PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Development of a clinical pharmacy model within an Australian home nursing service using co-creation and participatory action research: the Visiting Pharmacist (ViP) study
AUTHORS	Elliott, Rohan; Lee, Cik Yin; Beanland, Christine; Goeman, Dianne; Petrie, Neil; Petrie, Barbara; Vise, Felicity; Gray, June

VERSION 1 – REVIEW

REVIEWER	Amy Tan The University of Sydney, Australia
REVIEW RETURNED	07-Aug-2017

GENERAL COMMENTS	Thank you for the opportunity to review this paper. The study is interesting and I believe that the content and model described will be of benefit to readers. However, I have suggested areas of improvement to strengthen and improve the flow of content. 1) There were various 1-2 sentence paragraphs throughout the article that were awkward to read. Please combine paragraphs where applicable. 2) I would like to suggest the author frame which clinical pharmacy component they are investigating clearly in the title, abstract, introduction, methods, results, discussion and conclusion. The way the article is written, it was hard to ascertain what the focus clinical pharmacy service is. For example, the title and abstract suggest that the study is looking at clinical pharmacy service (implying a comprehensive lot of services). But the background/introduction section focused on evidence on pharmacists' contribution to medication review only whereas there are plenty of evidence elsewhere about other clinical pharmacy components. The methods (line 31-33, page 7) then expanded on the medication review role (but only a partial portion of the entire clinical pharmacy component). As I read on, my impression is that the study focused on the pharmacist's role in medication review, reconciliation, information provision and transfer of information which is very similar to a home medicines review except with an enhancement feature where nurses are involved. The discussion then compared the study model with current HMR models which again emphasises the focus on medication review aspect rather than 'clinical pharmacy' as a whole. My point is, clinical pharmacy and medication management can mean a lot of things. See 'Stowasser D et al. Understanding the medicines management pathway. J Pharm Pract Res 2004; 34: 293–296' and 'Tan, A. C. W., Emmerton, L. and Hattingh, H. L. (2012), A review of the medication pathway in rural Queensland, Australia. International Journal of Pharmacy Practice, 20: 324–339.'

	My suggestion is for the authors to rephrase (where applicable) statements relevant to clinical pharmacy into something more specific like 'enhanced medication review model' (which is what I believed this article is about) e.g. title: development of an enhanced medication review model within a home nursing service...." and focus the article (background, research question, methods, results, discussion, conclusion) on medication review services (I get that other minor things like information provision, medication reconciliation etc are included but these are also included as part of the standard HMR). 3) "Data collection and analysis: Feedback and reflections from minutes, notes and interview transcripts from: project team meetings, clinical pharmacists' reflective diaries and interviews, meetings with community nurses, multidisciplinary stakeholder reference group meetings and in-depth interviews and focus groups with 27 older people, 18 carers, 53 nurses, 15 GPs, 7 community pharmacists." This suggests (to me) that the article was going to be qualitative but there was no qualitative analysis and findings and quotes presented. After reading the results, it appears that the aim of this paper was for the authors to describe the development and implementation of the study model (with some feedback, enablers and challenges) - I noted the authors were going to publish the detailed analysis of the data collection elsewhere (lines 15-23, page 9). If interview and focus group data will be reported elsewhere, then it was unnecessary to report them as methods here because the methods refer to what is being reported in the paper. If some data from the interview and focus group is reported in this paper and then a more detailed one in another paper, I then think this is a double-reporting/publication problem. From what I understand, the methods described was for the entire project, whereas the paper described the development of the model (i.e. one part of the project). I would like to suggest that the authors clarify that: i) this paper describes the development of the model, ii) model framework as reported, iii) who's involved in the development and what consultations have taken place to contribute to specifically to the model development. I think all that needs to be done is rephrasing the existing content to capture these. And the authors could end with a simple statement that the model is tested with so and so, in xxx setting, and evaluations include outcomes, interviews, etc etc. which will be reported elsewhere. This will remove the unnecessary information about other things that are not relevant to this paper so readers (like myself) are focused and not confused. 4) The results presented are comprehensive but I believe can be reorganise to facilitate reading. I have made notes on the PDF with my suggestions. I personally would like to read the results section as such: 1) model description (as reported) with the pharmacist's role and how it's set up (+ organisational support and resources, + competency required i.e. is the pharmacist accredited to do HMR - or maybe description of accreditation should have been reported under methods), 2) the process involved in the 'enhanced medication review' - initiation, nurse's involvement, etc, 3) Key differences between the enhanced model reported in the study as compared to other models (e.g. HMR)

	5) In the results section, after reporting the model development results, the authors proceeded to describe feedback, enablers and disablers under a general heading - thematic analysis subheading would help readers here. However, the bigger concern is that what I am reading here are outcomes of the model (from my understanding) which the authors reported that they will be reporting elsewhere so I'm confused about the content being here. Perhaps the authors are trying to report pre-liminary feedback that lead to the development of the model rather than the outcomes? In which case it's not made clear in the article because the way it's written sounded like feedback after the implementation of the model. I haven't critiqued the content of the feedback and enablers/challenges subsection in the results section because I feel the former concern should be addressed first. 6) Discussion: I understand the strengths in the model being unique. However, I feel that an important discussion point that's missing is that this study model is an enhanced version of the HMR (with all the additional bonus that the authors have described) and addresses several gaps in the current HMR model (which the authors didn't quite discuss or if it has been then it's not clearly presented). I'm just making some guesses here in terms of the gaps so please check for accuracy since the authors would have done the lit review on this. 1) HMR can be initiated by a GP for a community-based patient regardless whether the patient is independent or currently using a nursing agency - the gap here is that a GP may not necessary have thought of initiating a HMR referral for the nursing agency patient who is more likely to have medication issues and so this study model addresses the gap by having the agency nurse initiate the referral/medication review. And this is particularly important because a patient who requires nursing help is more likely to also require medication management help. 2) Nurses providing home services may have various skills and training and quite often they may not be skilled or trained enough in the area of medication management (e.g. enrolled nurses (EN) and personal carers will know a lot less about medication than registered nurses (RN) and maybe endorsed enrolled nurses (EEN)). This study model addresses the gap where there is a pharmacist support for these nurses as opposed to the HMR model that doesn't necessarily come with that. 3) This model makes it more integrated between the GPs, pharmacists, nurses, patients and carers which is always good for quality medication management. 4) And perhaps a discussion that current medication review model (e.g. HMR) is rigid and needs to be reviewed considering the results/findings presented in this paper - which can lead to the discussion of funding. The authors have alluded to some of the points above but it was not presented in a clear way so hopefully this structure is helpful for revising the paper. 7) Great work on the authors for including recent and up-to-date references. Thank you again for the opportunity to review this paper and I wish the authors the best in this project as I believe it is a step up in improving medication management in community patients.

REVIEWER	Jeffrey Clark Washington State University College of Pharmacy Department of Pharmacotherapy United States of America
REVIEW RETURNED	09-Aug-2017

GENERAL COMMENTS	This is a very important research area as incorporation of a pharmacist into this practice setting that lacks the safety mechanisms available in institutionalized care has the potential to impact a wide range of healthcare related outcomes while potentially resulting in decreased expenses. Page 7: I liked the incorporation of the Australian standards of practice for clinical pharmacy and guidelines for medication management. Page 11 Line 13: I like the inclusion of the community pharmacy in the list of people receiving the medication review. This can be very important for coordination of care. Required Revisions Page 5 paragraphs #1, #2, & #3: Please provide more details on the difference between home nursing services in Australia and home healthcare services in the United States and Brittan. I was surprised by the 3rd paragraph which indicated the nurses were administering medications in the home. To fix this issue at Line 15: Please define "medication management support" -- Does this term mean help with filling the medication box for self-administration or does it refer to assistance with medication administration? Line 35: I am not sure "medication administration charts" is needed. I would suggest "treatment authorizations (physician's orders authorizing the nurse to administer medicines or assist with administration)" Page 5 Line 40: Which population is included in this study? Is it those having all medications administered by nursing? Some medications administered by nursing? Or those self-administering? Page 5 line 48: "do not routinely receiving comprehensive medication reconciliation and review on admission to identify medication errors and potentially inappropriate or unnecessary medicines or to simplify complex medication regimens." There is a key distinction that needs to be made. In the United States, patients do not receive the above from a pharmacist. However, home healthcare regulations require a medication review to be preformed, which is usually done by the patient's nurse. Occasionally, this review will be done by the patient's physical therapist. The code of federal regulations read: § 484.55 Condition of participation: Comprehensive assessment of patients. Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes.

	The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. The comprehensive assessment must also incorporate the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary. Subsection C (c) Standard: Drug regimen review. The comprehensive assessment must include a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy. Page 6 Line 38: As on page 5, it still isn't clear what is meant by medication management support. Please provide definition as above. Page 7 Line 53-58. The line starts out with 8 healthcare professionals and researchers. I only count 6. I see 1 nurse, 1 clinical pharmacist, 1 community pharmacist, 2 nurse mangers and a 1 sociologist listed. Please clarify. Page 7 line 58: The objective or the methodology need to be clarified. What is the purpose of the reference group? No comparative data was provided. The aim of the study is listed as "developing a collaborative person centered model of clinical pharmacy support for nurses and clients of a home nursing service…" Considering the aim, could you clarify why a "multidisciplinary stakeholder reference group" was selected. Is this group going to be compared to the 8 healthcare professionals and researcher's approach? What outcome are we comparing? Is this group just an advisory board? Page 14 Line 51 and following: The section "enablers and challenges" doesn't seem appropriate for the results section, but rather seems to be more of a discussion as it loses its objectivity. Please move commentary and opinion to the discussion. For examples, the statement "over time, as the model becomes more established and GPs become familiar with the service, this may become less of an issue" seems to be the opinion of the authors rather than a result of the study. Page 16 line 23: "this is the first that we know of that describes the development of a comprehensive clinical pharmacy for home nursing clients." I think you are correct on this being the first to study and describe the development process. However, please add a distinction as other comprehensive services have been described for home nursing clients (the term home nursing clients is synonymous with home healthcare clients), but it seems that how they developed has been fully elaborated. For example, very similar to the model in the current study, the following article describes a home healthcare agency where the pharmacist accompanied the visiting nurse on 80 visits. Cooper JW, Griffin DL, Francisco GE, Francis WR.

	Home health care: Drug-related problems detected by consultant pharmacist participation. Hosp Formul. 1985;20:643-650. Reidt et al also describe a similar model in at least 3 artcles. Another example would be in the academic setting, O'Neal F, Frame TR, Triplett J. Integrating a student pharmacist into the home healthcare setting. Home Healthcare Now. 2016;34(6):308-315. Additionally, the term comprehensive medication management is a newer term in the literature that seems to have been defined by Linda Strand and colleagues. It may be good to acknowledge the definition and that some older services, although they don't use this term, would meet this definition. Page 16 Line 40. Greater clarification is needed, as I would view the visiting nursing service you described in Australia similar to the home healthcare services in the United States. Recommended Revisions Page 9 Line 50: I agree "detailed analysis of interview and focus group data and outcomes of pharmacist medication review is beyond the scope of this paper" however, I would find it helpful if you quantified the number of home visits, medication reconciliations and comprehensive medication reviews Likewise the number of referrals received on page 10 Line24 . Additionally, on page 10, line 51 you mention home visits were usually conducted with the nurse. Would you quantify these items? Doing so will provide greater insight into the type of service provided. Page 13 line 8: Regarding the model improving access to HMR. Was improvement the consensus of the stakeholders or is improvement the conclusion of the author? This seems like a reasonable conclusion, however, I don't see that the baseline HMR rate was reported or that a rate of HMR was quantified and compared to the ViP model. Please report difference or consider altering the wording. Page 13 line 33: Is the statement "under the existing HMR model nurses are usually not made aware" a quantifiable finding of this study? Is it the opinion of the stakeholders? Is known background information? Please quantify. Page 13 line 51 through 58: "most GPs were happy…" How was this information quantified? Consider stating the "majority of GPs on survey expressed satisfaction with the model. Can you also quantify the number preferring to organize the HMR for the client. Likewise on page 14 line 4 and line 10, would you quantify the number usually willing and the number of the some who were less cooperative. Optional Revisions Reference #5 cites a textbook chapter. Does the textbook refer to an original source? Page 6 line 48: The study design is unique and may not be familiar to all the readers. Please provide a standard definition of "co-design and participatory research" design. It may be helpful to compare and contrast how this design is similar to a quality improvement project in the hospital setting. Page 7: Line 36: Which aspects were used from the guides mentioned?

VERSION 1 – AUTHOR RESPONSE

Reviewer 1
Reviewer Name: Amy Tan
Institution and Country: The University of Sydney, Australia
Please state any competing interests: None declared
Please leave your comments for the authors below:

Thank you for the opportunity to review this paper. The study is interesting and I believe that the content and model described will be of benefit to readers. However, I have suggested areas of improvement to strengthen and improve the flow of content.

1) There were various 1-2 sentence paragraphs throughout the article that were awkward to read. Please combine paragraphs where applicable.

RESPONSE: Thankyou for your feedback. We have combined some paragraphs in the revised manuscript as recommended.

2) I would like to suggest the author frame which clinical pharmacy component they are investigating clearly in the title, abstract, introduction, methods, results, discussion and conclusion. The way the article is written, it was hard to ascertain what the focus clinical pharmacy service is. For example, the title and abstract suggest that the study is looking at clinical pharmacy service (implying a comprehensive lot of services). But the background/introduction section focused on evidence on pharmacists' contribution to medication review only whereas there are plenty of evidence elsewhere about other clinical pharmacy components. The methods (line 31-33, page 7) then expanded on the medication review role (but only a partial portion of the entire clinical pharmacy component). As I read on, my impression is that the study focused on the pharmacist's role in medication review, reconciliation, information provision and transfer of information which is very similar to a home medicines review except with an enhancement feature where nurses are involved. The discussion then compared the study model with current HMR models which again emphasises the focus on medication review aspect rather than 'clinical pharmacy' as a whole. My point is, clinical pharmacy and medication management can mean a lot of things. See 'Stowasser D et al. Understanding the medicines management pathway. J Pharm Pract Res 2004; 34: 293–296' and 'Tan, A. C. W., Emmerton, L. and Hattingh, H. L. (2012), A review of the medication pathway in rural Queensland, Australia. International Journal of Pharmacy Practice, 20: 324–339.' My suggestion is for the authors to rephrase (where applicable) statements relevant to clinical pharmacy into something more specific like 'enhanced medication review model' (which is what I believed this article is about) e.g. title: development of an enhanced medication review model within a home nursing service...." and focus the article (background, research question, methods, results, discussion, conclusion) on medication review services (I get that other minor things like information provision, medication reconciliation etc are included but these are also included as part of the standard HMR).

RESPONSE: Whilst medication review was a central component of the clinical pharmacy service described in this manuscript, there were several other aspects of the service also described in the text and in Table 2. These included reconciling home nursing medication orders with a best-possible medication history, assisting community nurses with obtaining up-to-date medication orders from prescribers, providing a medicines information service for community nurses, contributing to the development or revision of organisational medication management policies and providing nurse education. These types of service are not provided as part of most ‘medication review’ services.

Most medication review models provide a (usually one-off) review of a patient's medications followed by liaison with their medical practitioner to address medication-related issues, rather than providing a more comprehensive range of clinical pharmacy services including supporting community nurses to safely undertake their medication management work. Because our model provided a range of clinical pharmacy services, and was based on published Standards of Practice for Clinical Pharmacy, we feel it is appropriate to describe it as a clinical pharmacy service in the title and throughout the manuscript, rather than an 'enhanced medication review' service.
On reflection we agree that the Background section focused mainly on medication review and did not make clear the distinction between medication review and clinical pharmacy services more broadly, and we have therefore re-written the Background. We have also modified the Results section to better highlight the services provided beyond traditional medication review: In the section titled 'The clinical pharmacy model' we added 'Clinical pharmacist roles are summarised in Table 2' (Table 2 summarises the broad range of clinical pharmacy services provided), added new sections titled 'Direct client care without home visit' and 'Indirect care', and changed the 'Medication review process' heading to 'Direct client care with home visit'. We have also modified Table 4 (last two rows) to further highlight broader clinical pharmacy services.

3) "Data collection and analysis: Feedback and reflections from minutes, notes and interview transcripts from: project team meetings, clinical pharmacists' reflective diaries and interviews, meetings with community nurses, multidisciplinary stakeholder reference group meetings and in-depth interviews and focus groups with 27 older people, 18 carers, 53 nurses, 15 GPs, 7 community pharmacists."
This suggests (to me) that the article was going to be qualitative but there was no qualitative analysis and findings and quotes presented. After reading the results, it appears that the aim of this paper was for the authors to describe the development and implementation of the study model (with some feedback, enablers and challenges) - I noted the authors were going to publish the detailed analysis of the data collection elsewhere (lines 15-23, page 9). If interview and focus group data will be reported elsewhere, then it was unnecessary to report them as methods here because the methods refer to what is being reported in the paper. If some data from the interview and focus group is reported in this paper and then a more detailed one in another paper, I then think this is a double-reporting/publication problem.
From what I understand, the methods described was for the entire project, whereas the paper described the development of the model (i.e. one part of the project). I would like to suggest that the authors clarify that: i) this paper describes the development of the model, ii) model framework as reported, iii) who's involved in the development and what consultations have taken place to contribute to specifically to the model development. I think all that needs to be done is rephrasing the existing content to capture these. And the authors could end with a simple statement that the model is tested with so and so, in xxx setting, and evaluations include outcomes, interviews, etc etc. which will be reported elsewhere. This will remove the unnecessary information about other things that are not relevant to this paper so readers (like myself) are focused and not confused.

RESPONSE: This study used a co-design and participatory action research approach to develop a model of clinical pharmacy for a home nursing service. As part of that methodology we consulted widely with stakeholders and collected data from multiple sources, both prior to and during development/implementation of the model. Data collection and stakeholder consultations took a wide variety of forms, including project team meetings, reference group meetings, focus groups, interviews, reviews of case notes and reflective diaries, etc. We feel that it is necessary to describe all of these forms of consultation and data collection in the manuscript because they all helped to inform the development and refinement of the model.
In this manuscript we have summarised key findings from stakeholder consultations, but it is beyond the scope of this paper to provide detailed thematic analysis and quotes.

On reviewing the manuscript we note that we said consultations occurred before, during and *after* implementation. This may have been confusing and we have now changed it to read that consultations occurred before and during implementation, because the 'post-implementation' consultations, including interviews and focus groups, were conducted during the implementation period to inform development of the model and ensure it was meeting stakeholders' needs.

4) The results presented are comprehensive but I believe can be reorganise to facilitate reading. I have made notes on the PDF with my suggestions. I personally would like to read the results section as such: 1) model description (as reported) with the pharmacist's role and how it's set up (+ organisational support and resources, + competency required i.e. is the pharmacist accredited to do HMR - or maybe description of accreditation should have been reported under methods), 2) the process involved in the 'enhanced medication review' - initiation, nurse's involvement, etc, 3) Key differences between the enhanced model reported in the study as compared to other models (e.g. HMR)

RESPONSE: We have moved the reference to Table 4 (contrasting our model to the HMR model) to the section describing the clinical pharmacy model (it is now Table 3 in the revised manuscript). We have made other changes to the Results section to more clearly make the distinction between the medication review components and other aspects of the clinical pharmacy service, as described above (see reviewer's 2nd comment).
The pharmacists who delivered the clinical pharmacy service in this study were accredited to do HMRs, but we chose not to mention this in the manuscript because our clinical pharmacy model did not use the HMR program, and we therefore felt it was not relevant and could be potentially confusing to readers. The accreditation process to which the reviewer refers is required by pharmacists to claim payment from the Commonwealth government for undertaking HMRs. In other settings where clinical pharmacy services are delivered, such as hospitals, this accreditation is not required. Competencies required by the pharmacists are described in the Results section, under the subheading 'Pharmacist competencies'.

5) In the results section, after reporting the model development results, the authors proceeded to describe feedback, enablers and disablers under a general heading - thematic analysis subheading would help readers here. However, the bigger concern is that what I am reading here are outcomes of the model (from my understanding) which the authors reported that they will be reporting elsewhere so I'm confused about the content being here. Perhaps the authors are trying to report pre-liminary feedback that lead to the development of the model rather than the outcomes? In which case it's not made clear in the article because the way it's written sounded like feedback after the implementation of the model. I haven't critiqued the content of the feedback and enablers/challenges subsection in the results section because I feel the former concern should be addressed first.

RESPONSE: The reviewer is correct that we are reporting preliminary feedback helped inform and validate the development of the model. Using the participatory action research approach, stakeholder input and other sources of data were used both prior to development of the model and during the development/implementation phase to inform and validate the model. The participatory action research approach and the fact that data were collected both before and during development/implementation is described in the section of the manuscript titled "Theoretical study framework", within the Methods section.

We have modified the first paragraph of the Results section to clarify that the data/stakeholder feedback mentioned there (Table 1) was gathered prior to development of the model. It now reads: “Stakeholder consultation and audit of medication management client records prior to developing the clinical pharmacy model highlighted key issues that the model needed to address (Table 1).” We have also modified the title of the section that summarised stakeholders’ feedback that was provided during the implementation phase of the model’s development. It now reads: “Stakeholder feedback during implementation”

6) Discussion: I understand the strengths in the model being unique. However, I feel that an important discussion point that's missing is that this study model is an enhanced version of the HMR (with all the additional bonus that the authors have described) and addresses several gaps in the current HMR model (which the authors didn't quite discuss or if it has been then it's not clearly presented). I'm just making some guesses here in terms of the gaps so please check for accuracy since the authors would have done the lit review on this. 1) HMR can be initiated by a GP for a community-based patient regardless whether the patient is independent or currently using a nursing agency - the gap here is that a GP may not necessary have thought of initiating a HMR referral for the nursing agency patient who is more likely to have medication issues and so this study model addresses the gap by having the agency nurse initiate the referral/medication review. And this is particularly important because a patient who requires nursing help is more likely to also require medication management help. 2) Nurses providing home services may have various skills and training and quite often they may not be skilled or trained enough in the area of medication management (e.g. enrolled nurses (EN) and personal carers will know a lot less about medication than registered nurses (RN) and maybe endorsed enrolled nurses (EEN)). This study model addresses the gap where there is a pharmacist support for these nurses as opposed to the HMR model that doesn't necessarily come with that. 3) This model makes it more integrated between the GPs, pharmacists, nurses, patients and carers which is always good for quality medication management. 4) And perhaps a discussion that current medication review model (e.g. HMR) is rigid and needs to be reviewed considering the results/findings presented in this paper - which can lead to the discussion of funding. The authors have alluded to some of the points above but it was not presented in a clear way so hopefully this structure is helpful for revising the paper.

RESPONSE: We have expanded the first paragraph of the Discussion to further highlight the differences and advantages of this model over the Australian HMR program. The limitations of the HMR program were discussed in detail in the Background section (as it was of the main reasons that the new model, and the study, were necessary), and noted in Table 2, so we have not gone into a lot of detail in the Discussion, in order to minimise repetition. That paragraph now reads (with new text highlighted yellow):
“This study describes the successful development of a collaborative, person-centred model of clinical pharmacy support for nurses and clients of a home nursing service that incorporates direct client care and indirect care (nurse support). The model targeted a group of community-dwelling older people known to be at high risk of medication-related problems and to have poor access to clinical pharmacy support. It delivered a range of clinical pharmacy services based on best practice standards and guidelines for clinical pharmacy and medication management. Although a form of clinical pharmacy support was already available in Australia, via the HMR program, previous research and extensive stakeholder consultation indicated that the HMR model was not able to address the needs of this patient group and the nurses supporting their medication management. The new model enabled timely access to clinical pharmacist advice and medication review to address medication issues and facilitated communication and information sharing between the home nursing service, prescribers and community pharmacies.”

We have also added some text in the Discussion section about the fact nurses require support from clinical pharmacists, and that staff with lower levels of training in pharmacology and therapeutics (e.g. personal care workers) are increasingly being used for some medication management tasks in the community: “Whilst community nurses play an important role in identifying and resolving medication-related problems for their clients, the complexity of modern pharmacotherapy means that they increasingly require support from clinical pharmacists whose core expertise is reviewing medication management to ensure safe and appropriate use of medicines. Increasing use of staff with lesser training in pharmacology and therapeutics (e.g. enrolled nurses and personal care workers) for some medication management activities in the community further underscores the need for pharmacist input. The need for this support has been recognised in hospitals and nursing home settings, with widespread implementation of clinical pharmacist roles. But in the home care setting these roles are uncommon.”
In the ‘Setting’ section of the Methods we’ve also added that personal care workers were used within the home nursing service that participated in this study.

7) Great work on the authors for including recent and up-to-date references. Thank you again for the opportunity to review this paper and I wish the authors the best in this project as I believe it is a step up in improving medication management in community patients.

RESPONSE: Thankyou for your feedback.

Reviewer 2
Reviewer Name: Jeffrey Clark
Institution and Country: Washington State University, College of Pharmacy, Department of Pharmacotherapy, United States of America
Please state any competing interests: None Declared
Please leave your comments for the authors below

General comments:
This is a very important research area as incorporation of a pharmacist into this practice setting that lacks the safety mechanisms available in institutionalized care has the potential to impact a wide range of healthcare related outcomes while potentially resulting in decreased expenses.

Comment:
Page 7: I liked the incorporation of the Australian standards of practice for clinical pharmacy and guidelines for medication management.

Comment:
Page 11 Line 13: I like the inclusion of the community pharmacy in the list of people receiving the medication review. This can be very important for coordination of care.

RESPONSE: Thankyou for these positive comments.

Comment: Required Revisions
Page 5 paragraphs #1, #2, & #3: Please provide more details on the difference between home nursing services in Australia and home healthcare services in the United States and Brittan.

RESPONSE: In paragraph #1 of the Background section we have clarified that we are referring to home nursing services in Australia. In paragraph #4 we have indicated that these services are similar to home care services in other countries.

Comment: I was surprised by the 3rd paragraph which indicated the nurses were administering medications in the home. To fix this issue at Line 15: Please define “medication management support” Does this term mean help with filling the medication box for self-administration or does it refer to assistance with medication administration?

RESPONSE: We have added more detail to paragraph #1 of the Background section to clarify what is meant by ‘medication management support’: “The level of support provided depends on the client’s capacity to self-administer their medicines and the availability of other supports such as family carers. It ranges from monitoring medicine-taking, to prompting or assisting with self-administration of medicines, through to administering medicines from a locked box stored in the patient’s home.”

Comment:
Line 35: I am not sure “medication administration charts” is needed. I would suggest “treatment authorizations (physician’s orders authorizing the nurse to administer medicines or assist with administration)”

RESPONSE: We have changed this as recommended in paragraph #3 of the Background section (and throughout the manuscript).

Comment:
Page 5 Line 40: Which population is included in this study? Is it those having all medications administered by nursing? Some medications administered by nursing? Or those self-administering?

RESPONSE: We have clarified that the population included older people receiving any level of medication management support in the ‘Participants’ section of the Methods:
“… older people referred to the home nursing service for *any level of* medication management support”

Comment:
Page 5 line 48: “do not routinely receiving comprehensive medication reconciliation and review on admission to identify medication errors and potentially inappropriate or unnecessary medicines or to simplify complex medication regimens.” There is a key distinction that needs to be made. In the United States, patients do not receive the above from a pharmacist. However, home healthcare regulations require a medication review to be performed, which is usually done by the patient’s nurse. Occasionally, this review will be done by the patient’s physical therapist.
The code of federal regulations read:
§ 484.55 Condition of participation: Comprehensive assessment of patients.
Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient’s current health status and includes information that may be used to demonstrate the patient’s progress toward achievement of desired outcomes. The comprehensive assessment must identify the patient’s continuing need for home care and meet the patient’s medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient’s eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. The comprehensive assessment must also incorporate the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary.
Subsection C
(c) Standard: Drug regimen review. The comprehensive assessment must include a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

RESPONSE: We have added details in paragraph #4 of the Background section to note that medication review is mandated for home healthcare clients in the USA.

Comment:
Page 6 Line 38: As on page 5, it still isn't clear what is meant by medication management support. Please provide definition as above.

RESPONSE: This is now explained in the Background section (paragraph #1) as described above, and in the Methods section (paragraph #1) as follows: "…2,534 clients, of whom 1,089 (43%) received medication management support (monitoring, prompting or assistance with self-administration, or nurse administration of medicines)."

Comment:
Page 7 Line 53-58. The line starts out with 8 healthcare professionals and researchers. I only count 6. I see 1 nurse, 1 clinical pharmacist, 1 community pharmacist, 2 nurse mangers and a 1 sociologist listed. Please clarify.

RESPONSE: This was an error and has been corrected.

Comment:
Page 7 line 58: The objective or the methodology need to be clarified. What is the purpose of the reference group? No comparative data was provided. The aim of the study is listed as "developing a collaborative person centered model of clinical pharmacy support for nurses and clients of a home nursing service…" Considering the aim, could you clarify why a "multidisciplinary stakeholder reference group" was selected. Is this group going to be compared to the 8 healthcare professionals and researcher's approach? What outcome are we comparing? Is this group just an advisory board?

RESPONSE: The role of the reference group has now been clarified in the Methods, under the Participants subheading: "A purposively selected multidisciplinary stakeholder reference group was established to provide input into planning and implementation of the model, to ensure it met stakeholders' needs and was acceptable to all stakeholders."

Comment:
Page 14 Line 51 and following: The section "enablers and challenges" doesn't seem appropriate for the results section, but rather seems to be more of a discussion as it loses its objectivity. Please move commentary and opinion to the discussion. For examples, the statement "over time, as the model becomes more established and GPs become familiar with the service, this may become less of an issue" seems to be the opinion of the authors rather than a result of the study.

RESPONSE: We have removed the aforementioned statement from the Results section. The remainder of that section is based on feedback from stakeholders as part of the participatory action research process and is not author commentary or opinion. We believe the enablers and challenges are an important part of the study findings and therefore we have retained it.

Comment:
Page 16 line 23: "this is the first that we know of that describes the development of a comprehensive clinical pharmacy for home nursing clients." I think you are correct on this being the first to study and describe the development process. However, please add a distinction as other comprehensive services have been described for home nursing clients (the term home nursing clients is synonymous with home healthcare clients), but it seems that how they developed has been fully elaborated.

For example, very similar to the model in the current study, the following article describes a home healthcare agency where the pharmacist accompanied the visiting nurse on 80 visits. Cooper JW, Griffin DL, Francisco GE, Francis WR. Home health care: Drug-related problems detected by consultant pharmacist participation. Hosp Formul. 1985;20:643-650. Reidt et al also describe a similar model in at least 3 articles. Another example would be in the academic setting, O'Neal F, Frame TR, Triplett J. Integrating a student pharmacist into the home healthcare setting. Home Healthcare Now. 2016;34(6):308-315.

RESPONSE: We have reworded this section and added additional references. We had already cited Reidt's main paper, but have now added a second paper which provided more detail regarding their model. We have also cited Cooper et al. We have not cited O'Neal et al as we felt it was not relevant because it utilized pharmacy students instead of pharmacists, and focused on transitions of care from hospital to home care.

Comment:
Additionally, the term comprehensive medication management is a newer term in the literature that seems to have been defined by Linda Strand and colleagues. It may be good to acknowledge the definition and that some older services, although they don't use this term, would meet this definition.

RESPONSE: We have decided not to mention the 'comprehensive medication management' model. Although there are some similarities with our model, there are major differences. For example, it is physician-led and it does not involve or support community nurses in delivering medication management services. There are many different models of clinical pharmacy and we feel it is beyond the scope of our article to discuss them all. We have discussed the 'Home Medicines Review' model because this is the most commonly used model in Australia.

Comment:
Page 16 Line 40. Greater clarification is needed, as I would view the visiting nursing service you described in Australia similar to the home healthcare services in the United States.

RESPONSE: We have noted the similarity with home healthcare services in the USA in the Background section. In the Discussion section, paragraphs #3 and #4, we have also linked the home nursing service and other related services such as home healthcare in the USA.

Comment:
Recommended Revisions
Page 9 Line 50: I agree "detailed analysis of interview and focus group data and outcomes of pharmacist medication review is beyond the scope of this paper" however, I would find it helpful if you quantified the number of home visits, medication reconciliations and comprehensive medication reviews Likewise the number of referrals received on page 10 Line24 . Additionally, on page 10, line 51 you mention home visits were usually conducted with the nurse. Would you quantify these items? Doing so will provide greater insight into the type of service provided.

RESPONSE: We have added further detail in the Results section to address these recommendations: "Eight-four (88%) referred clients received a pharmacist medication review and medication reconciliation. Of these, 82 required a pharmacist home visit. Seventy-three (89%) home visits were made in conjunction with a nurse, and 9 (11%) were made by the pharmacist alone. Eleven (13%) clients received a second pharmacist visit."

Comment:
Page 13 line 8: Regarding the model improving access to HMR. Was improvement the consensus of the stakeholders or is improvement the conclusion of the author? This seems like a reasonable conclusion, however, I don't see that the baseline HMR rate was reported or that a rate of HMR was quantified and compared to the ViP model. Please report difference or consider altering the wording.

RESPONSE: The wording has been changed to clarify that this was reported by the community nurses: "Nurses reported that the model improved access to clinical pharmacist consultations and medication review.."

Comment:
Page 13 line 33: Is the statement "under the existing HMR model nurses are usually not made aware" a quantifiable finding of this study? Is it the opinion of the stakeholders? Is known background information? Please quantify.

RESPONSE: The wording has been changed to clarify that this was reported by the community nurses: "Nurses noted that under the existing Australian HMR model they are usually not aware when a medication review is being conducted.."

Comment:
Page 13 line 51 through 58: "most GPs were happy…" How was this information quantified? Consider stating the "majority of GPs on survey expressed satisfaction with the model. Can you also quantify the number preferring to organize the HMR for the client. Likewise on page 14 line 4 and line 10, would you quantify the number usually willing and the number of the some who were less cooperative.

RESPONSE: The wording has been changed to clarify that these data were based on experiences and opinions of the GPs and pharmacists who participated in stakeholder feedback. These data were not quantified.

Comment:
Optional Revisions
Reference #5 cites a textbook chapter. Does the textbook refer to an original source?

RESPONSE: Additional reference added (Ellenbecker 2004).

Comment:
Page 6 line 48: The study design is unique and may not be familiar to all the readers. Please provide a standard definition of "co-design and participatory research" design. It may be helpful to compare and contrast how this design is similar to a quality improvement project in the hospital setting.

RESPONSE: An explanation of this methodology is provided in the Methods, under the subheading 'Theoretical study framework'.

Comment:
Page 7: Line 36: Which aspects were used from the guides mentioned?

RESPONSE: Some of this detail was provided in the Methods, under the subheading 'Framework for development of the model'. We have added additional details:
"Relevant sections of the guidelines for medication management included administration of medicines, dose administration aids, medication lists, medication review and risk management."

VERSION 2 – REVIEW

REVIEWER	Jeffrey Clark Washington State University Dept. of Pharmacotherapy United States of America
REVIEW RETURNED	29-Sep-2017

GENERAL COMMENTS	This is an excellent study that holds great promise to impact the creation of similar pharmacy services internationally. Thank you for the opportunity to review this article. All required changes have been implemented. Just a quick comment regarding the similarity and differences between nursing services in Australia and home healthcare in the United States. In-home medication administration is not routinely done by home healthcare nurses in the united states. This is why I think it was important to draw attention to that detail in my previous review, and you have adequately done this in your revision. Based on the descriptions I found online all other nursing services seem to be similar. However, I cannot determine if a further distinction between the two services is the length of stay on the service. Of note, the average length of state for home healthcare in the U.S. is between 45 to 65 days, which is about half of what it was 20 years ago. This may be important as you talk about the pharmacist's ability to provide follow-up and support after the medication review. Establishing the length of stay may give a time frame over which that will happen.