Reviewer’s report

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

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Reviewer: Barbara Mintzes

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General comments:

The authors have done a good job of responding to most of the comments, and the paper provides more justification and description of methods than previously. However, I felt that the main aims of the review – to evaluate methodologies to measure medicine access, and to standardize methodologies, increasing study comparability, remain relatively weakly implemented. This is because such key issues in the evaluation of a quantitative survey method, such as sampling frames and sampling methods, instrument design, accuracy of self-report, recall bias, and the adequacy of specific outcome measures in measuring access etc. have either been minimally or not at all addressed.

I also found myself puzzling at which studies had and had not been included, and the decision to include specific chronic and acute diseases and not others.

Inclusion/ exclusion criteria for studies

There is now greater detail in the methods section. However, it could be better organized. The inclusion criteria are briefly described in the first paragraph under methods, as are some of the exclusion criteria. [last sentence, which is unclear – I presume it means that they excluded studies that looked at the appropriateness of medicine prescribing and use, not whether or not a medicine could be obtained.]

Under inclusion criteria, the outcome (“access”) is now more operationally defined. It would be useful to have an operational definition of ‘quantitative studies that measured medicine access on household levels”. This can now be partially deduced from the paragraph on exclusion criteria, which states that studies ‘that were not household-based interviews’ were excluded. Presumably the authors included any study using face-to-face, mail, internet-based or telephone surveys for which the unit of analysis is the household or an individual within the household. Did a specific sampling method need to be used to identify households (for example random samples, systematic samples, by geographical area; population etc.)? Were cross-sectional studies included as well as longitudinal studies (prospective cohort analyses)? Were studies that included the general population from a specific region excluded if they were not based on households but rather on individuals (for example population-based prescription database analyses)? If so, what was the rationale for this?

Organization of this section: the inclusion and exclusion criteria are now divided
between a paragraph before and after the search strategy. They should be in the same section.

The description of the data extraction form is not needed in such detail, (points under “from the selected studies…” as I mentioned previously. As the authors would like to keep it in the paper, I would suggest making it into a box in the methods section, rather than including in the text, to improve readability.

Results

The paragraph that starts “more than nine thousand…” should be in results, not methods, as it refers to what the authors found after they applied these search methods.

The authors have described a very comprehensive search strategy, similar to one that would have been employed in a systematic review, but then report very minimally on the process of selection of studies for inclusion or exclusion. The trajectory from >9000 to 9 studies remains unclear. Did the authors do a first triage and exclude irrelevant studies, reviews etc. They would have then had a subset of potentially relevant studies and could have provided the reasons for exclusion, among these studies, as well as describing any methods used such as duplicate independent review, adjudication of differences. They refer to this step in a general manner -- they state that most were excluded because they were related to excluded chronic conditions (AIDS, tuberculosis) or medicine access of people covered by insurances. I was puzzled at the latter exclusion criteria, as if access is a measure of a person’s ability to obtain a medicine either for free or by payment, whether or not they are covered under a public insurance systems that are population-wide as well as private insurance would have a profound influence on access.

There are also quantitative, population based studies that have examined the way changes in insurance systems affect access. See for example Tamblyn R et al. Adverse events associated with prescription drug cost-sharing among poor and elderly persons. JAMA. 2001 Jan 24-31;285(4):421-9. I assume this study was excluded because it is population rather than household based. This makes sense if the main aim of this paper is to evaluate a specific research methodology, household surveys. It is inconsistent with an aim to collect the full research evidence on access to medicines at a population level.

I am also curious about the mention of the multicenter WHO study that included 71 countries. The text suggests that only the Brazilian survey was included, not the survey in the other 70 countries, (under discussion). This is confirmed by the table of included studies – no global WHO studies are included. I did not understand why this global survey failed to meet inclusion criteria, but one of the country studies that contributed to was included.

On the other hand, the one study that used adherence to measure access was a puzzle, in that there are many studies of adherence in relation to access (including the one by Tamblyn et al, cited above). There are also many methodological problems with self-report as a measure of medication adherence, and the assumption that adherence reflects access alone is also likely to be
problematic, given that in many cases it is likely to be affected as well by the patient’s experience or expectations of effectiveness, by adverse effects, treatment preferences etc.

Discussion
There is a lot more detail in the discussion than previously, and it goes a long way towards describing how research criteria could be developed and applied, to ensure better consistency of methods to measure medication access. I am not sure how this relates to the WHO survey in 71 countries and whether the authors believe that the methods used in this survey were unreliable and require improvement. Given that a multinational study has already been carried out with a single instrument, protocol, and definition of access, the call for standardization appears to be a call for something different than what has already been done. I wasn’t sure how the current call differs. If the research methods were not rigorous enough, it is also possible to create a small checklist for more rigorous methodology. It is also unclear how reliable the method were for the 9 studies under consideration. The approach of applying specific criteria and then commenting on presence/absence or rigour (as in a Cochrane systematic review ‘risk of bias’ table) would have been helpful.

I found the discussion of the definition of access useful. One issue that is not discussed is whether the user attempts to triage between necessary or essential medicines and non-essential medicines, and whether researchers also apply these definitions when measuring medication access.

Recruitment strategies: were these all household based? It is also unclear what sampling techniques were used to identify study participants in the various studies.

Recall periods: in calling for different recall periods for acute and chronic treatments, the authors need to discuss the issue of recall bias, and how to minimize it, particularly in terms of their recommendations on chronic treatment.

Data collection: do the authors envision any alternatives to self-report?

WHO indicators: a box describing these would have been useful.

Low response rate: at one point the authors describe a <85% response rate as low. It is unclear how this threshold was set. It is very optimistic for many cross-sectional studies. It might be worth reviewing the response rate literature and also briefly discussing methods to ensure generalizability of results – both the sampling method and response rate need to be addressed.