first point of contact for most patients. Pharmacy assistants have not been widely considered in interventions, despite being a key determinant of successful clinical guideline implementation. Workflows that facilitate appropriate internal referral of patients from pharmacy assistants to pharmacists are essential for pharmacist-initiated health interventions based on guidelines. Strategies such as CDSS have been demonstrated to be successful. This is possibly because they integrate with existing workflows around dispensing. However, the sustainability and limitations of this strategy need further investigation.

This thesis also demonstrated that interventions that are tailored to address barriers to practice are successful in community pharmacy. While the academic detailing in the initial implementation of the SABA guidelines had been unsuccessful in changing practice, the tailored intervention via academic detailing and small group workshops had produced practice improvement. These results indicate the need for a sound rationale to underpin an implementation-intervention and explain some of the variability in results seen in the literature. Triangulation methods in research allow for contemplation of the many complexities that effect outcomes. Formalised theory and taxonomies could be beneficial in developing the reasoning underpinning an implementation-intervention, although a considered, pragmatic approach can also provide a sound rationale.

The intervention in this thesis was to facilitate implementation of asthma (SABA) guidelines, which further validates the notion that tailoring of interventions is important. There were unique barriers associated with patients’ attitudes to asthma
that were confirmed by this thesis. Patients were found to have poor awareness of their asthma control, and these perceptions determined that they are unlikely to engage and seek medical advice proactively. Without understanding and tailoring interventions to account for these specific barriers, practice change is unlikely to occur.

The findings of the thesis indicate that small group workshops are an appropriate strategy, from a design perspective, in achieving behaviour change. However, they have limited application in community pharmacy due to logistical constraints. Alternatively, academic detailing is feasible for high penetration as an implementation strategy, but its reliance on internal communication may reduce the effectiveness of implementation-interventions. Further research is required to understand the relative benefits, outcomes and limitations of both small group workshops and academic detailing.

To improve the evidence base for clinical guideline implementation to community pharmacy better reporting of research is required. Use of theory and taxonomies could improve reporting and comparability of studies. This could be achieved with both prospective and retrospective application. As there is minimal evidence of the effect on patients of clinical guideline implementation, future research should focus on patient outcomes and not just practice outcomes.

This thesis makes a valuable contribution to the current paucity of knowledge on how to maximise the benefits of clinical guidelines through effective implementation, in the community pharmacy setting. This is crucial knowledge for a profession that is looking
to cement a role as primary healthcare professionals and expand clinical service offerings.
8.6 References


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