Author's response to reviews

Title: Experiences of pharmacists involved in the delivery of a specialist asthma service in Australia

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Author's response to reviews: see over
1. The role of community pharmacy and GP in Australia primary health care system should be described in the background. Are they separate entity or contracted to each other? [Minor Essential Revisions]

This has been addressed by addition of a phrase into the following sentence (page 4): “This role uniquely positions pharmacists as intermediaries between patients and prescribers, yet practising independently from prescribers, with roles incorporating medication review, case identification and disease monitoring, patient education and advocacy, and referral to prescribers and other health professionals.”

2. Pp9, para2: How does rapport between interviewer and pharmacist established? [Minor Essential Revisions]

A phrase has been added into the following sentence (page 9): “In cases where the interviewer/facilitator was not known to the pharmacist, rapport was established prior to the discussion via introduction to the researcher and general conversation about pharmacy practice, and an overview of how the focus group discussions would unfold.”

3. There are several instances where heavy research documentation were cited by the respondents. It is not clear however from the manuscript about the nature of data collected or its intensity. This could be inserted in the methodology section. [Major Compulsory Revisions]

The following sentence has been added to the Method (page 8) to clarify the documentation component of the study: “The initial patient consultation required completion of several validated questionnaires by the patient, with further questionnaires at subsequent visits (partial data were included in the case of patients withdrawing from the service). Further, the pharmacists maintained research-related documentation, including records of their clinical interventions, patients’ spirometry readings, and communication with patients and other healthcare providers.”

4. A paragraph/table describing the characteristic of participants and their pharmacy should be included in the results section. This might help readers to see the context of their perceptions e.g. maybe the logistic issue arises because of their smaller pharmacy? [Major Compulsory Revisions]

The focus group and interview transcripts were de-identified by the transcriber in accordance with the ethical approval for the research. For this reason, we are unable to describe individuals’ responses in relation to their pharmacy characteristics. The Methods section refers to our sampling of rural and urban pharmacists for feedback on their experiences with
provision of this service. The Results section makes some reference to the range of experiences of the pharmacists, such as challenges with particular groups of patients, although we consider these to be related more to the pharmacists’ approach to recruitment and application of the program than to characteristics of their pharmacy.

We acknowledge that there was some diversity in the size, clientele and location of the pharmacies in which our participants practised; this was intentional, and the service model was designed to be standardised yet accommodating of this diversity. Some of this diversity became apparent in responses relating to (for example) clients’ responses to recruitment attempts, and this adds to the richness of the data when evaluating a standardised service implemented in a variety of practices.

5. Pp15 - 16 gives an interesting insight of the challenges such research can be on interprofessional collaboration. Can stronger rapport with GP facilitate the communication? [Discretionary Revisions]

We agree that stronger rapport between the pharmacist and GP would facilitate patient-related communication. This was highlighted on page 15. Later, in the Discussion, we referred to the problem: “A number of pharmacists were challenged clinically by complex patient cases, testament to the need for collaboration between pharmacists and GPs for such patients.” The extent of this collaboration, however, was often less than ideal, consistent with research conducted into pharmacist-GP relationships in Australia,(20) which reported a “generally favourable attitude towards one another” but “limited understanding/confidence in the breadth of knowledge of their cross-disciplinary colleagues.” Moreover, previous Australian research into pharmacist professional services supports the critical role that open communication plays in facilitating inter-professional collaboration (Van C, Mitchell B, Krass I. GP-pharmacist interactions in professional pharmacy services. Journal of Inter-Professional Care 2011; 25: 366-72.)

REVIEWER 2

Title: suggest add ‘community’ before ‘pharmacists’

This has been added.

Introduction
1. Major compulsory revision: The paper needs a more international context. References cited are almost all from Australian practice. There is relevant learning from other studies, for example services for asthma and other conditions provided by community pharmacists have been trialled in other countries, eg McLean et al in Canada, Bunting et al in the US, etc.

The suggested references to the American (Bunting) and Canadian (McLean) research have been incorporated into the following sentence in the Background to acknowledge international developments in disease state management services, specifically for asthma: “To this end, services based on the management of asthma,(1-7) diabetes,(8, 9) hypertension(10) and bodyweight(11) have been tested, with positive clinical(1, 3, 5-9) and economic(4, 6, 7, 9) impact data.” It should be noted that our Background covers numerous topics: changing roles for pharmacists, the movement towards disease state management
services, and the concept of pharmacists adopting such services as participants in research and thus being the subject of evaluation themselves. While we agree that it is important to acknowledge international developments in disease state management services, most are demonstration projects with focus on clinical, quality of life and economic outcomes; few, if any, of these studies have involved evaluation from the pharmacist participants’ perspectives, as per our sentence: “Despite the emergence of a number of specialist disease-management services in pharmacies, there has been little published research to explore pharmacists’ experiences as pioneers of a structured disease state management service…”

International research has been cited in justifying the need for our study: “Internationally, Canadian researchers have reported common challenges in pharmacists’ engagement with disease state management services, including time constraints, access to information, formation of working relationships and absence of a practice model.(18) Whether these are universal depends on the program under study and constraints of each country’s healthcare system.” This study provided international context for discussion of findings relating to the pharmacists’ perceptions of their relationships with GPs (added to the Discussion, page 22).

Tsuyuki has written about the extent to which community pharmacists engage with new practice models and why. This and related literature are not mentioned. Nor is the role of the pharmacy team in supporting new services. Theories of innovation and adoption are mentioned in the introduction and need to be revisited in the discussion or conclusions.

The added reference 18 (above) is one of Tsuyuki’s works on practice change management, and is considered the most relevant international comparison to our Australian research. We have updated this section. The role of the pharmacy team in supporting new services did not emerge as an obvious theme in our study, although ‘enabling’ the service through staff management was elucidated in the section titled Logistics of Service Provision. The focus on innovation, adoption and new practice models has been reiterated early in the Discussion, as requested, with the addition of: “The pharmacists involved in this trial could be considered ‘early adopters’,(14, 15) and their engagement with a new style of practice provided insight into challenges and enablers(18) for extended pharmacy services.”

Methods

2. Minor essential revision: Pharmacists were asked to recruit up to 10 patients. Over what period of time? When was a patient considered to have ‘completed’ the service? Could they miss any appointments or were they only included if they attended all 3/4?

The following sentences have been added to the Methods: “Pharmacists had two to three months to complete recruitment, and progress was monitored and encouragement provided approximately three weeks after the training” and “…partial data were included in the case of patients withdrawing from the service.” Only those who completed all visits were considered to have completed the service

3. Minor essential revision: Patients were to be recruited to the service if they had sub-optimal asthma control or had not had a review in the previous 6 months. Please explain how were pharmacists expected/trained to identify suitable patients?

The inclusion criteria are covered in detail in Reference 2, as cited in the text. Pharmacists used a tick-box recruitment guide to ask the relevant questions. (2)
4. Major compulsory revision: The authors say that “transcripts were analysed manually for the identification of underlying concepts”. More description of the analytical method used is needed, please expand. Both confirmative and disconfirmative evidence are important. The discussion makes reference to some negative accounts and the Results section needs to reflect these.

The description of the data analysis has been expanded as follows: “The transcripts were analysed manually for the identification of underlying concepts by one researcher in accordance with the semi-structured focus group guide, with consensus then achieved by two more investigators for interpretation of the content. Comments were extracted as both confirmative and disconfirmative evidence to explore the breadth of responses and pharmacists’ experiences.” The disconfirmative evidence referred to in the Discussion related to the criticisms aired by the pharmacists in the Results section: “We found that the elucidation of ambivalent and negative experiences (“disconfirming evidence”), particularly regarding the study workload… Another example of disconfirming evidence had been presented in the Results in the form of comments about some patients’ asthma control deteriorating (refer to point 5).

Results

5. Major compulsory revision: The authors say that 8 ‘concepts’ were derived from the transcripts. However the 8 listed are a mix including some specific areas of questioning in the data collection schedule and not all are ‘concepts’. Some reorganisation of data would be helpful, for example the section on ‘Perceptions of the patients experiences’ of the service contains several quotes about unexpected deterioration in asthma control which do not seem to fit there. The authors need to review their data, perhaps with some reorganisation.

The interview guide comprised five groups of questions, while the Results were reported under eight headings. The reviewer is correct in identifying two of the eight Results headings as replicated from the interview guide headings. This was intentional, as the ‘concept’ arising from this group of questions was consistent with the interview guide. To improve clarity, the sentence “The discussion topics and resulting themes are presented below” has been deleted, and the Results section may now be interpreted as comprising a number of subheadings which are not necessarily themes. We hope this makes our process clearer.

The deterioration in asthma control was presented as disconfirmative evidence in the Results section, to balance reports of improved asthma control.

6. Major compulsory revision: Further information is needed to enable the reader to assess whether there might be bias in the sample of participants. Please state the number of pharmacists who were invited to take part and who declined, and provide information about the performance of the pharmacists who took part in the focus groups/interviews in recruitment and delivery of the service. This would help the reader to understand the spread of experience of the service among pharmacists in the sample and the extent to which the service was embedded.
The Results section (page 11) states that “All pharmacists approached to give feedback agreed; however, in a small number of cases, the pharmacist could not commit to attending the focus group. Overall, 32 pharmacists were involved in either a focus group or individual interview…” The sampling strategy was described on page 9. There is a natural bias in this type of demonstration project, towards pharmacists who are more innovative and professionally engaged; this is acknowledged in the description of our sample as “early adopters”. In addition, we made it clear that the person interviewing them was someone who had not been involved in their education or support up until then, and thus they should feel free to give any feedback.

Discussion
7. Major compulsory revision: The discussion needs to be more balanced and to better reflect the issues raised by the data. The authors need to be more critical in their reflection. Some suggestions are made below.

7a. Pharmacies recruited a median of 5 patients and pharmacists’ accounts indicate that some of the patients who could have benefited most from the service did not receive it. These issues need exploration.

The Results section presented a number of quotations from pharmacists who reflected on their patient recruitment strategy, the range of needs of their patients, and their inability to service all patients’ needs. These were drawn together in the Discussion as follows: “Some pharmacists expressed regret at the expedient manner in which they recruited patients for the study, and proposed different methods of recruitment that allowed them to target specific patients as they presented. A frequently expressed theme was the desire to expand the service to children. Pharmacists also reflected on the variable nature of asthma and therefore the need for an ongoing service.”

7b. Patients who did not attend (DNAs) were reported to be a problem for some pharmacists and there was difficulty engaging with some patient groups. Patients who were working needed to attend at weekends. Young people were reported not to attend. The authors say that patients’ reluctance to attend follow-up appointments might have been due to the lengthy initial consultation required. Alternative explanations are that the organisation and delivery of the service did not meet some patients’ needs and/or that some patients were not sufficiently convinced that they needed the service. An important part of community pharmacy’s argument for service provision has been that it can reach ‘hard to reach’ groups that do not engage with GPs. The authors need to address this.

We thank the reviewer for these insights, with which we agree. A sentence in the Discussion has been expanded to include these concepts: “Pharmacists in our study also reported variable commitment to the program by some patients (working people and younger patients), presumed due to undervaluing of the service by these patients, inability for the organisation and delivery of the service to meet their needs, and/or the lengthy consultations associated with research documentation.”

7c. Pharmacists were encouraged to contact, and preferably meet with, local GPs. Their accounts indicate little meaningful contact or engagement with doctors. This is a consistent finding across many countries. Australia has employed local facilitators to improve pharmacist-GP joint working for home medicines reviews, the authors could reflect more on these aspects.
We believe that a more solid and collaborative pharmacist-GP relationship is required for a successful disease state management service than is required for home medicines reviews, which are stand-alone reviews commissioned by the GP and follow a protocol for reporting of the consultant pharmacist’s recommendations, from which there may be no feedback from the GP. While services such as home medicines reviews are accepted as a positive development for recognition of pharmacists’ expertise, a disease state management service requires more proactivity by the pharmacist and the provision of relevant screening/diagnostic tests, which can be perceived as challenging to the GP’s role. For this reason, we have reflected upon Canadian findings about GPs as “gatekeepers”.

7d. Some pharmacists seemed surprised that patients’ asthma might both improve and decline at different times and between appointments and some of the quotes reflect this exposure to the challenges of the unpredictability of managing a chronic condition. The authors could reflect on how to take this into account in future service development and implementation.

Thank you for making this point; it was one we had not reflected on. A sentence has been added to the Discussion section on spirometry (page 24): “Future iterations of this asthma management service could focus more on the fluctuations of asthma control and the visits could be tailored accordingly. Pharmacists must be cognisant of how fluctuations appear in spirometry measurements and the level of asthma control, to be expected to respond with appropriate medication.”

7e. Only one quote indicated that pharmacists might have changed their practice as a result of participating (FG1-5) reporting more involvement in checking inhaler technique. Yet the authors say in the discussion that the pharmacists’ involvement in the trial is likely to have benefits beyond the patients in the study. What is the evidence for this?

The quotation from FG1-5 was indicative of numerous comments from pharmacists. Regarding ongoing benefits, we accept that there is no evidence for this, and indeed, it would be challenging to measure. However, a number of the pharmacists expressed what we perceived would be long-term improvements to their professional services (e.g. developing a habit of checking inhaler technique for all their patients) or a desire to adopt this as an ongoing service (e.g. FG2-N3). A sentence to this effect has been added early in the Discussion: “A number of the pharmacists expressed what we perceived would be long-term improvements to their professional services (e.g. developing a habit of checking inhaler technique) or a desire to adopt this as an ongoing service. The pharmacists involved in this trial could be considered ‘early adopters’, (14, 15) and their engagement with a new style of practice provided insight into challenges and enablers(18) for extended pharmacy services.”

7f. A model where consultation can only be provided face to face in the pharmacy might not meet the needs of all patients. In the UK the recently introduced New Medicines Service offers patients a choice of face to face or telephone consultations based on the Clifford/Barber RCT which showed that telephone-delivered consultations were effective. Please comment on whether the asthma implementation trial provides further evidence that the ‘traditional’ pharmacy model needs to be reconsidered and made more flexible.
A feature of our service was the provision of spirometry for asthma patients, which is not feasible for a telephone or online service. The novelty value of the spirometry was explored in the Results, and these readings are considered valuable for ongoing motivation of patients to attain control of their asthma. In addition, we have considerable data about the benefits of improving inhaler technique for asthma control. Physical demonstration and feedback is required to improve technique (Basheti et al., JACI 2007). There is certainly potential for between-visit telephone check-up consultations between the pharmacist and patient, and telephone reminders were used to encourage attendance at the scheduled pharmacy consultations. A sentence has been added to the Discussion: “The inclusion of spirometry (or indeed, any diagnostic procedure requiring the pharmacist’s involvement) limits this type of service to face-to-face consultations, which further engages the patient in a direct care relationship with the health practitioner.”

Conclusion
8. Compulsory major revision: The authors need to review their conclusions. The paper does not provide evidence that pharmacists did “strategically manage the challenges” of delivering the service.

We have not claimed that the pharmacists did achieve this. Perhaps we had not been clear. The sentence is (emphasis added): “Overall, their positive experiences demonstrated that if the challenges were managed strategically, implementation of such a service model would be possible.”

REVIEWER 3

Minor Essential Revisions
1) While the methods are appropriate, more details on the data coding process should be added. For example, it is not clear if the coding was done independently, and then consensus was reached. Further, were a few cases used to develop a set of codes that were then used for all of the cases.

Please refer to our response to Reviewer 2 point 4.

Discretionary Revisions
2) For readers who are not familiar with community pharmacies in Australia, it would be useful to add a paragraph briefly describing such pharmacy practices. For example, such variables as prescription volume, staffing levels, ownership, and typical/range of services offered would be informative.

As per our response to Reviewer 2 point 1, the Background section covers a considerable number of topics. However, we have established that pharmacists (in Australia) practise independently from prescribers (Background paragraph 1). Further information about the development of various disease state management services in Australia is available in the references cited throughout the Background, and we now have expanded the number of references.

3) It is not clear how dispersed geographically these pharmacies were. I wondered about peer support or recognition being an experience of the pharmacists. I know for past projects
that we have encouraged the participating pharmacists to talk with each other as some type of a support group. I did not see anything about this in the focus group questions, but I imagine it may have occurred. If available, some findings and/or comment on this issue could be useful.

The four Australian States/Territories involved in this research have now been added: “Recruitment of the service providers was undertaken geographically by pharmacy, with proportional representation of the number of community pharmacies in regional and metropolitan areas in four States/Territories in Australia (New South Wales, Victoria, Queensland and the Australian Capital Territory).”

While the pharmacists met each other at the initial training, there was no formal peer support network (e.g. online community) established throughout the study. However, the academic research team maintained contact with individual pharmacists via visits and telephone calls; this was referred to in the Discussion: “…their involvement in this program was an opportunity for them to provide a structured service independently, yet under guidance of academic researchers. The ‘hand holding’ was a feature of the study design, as it was expected that engagement of the pharmacists with the academic researchers would be key to their commitment to this project.”

4) I was glad to see the recommendations for involving pharmacists in such studies. Based on the stated results and my own experience, I have a couple of suggestions for consideration by the authors. As part of the training it is useful to distinguish training for service skills and knowledge (E.g. pathophysiology, therapeutics, communication) from training for the study components (E.g. human subject issues, data collection). Both components should be addressed. A second thought is to include assistance to the pharmacy practices to fit the new service into their operations. This might include discussion on staffing, work flow, use of appointments, physician relations, service area in the pharmacy. Most of these were mentioned in the findings, and repeatedly show up in studies of barriers to implementing new services in pharmacies.

We thank the reviewer for these suggestions. We have incorporated them as follows: “The training component of the service should involve training in the research requirements (specifically patient recruitment, consultation and documentation) and the physical requirements for provision of professional services (work flow, staffing, appointment systems and the consultation area).”

EDITOR’S COMMENTS

Ethics statement

Research involving human subjects (including human material or human data) that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee. Research carried out on humans must be in compliance with the Helsinki Declaration (http://www.wma.net/en/30publications/10policies/b3/index.html). A statement to this effect must appear in the Methods section of the manuscript, including the name of the body which gave approval, with a reference number where appropriate.
These had been addressed in the submitted manuscript: “The study was conducted in accordance with the Helsinki Declaration, and the study protocol was approved by the Human Research Ethics Committee of The University of Sydney (11-2008/11419), with secondary approvals from the Medical Research Ethics Committee of The University of Queensland, the Human Research Ethics Committee of Charles Sturt University, and the Monash University Human Research Ethics Committee.”

2. Authors' Contribution

Please place the Authors' Contributions section after Competing interests. Please check the instructions for authors on the journal website for the correct format to use for Authors' Contributions.

The Authors’ Contributions are positioned after the Competing Interests, and currently state “All authors contributed to the study design, the preparation of clinical materials, interpretation of data and writing of this manuscript. LS and CA were involved in conducting the focus groups. KL and CA performed the initial data synthesis from the focus groups. LE performed the detailed data analysis and drafting of the manuscript. All authors have read and approved the final manuscript.”

1. Tables

Please note that we are unable to display vertical lines or text within tables, no display merged cells: please re-layout your table without these elements. Tables should be formatted using the Table tool in your word processor. Please ensure the table title is above the table and the legend is below the table. For more information, see the instructions for authors on the journal website.

The vertical lines have been removed from Table 1.

2. Additional files

All additional files must be mentioned in the text in numerical order, or removed from the system. Please ensure all files are referred to as additional files (not, for example, supplementary data). Please add a section titled "Additional files" at the end of the manuscript (after the tables) listing the following for each file: the title of the data, and a short description of the data.

Our manuscript includes one Additional File, labelled “Additional file 1 – Interview guide (truncated to remove introductory statements and prompts)”.