Mapping the terrain: A conceptual schema for a mental health medication support service in community pharmacy

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Abstract

Objective: Mental health–related problems pose a serious issue for primary care, and community pharmacy could make a significant contribution, but there is a dearth of information.

Methods: This article reports synthesis of the literature on mental health interventions across a range of pharmacy models, and pharmacy services in contexts beyond mental health. To best inform the design of a community pharmacy medication support intervention for mental health consumers, the literature was reported as a conceptual schema and subsequent recommendations for development, implementation and evaluation of the service. A broad conceptualisation was taken in this review. In addition to mental health and community pharmacy literature, policy/initiatives, organisational culture and change management principles, and evaluative processes were reviewed. Key words were selected and literature reviews undertaken using EMBASE, PubMed, CINAHL and Web of Science.

Results: Recommendations were made around: medication support intervention design, consumer recruitment, implementation in community pharmacy and evaluation. Surprisingly, there is a scarce literature relating to mental health interventions in community pharmacy. Even so, findings from other pharmacy models and broader medicines management for chronic illness can inform development of a medication support service for mental health consumers. Key learnings include the need to expand medicines management beyond adherence with respect to both intervention design and evaluation.

Conclusion: The conceptual framework is grounded in the need for programmes to be embedded within pharmacies that are part of the health system as a whole.

Keywords

Community pharmacy, mental health, conceptual schema

Introduction

Mental health problems constitute a significant part of primary care consultations.[1] Optimal treatment of mental illness focuses on both symptom and functional recovery with a range of pharmacological, psychosocial and psychological interventions available.[2] The appropriate use of medication is an integral part of effective management; however, medicines are often used sub-optimally.[3–10] Medication adherence for these enduring conditions is an on-going concern.[11–13] To achieve better medicines-related outcomes for people affected by mental illness, health professionals need to provide collaborative and integrated care that involves the wider primary care team and supports the recovery process.[14–18]

In Australia, the majority of medications for mental health conditions are prescribed by general practitioners (GPs) and

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dispensed by community pharmacists. As a result, community pharmacists are encountering medicines-related problems (MRPs) associated with mental health on a daily basis.[19] Pharmacies are a health-care hub and pharmacists are in a strong position to assist mental health consumers with high prevalence conditions such as anxiety and depression.[20] (In this article, mental health consumers refer to people who have a lived experience of a mental illness such as depression or anxiety. They may be viewed as health consumers in other contexts as comorbidity with other physical health conditions is not uncommon. This terminology was applied following consultation with consumers, caregivers and advocates with considerable experience with mental health services.) Pharmacists' skills and experience can be applied within their scope of safe and appropriate use of medicines to improve the quality use of these medicines for consumers with mental illness.[19] Despite this, the literature is sparse, and compared with other chronic diseases, there is a dearth of information which evaluates models of medication management for mental health consumers within community pharmacy. This is surprising as there have been several reviews published outlining the impact of community pharmacy–based disease state or medicines management services in areas other than mental health.[16,21,22]

This review set out to investigate the literature pertaining to mental health services delivered by community pharmacy. This article explores the role of community pharmacy in supporting mental health consumers (and carers) to address MRPs. The focus is on both individual- and organisational-level change within community pharmacies. This article outlines a conceptual schema, which helps to describe the literature from a range of concepts which together provide evidence for the best way to progress with service development and evaluation. In the simplest terms, a conceptual schema is a platform for making sense of multiple streams of literature. This literature is made sense of through narrative analysis across areas outlined in the schema, rather than a systematic literature review which outlines individual studies as findings. The aim of this article is to draw together a range of literatures that help the development, implementation and evaluation of a medication support service focussed on mental health. Medication management support could include but is not limited to symptom management (control of anxiety and pain), support for lifestyle change (diet and exercise), improving adherence (having a routine and a plan), medicines management plan (reducing particular MRP), better information (understanding illness and medicines) and improving sleep hygiene.

As part of the implementation of the service, approximately 500 mental health consumers with anxiety and depressive disorders will be invited to receive care from 100 pharmacies across Australia, to help overcome challenges faced with their medication. This article reports the development phase. The outcomes of the service implementation are forthcoming.

In order to build, implement and evaluate a service model for medication management for mental health consumers visiting community pharmacy, there is a need to understand what has previously 'worked' and/or 'not worked'. This understanding needs to draw on the experience from chronic disease programmes and conditions with stigma. This article is a scoping review of the literature which is guided by a conceptual schema. The framework is broad; it is not a theory, but a conceptual schema which draws together ideas and provides the ingredients for service design[23] – in this case for community pharmacy. Therefore, this article presents the schema that will direct the design, implementation and evaluation of the proposed mental health intervention at the level of individual staff members as well as the community pharmacy organisation as a whole.

Mental health–related problems pose a serious issue for primary care and the appropriate use of medication is an integral part of effective management. However, medicines are often used sub-optimally and community pharmacy could make a significant contribution to mental health consumers, but there is a dearth of information about how this might best be done. This article shifts the focus of the current literature from medicines adherence; expanding beyond this to include other aspects of MRPs and posits a conceptual framework and recommendations for development and evaluation of a professional service. This process includes considerations of organisational aspects and change management strategies, which was not part of the aim of previous studies.

Methodology and methods

This is not a systematic review about a single research question but a scoping review which looks to relevant literature to be reported on and applied.[24,25] In a sense this is precursor work to inform the development of a service that is informed on evidence from the literature. This work therefore represents translational (into practice) research rather than an empiric work stream. Therefore, this article presents a conceptual schema which has informed the development of a community pharmacy service with a focus on clients who have MRPs associated with issues of mental health. In this way, the research explores different topic areas and has a different set of questions for the component parts; each contributing to the service design and implementation as a whole. The analytic process involves literature synthesis and interpretation so that key issues emerge.[26]

Conceptual schema

The reason for the schema development is twofold. First, that it provides a framework in which to explore narrative around the important aspects of service implementation. This literature does not appear 'in a single place' and to date it has not been brought together in one place. Pharmacy practice researchers
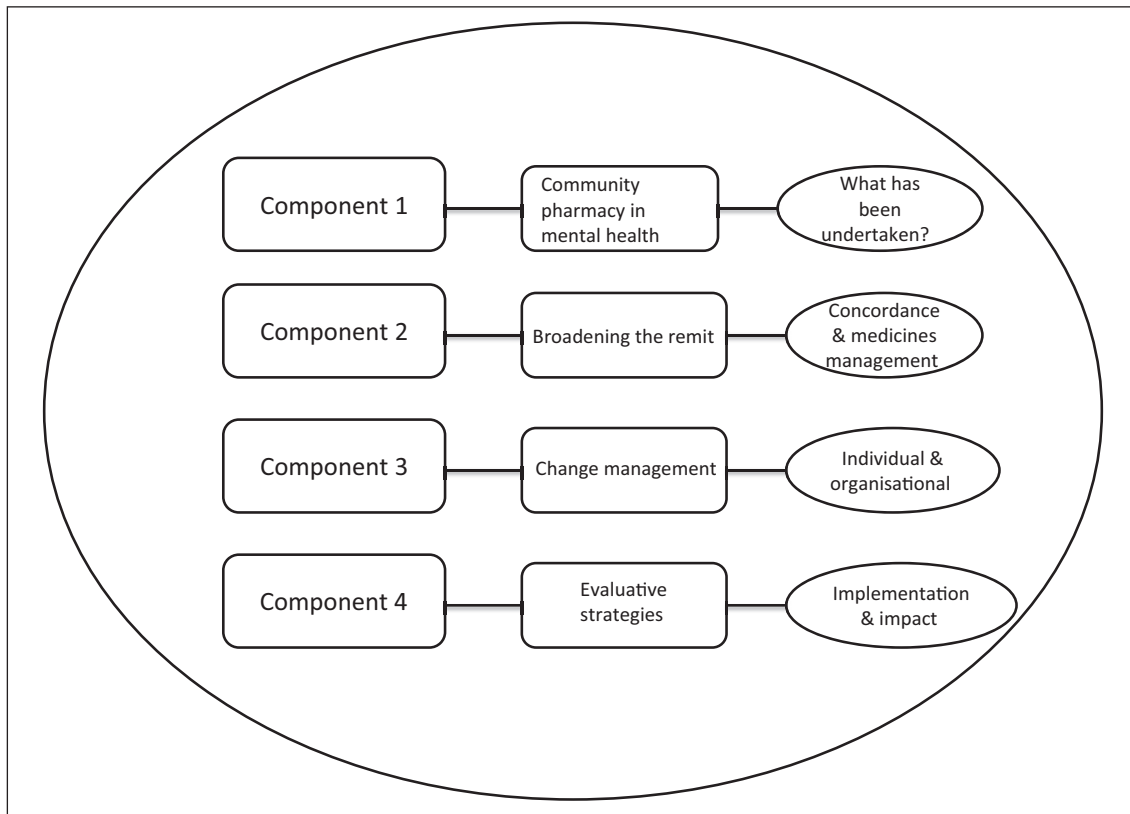
Figure 1. Conceptual schema.

have been relatively naïve in applying organisational level approaches to service development despite this being standard process outside of the community pharmacy sector. Second, the schema was used to develop and orient the whole service. Based on the schema the service was developed, staff were trained and the service was implemented and evaluated at multiple levels (forthcoming).

Potentially, the schema could cover a vast and diverse literature. However, a practical service design needs to be developed, implemented and evaluated. As a result, the review will be focussed and contained while providing depth within four components of particular relevance to the service (Figure 1). These components are broad in nature so that the scope of the review provides depth and breadth, and there is some overlap and linking between them which is addressed throughout. The schema provided a guide for the search such that the intervention could be contextualised within local and international literature, as well as policy.[27]

Systematic approaches will be taken to apply search terms within each of the four components of the broader conceptual frame, so that depth and breadth will be achieved in accordance with the questions needing to be answered. The analytic process will go beyond description of individual studies to a level of synthesis and interpretation to expose higher level findings from the detail of the individual study groupings.[26]

Components of literature search

Search terms. The following terms were applied to the various components of the search: community pharmacy, community pharmacist AND mental health, interventions, services, service provision, medicines management, adherence, concordance, assessment and skills, attitudes, beliefs, stigma, self-efficacy, collaboration, change, change management, practice change, barriers, facilitators, organisational change, organisational change, organisational culture, organisational culture, programme evaluation, service evaluation, intervention evaluation, programme effectiveness, service effectiveness, intervention effectiveness, implementation evaluation, and quality of service.

Databases/search tools. This literature review spans the fields of pharmacy practice research, health services research, and organisational and business management theory. Based on this, different databases were utilised for different aspects of the search. An electronic search was conducted to identify current literature relating to each of the four components of the schema. Databases included MEDLINE, CINAHL, ProQuest, Emerald, PsycINFO, ScienceDirect, PubMed, Web of Knowledge and International Pharmaceutical Abstracts (IPA). In addition, The Cochrane Library, Pharmacy Guild of Australia, Pharmaceutical Society of Australia, and various

Australian government health websites were searched. GoogleScholar was the 'lay' search engine utilised, but only after academic search engines were exhausted. University libraries were searched in order to access doctoral theses relevant to this area.

Analysis and interpretation. Only full original papers published in peer review journals were included when assessing studies. A search of literature within each component of the conceptual schema was undertaken and the titles and abstracts of relevant papers reviewed. Those deemed appropriate from their abstracts were read in full. The approach to analysis, interpretation, and summary of the findings within each component was robust, yet subtly different for each. This is not a systematic review based on a single research question (see Table 1) but an amalgam of components each of which covers a different topic area and a different set of questions; each contributing to the programme as a whole.

Component 1. Analysis involved assessing systematic reviews and meta-analyses to determine the structures, processes and outcomes of mental health randomised controlled trials (RCTs) in community pharmacy.[28] Studies discovered through searching that were not included in the systematic reviews were added. In addition to making sense of 'what did and did not work', a synthesis of the literature as a whole was undertaken in order to describe the focus/elements of the whole body of work in this topic area, for example, country and culture and lack of focus on collaboration.[26,27,29]

Component 2. Analysis for this component required thought around the broader facets of medication management and identification of MRPs other than adherence. Alignment with government policy, funded programmes, and professional practice guidelines were reviewed and application to this project considered. Collaboration was deemed to be a significant theme within this project and for the intervention and so tabulation of Australian medicines management programmes requiring significant collaboration (outside of mental health) was reviewed to provide an understanding of how that might work (facilitators) and/or the barriers to collaboration.

Component 3. Component 3 involved review of journal articles and standard management textbooks on organisational change.[30,31] This is a broader and more wide ranging topic and both system and human factors were addressed. The literature was brought together at two levels – the individual practitioner and the 'whole of organisation'. Models used in pharmacy were considered, together with potential change tools from the management literature not previously applied in the pharmacy practice context. A synthesis of the facilitators and barriers to the implementation of clinical services in community pharmacy was generated; mostly from Australasian literature. This was considered appropriate due to the context of the study and the significant focus on, and

requirement of, change as part of this intervention.

Component 4. Analysis of the findings for Component 4 followed a similar process to Component 3, in that literature from both pharmacy practice and management science was reviewed. This included peer-reviewed journals, books and doctoral theses. In addition to community pharmacy–based mental health studies, the evaluation of medicines management programmes in other disease states was reviewed. A synthesis of the approaches taken to evaluation was conducted by tabulating the studies and then grouping the evaluative processes into like categories for interpretation.[26,27,29]

Findings: Literature synthesis and recommendations

Component 1 – community pharmacy–based mental health RCTs

> This component explores controlled studies in the area of mental health within community pharmacy in order to better understand what 'has worked' in this context and the gaps in the literature that required addressing through service design.

Blalock et al.[16] suggest many studies demonstrate benefits of pharmacist-provided services on patient health, but that evidence is limited for the community pharmacy setting. Four systematic reviews of pharmacy interventions for improving medicines use in mental health consumers conducted between 2005 and 2012, largely focussed on impact on medication adherence and depressive symptoms. The majority of studies are in-patient[32] or clinical pharmacy services.[15,17] Scarcity of literature on services delivered in community pharmacies is surprising given the prevalence of mental illness and its impact.[1,33]

Chong et al.[17] reviewed 26 studies mainly in primary care and only 3 of 22 studies reported by Bell et al.[15] pertained to community pharmacy. Two later reviews[35,36] identified additional community pharmacy studies, associating improved antidepressant adherence with pharmacist intervention.[35,37–39] However, authors cautioned that data are limited[35] and did not differentiate service models.[36] Two RCTs added through this review, focussed on patients initiated on antidepressants,[40] and a pilot of community pharmacist and key worker home visits to older adults with mental health problems.[41]

Evidence of pharmacist intervention improving medication adherence and consumer outcomes is predominantly from the Netherlands and the United States and outside of community pharmacies. Reflection on whether interventions align with Australian community pharmacy is warranted[42] and the impact of community pharmacy interventions needs exploration.

What does and does not work for consumer interventions in mental health. Complex, multifaceted interventions more

Table 1. Components of literature search.

Component no.	Search section	Questions to answer
1.	Community pharmacy interventions in mental health (structure, process outcome)	Where does the current evidence lie in mental health interventions? Elements of intervention (structure), how delivered (process), outcomes achieved (outcomes)
2.	Expanding medicines management beyond adherence	In addition to compliance, what other medicines-related problems need to be addressed? Are there models other than Stowasser's that warrant consideration? What are the key components of a medication management service? What can be learned from other areas of chronic disease management? Interventions to meet consumer needs based on Stage 2 findings: Role, relationships, stigma, knowledge, skills, attitudes What can be learned from other pharmacy delivery models (i.e. clinical pharmacist in primary care)?
3.	Change management – barriers/ facilitators • Individual practice change • Organisational change	Are there barriers and facilitators to service provision in community pharmacy that are specific to mental health initiatives? What work has been published about organisational-level and individual practice–level change in community pharmacy? How is the intervention going to support the potential need for change? Working with others – what are the issues? How does the intervention need to be designed to assist this?
4.	Service evaluation • Implementation processes • Impact on participants	How does service evaluation literature apply to community pharmacy? What aspects of the implementation process can be evaluated? How can change in practice be evaluated? How can the impact on staff be evaluated? How can the impact on and outcomes for consumers be evaluated?

effectively improved adherence to antidepressants than information transfer (education) alone.[17] Disentangling the influence of different interventions on various outcomes is challenging. The majority of interventions emphasise educational aspects over behavioural strategies.[36] Neto et al.[43] suggest that simply advising patients to take medication as recommended is less helpful and could lead to medication-related reactance. Brehm's[44] Theory of psychological reactance proposes that when individuals perceive that their freedom to select 'when and how' to conduct their behaviour is restricted, individuals tend to re-assert freedom of choice and act in the opposite fashion. Shared decision-making between pharmacists and patients could limit this,[45] and Neto et al.[43] proposed strategies used to elicit reduction of risky behaviours for promoting adherence. Incorporating these concepts in interventions will support pharmacists to identify and counter medication-related reactance. These strategies also reflect aspects of the four domains of patient-centred care; individualised, respectful, holistic and empowering care identified as important to health service delivery by Morgan and Yoder.[46]

Chong et al.[17] concluded that combining educational, behavioural, affective and provider-targeted strategies was more likely to improve adherence to antidepressants and therefore clinical outcomes. Examples include motivational interviewing and goal-setting with monitoring.[17] Pharmacist coaching combined with multi-media education has variable impact on adherence and symptoms of depression or anxiety.[38,47–49] Pharmacist monitoring was predictive of patient satisfaction and self-reported adherence when initiating antidepressants,[39] and telephone calls improved adherence.[50] A single RCT attributed improved adherence and reduced patient-reported MRP to home visits from trained community pharmacists and key workers.[41] Interventions usually involved consumers commencing antidepressants and excluded other cohorts possibly requiring support.

Provider-targeted strategies such as feedback to the GP present in clinical pharmacy service models[15,17,32] are missing from community pharmacy interventions. The literature supports the design of a comprehensive multifaceted service where patients are supported by multiple strategies, referred as necessary and health professionals are notified of patient progress in a collaborative fashion. Paradoxically, service design is expected to be simple, pragmatic, easily implemented and not time consuming or onerous on pharmacists.

Recommendations for Component 1: mental health community pharmacy RCTs

A full synthesis of the literature for this component has been reported elsewhere (forthcoming) and the following recommendations are made from the literature (Box 1).

Medication support intervention design:
- The intervention should combine structured counselling, information provision and behaviour change strategies
- Training should build skills that facilitate a concordant approach
- Train pharmacists to look beyond adherence
- Integrate collaboration with other health professionals, especially general practitioners
- Define standard clinical practice

Consumer recruitment and engagement:
- Expand and make explicit the consumer eligibility criteria beyond people initiating therapy (i.e. collecting a newly prescribed medication)
- Define clear entry and exit points to the medication support intervention
- Have processes that monitor consumer recruitment and identify slow adopters
- Evaluation
- Broaden the evaluation to include implementation process, change, and impact on all stakeholder groups

Component 2 – expanding medicines management beyond adherence

This component represents the movement away from adherence as the only medicines-related problem (MRP) and the broadening of medicines management models involving multifaceted interventions, collaboration and alignment with funded clinical programmes.

Adherence has been defined as the extent to which a person's medication taking behaviour coincides with medical advice.[51] Many studies focus on adherence as a key outcome, and this review expands the focus to reflect a myriad of other MRPs.[52–56] There is evidence that improvement in clinical outcomes may not be mediated through adherence alone,[17,32] and that adherence strategies can be part of multifaceted interventions, making it difficult to demonstrate a causal link.[21] Challenges in obtaining robust measures of adherence further limit its value as a sole measure of success[57] and adherence does not reflect the influence of external factors or the importance of inter-professional collaboration to patient outcomes.

Identifying other MRPs. International literature provides evidence of pharmacist detection and management of a range of MRPs,[58] through community pharmacy medication management programmes,[59] pharmacy surveys,[60] aggregate analysis of incidents involving psychotropics,[61] medication error detection in pharmacy,[62] and identifying preventable drug-related morbidity.[63,64] MRPs include inappropriate adherence, need for additional therapy, wrong drug, unnecessary therapy, adverse drug reaction, dose too low or too high and drug interactions.[59,60]

Australian literature exploring MRP beyond adherence focussed on identification/detection, classification, documentation and management of MRP.[52–56] Analysis of 6239 clinical interventions in Australian community pharmacies reported medication selection problems (30.8%) and educational issues (24.4%), most commonly, followed by incorrect doses (20.1%). Common MRP experienced by mental health consumers included potential adverse drug reactions, suspected adverse drug reactions, potential drug interactions and taking additional medicines unknown to the GP.[65] Antidepressants were the most commonly prescribed nervous system agent, followed by analgesics then antipsychotics.[65]

These findings highlight the importance of inter-professional collaboration to patient outcomes and MRP management.[59,65] Australasian literature explores integration of community pharmacists into primary health teams for medicines management.[66–76] Review of literature exploring collaborative medication review between pharmacists and GPs found decreased numbers, greater recognition and resolution of MRP; increased compliance and patient knowledge; and improved prescribing, quality-of-life scores, medication appropriateness index scores, and clinical values.[77] Most studies described positive outcomes on satisfaction for patients and health-care providers. Patient involvement was important for motivation to change and sustained intervention impact.

Interventions are multifaceted and complex. The type of intervention that results in the greatest and most sustained improvement is unknown.[17,21] Interventions are often complex, adherence does not always mediate outcomes and disentangling cause and effect may be impossible. It makes sense to adopt complex multifaceted interventions that work 'as a package' and recognise management of chronic health conditions, and related treatment burden extends beyond medication adherence.[78,79] Systematic reviews of the clinical services and cost-effectiveness of RCTs of community pharmacy services in 2003[22] and a decade later[16] support this.

Adherence as a measure of intervention impact. No single method of assessing medication compliance or adherence was identified as completely valid and reliable in a literature review conducted during an adherence study.[57] Direct measurement is challenging, multiple methods are used and there is a predominance of indirect methods which lack robust evidence and can be difficult to interpret.[17] It is important to combine validated measures of adherence[80–83] with other forms of evaluation.

Measuring adherence does not reflect the influence of external factors. Modifiable factors may include medication complexity, relationship between patient, pharmacist and prescriber, health and medication beliefs, patients' understanding and perception of illness and treatment, access to health-care providers, side-effects, and forgetting to take medications.

Mental health consumers participating in a medication support intervention will likely experience MRP reported above and benefit from complex, multifaceted interventions that extend medicines management beyond adherence. Multiple measures are needed to effectively evaluate the

impact and sustainability of these interventions. Interventions should incorporate measures that complement adherence, consider modifiable contextual factors and utilise and explore inter-professional collaboration.

Recommendations for Component 2: expanding medicines management beyond adherence

Recommendations in order to broaden the focus beyond adherence are outlined in Box 2.

Box 2. Recommendations to expand medication management beyond adherence.

Identify, document and address other MRPs as well as adherence

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A synthesis from the literature suggests the following MRPs have relevance:
- Unnecessary and inappropriate prescribing (over-prescribing)
- Drug selection
- Dosing – under and overdosing
- Drug interactions
- Complexity and the need for simplification
- Under prescribing – untreated indications
- Lack of therapeutic response
- Lack of appropriate monitoring
- Educational issues and cost barriers

Utilise standard approaches for identification and documentation of MRPs using current systems

Training that increases awareness and improves skills

Provide insight into consumer/carer experiences
- Service that they value and which exceeds expectations
- Desire for engagement and information (e.g. on side-effects)
- Opportunities to support consumers through therapy change

Emphasise practical skill development in motivational interviewing

Provide consumer friendly resources and allow participants to revisit training as needed

Evaluate intervention impact

Incorporate measures beyond adherence (e.g. consumer perspectives on service quality)

MRPs: medicines-related problems.

Component 3 – change management: individual practice and organisational change

Widening the framework; implementing and evaluating change. The aim of most of the studies outlined in Component 1 of this review was to assess effectiveness, not necessarily implementation or change management of the services provided. This aspect has been identified as an important part of the service design, implementation and evaluation of an initiative for mental health clients in the community

pharmacy context. Evaluation in the mental health studies outlined in Components 1 and 2 was focussed largely on consumer health outcomes (disease specific and quality of life) and adherence ratings using validated and accepted measures. However, the findings suggest a need to widen the evaluation to include consumers, pharmacists, pharmacy staff and other health professionals (see also Component 4).

Individual practitioner–level change. There are two aspects of change to consider at the individual level: change in attitude and technical change in practice. Readiness to change statements correlate with actual behaviour and this needs to be used as a surrogate for actual change.[84] There is Australasian literature addressing practice change in community pharmacy.[85–93] Local findings are important as change is contextually bound and management of change is impacted on by local environmental factors.

An Australian study used the Stages of Change Model[57] to assess change for both pharmacists and consumers and to outline strategies for each stage: pre-contemplation, contemplation, preparation, action – maintenance and review. This appeared to be an adequate approach, at least for an adherence-based initiative, but should be widened in this intervention to include all MRPs that could be identified by community pharmacy and strategies to address them.[18]

Barriers and facilitators to implementing cognitive services. Australasian studies have identified a series of barriers and facilitators to effective implementation of cognitive pharmacy services.[87,89,92,93] Physical and human factors should be considered including pharmacy layout and interactions among pharmacy staff, customers and external stakeholders.[89] Pharmacist confidence has been a significant barrier to change and the implementation of enhanced clinical services in New Zealand[93] and Canada[94,95] and has been reported as a facilitator for change in Australia.[85] The importance of skills, knowledge, attitudes and beliefs of staff at all levels in dealing with mental health consumers will be given due credit in the design.[96–100] The concept of 'self-efficacy' is therefore important at the individual level and 'whole of pharmacy level'.

Organisational change. There has been a focus on organisational-level change in pharmacy practice in Australasia.[85] Organisational-level change centres on systems and human factors. At the collective (all staff) level, this has been described as 'organisational culture'.

The importance of organisational culture, the collective thought and action – the ways we think and act for the change process (both enabling and resisting) – is well recognised within the broader management literature.[101–103] Beliefs and values drive attitudes to behaviour and practice which influence outcomes for individuals and organisations.[103,104] It is an important concept that until recently has not been given sufficient attention by pharmacy practice researchers.[42] This is surprising based on the fact that so much of what we do in

our organisations is influenced by the way staff collectively think and act and follow the tenet of: 'the way we do things around here'. There are tools to assess the organisational culture pre- and post-intervention[104,105] but critiquing each of the available tools (relative to pharmacy) needs to be undertaken and this lies outside the scope of this article.

The Pharmacy Change Readiness Wheel (PCRW) has been designed for use in Australian community pharmacy. The PCRW depicts individual-level practice change, the readiness and management of organisational level change, and the overlap between the two. Custom-designed modules of training about the PCRW have been delivered (in the Australian context) prior to the implementation of an asthma service.[106] The PCRW includes questions of a business/management nature but also the need for change/change orientation. This systematic approach to management of practice change using theoretical concepts had not previously been undertaken in Australian community pharmacy.[106] Importantly, pharmacists were unaware of the complexity of change as a concept and of effective change management strategies during this study. Education and training will attempt to ensure this is not an issue for the current intervention.

Collaboration. Compared with hospital pharmacy, there has been a lack of integration of community pharmacy into mental health teams and within the primary care sector. This will require a significant degree of change at multiple levels including individual pharmacy staff (micro), community pharmacy as an organisation (meso), and at the environmental policy level (macro).[92] A lack of sustainable and viable service models has not helped with the required change.[19,87,89,93] However, in Australia, there are now sustainable funding streams to align this type of activity with. Under the 5th Community Pharmacy Agreement (5CPA) the time has come to design and evaluate a mental health medicines management model which aligns with funded clinical programmes.[107]

Recommendations for Component 3: change management

Training about change management and assessment of implementation processes at the organisational level is an integral part of the conceptual schema guiding this intervention. The project involves multi-level service change at micro (individual) and meso (organisational) levels. The implementation process needs to address both levels and in fact this is one of the contributions of this article. Organisational-level assessment needs to occur in addition to readiness and actual practice change of individual staff. This intervention is not 'usual care' and the implementation phase is likely to be more effective if lead pharmacists in participating community pharmacies are trained in change management, as it specifically relates to the intervention. There is strong linkage between the alignment outlined in the previous section and change

Box 3. Recommendations for change management.

Implementation of intervention by community pharmacy:
- Consider issues of alignment outlined in Component 3
- Assess readiness to change in pharmacy and target pharmacies based on this
- Assess current and preferred/required culture for improving effectiveness
- Think about change management as a broad construct
- Delineate the cross-over between individual practitioner change and organisational-level change
- Adopt tools which help both planning and evaluation of change
- Provide change management strategies
- Anticipate and address barriers

Evaluation of intervention:
- Extend evaluation beyond adherence and health outcomes
- Consider consumer perspectives, pharmacists and pharmacy staff
- Use validated tools where available or adapt to mental health context
- Evaluate impact of implementation and related change

management (Boxes 2 and 3). There are several change schemas that could be applied from management science, but not all have been validated in the pharmacy setting.[30,108] Most of these models are based on management and leadership principles rather than change among clinical practitioners. As previously described, the PCRW is a pharmacy-specific model assessing individual practitioner and organisational-level change.[85]

Component 4 – evaluative strategies

The literature review highlights the following issues which need to be considered as part of the evaluation planning.

A focus on adherence and health outcomes. The focus of evaluation in community pharmacy mental health RCTs was on health outcomes for consumers, degree of medicines adherence, and broader assessments such as quality of life. The focus has been on medicines adherence assessed through consumer self-report, electronic pill count, and pharmacy records. This will need to be addressed in the intervention and an Australian study using the Stages of Change Model provides adequate direction and strategies with regard to medicines adherence.[57] Data will need to be collected on other types of MRP identified and how they were addressed by the pharmacy.

Lack of evaluation of implementation process. The authors are not aware of any RCTs (at least in mental health delivered by community pharmacy) that evaluated the implementation process or the impact of programme implementation on pharmacists, other pharmacy staff, and different health-care providers.

A recent study has identified facilitators and barriers to implementing targeted medication adherence interventions in community pharmacy chains. The focus is on each individual pharmacy practice with the aim of describing adaptations of the targeted intervention and organisational structures. This qualitative work exposed five themes including all pharmacists' need to understand the relationship of patient care programmes to their corporation's vision; providing individualised, continual support and mentoring to pharmacists; anticipating barriers before implementation; encouraging active patient engagement; and establishing best practices regarding implementation of patient care services.[109]

This intervention is expected to be broader than adherence alone, and analysis of the medicines management literature for chronic disease demonstrates a large range of programmes and outcomes evaluated.

Pharmacist self-efficacy and readiness for change. Self-efficacy rating scales for pharmacists have been reported in community pharmacy literature[110–112] but have not been assessed in the case of mental health initiatives. An Australian study recommended applying the Stages of Change Model to assess readiness for change for pharmacists and their perceived importance of the need for change.[57] This overlaps with the discussion in Component 3 – change management.

Stakeholder satisfaction is very important. There were few studies that assessed consumer satisfaction with service provision including their perception of pharmacy staff attitudes while delivering the service. There is literature supporting the use of consumer satisfaction ratings in community pharmacy and these can be compared and contrasted with six simple questions asked in the National Compliance Trial (NCT) scale. If adopted, these scales will need to be amended to include a focus on pharmacist attitude towards mental health consumers.

Be cognisant of complexity. The evaluation needs to be carefully considered in line with findings from the Managing Mental Illness and Promoting and Sustaining Recovery (MMIP) project; the main issue being that the research process made the 'day to day' pharmacy operations more complicated. The MMIP study and its evaluation were perceived to be too complex by participants.[18] The paradox is that a simple intervention is needed; one that is required to align with funding streams, integrated with other health professionals and stakeholders, comprehensive and multifaceted, and step past the simple act of information provision to elicit consumer behaviour change. The evaluation is expected to be equally comprehensive and so collected data need to be succinct yet informative.

Through broadening this intervention there is an expectation that a wider data set (than previously) will be collected. Box 4 outlines the evaluation of medicines management programmes outside of mental health which can be drawn upon.

Box 4. Evaluation summary for non-mental health community pharmacy initiatives.

- Multifaceted interventions with a focus on evaluation of health outcomes for consumers
- A focus on adherence and outcomes with intervention effects that is difficult to 'unpack' and disentangle
- Some studies include evaluation of pharmacist perceptions, readiness to engage, and individual performance
- A minority of studies assess the experiences of other health providers and in particular GPs
- In studies that assess general practice involvement there is the acknowledgement that key stakeholders (doctors and nurses) need to be more integrally involved in both design and implementation
- Lack of conceptual schemas such as Stowasser's model, that is, 'the intervention' is in the broadest sense 'the model'
- Pre- and post-implementation surveys have been undertaken

GPs: general practitioners.

Holistic approaches: multi-stakeholder assessment of service quality. Donabedian suggests that quality of health service provision and the outcomes gained are dependent on the structure and processes in place.[28] Tools to measure quality of service provision are available for use in community pharmacy and these are outlined in the recommendations.[113,114] Feasibility studies suggest that they are relatively fast (5–8 min) and easy to complete which warrants consideration. There is, however, a scarcity of literature which evaluates the entire implementation process of medication management interventions and the impact on multiple stakeholders including pharmacists and their staff, consumers, and other health-care professionals, particularly GPs.

Recommendations for Component 4: evaluation tools

There are five domains to consider with respect to the tools for evaluation: the need to assess the implementation process, the change in organisational culture required, understanding mental health consumer satisfaction, determining pharmacy staff attitudes and levels of self-efficacy, and assessment of service quality. The merits of the various measurement tools need to be carefully considered (Table 2) in line with findings from the MMIP study; the main issue being that the research process made the 'day to day' pharmacy operations more complicated.

There does not seem to be pre-validated tools available which evaluate the implementation process or the impact on staff, consumers and other health-care professionals from that viewpoint. Likewise, a mental health–specific consumer satisfaction survey validated in community pharmacy was not found. Table 2 outlines the tools available for consumer satisfaction ratings in community pharmacy. Assessing

Table 2. Evaluative tools.

Domain	Tool	Description	References
Implementation process	Levels of collaboration will need to be assessed	Social network analysis	Scahill;[34] Roberts et al.;[91] Roberts et al.;[90]
	Assessing readiness for change	Pharmacy Wheel of Change Model	Roberts et al.;[85] Feletto et al.[106]
	Assessing organisational culture	20-item Competing Values Framework (CVF)	Cameron and Quinn;[101] Scott et al.[104]
Consumer satisfaction	General community pharmacy tools	Likert-based	Bultman and Svarstad;[39] Chong et al.;[17]
	NCT study	Six question Likert scale	Feyer et al. (2012)[57]
	MacKeigan–Larson Satisfaction Score (later revised as the Larson, Rovers, MacKeigan Score (LRMS))	The LRMS contains 20 items	MacKeigan and Larson (1989)[115]; Larson et al. (2002)[116]; Larson and MacKeigan (1994)[117]
	Satisfaction with Pharmacist Scale (SWPS)	The SWPS is considerably shorter than the LRMS	Hernández et al. (2000)
Pharmacy staff attitudes and self-efficacy	Attitudes and self-efficacy scales	Individual scales	Taylor et al.;[10] Martin et al. [110]
		Implementation issues	Zardaín et al. (2009)[118]; ; Morken et al.[111]
Overall service quality	Halsall et al. (UK) and White and Klinner (AUS) scales	Holistic service provision scales	Halsall et al.[113]; White and Klinner[114]

pharmacy staff attitudes, knowledge, skills, confidence and self-efficacy in dealing with mental health consumers is also critical. There are scales available to measure attitudes and self-efficacy particularly around implementation processes although these are not specific to mental health (Table 2). Change will need to be facilitated and assessed at the individual practice level and whole of organisational change, based on levels of readiness and organisational culture. These tools are valid and reliable. Training around change management is advisable and will need to be assessed.

Our review found two instruments for assessing overall quality of service provision from community pharmacy (Table 2) which demonstrated excellent face and content validity and reliability. Feasibility studies suggest that they are relatively fast (5–8 min) and easy to complete which should facilitate their utility in practice.

Conclusion

This review set out to explore the literature pertaining to mental health services delivered by community pharmacy. The objectives are to develop and trial strategies that improve and assist people with mental illness to manage their medication requirements and to evaluate the effectiveness of the strategies in a naturalistic study setting.

A four-component conceptual framework guided the search. Component 1 outlines a review of the literature pertaining to community pharmacy studies in mental health which were largely focussed on adherence and consumer health outcomes. Component 2 expanded the focus beyond adherence to medicines management and considered models

from outside of mental health. It also addressed the identification of MRP other than adherence, alignment with funded clinical programmes, and a greater focus on collaboration with other health-care providers. Component 3 centred on practice change at the individual level and whole of organisation change. The barriers and facilitators to implementation from consumers, pharmacy staff and other health-care providers were reviewed. There was significant Australasian literature in this area to draw upon. Component 4 involved a search of the processes of evaluation utilised within medicine management programmes and other services provided within the community pharmacy context and application for this intervention. A synthesis of this literature provides an understanding of the evaluation strategies and tools that could be adopted.

There is significant choice when thinking about the development and evaluation of an intervention of this nature and, with it, the potential for a high level of complexity. The literature suggests that multifaceted interventions that include behavioural strategies combined with information transfer are more effective than education alone. The challenge in the development of this intervention is treading the fine line between high engagement and simple interventions, alongside the need to develop a naturalistic study involving multiple stakeholders. Likewise, there is a need to collect data not only on impact but also on the implementation process from multiple viewpoints. The recommendations from a literature review based on a structured conceptual schema provide the foundation for an intervention to improve medicines-related outcomes for consumers with mental health problems.

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Declaration of conflicting interests

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