Author's response to reviews

**Title:** Nurse led versus lay educators support for those with asthma in primary care: a costing study

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**Author’s response to reviews:** see over
Dear Editor

Thank you for the reviewer’s feedback about our submission (Manuscript ID MS: 1773047170580474) entitled "An economic evaluation of nurse led versus lay educators support for those with asthma in primary care". We welcome the opportunity to refine our final manuscript. We have now amended our manuscript as suggested.

With best wishes

Yours sincerely

Dr Nicola Roberts
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RESPONSE TO REVIEWER’S COMMENTS

Reviewer’s report (Reviewer 2 - Ed Wilson)

Major compulsory revisions

Overall, this paper could be a useful contribution to the literature. However, I feel it needs reworking somewhat before publication. My major issue is with the measure of effectiveness (frequency of unscheduled healthcare use). This is itself a measure of resource use, not effect. This risks double counting costs and there is no measure of patient benefit included. It therefore cannot be considered an economic evaluation but a cost analysis. I'd recommend changing the title and rewording it as a cost comparison, pointing out (perhaps in the discussion) that there is no measure of patient benefit, therefore a full economic evaluation is not possible, and something that could be considered for future research. Similarly, all references to one intervention being more effective or efficient than the other should be removed (e.g. discussion p16, first sentence and abstract final sentence). Finally, I was also unsure how the per patient costs in Table 4 were calculated as my own calculations resulted in very different means (see below).

Response: The measure of effectiveness for the original randomised controlled trial was unscheduled healthcare (Partridge et al Thorax 2008;63:778–783. doi:10.1136/thx.2007.084251) and is therefore appropriate for our costing study. However as Reviewer 2 points out this is not a measure of patient health gain and therefore we are happy to re-portray this study as a costing study. The title has been changed to reflect this. We separated the interventions’ resource use which was used to reflect costs from the unscheduled healthcare (effect) to ensure that there was no double-counting. As suggested we have amended the abstract, the title and the conclusion of the abstract.

Table 3 has been amended to show the potential median and range of the different usage of healthcare resources for each study arm. An extra sentence has been added to the methods (Page 8) to better explain the calculations for the mean costs per patient in Table 4. The standard deviations have also been added to Table 4.

Please state price year of the analysis

Response: Price was stated in Page 6 (2004/2005)

Abstract, final sentence: As stated above, given that there is not really an outcome measure in this analysis, I don't think it's possible to claim lay-trainers would increase efficiency. I'd also suggest
rewording the final sentence to say something along the lines that contracting lay-trainers would *on average* reduce costs, but there is a high degree of uncertainty around this.

**Response:** Thank you, the abstract has been amended to reflect this.

Training, P7: would nurses have reclaimed accommodation costs from the NHS? If so, this should be included in the training costs.

**Response:** The nurses only underwent a one day training course at Warwick, no overnight accommodation would have been needed for this. The accommodation cost for the lay educators was included in the course costs. For clarity, this has been made amended in the text on page 7.

Delivery, P7: '...many did not claim for the time they spent'. I'd recommend two analyses here - one assuming all costs were claimed as incurred, and another based on only those claimed. Note that there is still an opportunity cost of the lay educators' time as they could have been doing other paid work, or were foregoing leisure time. However, the analysis is restricted to the perspective of the NHS, so arguably these unclaimed costs should not be included.

**Response:** The full costs (including the opportunity cost for time) of the lay educators and nurses were included into the analysis, assuming that the consultations were completed as per the protocol. Lay educators did not claim for all the consultation time they spent as part of the study, a scenario analysis taking 50% off the cost of HC appointments for lay educators has been included in the results (Table 6).

Effectiveness outcome, P8, final paragraph: please state the time horizon of the analysis here.

**Response:** The time horizon of the analysis has been added to the text for clarity on page 6 and 8.

Results, training, P11: How often would lay trainers and nurses require re-training? As the training is a fixed cost, the cost per patient is heavily dependent on the number of patients seen and the frequency of retraining. Staff turnover will have an impact on this too. This needs discussing.

**Response:** Training was undertaken prior to the start of the study, and during the study period no additional training was required. There were some follow-up one day sessions and monthly mentoring sessions which were included in the training costs. However for implementation in
clinical practice regular updating of training should be considered and this has been added to the results section (page 10) and the discussion (page 13).

**Results, delivery, P11, Final sentence:** Table 2 does not report any tests for statistical significance.

**Response:** For this table the unit costs were divided by the number of participants, tests for significance cannot be undertaken.

**Table 4:** Please verify how costs of hospital admission were calculated. I estimate $88*932/205 = £400$ per patient in the practice nurse arm and $109*932/213 = £477$ in the lay educators arm. Please also verify how other summary costs were calculated too.

**Response:** Apologies for the lack of clarity on the calculation of the costs. The costs for each type of healthcare utilisation were completed for each individual patient, totalled and divided by the number of participants. A subset of the study groups had more than one admission or GP attendance. Table 3 and Table 4 have been amended with additional data to provide more clarity and the text has also been amended to provide further explanation.

**Results: effectiveness outcome, P12:** How come hospital admissions were higher in the lay arm yet costs were lower?

**Response:** This has been clarified in the text and in Tables 3 & 4 with additional data. In the practice nurse arm patients had a higher frequency of admissions per patient and there were fewer patients in this arm which made the costs lower in the lay arm (table 3)

**Appendix: please add reference for PSSRU**

**Response:** The reference for PSSRU has been added to the manuscript.

There are one or two typos that need checking throughout the manuscript.

**Response:** The text has been amended, thank you for highlighting these.

Discretionary revisions

**Sensitivity analyses, P9. I'm not sure how useful some of the scenarios are (in particular scenario 1) in the absence of any outcomes data (i.e. measure of patient benefit). As per my comment on Delivery P7 above, I'd recommend restricting the scenarios to a costing based on actual activity and costs incurred where possible (i.e. number of visits actually
completed and costs reimbursed to lay trainers), and one assuming all activity and costs were incurred and reimbursed as per the study protocol (i.e. analogous to PP and ITT).

Response: Sensitivity analyses 1, 3 and 5 have been removed in response to this comment, and an additional scenario analysis with 50% of the consultation costs for lay educators included.

Reviewer’s report (Reviewer 3 - Manuela Joore)
This paper presents an economic study of involving lay educators as opposed to practice nurses in asthma care. Involving laypersons in health care is generally assumed to be cheaper. To my knowledge, this study is one of few, if not the only, studies to explicitly calculate the difference between involving lay persons and health professionals.

Abstract: The type of economic study is not specified in the abstract, nor in the paper. Is this a cost / cost minimization / cost consequence analysis? It would be more clear to the readers if the authors state specifically which type(s) of economic analyses they performed. In the sentence ‘Assigning a cost to this measure...’ It was not clear to me which measure the authors refer to.

Response: Apologies for the lack of clarity. This has also been picked up by reviewer 2 and as recommended the title, abstract and methods have been amended to clarify that this is a costing study.

Methods: The data underlying this work is from 2004/5. This is some time ago. Could you please justify whether these data are still useful to investigate the costs of involving lay educators in asthma care today. It is unclear to me how the costs of the training were calculated. For instance: 19 lay educators were recruited, 15 were trained and 8 actively participated in the trial. How were the costs per patient calculated? Also, 45 nurses were trained, why was this a larger group? Is this to be expected to be the case in real life also?

As I understand correctly, the costs of wages of the nurses/hourly compensation for the laypersons for the training hours were not included in the analyses: what is the justification for this? What were the costs for the different components of the training of the laypersons, and how was this calculated? Why were accommodation costs not included, while the lay educators had residential training?

Response: Although the trial was completed a few years ago, the costing was carried out using the trial data. This study is still relevant as there are few studies which compare the costs of lay
versus usual care and is therefore of interest. Additional information has been added to the methods and results sections to justify.

The nurse numbers were higher for training as there were sometimes more than one practice nurse from each of the participating practices. The cost of delivering the intervention (i.e. staff time) is included in the analysis as shown in Table 2 and referred to in the manuscript as consultation costs. The nurses only needed a one day update to supplement their existing knowledge and therefore accommodation costs were not needed. Lay educators needed more comprehensive training (addressing such issues as consultation skills and record keeping, as well as asthma management) and therefore a residential course was appropriate.

**Why were costs of asthma medication not included? Could inclusion of these costs have altered the results?**

**Response:** The costs of asthma medication has not been considered in this costing analysis, as full data on this was not available. Data from steroid course utilisation shows similar numbers in each arm. Any change in prescription data in the lay educator arms were checked by a GP and it is anticipated that all nurses and lay educators checked medications according to national and international guidelines therefore there should be little if any difference in costs of medications. A sentence has been added to the text (page xxx) to explicitly deal with this comment.

**Please state clearly which type(s) of economic evaluation was/were used (the primary outcome was also costed; why is this not labelled a cost minimization analysis?)**

**Please justify the use of independent sample t tests. Was data normally distributed? If not why was bootstrapping not considered?**

**Response:** As reviewer 3 points out, this evaluation was in effect a cost-minimisation study, however, given the comments from Reviewer 2, it was deemed most appropriate to re-portrayed this study as a costing study. This is now explicitly stated in the title, abstract and methods for clarity. The statistical analysis has been changed as appropriate for the skewed data in this study. Bootstrapping was not considered appropriate or beneficial for this study.

**Results:** Compliance to the intervention was rather low in both groups, although slightly higher in the lay educators group. Taking into account the compliance rate; were these interventions expected to be effective at all? The authors might wish to add some discussion on this matter in the discussion session. The unit cost of an hourly rate for a lay educator is first stated in the Result section. Please mention this in the methods. Also, what is the
source/justification of this amount? Especially as a large number of lay educators apparently did not claim (were these costs included anyway?), I would like to ask the authors to perform a sensitivity analysis on this input.

**Response:** This analysis was a costing exercise for an already published randomised controlled trial, it is not appropriate to discuss the effectiveness/compliance of the intervention as part of this analysis. The hourly rate was the advertised rate for the lay educators at recruitment. This has now been added to the methods section. The costs of the consultations assuming full reimbursement for delivering all consultations was used in the baseline analysis and subsequent sensitivity analyses.

**Discussion:** 1st paragraph. Of course the hourly rate of the lay educator is substantially lower than the hourly wage of a practice nurse, however, the costs of intervention delivery were roughly the same. Please make sure this is clearly stated in the conclusion.

**Response:** The total cost of training and healthcare delivery costs were similar for both arms, this has been amended in the discussion.

Please discuss the generalisability of findings to other jurisdictions than the UK.

**Response:** This has been added to the discussion

**Minor essential revisions**

Please use a similar amount of decimals in all numbers quoted in the paper. Paragraph on effectiveness outcome: pound 160.66 and pound 134.78 seem to be in wrong order.

**Response:** Thank you, this has been changed.

Table 3: Do I understand correctly, these are not costs but number of contacts/events?

Please change wording in the table accordingly. Table 4: Please include unit costs, number of hospital and ICU days to provide greater clarity.

**Response:** Table 3 and 4 have been amended. Information about the unit costs were included in the Appendix.
Reviewer's report (Reviewer 1 - Bradley Chipps)

Methods: Delete or move to online the "sensitivity analysis-scenario analysis" section.

Response: Changes have been made as suggested by the other reviewers this section has been significantly reduced. We have not removed the suggested section as this has now been reduced and the other two reviewers have not suggested deleting any sections or tables.

Results: Place P values for all cost analyses.

Response: Where relevant, this has been done.

Results: Move "scenario analysis" to online

Response: See point 1.

Discussion: Delete Paragraphs 3 and 5.

Response: Paragraph 5 has been shortened with the amendments made to the scenario analysis.

Delete section "can lay trainers be used in real life?"

Response: This section has been rewritten to discuss the roles of expert patients and volunteers in research studies.

Recommend deleting or moving to online- Tables 1,3,4

Response: These tables play an important role in the paper, we would be happy to consider moving some of the tables to an online repository if necessary.