## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

## ARTICLE DETAILS

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| **TITLE (PROVISIONAL)** | Quality of Refractive Error Care (Q.REC) in Cambodia, Malaysia and Pakistan: protocol for a cross-sectional unannounced standardised patient study |
| **AUTHORS** | Burnett, Anthea; Lee, Ling; McGuinness, Myra; Varga, Beatrice; Perez Hazel, Yadira; Ho, Suit May |

## VERSION 1 – REVIEW

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| **REVIEWER** | Woodhouse, Margaret<br>School of Optometry and Vision Sciences, Cardiff University |
| **REVIEW RETURNED** | 05-Oct-2021 |

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| **GENERAL COMMENTS** | This is a well-written protocol for an important study and I applaud the authors for their design plans. I would like to see a few minor points addressed, in order to make it clear that the study will be comprehensive.<br>Page 9, lines 24-26. “Participating USPs will be reimbursed for participation, plus any travel, accommodation or meal expenses.” One assumes that the USPs will also be reimbursed for the cost of spectacles. This should be mentioned<br><br>Page 9, line 51. Under procedures, will the USP ‘pretend’ that they have lost their spectacles? Presumably the refraction services will not be able simply to measure the current Rx and duplicate it?<br>Page 10, line 33. Criteria. It is feasible that prescriptions (particularly plus and/or astigmatism and young USPs) might be reduced deliberately. Can this be taken into account? It would not constitute an incorrect Rx if the practitioner had made a clinical judgement to reduce the correction, for example, to aid adaptation. Missing from the criteria are tolerances for visual acuity. The authors state later that optimal will be categorised as “achieving best-corrected binocular visual acuity versus not achieving”. Acuity is not a fixed entity and has inherent repeatability just as any biological measure does.<br>Page 11, line 25. Secondary outcomes need to include dispensing techniques (for example, inter-pupillary distance measure, adjustments of frame on collection). Dispensing techniques are mentioned earlier, and in the Discussion, and they should be included here. Comfort and fit of the frame should be measured, not just comfort of the lenses. The importance of quality dispensing must not be ignored. A refraction could be perfect, but if the frame is ill-fitting and/or uncomfortable, the effort of refraction is wasted.<br>Page 13, line 22. Safety in mentioned here in the Discussion, but not earlier. How is safety to be assessed? |

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| **REVIEWER** | Lovell-Patel, Rupal<br>University of Central Lancashire, School of Medicine |
| **REVIEW RETURNED** | 01-Nov-2021 |

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| **GENERAL COMMENTS** | The inclusion and exclusion criteria for USPs are clearly stated but there is no inclusion/exclusion criteria for the optical services, yet the managers of the optical services need to decide if they meet the criteria to take part in the project?<br>Are the USPs assessed by all the study optometrist/refractionist to then agree on a final prescription or only one clinician? If it just one clinician, how accurate are their results? Each clinician has inter and intra variability so ensuring that an average outcome is agreed as a baseline before all other optical services are compared to will reduce variability.<br>What references did you use to decide on the Criteria for Optimally Prescribed Spectacles? Which standards did you review for tolerances of ophthalmic lenses as based on the prescription range, the tolerances will need to change but this is not evident in Table 2. |

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| **REVIEWER** | Malhotra, Sumit<br>All India Institute of Medical Sciences, Centre for Community Medicine |
| **REVIEW RETURNED** | 08-Nov-2021 |

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| **GENERAL COMMENTS** | The protocol by Burnett et al. is an important manuscript and details about a novel methodology to evaluate quality of refractive error care in Cambodia, Malaysia and Pakistan<br>The paper requires minor revision<br>Specific Comments of the paper<br>1. The dates of the planned study are not mentioned. This is a critical parameter for inclusion.<br>2. In the abstract under methods section- it is mentioned prospective and cross sectional. Suggest to remove the word prospective.<br>3. In the methods section, sample size considerations- there is difference in the desired margins of error for Malaysia/ Pakistan (7%) and Cambodia (4%). Why authors chose a different margin of error? Also, there is difference in anticipated proportion of spectacle optimal quality in these three different settings. It will be worthwhile to explain.<br>4. In the section on development of USPs- training- some more light on training content and methodology. A minimum level of performance by USP and in case any USP is not able to perform upto standards, what is the path adopted?<br>5. In the section on dissemination, suggest to include also local optical services from where data has been collected as measures to provide feedback, and other optical associations.<br>6. Some quality control/ assurance measures while data is collected by the USPs. How this will be ensured?<br>7. In the section on database management- it will be important to include information on measures for quality assurance of the data that will entered.<br>8. It will be useful to add/ annexe study instruments, advertisements for USPs templates and some training material for USPs.<br>9. References require a relook as per journal style. |

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| **REVIEWER** | Marques, Ana Patricia<br>London School of Hygiene and Tropical Medicine International Centre for Eye Health |
| **REVIEW RETURNED** | 08-Nov-2021 |

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| **GENERAL COMMENTS** | BMJ Open. Title: “Quality of Refractive Error Care (Q.REC) in Cambodia, Malaysia and Pakistan: A cross-sectional unannounced standardised patient study protocol”<br>The manuscript reports a protocol of a prospective cross-sectional study that aims to evaluate the quality of refractive error care in Cambodia, Malaysia and Pakistan. This is an interesting study that will provide insights about the quality of refractive error care and identify potential areas of improvement.<br>Overall, I found the manuscript to be well written and well-structured although a bit too short in a few methodological details. I think that adding a few more details about the standards of quality of care authors aim to measure and about how USPs will collect data about refraction/dispensing techniques, subjective visual acuity and comfort while using spectacles will add clarity to the protocol.<br><br>Here are my comments to the manuscript:<br>Abstract<br>Page 4 line 27 – I think there is a typo in the word Optometrist.<br>Main text<br>Background<br>I think it would be useful to provide a brief explanation about the optimal quality standards defined by Lee et al 2021. Readers shouldn’t have to read another paper to have a clear understanding of what the study aims to measure.<br><br>Methods<br>Authors should include more information about the dates where the study began/ will begin and when they estimate data collection will be completed.<br><br>Study population<br>Although this might be a detail that has already been approved by the ethics committees it seems a bit strange to me to ask for a withdrawal form to declare services wish to opt-out from the study instead of a form asking a declaration to attest they´ve read the Participant Information Station and wish to participate and receive feedback. Could the authors please explain why they decided to proceed this way.<br>I also think it would be useful to explain how, and if applicable, who will deliver the forms that will be sent to the local services.<br>USP Optical service visit<br>More information should be provided about the electronic checklist USPs will complete after each visits. The authors mention that, as a secondary outcome they aim to study the association between optimal quality and refraction/dispensing techniques, subjective visual acuity and comfort while using spectacles. Nevertheless it is unclear how this information will be assessed, which instruments/ tolls are going to be use to collect this. Which items will be collected to understand service characteristics? How do authors define subjective visual acuity and how will they measure it? How will comfort wearing glasses be measure? From my point of view more details about these variables should be provided.<br>Study population |

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| | At page 10 line 29 shouldn´t it be Table 2 instead of Table 1?<br>Service characteristics (page 11)<br>This subheading doesn´t seems to reflect the description given here. Authors describe how spectacles characteristics will be analysed but the subheading is called “service characteristics”.<br>Secondary outcomes<br>Authors mention service characteristics – refraction techniques and refraction equipment used – will be analysed without specifying how this information will be collected.<br>Discussion<br>At the discussion section Authors mention that currently Q.REC indicators are focus on whether refractive error care is effective, equitable and safe. I agree that measuring “the appropriateness of prescribed and dispensed spectacles is an appropriate way to evaluate if the refractive error care are effective/ have quality but it is not clear how can be used to assess equity and safety. Could the authors please clarify this? Is it possible that current Q.REC have several dimensions but in this study only a few are being evaluated? |

**VERSION 1 – AUTHOR RESPONSE**

Reviewer: 1
Dr. Margaret Woodhouse, School of Optometry and Vision Sciences
Comments to the Author:
This is a well-written protocol for an important study and I applaud the authors for their design plans. I would like to see a few minor points addressed, in order to make it clear that the study will be comprehensive.
Page 9, lines 24-26. “Participating USPs will be reimbursed for participation, plus any travel, accommodation or meal expenses.”
One assumes that the USPs will also be reimbursed for the cost of spectacles. This should be mentioned
Response: This section has been modified so that it is clear that USPs will also be reimbursed for the cost of spectacles. Page 8, line 11.

Page 9, line 51. Under procedures, will the USP ‘pretend’ that they have lost their spectacles? Presumably the refraction services will not be able simply to measure the current Rx and duplicate it?
Response: The USPs will visit the optical services with their existing spectacles (if they are current spectacle wearers) and request a new pair . The USP observations includes whether or not the optical service appear to measure the Rx of existing spectacles – please refer the Supplementary file 1 for the USP observation record form. . Page 9, line 13.

Page 10, line 33. Criteria. It is feasible that prescriptions (particularly plus and/or astigmatism and young USPs) might be reduced deliberately. Can this be taken into account? It would not constitute an incorrect Rx if the practitioner had made a clinical judgement to reduce the correction, for example, to aid adaptation.
Response: Additional information has been included to account for potential prescriptions where deliberate reduction for adaption might be involved. Page 9, lines 38-44.

Missing from the criteria are tolerances for visual acuity. The authors state later that optimal will be categorised as “achieving best-corrected binocular visual acuity versus not achieving”. Acuity is not a fixed entity and has inherent repeatability just as any biological measure does.

Response: Not achieving best-corrected binocular visual acuity has been considered as less than 1.5 lines on a logMAR visual acuity chart as per test-retest reliability of visual acuity measurement literature. This has been included in Secondary outcomes subsection. Page 8, lines 36 – 44.

Page 11, line 25. Secondary outcomes need to include dispensing techniques (for example, inter-pupillary distance measure, adjustments of frame on collection). Dispensing techniques are mentioned earlier, and in the Discussion, and they should be included here. Comfort and fit of the frame should be measured, not just comfort of the lenses. The importance of quality dispensing must not be ignored. A refraction could be perfect, but if the frame is ill-fitting and/or uncomfortable, the effort of refraction is wasted.
Response: We agree with this response and would like to include additional questions around comfort and fit in future studies. However, in this study we have only included basic questions around 'discomfort'. This has been noted as a possibility for future research in the discussion. Page 13, lines 34-36.

Page 13, line 22. Safety in mentioned here in the Discussion, but not earlier. How is safety to be assessed?

Response: We have clarified that by 'safety' we are referring to spectacles result in unnecessarily reduced vision. Page 12, line 51-53.

Reviewer: 2
Ms. Rupal Lovell-Patel, University of Central Lancashire
Comments to the Author:
The inclusion and exclusion criteria for USPs are clearly stated but there is no inclusion/exclusion criteria for the optical services, yet the managers of the optical services need to decide if they meet the criteria to take part in the project?
Response: We have amended the Study Population section of Methods and Analysis, to remove this apparent contradiction. Page 6, line 37.

Are the USPs assessed by all the study optometrist/refractionist to then agree on a final prescription or only one clinician? If it just one clinician, how accurate are their results? Each clinician has inter and intra variability so ensuring that an average outcome is agreed as a baseline before all other optical services are compared to will reduce variability.
Response: All USPs undergo three baseline refractions by the study optometrists/refractionists. If the refraction components are not within 0.75DS, a fourth refraction is required. The most senior optometrist will then decide which three refraction results will be used for the averaged baseline refraction for that USP. This detail has been included in the baseline refraction section. Page 8, lines 36 – 49.

What references did you use to decide on the Criteria for Optimally Prescribed Spectacles? Which standards did you review for tolerances of ophthalmic lenses as based on the prescription range, the tolerances will need to change but this is not evident in Table 2.

Response: We have provided a reference as a footnote to Table 2, which describes the literature used to develop and test the criteria. Page 9, line 56.

Reviewer: 3
Dr. Sumit Malhotra, All India Institute of Medical Sciences
Comments to the Author:

The protocol by Burnett et al. is an important manuscript and details about a novel methodology to evaluate quality of refractive error care in Cambodia, Malaysia and Pakistan
The paper requires minor revision
Specific Comments of the paper
1. The dates of the planned study are not mentioned. This is a critical parameter for inclusion.
Response: Due to the unfolding COVID situation it has been very difficult to establish firm plans for data collection. Enrolment began in October 2021 in Pakistan, and December 2021 in Cambodia. Enrolment will be begin in Malaysia when staff are relieved from COVID duties. As suggested, this information has been included in the Study Setting section. Page 5, lines 50 – 52..

2. In the abstract under methods section- it is mentioned prospective and cross sectional. Suggest to remove the word prospective.
Response: As suggested, the word prospective has been removed. Page 2, line 23.

3. In the methods section, sample size considerations- there is difference in the desired margins of error for Malaysia/ Pakistan (7%) and Cambodia (4%). Why authors chose a different margin of error?
Response: Each location is funded separately and as the study budget for Cambodia was larger than the other two sites, a decision was made to maximise the sample size, so as to reduce the margin or error and make additional learnings on the precision of the intraclass coefficient. This detail has been added to the sample size considerations section. Page 7, lines 20 – 28.
Also, there is difference in anticipated proportion of spectacle optimal quality in these three different settings. It will be worthwhile to explain.
Response: As suggested the difference in the anticipated proportion of spectacle optimal quality has been clarified in the text. Malaysia has a more developed and regulated optometry industry than Cambodia or Pakistan, so it was anticipated that the proportion of spectacles that are optimal quality is higher. This detail has been added to the sample size considerations section. Page 7, lines 15 – 19..

4. In the section on development of USPs- training- some more light on training content and methodology. A minimum level of performance by USP and in case any USP is not able to perform upto standards, what is the path adopted?
Response: We have provided further clarification on the training methodology. Post-Training observations by a study optometrist will be conducted to identify whether the USPs can accurately identify elements of refraction and dispensing techniques. If USPs are unable accurately identify elements of refraction and dispensing techniques, further training will be provided. Page 8, lines 23 – 26.

5. In the section on dissemination, suggest to include also local optical services from where data has been collected as measures to provide feedback, and other optical associations.
Response: We have clarified that all participating service owners will have the opportunity to receive a summary of the results in their preferred language. Page 11, lines 18-22.

6. Some quality control/ assurance measures while data is collected by the USPs. How this will be ensured?
Response: As suggested we have included the following additional information about data quality assurance in the Database Management section: Data quality will be assured by conducting daily queries to identify and resolve discrepancies, and by using data quality rules. Page 10, lines 47 – 51.

7. In the section on database management- it will be important to include information on measures for quality assurance of the data that will entered.

Response: As suggested we have included the following additional information about data quality assurance: Data quality will be assured by conducting daily queries to identify and resolve discrepancies, and by using data quality rules. Page 10, lines 47 – 51.

8. It will be useful to add/ annexe study instruments, advertisements for USPs templates and some training material for USPs.
Response: All study instruments will be provided in a supplementary file. Training materials and other study materials will be made available upon request. Page 9, line 41.

9. References require a relook as per journal style.
Response: As suggested, the references have been reformatted, as per the journal style.

Reviewer: 4
Ms. Ana Patricia Marques, London School of Hygiene and Tropical Medicine International Centre for Eye Health
Comments to the Author:
BMJ Open. Title: "Quality of Refractive Error Care (Q.REC) in Cambodia, Malaysia and Pakistan: A cross-sectional unannounced standardised patient study protocol"
The manuscript reports a protocol of a prospective cross-sectional study that aims to evaluate the quality of refractive error care in Cambodia, Malaysia and Pakistan. This is an interesting study that will provide insights about the quality of refractive error care and identify potential areas of improvement.
Overall, I found the manuscript to be well written and well-structured although a bit too short in a few methodological details. I think that adding a few more details about the standards of quality of care authors aim to measure and about how USPs will collect data about refraction/dispensing techniques, subjective visual acuity and comfort while using spectacles will add clarity to the protocol.

Here are my comments to the manuscript:
Abstract
Page 4 line 27 – I think there is a typo in the word Optometrist.
Response: Apologies, this has now been fixed.

Main text
Background
I think it would be useful to provide a brief explanation about the optimal quality standards defined by Lee et al 2021. Readers shouldn't have to read another paper to have a clear understanding of what the study aims to measure.
Response: As suggested, additional information about the Lee et al 2021 study has been added. Page 4, lines 26 – 30.

Methods
Authors should include more information about the dates where the study began/ will begin and when they estimate data collection will be completed.

Response: Due to the unfolding COVID situation it has been very difficult to establish firm plans for data collection. Enrolment began in October 2021 in Pakistan, and December 2021 in Cambodia. Enrolment will begin in Malaysia when staff are relieved from COVID duties. As suggested, the following information has been included in the Study Setting section: It is anticipated that enrolment will commence in October 2021. Page 5, lines 50 – 52..

Study population

Although this might be a detail that has already been approved by the ethics committees it seems a bit strange to me to ask for a withdrawal form to declare services wish to opt-out from the study instead of a form asking a declaration to attest they´ve read the Participant Information Station and wish to participate and receive feedback. Could the authors please explain why they decided to proceed this way.
Response: As suggested, the following additional information has been included to explain why the 'opt-out' approach has been used: As the public (potential optical service clients/patients) have a right to understand the quality of the services that they might be expect to receive in each location an opt-out approach will be used to ensure that there is a high participation rate. Also, the research is likely to be compromised if optical stores are aware that they are providing optical services to a USP due to the Hawthorne effect (where clinicians modify their behaviour in response to being observed). The quality of each individual store will not be published in any way so the privacy of each store will be maintained. Page 6, lines 44 – 56.

I also think it would be useful to explain how, and if applicable, who will deliver the forms that will be sent to the local services.
Response: As suggested, the following additional information has been provided about the delivery of the invitation letters: The Participant Information Statement and Withdrawal Form, will be hand delivered, or sent via registered post. Page 6, line 31 – 34..

USP Optical service visit
More information should be provided about the electronic checklist USPs will complete after each visits. The authors mention that, as a secondary outcome they aim to study the association between optimal quality and refraction/dispensing techniques, subjective visual acuity and comfort while using spectacles. Nevertheless it is unclear how this information will be assessed, which instruments/ tolls are going to be use to collect this. Which items will be collected to understand service characteristics? How do authors define subjective visual acuity and how will they measure it? How will comfort wearing glasses be measure? From my point of view more details about these variables should be provided.
Response: All study instruments will be provided in a supplementary file. Training materials and other study materials will be made available upon request. Page 9, line 41.

Study population
At page 10 line 29 shouldn´t it be Table 2 instead of Table 1?
Response: Thank you, yes. This has been changed to Table 2.

Service characteristics (page 11)
This subheading doesn´t seems to reflect the description given here. Authors describe how spectacles characteristics will be analysed but the subheading is called "service characteristics".
Response: This has been changed to 'spectacle characteristics. Page 10, line 7.

Secondary outcomes
Authors mention service characteristics – refraction techniques and refraction equipment used – will be analysed without specifying how this information will be collected.
Response: All study instruments will be provided in a supplementary file. Page 9, line 41.

Discussion
At the discussion section Authors mention that currently Q.REC indicators are focus on whether refractive error care is effective, equitable and safe. I agree that measuring "the appropriateness of prescribed and dispensed spectacles is an appropriate way to evaluate if the refractive error care are effective/ have quality but it is not clear how can be used to assess equity and safety. Could the

authors please clarify this? Is it possible that current Q.REC have several dimensions but in this study only a few are being evaluated?
Response: We have clarified that by 'safety' we are referring to spectacles result in unnecessarily reduced vision. Equity can be evaluated by examining associations between refractive error quality and USP characteristics such as gender, age, and ethnicity. Page 12, lines 51 - 53.

**VERSION 2 – REVIEW**

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| **REVIEWER** | Woodhouse, Margaret<br>School of Optometry and Vision Sciences, Cardiff University |
| **REVIEW RETURNED** | 05-Jan-2022 |

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| **GENERAL COMMENTS** | The authors have addressed all of my concerns and I am happy for the paper to proceed to publication. I did spot one typo - the word 'acknowledged' is mis-spelled on page 13 of the pdf, line 20/21 |

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| **REVIEWER** | Lovell-Patel, Rupal<br>University of Central Lancashire, School of Medicine |
| **REVIEW RETURNED** | 10-Jan-2022 |

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| **GENERAL COMMENTS** | Comments from previous reviews have been considered and the manuscript has been updated accordingly. The protocol is clearer to follow and could be replicated, if any other researcher wanted to follow a similar project in other developing countries. There are more details around training of USPs and the assessment of USPs' refraction.<br><br>If the service providers randomly selected declined (opt-out as described in line 20 of the Ethics and Dissemination section) to take part in study, how does the study team plan to deal with keeping to the same number of service providers - like to like replacement in terms of the location/type of optical service provider or stay with random selection? |

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| **REVIEWER** | Marques, Ana Patricia<br>London School of Hygiene and Tropical Medicine International Centre for Eye Health |
| **REVIEW RETURNED** | 20-Jan-2022 |

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| **GENERAL COMMENTS** | Thank you for your revisions, I think the manuscript has improved and it is much clearer. |

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## VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

Dr. Margaret Woodhouse, School of Optometry and Vision Sciences

Comments to the Author:

The authors have addressed all of my concerns and I am happy for the paper to proceed to publication. I did spot one typo - the word 'acknowledged' is mis-spelled on page 13 of the pdf, line 20/21

Response: The spelling of ‘acknowledged’ has been corrected. Page 12, line 20/21.

Other minor spelling and grammar checks have also been done.

Reviewer: 2

Ms. Rupal Lovell-Patel, University of Central Lancashire

Comments to the Author:

Comments from previous reviews have been considered and the manuscript has been updated accordingly. The protocol is clearer to follow and could be replicated, if any other researcher wanted to follow a similar project in other developing countries. There are more details around training of USPs and the assessment of USPs' refraction.

If the service providers randomly selected declined (opt-out as described in line 20 of the Ethics and Dissemination section) to take part in study, how does the study team plan to deal with keeping to the same number of service providers - like to like replacement in terms of the location/type of optical service provider or stay with random selection?

Response: We have amended the Sampling strategy section of Methods and Analysis, to include that optical services will only be selected after the period to opt-out. Page 6, line 52.

Reviewer: 4

Ms. Ana Patricia Marques, London School of Hygiene and Tropical Medicine International Centre for Eye Health

Comments to the Author:

Thank you for your revisions, I think the manuscript has improved and it is much clearer.

Response: Thank you for the feedback.