

PEER REVIEW HISTORY

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ARTICLE DETAILS

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| TITLE (PROVISIONAL) | A cohort study of influences, health outcomes and costs of patients' health seeking behaviour for minor ailments from primary and emergency care settings. |
| AUTHORS | Watson, Margaret; Ferguson, James; Barton, Garry; Maskrey, Vivienne; Blyth, Annie; Paudyal, Vibhu; Bond, Christine; Holland, Richard; Porteous, Terry; Sach, Tracey; Wright, David; Fielding, Shona |

VERSION 1 - REVIEW

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| REVIEWER | <p>Ellen Schafheutle Position: Senior Lecturer in Law & Professionalism in Pharmacy Institution: The University of Manchester Country: UK</p> <p>I am a co-applicant on an NIHR researcher led outline bid around minor ailments, which was submitted in September 2014. I have otherwise not worked with the lead or other authors previously, and I have had no involvement with the study reported in this paper.</p> |
| REVIEW RETURNED | 28-Oct-2014 |

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| GENERAL COMMENTS | <p>GENERAL COMMENTS</p> <p>This is an interesting and very timely paper which reports a study exploring the presentation of what may be considered to be minor ailments to community pharmacies, general practice and emergency departments. It adds to our current understanding, particularly by exploring ED consultations, and it adds benefit by investigating both health outcomes (at 2 week follow-up) and cost (for cost benefit analysis only). I do feel that its findings make an important contribution, but I think that particularly the discussion needs to be more reflective of what the findings mean, what their limitations are and what further research would be required to address these further. I have made very detailed comments to the authors below, which I hope both editors and authors will find valuable to make this into a much stronger paper and contribution to our current state of knowledge.</p> <p>Whilst the authors acknowledge a number of potential study limitations, I think there are others which ought to be included, ideally with suggestions as to how this should be addressed in the future. I make reference to this in my detailed comments below. Importantly, there appear to be some key (significant) differences between those patients presenting to ED as opposed to GP or CP. The patterns observed here would suggest that the perceived severity, experiencing these symptoms for the first time and the perception of urgency are all important to consider in further study.</p> |
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| | <p>A number of specific, detailed comments can be found below, listed under the relevant manuscript headings, with page and line details also provided:</p> <p>ABSTRACT</p> <p>I think the abstract could be rebalanced, by reducing the detail in the methods and shortening the conclusion, thus allowing more key findings to be included, such as those relating to the differences in patient/ condition profiles for those presenting in EDs. The conclusion then ought to be less community pharmacy focussed, as this study does not (yet and on its own) provide evidence of community pharmacies as a recommended NHS setting. It does, of course, suggest a very important potential, but this will need to be explored in further study.</p> <p>INTRODUCTION</p> <p>Page 6, line 18. "Recent estimates suggest that 5% and 13% of consultations in ED and GP, respectively, are for minor ailments that could be managed in community pharmacy." [5] – Is reference 5 to the report of the study on which this manuscript is also based? If so, I am not sure this is appropriate. Are there any other published figures that could be cited? - The same comment applies to page 8, line 53. Is this the report to the study on which this manuscript is based?</p> <p>Page 6, line 32. Is it worth making the point that, over the past 30 years or so, increasing numbers of prescription only medicines have been deregulated to Pharmacy (P) status, which increases the options for treatment available for dealing with minor ailments, without prescription, through community pharmacies. This would help support the point made in line 48, that community pharmacies are an available option which may be cheaper (I don't think we have the evidence as yet that they are; that is part of this study).</p> <p>Page 6, line 34: Will the mostly medical readership of BMJ Open be familiar with local and national NHS funded minor ailment schemes? If not, I would suggest a sentence or two for explanation/ clarification.</p> <p>Page 6, line 38. Should 'may be effective' better read 'appear to be effective'?</p> <p>AIMS & OBJECTIVES</p> <p>Page 7, line 10. I do not think that objective 2 is addressed in this paper?</p> <p>METHODS</p> <p>Page 7, line 43. Would it be valuable to include (n=) how many eligible GPs and pharmacies there were in both areas, and how many expressed an interest in study participation?</p> <p>Page 8 & 9. I am not entirely clear from the description in this section how participants were recruited. It sounds like a researcher was present in each setting, but that – due to restraints imposed by ethics committee approval – potential participants could not be identified by site staff, but that public notices were displayed to</p> |
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| | <p>which participants could respond and then make themselves known to the researcher?</p> <p>Page 8, line 8. Data collection occurred between July 2012 and April 2013. How many researchers were involved in recruitment and data collection? How long did the researcher(s) spend in each setting, i.e. how many days, for how many hours?</p> <p>Page 8, line 10. Requested medicines for the treatment of one of the four MAs were included in recruitment. Would this introduce an inherent bias in the types of patients, and the reasons of going to a pharmacy, selected for study participation? I think this deserves a comment, or acknowledgement in potential study limitations, as we know there are differences between patients who present with symptoms and those who request a particular product. Maybe the authors could provide detail on how many patients sought advice for one of the four MAs, and how many asked for a specific product?</p> <p>Page 8, line 14. The timing for recruitment needs to be justified. Was a time between 9:00 and 18:00 chosen to make sure that all three site options (ED, GP, CP) were indeed available?</p> <p>Page 8, line 28. Again, is the difference in approach to recruitment acceptable? Pharmacy staff directed customers to the researcher, whereas in GP and ED recruitment was reliant entirely on patients spotting posters? See my earlier comment requesting some clarification on how recruitment worked. This also relates to page 9, line 5. Was the process for data collection the same across all settings or not? If not, this ought to be explicit and potentially acknowledged as a possible study limitation?</p> <p>Page 9, line 10. What is mean by 'consultation'? Clarity on this will help clarify the recruitment process. – Ditto for page 11, line 23. "index consultation"?</p> <p>Page 9, line 12. What did the 'non validated measures' ask/measure? How were they developed, and was there really no process or attempt at piloting, validation? I can't quite imagine that. For example, how were the 'triggers for choice of site' questions/options (page 10, line 14) developed and validated?</p> <p>Page 9, line 21. Was any information collected on other co-existing, particularly long-term conditions, and if patients were taking regular prescription medicines? We know from existing research that going to a GP for something else, such as getting a prescription, is a driver/ incentive for patients to raise their minor ailment while they are there. Again, if these data were not collected, this may need to be acknowledged.</p> <p>Page 9, line 30. What cost data were collected?</p> <p>Page 10, line 25. A reference is required to support that "the prevalence of minor ailments is higher in community pharmacies and general practices compared with EDs." Also, were the researchers able to record any data on frequency of presentation of the four MAs in each setting? If there are only very few in EDs, is this a problem? Whereas if the incidence is high then this has much bigger cost etc implications.</p> <p>Page 10, line 24. I don't have much stats expertise, but I don't</p> |
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| | <p>understand why target recruitment in the higher prevalence sites was set as higher, if 81 in each were calculated as sufficient (based on 70% symptom resolution). Relating to this (page 12, line 30) is it appropriate to stop recruitment below the target sample size?</p> <p>Page 10, line 24 and line 29 duplicate the same information/ justification</p> <p>Page 10, line 41: 'valid' percent?</p> <p>RESULTS</p> <p>Page 13, line 30. Resolution rates in community pharmacies (44.3%) do appear higher than in ED (37.3%) and GP (35.7%). Is it likely that these appear "similar" due to the sample size? What impact has the overestimation of symptom resolution of 70% (page 10, line 20) had on the appropriateness of study size calculation and likelihood of this study being underpowered? I think it is something which ought to be commented on.</p> <p>Page 14, line 6. The finding that a higher proportion of participants were sold or supplied medicines in community pharmacies is not unexpected, esp. as patients who went to the pharmacy requesting a particular product were included. Do the authors know whether there was a difference between those who requested specific products and those who presented with symptoms (the latter being more similar to the patients presenting in ED and GP)? Also, do the authors know what medicines were sold, supplied or prescribed? If any were prescription only medicines, these would not have been available as P/ OTC products in community pharmacies.</p> <p>Page 14, line 15-28. I am not familiar with the satisfaction tools the authors used, so in order to be able to make sense of the findings, I think it would be valuable to provide a bit of detail which would aid this understanding.</p> <p>Page 14, line 34-41. Is it worth presenting differences if these were not actually found to be significant?</p> <p>Page 14, line 31. Can these data not be included?</p> <p>Page 14/15. Might there be any other confounders which would impact on QALY scores etc? Would the more well before (which seem to be more likely to go to CPs) also be those who have higher quality of life scores afterwards? Can this be linked sufficiently clearly to the MA and its resolution?</p> <p>DISCUSSION</p> <p>Page 17, line 19. Is it worth mentioning the order of costs, i.e. CP – GP – ED?</p> <p>Page 17, line 26. It is not just the perceived severity of the MA, but a whole range of other (perceived) factors which were higher in ED – as taken from the results section: ED: Significantly younger; different MA profiles (ED highest was musculoskeletal); significantly more likely to experience MA symptoms for the first time, and for shorter onset; symptom severity perceived as higher, and stated that needed to consult in next 24 hours; and more likely to return to ED within the following 2 weeks</p> |
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| | <p>I think these are very important findings which warrant comment in the discussion, and maybe some recommendations as to what further research might be needed to explore this further. One relates to the fact that there is no information on symptom or condition severity, other than the patient's perception of this (admittedly also very important to capture!). Future study may need to include health professional judgement of how appropriate they felt each consultation was, i.e. whether they thought it could or should have been dealt in community pharmacy. The patterns observed here would suggest that the perceived severity, experiencing these symptoms for the first time and the perception of urgency are all important to consider in further study.</p> <p>Page 17, lines 31-46. Whilst I fully appreciate the importance of good communication, I do not think this paragraph is relevant here. There are more important findings the authors should fully reflect on.</p> <p>Page 18, lines 11-16. I think the authors either need to expand this section, or drop it altogether.</p> <p>As noted in a number of earlier comments, I think the study limitations ought to be more clearly and comprehensively acknowledged. This does in no way call into question the validity and importance of this study, which does indeed add to our current understanding, and is important in the current climate of making the most efficient use of ED and GP services, where minor ailments could (and should) be managed through community pharmacies where this is possible and appropriate.</p> |
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| REVIEWER | Helen Boardman Nottingham University, UK |
| REVIEW RETURNED | 31-Oct-2014 |

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| GENERAL COMMENTS | <p>The paper clearly describes a study investigating consultations for a range of minor ailments at pharmacies, GP practices and emergency departments. My main concern with the paper is that the declared hypothesis does not match the sample size calculation and statistical analysis. You state that the hypothesis is that there is no difference but the sample size determination is to detect a difference, as is the statistical analysis, and therefore there is a concern that the same size will have been insufficient to test your hypothesis.</p> <p>Discussion: Need to comment on response rates to the follow-up questionnaire which differ across the settings and the likely influence on the results. Also comment on the number of participants excluded from the costs analysis due to incomplete data which again varies across settings and the likely influence on the results. Page 19, line 37 - you state the outcome was equivalent but you did not test for this - only that there were no significant differences.</p> <p>Tables: 1, 2, 5, 6 & 7 do not explain where the p-values were obtained - i.e. what is compared and what test was used.</p> <p>Typographical and other minor comments:</p> |
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| | <ol style="list-style-type: none"> 1. Introduction, page 6, lines 7 & 12 - states numbers are 'between' then only gives one year date. 2. Page 13, line 17, 51/18 - assuming this should be 51/81 3. Page 14, line 8-12, add p-value for the comparison 4. Page 14, line 24 suggest change to 'significantly different' 5. Table 1, presentation of number of missing participants for age is not consistent with the rest of the table. Baseline EQ5D VAS has no n=?? for the ED 6. Table 2, Outcome of the index consultation - n= missing from overall number of participants 7. Table 7, 'Knowing the doctors/nurses' should this be staff as it also relates to pharmacy staff. |
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VERSION 1 – AUTHOR RESPONSE

A cohort study of influences, health outcomes, and costs of patients' health seeking behaviour for minor ailments from primary and emergency care settings.

Response to reviewer comments

Changes in response to the reviewers' comments are presented in red font throughout the revised manuscript.

Reviewer 1

| <u>Comment</u> | <u>Response</u> |
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| <p>ABSTRACT</p> <p>I think the abstract could be rebalanced, by reducing the detail in the methods and shortening the conclusion, thus allowing more key findings to be included, such as those relating to the differences in patient/ condition profiles for those presenting in EDs. The conclusion then ought to be less community pharmacy focussed, as this study does not (yet and on its own) provide evidence of community pharmacies as a recommended NHS setting. It does, of course, suggest a very important potential, but this will need to be explored in further study.</p> | <p>The abstract and conclusion have been amended to reflect the reviewer's suggestions.</p> |
| <p>INTRODUCTION</p> <p>Page 6, line 18. "Recent estimates suggest that 5% and 13% of consultations in ED and GP, respectively, are for minor ailments that could be managed in community pharmacy." [5] – Is</p> | <p>We have referenced the full report for the full research programme which included this cohort study (reference 5). The derivation of the prevalence estimates are described in this report.</p> |

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| reference 5 to the report of the study on which this manuscript is also based? If so, I am not sure this is appropriate. Are there any other published figures that could be cited? - The same comment applies to page 8, line 53. Is this the report to the study on which this manuscript is based? | The full paper for the study component which derived these estimates is currently under review so we felt it was important and necessary to direct readers to a source of reference regarding these estimates in lieu of a peer reviewed publication. In addition, the most recent estimates prior to those stated in this paper were derived over 10 years ago and we do not consider these to reflect current health service demand or use. |
| Page 6, line 32. Is it worth making the point that, over the past 30 years or so, increasing numbers of prescription only medicines have been deregulated to Pharmacy (P) status, which increases the options for treatment available for dealing with minor ailments, without prescription, through community pharmacies. This would help support the point made in line 48, that community pharmacies are an available option which may be cheaper (I don't think we have the evidence as yet that they are; that is part of this study). | Information has been added regarding the increased number of reclassified medicines. We have retained our statement regarding community pharmacies being "potentially cheaper" because we feel this does not imply that they are cheaper but that this is a possibility. |
| Page 6, line 34: Will the mostly medical readership of BMJ Open be familiar with local and national NHS funded minor ailment schemes? If not, I would suggest a sentence or two for explanation/ clarification. | Information has been added to clarify the purpose of pharmacy-based minor ailment schemes. |
| Page 6, line 38. Should 'may be effective' better read 'appear to be effective'? | This has been changed to 'appear to be effective'. |
| AIMS & OBJECTIVES Page 7, line 10. I do not think that objective 2 is addressed in this paper? | This has been rephrased as "Whether satisfaction with index consultation is associated with health-related outcomes". |
| METHODS | |
| Page 7, line 43. Would it be valuable to include (n=) how many eligible GPs and pharmacies there were in both areas, and how many expressed an interest in study participation? | This information is presented in Appendix 1 and a cross-reference has been inserted in the method to this Appendix. |
| Page 8 & 9. I am not entirely clear from the description in this section how participants were recruited. It sounds like a researcher was present in each setting, but that – due to restraints imposed by ethics committee approval – potential participants could not be identified by site staff, but that public notices were displayed to which participants could respond and then make themselves known to the researcher? | The recruitment process has been clarified. To confirm, promotional materials were displayed in all sites. In addition, staff in all sites could direct patients/customers to the researcher. |

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| <p>Page 8, line 8. Data collection occurred between July 2012 and April 2013. How many researchers were involved in recruitment and data collection? How long did the researcher(s) spend in each setting, i.e. how many days, for how many hours?</p> | <p>Six researchers undertook data collection throughout the recruitment period and this information has been added to the manuscript. We do not have the total number of hours spent on this activity.</p> |
| <p>Page 8, line 10. Requested medicines for the treatment of one of the four MAs were included in recruitment. Would this introduce an inherent bias in the types of patients, and the reasons of going to a pharmacy, selected for study participation? I think this deserves a comment, or acknowledgement in potential study limitations, as we know there are differences between patients who present with symptoms and those who request a particular product. Maybe the authors could provide detail on how many patients sought advice for one of the four MAs, and how many asked for a specific product?</p> | <p>We did not collect data from community pharmacies regarding the nature of the presentation i.e. whether it was a direct product request or the presentation of a symptom/condition. The “presenting symptom” for all index consultations in all sites/settings is presented in Table 1 i.e. the number of patients presenting for each of the four minor ailments.</p> <p>Whilst we acknowledge the considerable literature regarding the effect of different presentation types in community pharmacy (much of which has been undertaken by Watson et al), we do not consider this to be relevant to this study because patients/customers who presented in participating community pharmacies had chosen this setting from which to seek care and as such, it is unclear what type of bias this would introduce in relation to the purpose of this study.</p> <p>No changes have been made to the manuscript in relation to this comment.</p> |
| <p>Page 8, line 14. The timing for recruitment needs to be justified. Was a time between 9:00 and 18:00 chosen to make sure that all three site options (ED, GP, CP) were indeed available?</p> | <p>Recruitment was conducted between 9am and 6pm Monday to Saturday inclusive for the EDs and community pharmacies and from 9am and 6pm Monday to Friday inclusive from general practices. These recruitment periods were selected to reflect the general opening hours of community pharmacies i.e. to represent periods when patients who presented at ED or general practice could have accessed a community pharmacy if they had opted to do so. This information is presented in the “Patient Recruitment” section.</p> |
| <p>Page 8, line 28. Again, is the difference in approach to recruitment acceptable? Pharmacy staff directed customers to the researcher, whereas in GP and ED recruitment was reliant entirely on patients spotting posters? See my earlier comment requesting some clarification on how recruitment worked.</p> <p>This also relates to page 9, line 5. Was the</p> | <p>The researchers were not permitted to approach patients/customers directly in any of the settings. Staff in all settings were encouraged to direct relevant patients/customers to the researchers. Posters were displayed in all participating sites to encourage patients/customers to approach the researchers.</p> |

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| <p>process for data collection the same across all settings or not? If not, this ought to be explicit and potentially acknowledged as a possible study limitation?</p> | <p>The same process for data collection was used across all settings. A sentence has been added to provide clarification.</p> |
| <p>Page 9, line 10. What is mean by ‘consultation’? Clarity on this will help clarify the recruitment process. – Ditto for page 11, line 23. “index consultation”?</p> | <p>A sentence has been added to explain “consultation”.</p> <p>A sentence has been added to explain “index consultation”.</p> |
| <p>Page 9, line 12. What did the ‘non validated measures’ ask/ measure? How were they developed, and was there really no process or attempt at piloting, validation? I can’t quite imagine that. For example, how were the ‘triggers for choice of site’ questions/ options (page 10, line 14) developed and validated?</p> | <p>Sentences and references have been added to describe the measures used and their development/piloting.</p> |
| <p>Page 9, line 21. Was any information collected on other co-existing, particularly long-term conditions, and if patients were taking regular prescription medicines? We know from existing research that going to a GP for something else, such as getting a prescription, is a driver/ incentive for patients to raise their minor ailment while they are there. Again, if these data were not collected, this may need to be acknowledged.</p> | <p>We did not collect any data regarding comorbidities or regular prescription medicines.</p> <p>The promotional materials displayed in all participating sites described the four minor ailments of relevance to the study. Participants will have presented to the researchers because they were experiencing one of the four ailments. The researchers did not explore whether the minor ailment was the primary reason for seeking care. A sentence has been added to the discussion to acknowledge the possibility of participants presenting for primary reason other than a minor ailment.</p> |
| <p>Page 9, line 30. What cost data were collected?</p> | <p>Cost data were derived from the satisfaction and follow-up questionnaires. The relevant statements have presented in red font in the data collection section. The cost data which were collected are described in the Statistical Methods and Analysis section and have been presented in red font.</p> |
| <p>Page 10, line 25. A reference is required to support that “the prevalence of minor ailments is higher in community pharmacies and general practices compared with EDs.” Also, were the researchers able to record any data on frequency of presentation of the four MAs in each setting? If there are only very few in EDs, is this a problem? Whereas if the incidence is high then this has much bigger cost etc</p> | <p>A reference has been added. We did not record the frequency of presentation of the four MAs in each setting: we were only able to document the MA of the participants. The prevalence of minor ailments presenting in emergency departments was estimated during an earlier component of the research programme with 5.5% of adult</p> |

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| implications. | <p>consultations during regular pharmacy opening hours being categorised as minor ailments suitable for management in a community pharmacy setting. This information is presented in the introduction.</p> <p>No changes have been made to the manuscript in relation to this comment.</p> |
| <p>Page 10, line 24. I don't have much stats expertise, but I don't understand why target recruitment in the higher prevalence sites was set as higher, if 81 in each were calculated as sufficient (based on 70% symptom resolution). Relating to this (page 12, line 30) is it appropriate to stop recruitment below the target sample size?</p> | <p>The target recruitment was 80 in each site, but as the prevalence was anticipated to be higher in GP/pharmacy and for the same amount of researcher time on site, we expected that a greater number of participants would be recruited in those locations. Therefore to improve our precision of estimates we decided to recruit double numbers if possible in these higher prevalence settings. Bigger numbers also meant if our actual prevalence was less than expected (which it was) we would still be powered to detect differences.</p> <p>No changes made to the manuscript.</p> |
| <p>Page 10, line 24 and line 29 duplicate the same information/ justification</p> | <p>The duplicated statement has been removed.</p> |
| <p>Page 10, line 41: 'valid' percent?</p> | <p>"Valid" has been added.</p> |
| RESULTS | |
| <p>Page 13, line 30. Resolution rates in community pharmacies (44.3%) do appear higher than in ED (37.3%) and GP (35.7%). Is it likely that these appear "similar" due to the sample size? What impact has the overestimation of symptom resolution of 70% (page 10, line 20) had on the appropriateness of study size calculation and likelihood of this study being underpowered? I think it is something which ought to be commented on.</p> | <p>The resolution rates were lower than expected. This affected the power of the study. However, if the study had been powered to a resolution rate of 40% +/- 10% (which was achieved with this study), we would have required 93 per group. As such, apart from ED, this sample size requirement was met. However, due to follow-up rates of less than the anticipated 80%, the number of patients contributing data to the analysis was less than required to achieve this power. As such, a Type II error may have been introduced i.e. potentially significant differences were not found.</p> |
| <p>Page 14, line 6. The finding that a higher proportion of participants were sold or supplied medicines in community pharmacies is not unexpected, esp. as patients who went to the pharmacy requesting a particular product were included. Do the authors know whether there was a difference between those who requested specific products and those who presented with symptoms (the latter being more similar to the patients presenting in ED and GP)? Also, do the authors know what medicines were sold,</p> | <p>We did not record the way in which customers/patients presented within community pharmacies in terms of direct medicine requests or symptom/condition presentations.</p> <p>All participants from all settings were asked to record the medicines/products that they were sold/supplied as a result of their index</p> |

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| supplied or prescribed? If any were prescription only medicines, these would not have been available as P/ OTC products in community pharmacies. | consultations, however, these data have yet to be analysed and are beyond the scope of this current paper. |
| Page 14, line 15-28. I am not familiar with the satisfaction tools the authors used, so in order to be able to make sense of the findings, I think it would be valuable to provide a bit of detail which would aid this understanding. | Further information is provided regarding the MISS-21 |
| Page 14, line 34-41. Is it worth presenting differences if these were not actually found to be significant? | Yes, we believe the presentation of differences that are not statistically significant is important to avoid selective reporting of only statistically significant findings. |
| Page 14, line 31. Can these data not be included? | For brevity, these data have been presented in tabulated form and we do not wish to repeat these within the text. A cross-reference is provided to guide readers to the relevant Table. No changes have been made in response to this comment. |
| Page 14/15. Might there be any other confounders which would impact on QALY scores etc? Would the more well before (which seem to be more likely to go to CPs) also be those who have higher quality of life scores afterwards? Can this be linked sufficiently clearly to the MA and its resolution? | <p>The linear regression model explored the inclusion of possible confounders when predicting follow up QoL. The adjusted model did so for ailment type, gender, employment, seriousness, length of time had ailment, age and baseline QoL. As the reviewer suggests, baseline QoL was a significant predictor ($P < 0.001$) (Table 3).</p> <p>With regard to symptom resolution, again the adjusted model included presenting symptom, gender, seriousness, belief on timing of treatment, length of time had symptoms, age and baseline QoL, so looking at the effect of site on resolution has been adjusted for these things.</p> <p>No changes to manuscript required.</p> |
| DISCUSSION | |
| Page 17, line 19. Is it worth mentioning the order of costs, i.e. CP – GP – ED? | The order has now been presented to reflect increasing costs. |
| Page 17, line 26. It is not just the perceived severity of the MA, but a whole range of other (perceived) factors which were higher in ED – as taken from the results section: ED: Significantly younger; different MA profiles (ED highest was | We thank the reviewer for these comments and suggestions. We have added a paragraph to the discussion to acknowledge these comments and |

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| <p>musculoskeletal); significantly more likely to experience MA symptoms for the first time, and for shorter onset; symptom severity perceived as higher, and stated that needed to consult in next 24 hours; and more likely to return to ED within the following 2 weeks.</p> <p>I think these are very important findings which warrant comment in the discussion, and maybe some recommendations as to what further research might be needed to explore this further. One relates to the fact that there is no information on symptom or condition severity, other than the patient's perception of this (admittedly also very important to capture!). Future study may need to include health professional judgement of how appropriate they felt each consultation was, i.e. whether they thought it could or should have been dealt in community pharmacy. The patterns observed here would suggest that the perceived severity, experiencing these symptoms for the first time and the perception of urgency are all important to consider in further study.</p> | <p>suggestions.</p> |
| <p>Page 17, lines 31-46. Whilst I fully appreciate the importance of good communication, I do not think this paragraph is relevant here. There are more important findings the authors should fully reflect on.</p> | <p>We have opted to retain the paragraph but moved it later in the discussion. We believe that the finding that symptom resolution is associated with satisfaction is important and novel and communication is an important component of any consultation. As such, we would prefer to retain this paragraph if possible.</p> <p>We agree with the reviewer regarding the need to discuss the other findings in more detail and as such, we have added a paragraph to address this point.</p> |
| <p>Page 18, lines 11-16. I think the authors either need to expand this section, or drop it altogether.</p> | <p>We have retained this section as we believe it is important to provide justification of the range of sites that participated in this study.</p> |
| <p>As noted in a number of earlier comments, I think the study limitations ought to be more clearly and comprehensively acknowledged. This does in no way call into question the validity and importance of this study, which does indeed add to our current understanding, and is important in the current climate of making the most efficient use of ED and GP services, where minor ailments could (and should) be managed through community pharmacies where this is possible and appropriate.</p> | <p>We thank the reviewer for these remarks and appreciate her acknowledgement of the value of this study.</p> |

Reviewer 2

| Comment | Response |
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| <p>The paper clearly describes a study investigating consultations for a range of minor ailments at pharmacies, GP practices and emergency departments. My main concern with the paper is that the declared hypothesis does not match the sample size calculation and statistical analysis. You state that the hypothesis is that there is no difference but the sample size determination is to detect a difference, as is the statistical analysis, and therefore there is a concern that the same size will have been insufficient to test your hypothesis.</p> | <p>The study was not powered on the basis of equivalence.</p> <p>A sample size calculation is always based on detecting a difference of a particular size, while any null hypothesis of a statistical test is expressed as no difference and we use the data to see if there is evidence against his null hypothesis.</p> <p>To avoid confusion on this matter the statement of hypothesis has been removed from the introduction.</p> |
| <p>Discussion: Need to comment on response rates to the follow-up questionnaire which differ across the settings and the likely influence on the results.</p> <p>Also comment on the number of participants excluded from the costs analysis due to incomplete data which again varies across settings and the likely influence on the results.</p> <p>Page 19, line 37 - you state the outcome was equivalent but you did not test for this - only that there were no significant differences.</p> | <p>Whilst the response rate differs across settings, this difference was not statistically significant ($p = 0.29$). This has been added to the manuscript in the results section.</p> <p>The number of participants per setting who contributed to the cost analyses has been added. There was no statistically significant difference in the proportion of participants per setting contributing to the incremental cost analyses.</p> <p>This statement has been revised and the term "equivalence" has been removed.</p> |
| <p>Tables: 1, 2, 5, 6 & 7 do not explain where the p-values were obtained - i.e. what is compared and what test was used.</p> | <p>Superscripts and table footnotes have been added to provide clarity. This is information is also presented in the methods.</p> <p>The superscripts used in Table 4 have been altered to numbers instead of letters to be in line with the rest of the paper.</p> |
| Typographical and other minor comments: | |
| <p>1. Introduction, page 6, lines 7 & 12 - states numbers are 'between' then only gives one year date.</p> | <p>2012/13 is the period for which these figures were provided i.e. the 12-month period between 2012-2013, hence the numbers stated represented the consultations during this 12-month period.</p> |
| <p>2. Page 13, line 17, 51/18 - assuming this should be 51/81</p> | <p>Yes. This now reads 51/81.</p> |
| <p>3. Page 14, line 8-12, add p-value for the comparison</p> | <p>P=0.115 now added</p> |
| <p>4. Page 14, line 24 suggest change to 'significantly different'</p> | <p>This has been changed to not statistically significant.</p> |
| <p>5. Table 1, presentation of number of missing participants for age is not consistent with the rest of the table. Baseline EQ5D VAS has no n=?? for the ED</p> | <p>The presentation now reflects the remainder of the table. N added for baseline EQ5D Vas for ED.</p> |
| <p>6. Table 2, Outcome of the index consultation - n= missing from overall number of participants</p> | <p>The "n" has been added.</p> |
| <p>7. Table 7, 'Knowing the doctors/nurses' should this be staff as it also relates to pharmacy staff.</p> | <p>Yes. This has been changed to "knowing the staff".</p> |

VERSION 2 – REVIEW

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| REVIEWER | <p>Ellen Schafheutle Manchester Pharmacy School The University of Manchester, UK</p> <p>I am a co-applicant on an NIHR researcher led outline bid around minor ailments, which was submitted in September 2014. I have otherwise not worked with the lead or other authors previously, and I have had no involvement with the study reported in this paper.</p> |
| REVIEW RETURNED | 12-Dec-2014 |

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| GENERAL COMMENTS | <p>I still stand by the point I made in relation to the original submission: “Page 8, line 10. Requested medicines for the treatment of one of the four MAs were included in recruitment. Would this introduce an inherent bias in the types of patients, and the reasons of going to a pharmacy, selected for study participation? I think this deserves a comment, or acknowledgement in potential study limitations, as we know there are differences between patients who present with symptoms and those who request a particular product. Maybe the authors could provide detail on how many patients sought advice for one of the four MAs, and how many asked for a specific product?” – I appreciate that, if the authors did not collect this information, they cannot report this. However, I would suggest that people who request a product have often used this before (not necessarily of course) and have a good idea about the condition they are treating and their needs for treatment. Somebody presenting with symptoms, leading to the sale of a particular product, may not be clear about what condition they have. As the option of requesting a particular product was only available in pharmacies, I do still think there may be a possible bias or at least difference in the types of patients who presented in the three settings.</p> <p>I am not convinced that the study limitations have been clearly and comprehensively addressed in the discussion, see my last comment on the original manuscript: “As noted in a number of earlier comments, I think the study limitations ought to be more clearly and comprehensively acknowledged. This does in no way call into question the validity and importance of this study, which does indeed add to our current understanding, and is important in the current climate of making the most efficient use of ED and GP services, where minor ailments could (and should) be managed through community pharmacies where this is possible and appropriate.”</p> <p>I believe that the other reviewer 2 comments have also been addressed satisfactorily.</p> <p>I think this paper is a valid and original contribution to our current understanding and I would recommend publication.</p> |
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