Author's response to reviews

Title: Development of explicit criteria for cataract extraction by phacoemulsification

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Author's response to reviews: see over
Responses to Reviewer # 1

Major Compulsory Revisions
1. The authors must define their category "indeterminate" (p.25) and how this is rated. I would have expected "indeterminate" indications to be considered "uncertain" so it is unclear how these are included as appropriate or inappropriate.

\textit{We have included the complete definition of the three agreement categories, as developed by the RAND researchers, in the text (Methods section). Those "indeterminate" just are included in the "uncertain" appropriateness category if the panel median scoring is between 4 and 6. "Indeterminate" can be also appropriate (if the panel median scoring is between 7 and 9 ) or inappropriate (if the panel median scoring is between 1 and 3).}

2. The criteria for surgical complexity (Appendix 1 - p. 2) need to be included in the text, and the method for determining how these are categorized needs to be explained.

\textit{It has been included in the text and on the Appendix 1. On field study the ophthalmologists report this data.}

3. The category "necessary and appropriate" has been omitted. This category has been helpful to justify surgeries for patients with diabetic retinopathy, in order to better visualize and treat the disease. It is unclear how the status of the diabetic retinopathy (Appendix 1 - p.22) is determined.

\textit{As far as now, we have not performed the necessity round. We agree with the reviewer that a necessary category would be helpful to determine underuse, but we avoided a new round just after the main panel meeting because of the fatigue of our panellists and expecting a low response rate. But we are considering it now. Again, the status of the diabetic retinopathy is reported by the ophthalmologists.}

4. If criteria are developed only from review of surgeries that have been performed as suggested (p.15), then it becomes impossible to consider underuse of the procedure.

\textit{It is correct. As far as now, underuse cannot be estimated, though we plan to undergo a last round to define necessity from the appropriate categories of the 2\textsuperscript{nd} round. In this case, the criteria can be used to estimate necessity if ophthalmologist agree to register all the necessary information of all patients attended at their outpatient clinics, either by medical records review, or, prospectively.}

5. Are any non-ophthalmic criteria being considered in relation to appropriateness, such as anticipated life-expectancy?

\textit{No, they were considered when developing the appropriateness variables, but the ophthalmologist of our research team considered that a short anticipated life-expectancy will not affect their decision of have the surgery if it improves the patients quality of life.}

6. Inclusion of another functional category, such as inability to work, should be considered

\textit{As far as we understand the reviewer question, even patients who cannot work can answer to our visual function scale, which is totally related to the ability, or limitations, of doing things by using their eyes (visual function). On those who work and present with glare who prevent him of working we consider them as having difficulties on daily activities (see also Appendix 1).}
Minor Essential Revisions

1. Phacoemulsification has been done since the 1970s and some of the cataract extractions that were reported previously in assessment of appropriateness were performed by phacoemulsification (p.2). *Changes done.*

2. The consensus development techniques were used in the 1980s and 1990s by the Rand investigators and others (p.2). *In that sentence we just mean that the methodology was developed by the RAND-UCLA group and that this happens at the beginning of the 1980's.*

3. Please clarify if all of the ophthalmologist panelists performed cataract surgeries. 
   *No, they do not. Some did perform cataract surgeries while some others focus their clinical activities in other ocular surgical techniques (doers and non-doers). We have clarified this point in the text.*

4. Please state if the preoperative visual acuity was the best-corrected acuity, and state how it was determined, if possible.
   *Yes, the preoperative visual acuity was the best-corrected acuity. It has to be determined by the ophthalmologist. We have clarified this point in the text (Methods) and in Appendix 1.*

5. Please consider the adequacy of the medical records and if there were problems in obtaining the required documentation.
   *This is actually a theoretical article about the development of the explicit criteria. Nevertheless a large study is currently undergoing (and still not finished), from which we took preliminary data to study the use of scenarios. All the data was collected prospectively (as patients were recruited) by the participant ophthalmologists. We first performed a pilot study to know if the medical records were a valid source of information for our purposes. We found (not published data) that for some relevant variables we can retrieve from medical records, but not in all centres. Due to that variability on valid information we decided to implicate to ophthalmologist in the retrieval of information. We have added a sentence (Methods section) to clarify this point.*

6. Consider cataract as a condition, not a disease (p.4). *Done.*

7. Effectiveness, not efficacy is being measured (p.5). *We did include in our bibliography review efficacy studies (as clinical trials), although it is not a common design in this intervention. As an example, we include here 3 of them:*


   Therefore, we consider that we are measuring efficacy while some other studies measured effectiveness.

8. Changes in ratings were measured, not estimated (p.7). *Done.*
9. Statistical analysis of kappa scores to assess agreement/disagreement would be helpful. 

Weighted kappa statistic and its 95% confidence interval has been also calculated to measure agreement between the classification tree analysis and the panel of experts. We have included the results in the text ("Global weighted kappa between the classification tree analysis and the panel of experts was 0.94 with a 95% confidence interval (0.92, 0.96)") and tables as follow: By category, it was 0.95 for the simple cataract (95% confidence interval (0.91, 0.99)), 0.92 for cataract with diabetic retinopathy (95% confidence interval (0.89, 0.95)) and 0.95 for cataract with other ocular pathologies (95% confidence interval (0.92, 0.98)).

10. Please clarify how the misclassification error (p.11) was determined. Misclassification error was calculated as the ratio of the number of indications erroneously classified by the classification tree and the total number of indications. We have added the previous sentence to the Statistical Analysis section of the manuscript.

11. Please clarify paragraph 2, last sentence, p.12. We tried to suggest hypothesis for the higher agreement rate for the simple cataract condition. Nevertheless, the percentage is slightly higher compare to the other conditions and after careful consideration we have decided to delete that sentence since it seems to be confusing. Also, some other reasons (as the lower number of scenarios) may play a more relevant role.

12. Non-ophthalmologists have often been included in the appropriateness panels because of their role in referring patients for surgery. If not referred, patients may not be considered as candidates for surgery. Clarification of how patients come to consideration for surgery might be helpful.

In our health care system, patients are usually referred for a first consultation to the ophthalmologist by primary care physicians. Primary care physicians have not the necessary instruments to explore patients, therefore never will indicate the intervention. Apart from primary care physicians only physicians working in emergency care services may, more rarely, referred a patient. Since the decision to have the intervention is taking exclusively by ophthalmologists we decided to include just ophthalmologists. Another different issue is the dissemination of the results of our work. In this case, we agree that not only ophthalmologists have to receive it but also other physicians who are the firsts contact of patients with the health care system.

13. Please clarify the last two sentences in first paragraph on p. 14. That was due to the criteria of our ophthalmologists who considered first, from the standpoint of surgical intervention, that all the diagnostic groups included in this category have in common that affect the anticipated postoperative visual acuity. Second, they considered that there was no other additional criteria-variable- for each of them to have them separately. We have introduced some changes in those sentences so that it can be easily understandable.