Author's response to reviews

Title: National Essential Medicines List and Policy Practice: A Case study of China’s Health Care Reform

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Author's response to reviews: see over
Dear editor,

Thank you for your kind response regarding our manuscript titled “National Essential Medicines List and Policy Practice: A Case study of China’s Health Care Reform”. I appreciate the suggestions from you and two reviewers and had made the corresponding corrections and changes.

Editor's comments:

Please remove statement on data availability from Competing Interest section and place this in the methods section.

I have removed statement on data availability from Competing Interest and placed this in the methods section (pp 5).

Reviewer 1

1、Much of the discussion in the paragraph immediately below “insert table 1” is a discussion of the issues underlying the implementation of the reform of 2009. They are presented very briefly with too little detail for the reader to understand the magnitude of the problems. This paragraph is not necessary since the background is discussed in the paragraph above and the specifics of the study are in the last paragraph of the introduction.

This paragraph was removed from the manuscript. Some of the relevant material was moved to the previous paragraph.

2、The methods section also includes much that is not directly related to the specifics of the study. For example, whether or not the essential medicines system is one of the biggest achievements of China’s health care reform is irrelevant for a methods section of a scientific paper. I suggest you focus just on the methods you used for this particular study.

The part that is not directly related to the specifics of the study was removed from the manuscript. There are some improving in method section.

3、In the methods part, I could not understand the idea of co-selection rate as explained.
The definition of co-selection rate was updated (see revised manuscript). The co-selection rate is the quotient of the total number of supplemented medicines from 29 provinces (5995) and the number of unique medicines (2064). That means on average every supplemented medicine was selected by 2.9 (5995/2064) provinces.

4. Under results, the last paragraph of page 6 gave judgments about whether there were enough medicines on the list in various categories without data about what was missing. For example, you write that there should be more medicines for “colds”. Table 2 lists 9 antipyretics, 7 respiratory, and 4 antiallergic medicines. It is impossible for a reader to know what is missing that is effective for “colds”. You write that the medicines for children and dosage forms are insufficient. This is known to be true globally. But your paper gives no indication of the magnitude of the problem in the Chinese list. These are just examples of the conclusions you list in your results section without data in the results that led you to these conclusions.

First, these conclusions are derived from results of DELPHI method (see methods section). Meanwhile, the authors believe that common compound preparations to treat diseases such as cold are lacking although there are individual drugs to treat certain symptoms. The sentence was rephrased to clarify this conclusion. Discussion about medicines for children was updated with references to support our conclusion. More data were provided in support our conclusion that there are not enough specialty medicines on the List (see revised manuscript).

5. Your discussion covers many ideas that may be valuable but are not focused on your data. For example, you state that the List has been playing a positive role in guarantying essential medicines. Yet you present no data about availability of essential medicines at the primary care sites before and after the implementation of the List. What do you mean by “guarantying”?

The primary health care institutions are required by the essential medicine policy to stock drugs on the List. Since the majority of patients fill their prescription at these institutions, the List helped to ensure the patients’ access to these essential medicines. The first paragraph under the Discussion section presented this background information. In addition, the inclusion of proven effective drugs on the List helps to reduce the irrational use of medicines in practice. We added additional data and information about improvement in drug access and rational prescription in the first paragraph and Discussion section.

Your discussion on pp10-14 is far ranging and discusses many issues about
China’s health care but it is not focused on the data in this study. The discussion in a scientific paper usually stays focused on the data itself and what it means.

Some irrelevant discussions about China’s health care and prescription practices in other countries were removed (pp 13-14).

Reviewer 2

1. Methodology requires small revision: as described in greater detail below, this paper might be better referred to as a Case Study and Discussion Paper. This should perhaps be added instead of what is written in the "Sample" section. Similarly, it was not entirely clear of the purpose of the interviews and questionnaires. Was this in the determination of the 'soundness' of the choices made for the EML only? It would be good to know a little more about this process and the process of analysis.

   Case Study replaced “Sample”. The purpose of the interviews and questionnaires is to help determine the soundness of the selection made for the EML. The third paragraph in the Data Collection and Analysis explained the process and analysis. Delphi method provides a credible and scientific way to answer certain questions. Experts do not know each other and they answer questions in back to back style to ensure the impartiality of the results. The contents of the questionnaire are to evaluate each drug on the list. Additional information about the process was added to the manuscript.

2. And on that note, this would require a more balanced list of alternative recommendations. Does the data really support the abolishment of the supplementary lists? Or does the data simply highlight the need for a more evidence based approach in the selection of the medicines on the supplementary lists? It seems clear that guidelines were not followed. Could a revision process at a central level be an alternative? There are no real options provided.

   Similarly, a number of challenges have been highlighted in the paper on why EMLs are not providing the results that were intended. While I actually agree that allowing some other medications not under EMLs might improve the situation, again this does not logically I follow the results provided. The study showed that the lists have some poor selection and are not founded on evidence, but does not really address the rational prescribing situation in China or the many factors affecting the system in China. These thoughts can be included in the paper, but it should be clear that this is not a direct conclusion from the results of the analysis carried out by the authors.
In the short term, the supplementary lists certainly need improvement to take an evidence based approach. But ultimately, the EML should learn from the provincial experiences and include most of drugs which fit the new selection criteria and meet local medical needs. Revision at the central level is exactly what the authors advocated in the manuscript (the first paragraph in the Advice section). The authors had three reasons for recommendation of abolishing supplementing policy. Firstly, if Revision was done properly, the national essential medicines should meet the most of basic medication needs of primary health care institutions. Secondly, even after the provinces added essential drugs, primary health care sector still can’t meet the actual needs of patients. Thirdly, the provincial supplemented lists were still shown to be unreasonable and random. They are affecting the availability of national essential medicines and the rational use of medicine.

Because of the specificity of the medical industry and the individual variations and the conflict with the current medical insurance system, that the physician only can prescribe drugs under EML is irrational. Meanwhile, based on the practice, even essential medicine list is scientific and reasonable, it couldn’t satisfy all the needs form doctors and patients. Thus, the authors recommended that physician should be able to prescribe other medicines not on EML under their discretion within a certain range. Meanwhile, effective measures should be put to place to encourage doctors to prioritize the essential medicines. However, allowing some other medications not on EMLs limitedly instead of supplementing policy could only remedy the problem partly, because there are many factors in China which causes irrational drug use. Poor selection is one of reasons. These factors main include: (1) Medical personnel don’t have the required level of knowledge and capability as well as poor prescription habits; (2) financial interests among pharmaceutical firms, hospitals and doctors (Hospitals profit by reselling drugs); (3) patients demand inappropriate use of medicines due to long-term doctor-induced habits and limited medical knowledge of the patient's. When many patients did not get the desirable outcomes, they often demand the use of antibiotics and parenteral. Some suggestions to address these issues were listed at the end of the article. The authors have revised the section in the paper.

Please let me know if these changes address your and other reviewers’ concerns. Thank you for your assistance in this matter.

Sincerely,
Yours