Author's response to reviews

Title: Measuring access to medicines: a review of quantitative methods used in household surveys

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Author's response to reviews: see over
Reviewer's report

Title: Medicines access: a review of household-level assessing methods
Version: 1 Date: 25 September 2009

Reviewer: Barbara Mintzes

Reviewer's report:

Medicines access: a review of household-level assessing methods

This paper addresses the methodologies that have been used to research an important issue: the extent to which the public has access to needed medicines. The authors examine one aspect of this research, household surveys. In general, I think that some changes are needed to the paper in large part in the introduction and discussion of results.

1) introduction
Why is this issue important from a public health perspective? It would be useful to have some recent examples of lack of adequate access and health repercussions of this lack of access, also some link to the various factors that can affect access, including medicine cost / price and availability, and the most recent overview from WHO for example of the extent to which inadequate access is a problem. This would strengthen the rationale for this study.

Secondly, I thought the discussion of methodologies needed to go beyond descriptions of the types of methodologies used before to an evaluation of the pros and cons of various methodological approaches that might be used. For example, all studies thus far have been cross-sectional. Is there a need for longitudinal studies? How might mixed methods be used to address this question? What types of sample size and response rates would be considered adequate, in order to examine for example whether access has improved to a clinically important extent? What extent might be considered clinically important?

The focus of this study was to evaluate how access is being measured, regardless of study design or sample size. The response rate influences the quality of the study and may affect results, but does not change the way of measuring the access. We point out that our aim was not adherence, but access, it means that our interest was not to evaluate if people were taking correctly the medicines, or taking at all, but simply if they could get the medicines they needed.

1. Is the question posed by the authors well defined?
I think that the question might be better defined. The authors state that the goal is to contribute to the standardization of methodologies. In addition to describing what exists, the authors could contribute their own recommendations to a greater extent. Additionally, a better operational definition of access could have been proposed.

A paragraph was included in the Conclusions section in accordance with the suggestion. In our study, we propose a review of access measurement methods defined as “obtaining the medicines free of charge or paying out-of-pocket”. Therefore, studies about accessibility
dimensions, adequacy and medicine acceptability were not included, as it is stated in the methods section.

2. Are the methods appropriate and well described?

The literature review is described in detail. I did not understand why studies with qualitative designs were excluded, as they might have provided useful additional data of a different type on household's access to medicines. This should be justified or such studies should be included. A description of inclusion as well as exclusion criteria would have been useful as currently it would not be possible to replicate this study without a detailed description of inclusion criteria.

The measurement of access in quantitative population studies is challenging. We did check some qualitative studies and they do not add to the subject. To explain this strategy, we included a brief sentence (Methods - exclusion criteria) discussing the qualitative approach.

It is also unclear how ambiguous situations were dealt with -- did the authors have a preset adjudication procedure to decide if a study was or was not measuring medication access via a household survey, or was this unnecessary?

The measurement of medicine access on household level was an inclusion criterion, as described in the first paragraph of the methodology.

The box with the types of data extracted is not really necessary; a more general description of types of data collected would have been fine for this type of publication.

We thank the reviewer for the suggestion, but we believe that information retrieved from papers not only shows data that were not discussed, but also helps the reader to understand the meaning of information presented.

Secondly, these types of studies may have been carried out by governments or NGOs and not be in the published literature. This seems like an area for which a grey literature / Internet search for organizational reports would have been useful as well as a search in bibliographic websites. This could be limited to key organizations and queries of individuals working in the field, such as WHO and NGOs that have focussed on access to essential medicines (Medecins Sans Frontieres, Oxfam, etc.)

This review attempted to include studies attending the inclusion criteria, even if not published. One of the selected studies was not published and was obtained through contact with the author. However, the author's background supports our choice, as the author publishes in this field. Institutional sites were also accessed, as explained in the second paragraph of the Methods section.

Thirdly, the important question for instruments used is whether or not they have been validated, not whether they are authors' own instruments or institutional.

Because of logistic reasons, none of these questionnaires was validated, as there is no gold-standard to evaluate access.

3. Are the data sound?
With the caveats above, yes. I would have also liked to see the key results of the included studies on medicine access in the tables, and not just the methods used. Some results are included, such as follow-up rates, but not others -- what the studies found on medicine access. Additionally, Rather than the box on data extraction, a box on types of research methods that could be used in these household surveys, and key methodological questions that should be addressed, would have been helpful.

The results (proportions) presented by the studies were not the focus of the review. We believe that such information is relevant, but another review study would be necessary to discuss the issue and our search strategy was not aimed at this outcome.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
N/A

5. Are the discussion and conclusions well balanced and adequately supported by the data?
The main problem with the discussion and conclusions was the descriptive nature of the discussion, rather than a more analytical approach to the discussion of results that went beyond what does and does not exist, and put forward clear recommendations. An example is the definition of access. Rather than simply stating that this should be clearly defined, a proposal for an operational definition would be extremely useful. The current report stops critiques limitations of the existing literature, but stops short of these types of recommendations and could propose them. If the goal is, as stated, to contribute to standardization of methodologies, then this type of extra step is needed throughout.

We improved both sections and believe that now the definitions and suggestions for future studies are more evident.

6. Are limitations of the work clearly stated?
The frustrations with the literature search and the limitations of the included studies are stated.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
Yes

8. Do the title and abstract accurately convey what has been found?
The title implies a more in-depth review of methodologies than has been carried out.

The study attempted to evaluate quantitative methodologies about this theme, and we believe that the search achieved our goal. Nevertheless, the title has been changed to: Measuring access to medicines: a review of quantitative methods used in household surveys.

9. Is the writing acceptable?
Generally acceptable yes; some English language editing needed for style.

We hope that the language changes made to the paper corrected the flaws identified by the reviewer.
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:
No competing interests
Reviewer's report

Title: Medicines access: a review of household-level assessing methods

Version: 1 Date: 14 October 2009

Reviewer: Anna Birna Almarsdóttir

Reviewer's report:

- Major Compulsory Revisions

1. The authors' aim is to evaluate methodologies to measure medicine access and explain how access is characterized. As such the question posed is broad and does not totally rhyme with the exclusion made later of all methodologies except surveys.
   The exclusion was justified in the revised version. The measurement of access in quantitative population studies is challenging. We did check some qualitative studies and they do not add to the subject. In terms of the way it measures access it is not possible to compare quantitative and qualitative studies. The recommendations on how to operationalize the measurement also applies specifically to quantitative studies.

2. The search strategies used for this review are adequately described, although I do not see why all the exclusions of different methodologies are necessary. Wouldn't it have been interesting to see the varying methodologies used to study access to medicines?
   The exclusions were justified. The exclusion of studies about access based on information about accessibility, availability, adequacy and medicine acceptability is explained because specific studies would lengthen the manuscript, as each dimension would be evaluated separately.

3. Why include some chronic diseases/medicine groups and then exclude others? Why not include patients/people in insurance schemes? Is information retrieved from such patients not applicable in a more general setting? This is not explained enough to the reader.
   We excluded some medicines prescribed for chronic diseases and unusual medicines, as specific legislations are distinct from country to country. Besides, patients belonging to insurance schemes would require a separate analysis because their access is different in many aspects, and this separate analysis would lengthen substantially the paper.

4. There is no mention of language restrictions in the search. Was it English, Portuguese, and Spanish? What effect can this have on retrieval?
   We did not use any language restriction and no paper was excluded because of the language.

5. The authors stress that carrying out a literature search on the issue of access to medicines involves a lot of manual work, as there are no clear key words in use. They have to weed through thousands of bibliographic references to find 9 small needles in the haystack. Maybe this result is reflected in all the various exclusions they do at the beginning? Could you reflect on this in the paper?
   All restrictions were employed because of the objectives of the study - to gather information about quantitative methodologies to measure of medicine access on household-level. The
A definition of “medicine access” was to obtaining the medicines for free or paying out-of-pocket. To allow for comparability among studies, we did not include studies involving medicines with specific legislation that were distinct in different settings. We believe that the explanations included in this new version of the manuscript elucidate the exclusion criteria and restrictions. As we explain better the exclusion criteria, considering the reasons for exclusions, the impact of these exclusions was not evaluated.

6. The discussion goes fairly thoroughly through the obstacles to reviewing the concept of medicine access and I agree with them that the concept is ill defined. They then turn to the methodological aspects of access evaluation. Although a very thorough discussion, it could be made more applicable if the authors did two things: Firstly, if they made an attempt to theoretically define “access to medicines” and how this theoretical view of the concept would translate into the operational definition of the concept. Secondly, if they illuminated their very good points by providing the reader with examples of how instruments/questions would be constructed based on their points. As it stands now, the guidelines are too vague for the reader to take note of how they could make an instrument to assess access to medicines. A paragraph was included in the Conclusions section according to this suggestion.

- Minor Essential Revisions
7. This is a review of a total of 9 articles with various research questions and methods within the scope of household surveying. The manuscript adheres to the tradition of making an overview in tables and a text explaining what the tables contain. The tables provide a good overview, although there are a couple of terms I think may be clarified or maybe it is the use of English that I do not understand. T.2. Column heading “Subjects recruitment to measure access” – what does this mean? Are these inclusion criteria into the study population? This was clarified in the methods section where the information retrieved from selected studies is described.

8. The English needs to be revised in order to be well understood.
- Discretionary
We hope that the language changes made to the paper corrected the flaws identified by the reviewer.

9. The title could be more exciting/catchy: I.e. Access to Medicines – an unclear concept?
The study simply mentions the concept of access as a starting point to evaluate methodologies of access measurement, then we decided to keep the original title, including the information that we are dealing with quantitative studies.

Level of interest: An article of importance in its field

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.