Author's response to reviews

Title: Complementary or alternative? The use of homeopathic products and antibiotics amongst pre-school children

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1559573450146160 - Complementary or alternative? The use of homeopathic products and antibiotics amongst pre-school children

Dear Dr. JA Le Good

Thank you very much for considering this paper for *BMC Family Practice*. We very much appreciate the comments from the reviewers and believe that they have helped to improve the paper.

Of particular concern was that the data were collected from 1995-1997 and reliant on parental reporting. However:

1) ALSPAC is by far the largest and most comprehensive community dataset currently available in the UK and only one, much smaller study (n=1230) has previously attempted to obtain prevalence rates of homeopathic product use in children from a community population. Thus, this study makes a valuable contribution that will inform future research.

2) Although we do not know if these data represent homeopathic use at the current time, a hospital survey in Cardiff carried out in 2004 found that homeopathic product use amongst children in its sample was 8%, which is comparable to our prevalence rate of 6%.

3) We appreciate concerns about parental reporting, which are present in any study of this type. But without knowing the direction and magnitude of the response and recall biases, it is difficult to know how they may have affected this study. Recall bias may have underestimated antibiotic and homeopathic product use while response bias may have overestimated these. So, the biases may have compensated for one another.

We have addressed the specific comments of each reviewer below.

**Mathie**

1) There needs to be greater clarity in describing numbers of children and questionnaire responses: figures of 13971, 12064 and 9723 are given without a stated link between these sub-sets.

This has been clarified in the text. “Of the 13971 children originally recruited into the cohort, 12064 still remained in the study at the 4.5 year timepoint. From these, 9723 questionnaires were returned with data of interest complete giving a response rate of 80.3%.”

This paper has now been cited.

3) Results reports multivariate analysis that does not appear to reconcile with data presented in Table 3: for "TV watched", the adjusted OR factor is not included as P>0.05.

We incorrectly included tv watching in our reporting of the results with regards to Table 3. We have therefore removed this from the results section.

4) In Implications of the Study, it would be worth making the point that children with wheeze and food allergies were more likely to use homeopathy.

Amended

5) In Conclusions, the word "promoted" seems incorrectly used.

The conclusion has been changed to “considered”.

6) Table 3: Maternal smoking categories are presumably numbers of cigarettes per day.

Amended

7) Discretionary Revisions (which the author can choose to ignore)
P4, para 1, line 13: Insert "alternative or complementary therapies" between "ensure that if" and "such as homeopathy".

Amended

Boon

1) Abstract - conclusion: "Use of homeopathic products was not associated with increases or decreased antibiotic consumption, suggesting that promoting homeopathic medicines as an alternative to antibiotics, while potentially important, needs to be further investigated." -- this conclusion goes far beyond the data presented in the paper which simply tell us there is no association between antibiotic use and homeopathic medicine use. The phrase "while potentially important" should be removed as the study sheds no light on the importance or efficacy of homeopathy as an alternative to antibiotics. I am also not sure that the data tell us that further investigation is necessary -- why if there is no association? I would like to see the conclusion limited to what the data
This has been revised to: “In this observational study, the use of homeopathic products was not associated with decreased antibiotic consumption, suggesting the use of homeopathic medicine complements rather than competes with the use of antibiotics in pre-school children. The characteristics of mothers giving homeopathic products to their children are similar to those associated with adult self-administration.”

2) Background - medicine, antibiotic and health services use among pre-school children: this section focuses on the "high" use of antibiotics -- arguing that it is too high, but fails to make a key point -- it is not the high use of antibiotics per se that is the problem, but rather high use of unnecessary or inappropriately prescribed antibiotics for viral infections that is the problem. I think this point needs to be made explicitly (rather than implicitly) in this section.

This has been revised to: “Inappropriate or unnecessary use of antibiotics for viral infections in children causes concern for policy makers, commissioners, clinicians, complementary therapists and parents [6] [7] [8] for two reasons.”

3) p. 12 conclusion -- the re-statement of the study aim in the conclusion ("...to explore the ALSPAC dataset to determine if homeopathic products could be promoted as alternative to antibiotics...." -- is both fundamentally different from the original aim as stated earlier in the paper (which focused on looking for a possible association) and cannot in fact be answered with with this kind of survey data. Determining if homeopathic products can be promoted in place of antibiotics depends on knowing what the antibiotics are being prescribed for and the effectiveness of homeopathic for that indication -- all things missing from this survey data. As with the abstract conclusion, the conclusion in the body of the paper needs to be limited to the findings discussed.

This has been revised to: “The aim of this study was to use observational data to investigate if homeopathic product users consumed fewer antibiotics and to describe the characteristics of pre-school children given homeopathic products. Use of homeopathic products was not associated with increased or decreased antibiotic consumption. Up to date, experimental data are needed before homeopathic medicines could be considered as an alternative to antibiotics.”

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Busato

1) The data were collected more than ten years ago. The perception of CAM in the general population may have changed quite dramatically in the meantime. The overall relevance of the results is therefore questionable.

This has been addressed at the beginning of this letter. In the text, this has been addressed in the following way. “These data are now over ten years old,
but with the exception of one smaller study of 1230 children [23], there are no other large community based contemporary studies addressing these questions. Furthermore, a more recent hospital based study found that 8% of the children in its sample had used homeopathic products, which is comparable to our results of 6% for prevalence.[21]”

2) Recall and selection bias may be a real problem of this study (as acknowledged by the authors). However, without any information about the direction and extent of bias it remains difficult to assess the value of the data presented in the paper.

This is a difficulty faced by all retrospective surveys. Without more data from those not returning questionnaires, knowing the effect of response and recall biases is problematic. However, in the discussion we suggest that recall bias may have underestimated antibiotic and homeopathic product medicine use and that response bias may have overestimated these. To a greater or lesser extent, the biases may have compensated for each other.

3) Multivariable logistic regression was used to analyze the data and variable selection was based on p-values obtained through bivariate analyses. Based on the data given in table 3, it is, however, possible that some explanatory variables were correlated; e.g. associations between health status data of children or between maternal anxiety and use of medical services. The reliability of individual effect estimates may consequently be compromised. Some additional analyses are therefore needed to evaluate the association between explanatory variables and to assess the respective effects on regression parameters.

We performed diagnostic tests in STATA and there was no evidence of collinearity for the final variables included in the predictive models, based on variance inflation factors (which were all around 1.00). In the text we have stated: “Collinearity amongst the final set of explanatory variables was assessed by evaluating variance inflation factors. There was no evidence of collinearity based on these values.”

McLay

1) The data appears to be 10 years old and reliant on parental reporting.

We have addressed this at the beginning of the letter and in Busato 2.

2) It is not entirely clear to me why the authors chose to look at homoeopathy and antibiotics. I would have thought that the number of GP visits in the
preceding month/12months or the number of prescriptions issued would be of more relevance.

We considered this initially, but data on number of GP visits and number of prescriptions were not collected in this ALSPAC questionnaire – nor in those preceding it.