PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	UK consensus definitions for Necrotising Otitis Externa: a Delphi study
AUTHORS	Hodgson, Susanne; Khan, M. M.; Patrick-Smith, Maia; Martinez-Devesa, P; Stapleton, Emma; Williams, O Martin; Pretorius, Pieter; McNally, Martin; Andersson, Monique; on behalf of UK NOE Collaborative, .

VERSION 1 – REVIEW

REVIEWER	González , Treviño JL Autonomous University of Nuevo Leon
REVIEW RETURNED	31-Mar-2022

GENERAL COMMENTS	--------

REVIEWER	Rojoa, Djamila Imperial College Healthcare NHS Trust
REVIEW RETURNED	31-Mar-2022

GENERAL COMMENTS	This is an important paper addressing the long-awaited need for a set of defining criteria for NOE. There has been an exponential rise in admission of patients with NOE in the UK in recent years, however, diagnosis uncertainty and lack of uniformity still remain. The results of this study will not only facilitate diagnosis and management on clinical grounds but also allow better quality studies to be carried out, which will help in risk stratification and severity grading. The methodology regarding Delphi consensus is strong and well performed. Minimal information available about the systematic search, pending the publication of the submitted paper. The strength of the study lies in its ability to set specific criteria in terms of diagnostic certainty, disease severity and monitoring outcomes. Criteria for definition of NOE include clinical, histological and radiological findings, all of which are in line with previous clinical studies and evidence synthesis (Byun YJ et al. Necrotizing Otitis Externa: A Systematic Review and Analysis of Changing Trends. Otol Neurotol. 2020 Sep;41(8):1004-1011). The criteria for possible NOE may be used as a guide where resources are not available in an acceptable time-frame, for instance patients presenting to the primary care setting with symptoms of OE refractory to treatment, for expedited diagnosis and referral to secondary care. Patient-related factors are known to affect disease progression and prognosis. Even though further studies with larger cohorts of patients are required to determine the independent impact of various comorbidities, the currently

	available pool of evidence shows that immunosuppression is an important risk stratifying factor for NOE. Similarly, previous studies have shown cranial nerve involvement on admission and radiological progression of disease beyond the EAC to hold importance prognostic value in terms of morbidity and survival, hence they are valid criteria included in the definition of complex NOE. Early MDT approach is a valuable contribution, it addresses the increasing antimicrobial (ciprofloxacin) resistance and combination therapy complexity, with the early interventions by microbiologists and allows early grading of severity by radiologists and better monitoring of disease progression throughout. This study adds a valuable dimension to the management of NOE, based on expert opinions, about a topic with uncertainty and controversies. It is a step towards standardising our practice regarding NOE, aiding in early diagnosis, reducing the length of antimicrobial therapy and minimising the risk of morbidity and mortality. Moreover, it serves as a breeding ground for further studies with more vigorous methodology to be performed, culminating in robust evidence synthesis which will drive the management of NOE forward.

REVIEWER	Peled, Chilaf Birmingham Children's Hospital NHS Foundation Trust, ENT
REVIEW RETURNED	22-Jun-2022

GENERAL COMMENTS	Thank you for your well designed and written study. I have enjoyed reading it, and believe it will contribute to other physicians and researches who are interested in the diagnosis and management of NOE. One important comment - in you consensus statement defining "definite NOE" and "possible NOE", you have failed to mention the correlation between NOE and diabetes. why is that ? is there no agreement that NOE is highly associated with diabetes ? please elaborate.

REVIEWER	Ben Mabrouk, Asma Taher Sfar university hospital
REVIEW RETURNED	22-Jun-2022

GENERAL COMMENTS	I think it would be interesting to present the initially proposed criteria for each definition, inspired by the meta-analysis, in the method section.

REVIEWER	Santaguida, Pasqualina McMaster University, Health Research Methods, Evidence and Impact
REVIEW RETURNED	06-Oct-2022

GENERAL COMMENTS	Thank you for the opportunity to review this interesting study on establishing clinical criteria and assessment for NOE. The methods used to achieve the goals of this research are complex and multicomponent. As such I can understand how providing sufficient detail (to meet reporting standards) can be a challenge. In my judgement the authors do not meet reporting standards for

	the methods they report. For example, although they report that the systematic review used the PRISMA reporting standards….they don't even state the research question or PICOS…so we can judge if this was sufficient to be used appropriately for the eDelphi. There are large missing links to guide the reader to understand how the different components were linked. As well, there are reporting standards for Delphi (please go to EQUATOR NETWORK). The authors have the option to report key aspects in online appendices. I would suggest that the eDelphi methods fro the final rounds confuse other consensus methods (such as nominal group processes). I am not aware of an eDelphi that has rounds in person. My understanding is that you then move to a different methodology for consensus (for example in person Nominal Group Technique). There is minimal description about how the in person meetings (rounds) were conducted. It is common to find many publicatiosn that combine Delphi and Nominal Group consensus methods….but these studies understand the difference. These authors make no distinction and as a result I don't have confidence that the purported advantages and limitations are truly understood. INTRODUCTION Page 8 of 35: Line 235 "Most published series are limited and of poor quality". Can you please cite what this literature is you are referring to. METHODS "Systematic Review" Page 11 of 35: line 286: PRIMSA should be PRISMA Why are the results reported in the methods. You should provide the basic methods rather than direct the reader to an unpublished review. Why would I accept the results without specifying the PICOTS to understand what these results are? Although the details are published elsewhere you must provide sufficient understanding of these methods to see how they relate to the subsequent methods. In my judgement this section is not sufficiently described. It is more important to describe the research question and eligibility rather than report the RESULTS of the review in the methods. "Delphi method" The purpose of a Delphi is not always consensus. It also identifies areas of dissensus. The methods described in sections iii forward are related to the Delphi. re are no methods described here. What was your criteria for consensus, what number of rounds established. How were experts recruited? These are the methods of a Delphi….the enumeration of these are confusing since they are related to the eDelphi.

	Page 13 of 35: line 327-329.; The main tenant of a Delphi is anonymity. Can you please explain how anonymity is maintained during in person meetings? What you have done is moved to OTHER consensus methods (likely a nominal group process). In my judgement your methods are not consistent with standard Delphi methods. Please provide more details about how these in person rounds were conducted. How did you maintain anonymity and evaluate consensus? How were the questions responses phrased …was it a yes/no or a Likert scale ranging from "strongly agree to strongly disagree" RESULTS: Page 15 of 3:line 366:Indicates that "all survey questions and facilitator communiques (I believe you mean summary of previous round findings that were vetted by a steering committee) are available in figshare"; What is Figshare? Why not place these in an online appendix? Page 15 of 3:line 368-9: What would have happened if the final consensus definitions would not have been endorsed….what does this mean for the methods? Were members of these organizations part of the Delphi experts? It is not clear why these are RESULTS. Perhaps this should be moved to the DISCUSSION. DISCUSSION: There are a number of current reviews of Delphi methods. Please consider Beiderbeck 2021 for a summary of appropriate Delphi methods. Please consider Bhandari 2021 as a summary of identifying and controlling biases in Expert-opinion research. Although these are narrative reviews they may be sufficient to help you identify how your methods match with current understanding of these consensus methods. The papers you cited related to methods were predominately others who used this method…but it doesn't mean their methods were correct. The authors are to be commended for addressing this important clinical issue but the reporting of these should be significantly improved for reproducibility and to ensure that methodological flaws and biases have been minimized or not.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. Treviño JL González , Autonomous University of Nuevo Leon
Comments to the Author:

Reviewer: 2

Miss Djamila Rojoa, Imperial College Healthcare NHS Trust
Comments to the Author:

This is an important paper addressing the long-awaited need for a set of defining criteria for NOE. There has been an exponential rise in admission of patients with NOE in the UK in recent years, however, diagnosis uncertainty and lack of uniformity still remain.

The results of this study will not only facilitate diagnosis and management on clinical grounds but also allow better quality studies to be carried out, which will help in risk stratification and severity grading. The methodology regarding Delphi consensus is strong and well performed. Minimal information available about the systematic search, pending the publication of the submitted paper.

The strength of the study lies in its ability to set specific criteria in terms of diagnostic certainty, disease severity and monitoring outcomes. Criteria for definition of NOE include clinical, histological and radiological findings, all of which are in line with previous clinical studies and evidence synthesis (Byun YJ et al. Necrotizing Otitis Externa: A Systematic Review and Analysis of Changing Trends. Otol Neurotol. 2020 Sep;41(8):1004-1011).
The criteria for possible NOE may be used as a guide where resources are not available in an acceptable time-frame, for instance patients presenting to the primary care setting with symptoms of OE refractory to treatment, for expedited diagnosis and referral to secondary care. Patient-related factors are known to affect disease progression and prognosis. Even though further studies with larger cohorts of patients are required to determine the independent impact of various comorbidities, the currently available pool of evidence shows that immunosuppression is an important risk stratifying factor for NOE.
Similarly, previous studies have shown cranial nerve involvement on admission and radiological progression of disease beyond the EAC to hold importance prognostic value in terms of morbidity and survival, hence they are valid criteria included in the definition of complex NOE.

Early MDT approach is a valuable contribution, it addresses the increasing antimicrobial (ciprofloxacin) resistance and combination therapy complexity, with the early interventions by microbiologists and allows early grading of severity by radiologists and better monitoring of disease progression throughout.

This study adds a valuable dimension to the management of NOE, based on expert opinions, about a topic with uncertainty and controversies. It is a step towards standardising our practice regarding NOE, aiding in early diagnosis, reducing the length of antimicrobial therapy and minimising the risk of morbidity and mortality. Moreover, it serves as a breeding ground for further studies with more vigorous methodology to be performed, culminating in robust evidence synthesis which will drive the management of NOE forward.

Thank you for your very helpful review. We are grateful for your encouraging comments and most of all for highlighting the lack of standardisation in our practice of managing this debilitating condition.

Reviewer: 3
Dr. Chilaf Peled, Birmingham Children's Hospital NHS Foundation Trust

Comments to the Author:
Thank you for your well designed and written study. I have enjoyed reading it, and believe it will contribute to other physicians and researches who are interested in the diagnosis and management of NOE.

One important comment - in you consensus statement defining "definite NOE" and "possible NOE", you have failed to mention the correlation between NOE and diabetes. why is that ? is there no agreement that NOE is highly associated with diabetes ? please elaborate.

Thank you for this comment. There is some discussion in the literature about why diabetes is an important risk factor. It may be that blood supply to the ear is poor because of vascular disease, some have proposed that the micro-environment in the ear is different in diabetics and more is conducive to infection. We have not expanded this discussion because we do not yet have data other than epidemiological data to explain this phenomenon. This will definitely be an area for further study.

Reviewer: 4
Dr. Asma Ben Mabrouk, Taher Sfar university hospital
Comments to the Author:

I think it would be interesting to present the initially proposed criteria for each definition, inspired by the meta-analysis, in the method section.

We would like to thank the reviewer for this comment. Unfortunately no papers have been published to date that specifically address the topic of case definition. Our systematic review has highlighted the number of different definitions that have been used in published studies in the past. Unfortunately the quality of the data from the systematic review is poor. This has been highlighted by the two previously published reviews. (Mahdyoun P, Pulcini C, Gahide I, et al. Necrotizing otitis externa: a systematic review. "Our review revealed the absence of strong scientific evidence regarding diagnostic criteria.." Otol Neurotol 2013;34:620-9 PubMed ; Byun YJ, Patel J, Nguyen SA, Lambert PR. Necrotizing Otitis Externa: A Systematic Review and Analysis of Changing Trends. Otol Neurotol 2020;41:1004-11 PubMed . 'All data were of low level scientific evidence and in many cases the reported data was unclear or not extractable.")
The initially proposed criteria for accepting each definition is set out in the methods section
We will submit the appendices and supplementary data to FigShare or as an appendix where it will be available to for review.

Reviewer: 5
Dr. Pasqualina Santaguida, McMaster University
Comments to the Author:
Thank you for the opportunity to review this work. Please see the attached comments.
Thank you for the opportunity to review this interesting study on establishing clinical criteria and assessment for NOE. The methods used to achieve the goals of this research are complex and multicomponent. As such I can understand how providing sufficient detail (to meet reporting standards) can be a challenge. In my judgement the authors do not meet reporting standards for the methods they report. For example, although they report that the systematic review used the PRISMA reporting standards....they don't even state the research question or PICOS...so we can judge if this was sufficient to be used appropriately for the eDelphi. There are large missing links to guide the reader to understand how the different components were linked. As well, there are reporting standards for Delphi (please go to EQUATOR NETWORK). The authors have the option to report key aspects in online appendices.
We would like to thank the reviewer for the support for this project and for recognising the challenges with trying to establish clinical criteria for the diagnosis of NOE. We have supplemented the section describing the systematic review. The process of performing the systematic review was robust. It is registered on PROSPERO on 23rd January 2020 (PROSPERO ID: CRD42020128957). In this systematic review we reviewed all the NOE clinical articles published to date. The issue is that the data is of poor quality – case reports and case series.

We would argue that we have presented the salient features of the systematic review. The key point is that, as others have reported, the published data on NOE is poor. There is no published consensus definition. We therefore need another method to define this condition until more data is available. The lack of robust data is confirmed by the conclusions of the two previous systematic reviews: Mahdyoun P, Pulcini C, Gahide I, et al. Necrotizing otitis externa: a sstematic review. "Our review revealed the absence of strong scientific evidence regarding diagnostic criteria.." Otol Neurotol 2013;34:620-9 PubMed ; Byun YJ, Patel J, Nguyen SA, Lambert PR. Necrotizing Otitis Externa: A Systematic Review and Analysis of Changing Trends. Otol Neurotol 2020;41:1004-11 PubMed . 'All data were of low level scientific evidence and in many cases the reported data was unclear or not extractable."

We have added more detail to the methods section in order to address the problem of how different components of the process eg face to face meeting and the questionnaire were linked.

Thank you for raising the CREDES criteria. We have already reported each of the points stipulated for reporting of a Delphi study using the CREDES criteria in the text and have addressed the SRQR above. For completeness we have shown where we have addressed each of the points for CREDES reporting below:

CREDES REPORTING

1. Justification: The constructivist nature of Delphi lends itself perfectly to ensuring engagement of experts in an essentially data free zone. We have set out the justification in the section entitled 'Delphi method'(Page 5, line 112-185).

Planning and Design

2. Planning and process: The Delphi is a flexible method which can be adjusted to the research aims which we have set out in the section entitled 'Delphi method'. (Page 5, line 112-line185)

3. Definition of consensus: We have set out the a priori criterion for consensus. This is in the section 'Predefined consensus criteria'(Page 8 line 172-181)

Study conduct

4. Informational input: The results from the study together with the comments were fed back to the participants. The consensus definitions were adhered to, to reduce any risk of bias. (Page 7; Line 158-181)

5. Prevention of bias: There were no conflicts of interest declared in the group. The risk of bias was minimised by producing the results for participants without interpretation.

6. Interpretation and processing of results: covered in methods section. (Page 5, line 112-line185)

7. External validation: This work has been reviewed and endorsed by the three national bodies that service ENT, Infection and Radiology. (Page 7 Line 145-147)

Reporting

8. Purpose and rationale: The reasons for choosing a Delphi technique are discussed. Methods section (ii and iii) (Page 6 Line 128-141)

9. Expert panel: The panel were all senior consultants from each of the specialist areas – ENT, Infection and Radiology. One of the core group MMN has led and published the European wide process to agree definitions for prosthetic joint infection. (Page 7; line 153-155)

10. Description of the methods: These have been described – systematic review provided background data, questions were written and reviewed and edited by the core group. (Page 5, line 112-line185)

11. Procedure: Flow chart included see Fig 1.

12. Definition and attainment of consensus: This is set out in the section 'Predefined consensus definitions'. Page 8, Line 173-181.

13. Results: The detail of the results is available in the Appendix which will be posted on FigShare, which is detailed in the manuscript. This is as per BMJ Open Instructions for Authors.

14. Discussion of limitations: The limitations have been discussed. Page 22, Line 521-526.

15. Adequacy of conclusions: The conclusions reflect the findings in this study. They are pragmatic definitions which will need modification as more robust data emerges.

16. Publication and dissemination: The systematic review has shown that there is a dearth of robust data investigating the diagnosis and management of this condition. The crux of the problem is that there is no widely agreed definition of NOE to facilitate the comparison of data across studies. This current study is a collaboration between 74 clinicians across the UK from the three main specialist groups which manage this condition to try to address this problem. There is an urgent need to publish this study in order to facilitate interpretation of the research that is done to investigate this condition and so to improve the management and outcomes
We would be delighted to submit any aspects of this study as part of an online appendix of supplementary information. In fact this is what we have proposed to do already (Page 10; Line 197).

I would suggest that the eDelphi methods fro the final rounds confuse other consensus methods (such as nominal group processes). I am not aware of an eDelphi that has rounds **in person**. My understanding is that you then move to a different methodology for consensus (for example in person Nominal Group Technique). There is minimal description about how the in person meetings (rounds) were conducted. It is common to find many publicatiosn that combine Delphi and Nominal Group consensus methods....but these studies understand the difference. These authors make no distinction and as a result I don't have confidence that the purported advantages and limitations are truly understood.
We would like to thank the reviewer for the comment – we would agree that it is common to find many publications that combine Delphi and Nominal Group consensus methods. We have expanded on the description of the face to face meeting – of which there was only one. The face to face meeting allowed further discussion about the subtleties of NOE diagnosis which are difficult to convey without opportunity for dialogue. The result of the face to face meeting was followed by Round 4 which followed the process agreed at the outset of the study. Round 4 was the opportunity to ensure that the feedback was anonymous and done in an equitable way according to Delphi guidance. The meeting provided an opportunity to galvanise support for the process and establish links for future studies.

INTRODUCTION
Page 8 of 35: Line 235 "Most published series are limited and of poor quality". Can you please cite what this literature is you are referring to.
We would like to thank the reviewer for pointing out that this sentence was not referenced. We have added two references which are the two systematic reviews which have reviewed all the NOE literature to date. Our systematic review provides evidence for the same conclusion. Mahdyoun P, Pulcini C, Gahide I, et al. Necrotizing otitis externa: a systematic review. "Our review revealed the absence of strong scientific evidence regarding diagnostic criteria.."
Otol Neurotol 2013;34:620-9 PubMed ; Byun YJ, Patel J, Nguyen SA, Lambert PR. Necrotizing Otitis Externa: A Systematic Review and Analysis of Changing Trends. Otol Neurotol 2020;41:1004-11 PubMed . 'All data were of low level scientific evidence and in many cases the reported data was unclear or not extractable."
METHODS
"Systematic Review"
Page 11 of 35: line 286: PRIMSA should be PRISMA
Thank you for pointing out this typo. It has been corrected.
Why are the results reported in the methods. You should provide the basic methods rather than direct the reader to an unpublished review. Why would I accept the results without specifying the PICOTS to understand what these results are? Although the details are published elsewhere you must provide sufficient understanding of these methods to see how they relate to the subsequent methods. In my judgement this section is not sufficiently described. It is more important to describe the research question and eligibility rather than report the RESULTS of the review in the methods.
Thank you for this raising point, however we would disagree that the results are reported in the methods. In the methods section we have set out how we have attained the results we have reported for the Delphi process.

Prior to commencing any Delphi process the literature should be reviewed. This is what the NOE systematic review set out to do. It is important to recognise that a review of all the published literature there is no agreed definition. The systematic review is under review for publication and we hope will be accepted publication in the next few weeks. However, our findings are no different to those of the previous two systematic reviews which have been published which show that there is no agreed case definition and that the quality of data is poor.
Mahdyoun P, Pulcini C, Gahide I, et al. Necrotizing otitis externa: a systematic review; Otol Neurotol 2013;34:620-9 PubMed . "Our review revealed the absence of strong scientific evidence regarding diagnostic criteria.."
Byun YJ, Patel J, Nguyen SA, Lambert PR. Necrotizing Otitis Externa: A Systematic Review and Analysis of Changing Trends. Otol Neurotol 2020;41:1004-11 PubMed . "All data were of low level scientific evidence and in many cases the reported data was unclear or not extractable."
The systematic review results are not reported in the results of the Delphi process. The results of the systematic literature review informed the methods for the Delphi process. Therefore we do not think it makes sense to include the results of the systematic review with the results of the Delphi study. This would be contrary to the Delphi process which is Preparing > Conducting > Analysing. The systematic review is a part of the preparation phase.
We accept that referring to our systematic review which is undergoing review has its limitations – but it is most important to acknowledge that none of the literature to date addresses the problem of case definition. There is no published consensus definition. We have edited the manuscript to describe the process more fully, but we do not think that this builds the readers' understanding of what we have done in the Delphi process.
The research question and reason for the study is found in (Line 76-109). We are not clear what is meant by 'eligibility', but we have expanded on who was included in the methods (Page 7; Lines 144-155).
"Delphi method"
The purpose of a Delphi is not always consensus. It also identifies areas of dissensus. The methods described in sections iii forward are related to the Delphi.
Thank you for this comment and we would agree that Delphi identifies areas of dissensus. The aim of the project was to identify areas of consensus as a starting point for agreeing definitions; and dissensus as a way to identify key areas for research. We provided opportunity for participants to feedback on all reasons for disagreement or agreement on each question. These were reviewed by the core group and fed back to participants.
re are no methods described here. What was your criteria for consensus, what number of rounds established. How were experts recruited? These are the methods of a Delphi….the enumeration of these are confusing since they are related to the eDelphi.
Thank you for this comment. We have set out the methods in the Methods Section (lines 96 to 160), Specifically Definitions part (iv) (lines 133-140) we have set out how experts were recruited (iii) (lines 144-155), what constituted consensus in Section (v) 'Predefined consensus criteria' (Lines 147-156).

Page 13 of 35: line 327-329.; The main tenant of a Delphi is anonymity. Can you please explain how anonymity is maintained during in person meetings? What you have done is moved to OTHER consensus methods (likely a nominal group process). In my judgement your methods are not consistent with standard Delphi methods. Please provide more details about how these in person rounds were conducted. How did you maintain anonymity and evaluate consensus?
We would agree that anonymity is one of the main tenants of Delphi. We have ensured anonymity throughout this process.
As set out in the methods, the one in-person meeting was held to engage and galvanise support for the process. No formal consensus was sought at the face to face meeting. It was an opportunity to discuss the subtle complexities of diagnosing this condition. Following on from this meeting a questionnaire was sent out to all participants of the previous rounds, irrespective of whether they had

attended the face to face meeting. All responses to the Delphi questionnaires were collected online anonymously.
We have expanded the methods section under (iv) Definitions to better explain the face to face meeting and outcomes.
How were the questions responses phrased ...was it a yes/no or a Likert scale ranging from "strongly agree to strongly disagree"
The questionnaire used a Likert scale. This is set out in the Methods Section, part (iv) (lines 162-163).
RESULTS:
Page 15 of 3:line 366:Indicates that "all survey questions and facilitator communiques (I believe you mean summary of previous round findings that were vetted by a steering committee) are available in figshare"; What is Figshare? Why not place these in an online appendix?
Figshare is an online resource which is 'a home for papers, FAIR data and non-traditional research outputs that is easy to use' https://figshare.com.
The submission guideline for BMJ Open is that supplemental data is posted on FigShare or Dryad. The specific instructions for BMJ Open are pasted below:
'Supplementary and raw data can be placed online alongside the article although we prefer raw data to be made publicly available and linked to in a suitable repository (e.g. Dryad, FigShare). We may request that you separate out some material into supplementary data files to make the main manuscript clearer for readers.'
https://bmjopen.bmj.com/pages/authors#submission_guidelines
However, we would be delighted to place this on another online appendix if the editors preferred this option.
Page 15 of 3:line 368-9: What would have happened if the final consensus definitions would not have been endorsed....what does this mean for the methods? Were members of these organizations part of the Delphi experts? It is not clear why these are RESULTS. Perhaps this should be moved to the DISCUSSION.
Line 368 is in the reference section. We think that this refers to the endorsement by the three major organisations which support ENT surgeons, Infection specialists and radiology specialists. If the results had not been endorsed there would be process whereby the reason for non-endorsement would be reviewed.
This sentence is in the results section because it refers to how the data was managed. It is not part of the discussion of the data. It is further endorsement and provides greater support from the wider ENT, Infection and radiology community for the conclusions presented.

DISCUSSION:
There are a number of current reviews of Delphi methods. Please consider Beiderbeck 2021 for a summary of appropriate Delphi methods. Please consider Bhandari 2021 as a summary of identifying and controlling biases in Expert-opinion research. Although these are narrative reviews they may be sufficient to help you identify how your methods match with current understanding of these consensus methods. The papers you cited related to methods were predominately others who used this method...but it doesn't mean their methods were correct.
We would agree that there are a number of reviews of Delphi methods. Thank you for suggesting the Biederbeck review which comprehensively demonstrates how to prepare, conduct and analyse a Delphi study based on the impact of COVID-19 on the European football ecosystem. Our Study methods, are consistent with what are suggested in this paper.
Thank you for suggesting the Bhandari review. It makes very interesting reading. We do not think that our process has lent itself to bias. We have been very cautious to make sure that the process was agreed a priori to reduce the risk of bias, that the participants maintained anonymity and that the core group were held accountable through the opportunity for feedback comments for each question. Whilst we would argue that the references we have used have applied this method correctly we have also sited the suggested papers in our references.

The authors are to be commended for addressing this important clinical issue but the reporting of these should be significantly improved for reproducibility and to ensure that methodological flaws and biases have been minimized or not.
We would like to thank the reviewer for this endorsement. Our view is that our methods, now described more fully as suggested, are robust and reproducible and that methodological biases have been minimised.

The main problem with the topic is the lack of robust data on NOE on which experts can base their opinion. We hope that the publication of this work will provide an opportunity for researchers to validate the definitions to ensure that the field is progressed and that we improve the diagnosis, management and outcomes of patients with this debilitating condition.