Author's response to reviews

Title: What proportion of prescription items dispensed in community pharmacies are eligible for the New Medicine Service?

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Author's response to reviews: see over
Response to Reviewers’ Comments

Reviewer’s report
Title: What proportion of prescription items dispensed in community pharmacies are eligible for the New Medicine Service?
Version: 1  Date: 10 January 2014
Reviewer: Carlos Alvarez

Reviewer's report:

Major:
1. This paper may be geared more to an English audience than an international audience. The importance of this study, as it is currently written, is unclear. While it is clear that this paper would have a policy impact in England, it is not clear what impact this paper would have in foreign countries.
   We believe that this study has relevance to policy concerning pharmacy services globally as it highlights the importance of basing payment structures on evidence. We have tried to make this clearer by adding the following sentences to the background (second paragraph):
   Research conducted in the UK and Finland has found that adequate remuneration is an important facilitator to service provision and where payment is seen as inadequate, it can inhibit the uptake of services [2-5]. The payment structure for the NMS has been identified as a potential barrier to implementation [6].

   And the following paragraph to the discussion (third paragraph):
   Studies examining the provision of other UK pharmacy services have found that adequate funding is important to the success of a service [2-4]. This is not unique to the UK; research conducted in Finland has also found that pharmacies must be adequately reimbursed for providing a service if the service is going to be successful long term [5]. This study suggests that the assumptions used to calculate the funding envelope for the NMS are flawed as the actually opportunity rate to provide the service is less than the theoretical rate that underpins the potential funding available. This highlights the importance of evidence based methodologies to calculate funding allocation and applies not only to service in the UK but pharmacy services worldwide.

2. It is unclear what makes a prescription eligible for NMS services. Since this is the primary outcome, it is important to have a clear definition of NMS. Are there other conditions that must be met to become eligible? This may help the reader understand why you decided to cluster pharmacies by distance.
   The four conditions eligible to receive the NMS have been added, and the eligibility criteria for the service has been explained by adding in the background (end of first paragraph):
   ‘A patient is eligible to receive the NMS if they are prescribed a new medicine indicated for one of and appears on the list of eligible medicines in the service
specification.[1] The NMS can only be conducted where the patient (or, in the case of children, patient’s parent) can provide written consent.’

3. The exclusion of pharmacies from the study due to having too low (<1,000 prescriptions/week) or high (“so busy”) prescription volume may have led to biased estimate of eligible prescription items. This needs to be highlighted in the limitation section of the discussion.

This has been added as to the limitations (third paragraph):
‘In this study pharmacies were excluded if they dispensed less than 1000 items per week or if the pharmacy’s staffing levels required more than one member of staff to take in and hand out prescriptions as this could have introduced potential selection bias. These demographic exclusions may reduce full generalizability and is a limitation of the study.’

**Minor:**

1. **Abstract**
   a. **Methods:** No need to specify which statistical package was used in the study. Best kept in the methods section within the body of the paper.
   
   This has been removed from the abstract.

   b. **Conclusions:** Page 3; please include comma after “Therefore,…”
   
   The comma has been added.

2. **Background**
   a. **Page 4:** Please clarify the difference between a community pharmacist and a superintendent pharmacist. This may be country specific.

   We have added the following statement after ‘superintendent pharmacists’ to clarify (first line, page 5):
   ‘a strategic role, taking ultimate responsibility for pharmacists employed by their organizations, and the services they provide’

   b. **Page 4:** It is unclear why distance would affect whether an item is eligible.

   We have clarified this point, changing the sentence to (line 5 page 5):
   ‘They suggested that the location of a pharmacy would affect the numbers of eligible items dispensed, as patients prescribed a new medicine by their doctor are more likely to get the prescription dispensed at the nearest pharmacy, even where this is not the pharmacy they regularly use. Additionally they suggested that this could mean that pharmacies co-located with health centres would see more eligible items than pharmacies located further away from GP practices.’

   c. **Page 4:** What is a “high street pharmacy”? ‘high street pharmacy’ has been changed to ‘pharmacies located further away from GP practices’ (line 10 page 5).

   d. **Page 4:** What drugs are listed as MDA? This can be further explained in the methods, if desired.
MDA prescriptions are a separate type of prescription used to treat substance misuse rather than referring to the drugs themselves. We have added the following information to help clarify this (line 12 page 5): (instalment prescriptions used in the treatment of substance misuse)

e. Page 4; Please define PSNC.
PSNC has been defined (page 5, 4 lines from bottom).

3. Methods
a. Page 5; The sentence “For convenience, the pharmacies sampled were located in the Nottingham area as that was where the researcher was based” should be removed. The previous sentence can read “This study was carried out in pharmacies in Nottingham belonging to a large chain to minimise inter-pharmacy variation.”
This has been amended as suggested (methods, first sentence).

b. Page 7; Is the estimate for the percentage of prescriptions items eligible for NMS 0.5% or 0.05%?
0.05% was an error; this has been changed to 0.5% (page 9, final line of methods).

c. Page 7; May want to consider using non-parametric one sample test such as the chi-square or one-sample binomial tests to determine statistical significance.
Unfortunately 1 sample t-tests cannot be used for proportions however the z value calculated from the difference between two proportions has been included (page 9, final line).

4. Discussion
a. Page 9; Please consider changing “anti-platelets” to “anti-platelet agents”.
This has been changed in the four places they are mentioned in the text.

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Needs some language corrections before being published
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests: I declare that I have no competing interests

We would like to thank the reviewer for their comments.

Reviewer’s report
Title: What proportion of prescription items dispensed in community pharmacies are eligible for the New Medicine Service?
Version: 1 Date: 16 January 2014
Reviewer: Kelly R Reveles
Reviewer’s report:
General: This paper describes the actual proportion of prescriptions eligible for the New Medicine Service in England, compared the predicted proportion. Although this topic is interesting, the paper lacks development in relevance and significance. The questions posed by the authors are well-defined, but need greater clarification on methodology and results. There are several areas that need to be addressed prior to accepting this manuscript for publication (see Major Compulsory Revisions below).

Major compulsory revisions

Abstract

1. **Background:** Include secondary objectives in the last sentence.
   The following sentence has been added:
   
   ‘The study also aimed to investigate whether the proportion of prescription items eligible for the NMS is affected by pharmacies’ proximity to GP practices.’

2. **Methods:** Specify inclusion/exclusion criteria for prescriptions.
   The following sentence has been added:
   ‘All NHS prescriptions were included in the sample, with only private, non-NHS prescription excluded’.

3. **Methods:** Add methodology for identifying locations near GPs.
   This has been amended to include:
   ‘calculated using postcode data available on the NHS choices website’

4. **Results:** Add your original sample size (8005) and final sample size (17).
   The sample size was 8005, the 17 refers to the number of prescription items within the 8005 that were eligible to receive the NMS. We have clarified this by adding the following sentence:
   ‘A total of 8005 prescription items were collected (a minimum of 1000 items per pharmacy) of which 17 items were eligible to receive the service.’

5. **Results:** The abstract says that 29.6% of prescriptions were picked up by patient representatives, but the results and discussion say that 28% were. Double check numbers and be consistent.
   This was an error and has been amended.

Background

1. **Paragraph 1:** Please list the four conditions that were selected for the NMS rollout (asthma and COPD, type 2 diabetes, antiplatelet/anticoagulant therapy, and hypertension)
   The four conditions have been added.

2. **Paragraph 2:** Do you have any additional references for the statements regarding pharmacists’ attitudes on the NMS opportunity rate and the reasons behind this? Please avoid the use of “unpublished” data if possible.
Ideally we would like to cite published sources however no published information was found after an extensive literature research, including grey literature. The unpublished data cited are the results of another part of our larger project which we hope to publish in the near future.

3. Paragraph 2: Since your objectives include identifying NMS opportunities near GPs, add more discussion and references that drove this hypothesis. Are there studies that have quantified the number of prescriptions filled at pharmacies near GPs or that prescriptions filled at pharmacies near GPs are more often for chronic conditions?

This hypothesis was based on data collected in another part of this project and anecdotal evidence. There is no data regarding dispensing figures for individual pharmacies or different types of pharmacies as this is commercially sensitive.

4. Paragraph 3: please be specific as to your primary and secondary outcomes.

This has been clarified and the paragraph now reads:

‘This study’s primary aim was to investigate the actual proportion of items dispensed in community pharmacies that are eligible for the NMS in practice and to compare this to the theoretical proportion of 0.5%. In addition the proportion of items eligible for the NMS at pharmacies close to General Practitioner (GP) practices was compared with those further away to determine whether distance from a GP practice affects the proportion of eligible items presented in pharmacies.’

Methods

1. Paragraph 1: Beside location, was there a systematic way of selecting pharmacies for inclusion? There were 8 pharmacies selected, but are the more pharmacies in that chain in the area for which you selected from?

There were 12 pharmacies after applying the exclusion criteria. There were 2 pharmacies that were <100m from GP practice (both were sampled), 9 that were 100m-500m (5 sampled) and 1 that was >500m away from the GP practice (sampled). When choosing 5 pharmacies to be sampled out of the 9 we were dependent on the willingness of the pharmacies to participate. This has been clarified in the paper (methods, paragraph 3).

2. Paragraph 1: Please add to your description of the sample size calculation that it was based on the primary outcome.

This has been added to the methods, paragraph 1.
This showed that 7852 prescription items were needed in total to detect a 0.5% difference (a 0.0025% change in prescription items eligible for the NMS), allowing for clustering effects, therefore data from at least 7852 prescription items would be collected.

What was the difference from the expected 0.5% NMS rate that you used to calculate the sample size?
We used a 0.5% difference i.e. we could detect a difference in the NMS rate as small as 0.0025%. The following sentence in the methods paragraph 1 has been changed to:

‘This showed that 7852 prescription items were needed in total to detect a 0.5% difference (a 0.0025% change in prescription items eligible for the NMS), allowing for clustering effects, therefore data from at least 7852 prescription items would be collected.’

3. Paragraph 1: In the abstract, you say that you collected 1000 consecutive prescriptions from each pharmacy, but in the methods you say that you collected 8000 total. Please specify and be consistent.

In both the abstract and the methods it now includes both 1000 prescription items from each pharmacy totalling 8000 items.

4. Paragraph 3: What was the prescription cutoff for “pharmacies so busy that more than one researcher would be needed to collect data?”

The threshold for pharmacies being too busy for the study was not based on prescription volume but rather where the pharmacy staffing levels required more than one member of staff to take in and hand out prescriptions. The sentence in the methods (paragraph 3) has been changed to read:

‘the pharmacy’s staffing levels required more than one person to receive and hand out prescriptions, meaning that more than one researcher would be needed to collect the data’

5. Paragraph 3: Be very specific as to the “atypical demographics” for which you excluded pharmacies and give reasons why you excluded those.

The sentence in the methods (paragraph 3) has been changed to:

‘...or if the pharmacy primarily catered to an atypical demographic meaning that the results from the pharmacy would be unlikely to reflect the average demographics seen by pharmacies.’

6. Paragraph 3: Please provide the number of pharmacies that were excluded for each exclusion criterion.

This has been added:

‘One pharmacy was excluded from the study because they dispensed less than 1000 items per week. Two pharmacies were excluded from the study because they required more than one person to receive and hand out prescriptions. One pharmacy was excluded due to its atypical demographic. This pharmacy was located within a university health centre and mainly caters to young people who are unlikely to require medicines for hypertension, COPD, type 2 diabetes or need antiplatelets or anticoagulants as these are conditions mainly affecting older people. Therefore this pharmacy could be expected to have a lower opportunity rate for the NMS than other pharmacies.’

7. Paragraph 4: You need to be very specific as to the inclusion and exclusion criteria for prescriptions. This should include 1) the conditions that are eligible for NMS, 2) how prescriptions were classified as for eligible conditions under NMS, 3) whether MDA, home care, and delivery prescriptions were excluded, and 4) and consent eligibility (did you use an age cutoff, was parental consent acceptable, and were patient representatives excluded from consenting?).
All NHS prescription items were included in the study regardless of whether they were eligible for the NMS or not. In order to clarify this I have added the following sentence to the background (paragraph 1):

‘A prescription item is eligible to receive the NMS if it has been prescribed for the first time for one of the four conditions and appears on the list of eligible medicines in the service specification.[1] The NMS can only be conducted where the patient (or, in the case of children, patient’s parent) can provide written consent.’

The following paragraph to the methods section (paragraph 4):

‘In each pharmacy the data was collected by a researcher taking in and handing out prescriptions to patients. Prescriptions were included in the study if they were an NHS prescription, regardless of who collected the prescription, what type of NHS prescription it was, or whether it was dispensed as part of a care home service. Prescriptions were only excluded from the study if they were private non-NHS prescriptions. A prescription item was eligible to receive the NMS if it was newly prescribed for hypertension, type 2 diabetes, asthma/COPD or was an anti-platelet or anti-coagulant agent, and the medicine was included in the list of medicines eligible for the NMS as specified in the service specification.[1] A prescription item meeting these criteria for the NMS was recorded in the study as eligible to receive the service regardless of who collected the prescription or whether it was part of a care home service. Therefore the study recorded the number of prescription items dispensed that were eligible to receive the NMS as well as actual NMS opportunities.’

Results
1. Paragraph 1: If you have this information, it would be really nice to know some of the characteristics of the pharmacies, like average number of prescriptions dispensed and number of pharmacists trained in NMS.
   Unfortunately we are unable to share this information as it is commercially sensitive.

2. Paragraph 2: Again, stating your inclusion/exclusion criteria in the methods is critical. How did you go from 6080 non-MDA, non-home care items to just 20 eligible prescriptions?
   Please see comment no.7 in methods.

Discussion
1. Paragraph 5: The reason for the differences in study conditions compared to national rates may also be due to the geographic location of the pharmacies chosen for the study (i.e., are the demographics in Nottingham different that the rest of the country?).
   The following sentence has been added (paragraph 7):

   [1]
Another possible reason for the difference between the study data and national data is that all the pharmacies sampled were in the same geographical location (Nottingham) and the demographics could potentially be different to demographics nationally.

2. New paragraph: Please create a separate paragraph at the end of the discussion that specifically states the limitations of the study, including sample size and generalizability based on location of pharmacies chosen. The limitations have been explicitly stated under a new subheading ‘limitations’ at the end of the discussion.

3. Paragraph 8: In this paragraph, you discuss that data collection was spread over five months. You need to expand on this in the methods section. If the pharmacies were sampled at various times, this should be included as a limitation of the study, as number and type of prescriptions dispensed can vary over time.

This has been included in the limitations:
‘The pharmacies in this study were sampled over 5 months which could be a limitation as number and type of prescription items can vary over time, meaning that the data collected from an individual pharmacy may not reflect its long term dispensing patterns. However, by sampling pharmacies over 5 months the effect of seasonal prescribing patterns on the whole sample was reduced.’

4. Paragraph 9: This winter storm only seems relevant if you aimed to collect 8000 prescriptions total versus a certain number per pharmacy, which would mean the certain pharmacies had more prescriptions dispensed. However, you state in the abstract that 1000 prescriptions were collected for each pharmacy. This paragraph has been removed.

5. Paragraph 9: This paragraph, addressing funding, seems that it would be the most important thing to discuss and should be addressed much earlier in the discussion. You really need to use this information to talk about the importance and relevance of your study. You also need to further describe how payments to pharmacies occur as part of NMS, so that readers have a better understanding of where the NMS funds go and what happens to the funds if the pharmacies do not meet the 0.5% NMS targeted rate. In other words, what are the public health implications of your study? What effect could it have on community pharmacies or the program in general?

This paragraph has been moved to earlier in the discussion and the funding mechanism and destination of unclaimed funding has been included. The second paragraph now reads:
‘Pharmacists were able to earn up to £55m in the first year of the service based on pharmacists performing the NMS for 0.5% of their prescription items each month. In order to be remunerated for the NMS conducted, pharmacies claim payment each month for completed NMS in the same way that payment is claimed for NHS prescriptions dispensed. The results from this study
would suggest that pharmacists were not able to access the full potential funding as the number of opportunities to carry out the NMS is less than 0.5% of their prescription items. NMS funding is outside the total agreed funding for pharmacy contractors, and if it is not earned then contractors are no longer able to access it and is not guaranteed to be made available for other public health initiatives. In April 2012 the PSNC communicated that theoretical assumption may not reflect the rate of NMS opportunities for all pharmacies and has stated that it will be reconsidered in the future.[2] This study suggests that the actual rate of NMS opportunities is less that the theoretical rate meaning that it would be possible to widen the scope of the NMS by including other conditions to increase the number of opportunities a pharmacist has to conduct the NMS and consequently the number of patients who could benefit, without exceeding the maximum investment allocated.’

Conclusions
1. Paragraph 1: Also address the conclusions of your secondary outcomes.
The following sentence has been added to the conclusion:

‘This study did not find a significant difference in the rate of NMS opportunities between pharmacies located close to GP practices compared to those further away.’

2. Paragraph 1: If you are going to state policy implications in your conclusions, they need to be much more developed in the background and discussion sections.
The following section has been added to the background (page 5, 7 lines from the bottom):

‘The implication of this is that pharmacies may not be able to access the full amount of funding allocated to the NMS if the rate of opportunities to provide the NMS is less that the theoretical rate of 0.5%. The Pharmaceutical Services Negotiating Committee (PSNC) has acknowledged that the theoretical assumption may not reflect the rate of NMS opportunities for all pharmacies and has stated that it will be reconsidered in the future when data regarding the actual rate of NMS opportunities are available. ’

In addition this has been further expanded in the discussion section, please see the response to comment no 5 for the discussion.

Minor essential revisions
Background
1. Paragraph 2: define “PSNC.”
This has been done

Methods
1. Paragraph 1: Since your sample size calculated to 7852, you should say that
you aimed to collect at least that many prescriptions. Saying that you would collect 8000 is a little misleading since you actually collected 8005.

- This has been changed

2. **Paragraph 3: define “m.” Is this miles?**
   - Meters has replaced ‘m’.

3. **Paragraph 4: change “the data was” to the data “were.”**
   - This has been changed

4. **Paragraph 4: define NHS**
   - ‘NHS’ has been defined.

### Discretionary revisions

#### Abstract

1. **Conclusions: Use the conclusions from the manuscript text for the abstract.**
   - This has been done.

#### Background

1. **Paragraph 1: It would add depth to the background to address the goals of the NMS (e.g., improve patient adherence) and requirements for pharmacists to provide NMS.**
   - The following sentence has been added (paragraph 1):
     - ‘The service aims to improve adherence to medicines and reduce medicines wastage.’

2. **Paragraph 3: You may consider adding a third objective to your study to determine the reasons why patients are ineligible or have missed opportunities for NMS.**
   - This was not one of our objectives when planning the study and the data collected about this are so few we do not feel it appropriate to include it as an objective.

#### Results

1. **It would be really nice to have a flow chart that starts with the number of prescriptions collected, then the number of items still included after each exclusion criteria is applied. Consider adding this as a Figure.**
   - No prescriptions that were collected in this study were excluded. The sample size was 8005 prescription items. The 17 items mentioned refers to the number of prescription items that were eligible to receive the NMS within the sample size of 8005.

#### Discussion

1. **Paragraph 3: Hypothesize as to the reasons a greater proportion of pharmacists engage in NMS compared to MUR.**
   - The following sentence has been added to the paragraph (now paragraph 5):
     - A study carried out before the implementation of the NMS suggested that pharmacist engagement and NMS uptake would be greater than it was for MURs because when MURs were introduced it was seen as a change in direction for pharmacy requiring a cultural shift, whereas the NMS was seen as a natural extension of the role of community pharmacists.[6]

#### Conclusions: none.

#### Tables

1. **Table 1: This table isn’t necessary, as the data are presented in the text.**
   - This table has been removed.
2. Tables 4: This table is probably not necessary; however, if you choose to delete it, please provide these numbers in paragraph 2 of your results section. This table has not been removed as we feel it is clearer in a table.

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Needs some language corrections before being published
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:
I declare that I have no competing interests.

We would like to thank the reviewer for their comments.