

## PEER REVIEW HISTORY

BMJ Paediatrics Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Assessing the impact of the Covid-19 pandemic on parental satisfaction in two European neonatal intensive care units
<b>AUTHORS</b>	Zorro, Carolina MacRae, Eva Teresa-Palacio, Marta Williams, Emma E. Aldecoa-Bilbao, Victoria Bhat, Ravindra Hickey, Ann Dassios, Theodore Greenough, Anne

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Reviewer name: Dr. Natalie Shenker Institution and Country: Imperial College of Science Technology and Medicine, United Kingdom of Great Britain and Northern Ireland Competing interests: None
<b>REVIEW RETURNED</b>	02-Feb-2022

<b>GENERAL COMMENTS</b>	<p>This original research uses a simple survey to examine the experiences of parents of infants cared for on two neonatal units, in the UK and Spain, at two different time periods during the first year of the COVID-19 pandemic. Thank you for the opportunity to review this paper, I have the following comments in its current form:</p> <p>Major comments</p> <p>Methods</p> <p>There is no statement of ethical approval. Was this waived as a service evaluation? Given the scope of questions and the free text fields, plus the prospective nature of the KCH data collection with surveys completed on the unit and therefore difficult to anonymise, this would need assessing by an ethics board. Where single comments have been referenced, this makes individuals potentially identifiable.</p> <p>The lack of baseline assessment is a significant problem, particularly as the authors note the differences in data collection between the two sites (prospective vs. retrospective). Without a comparator, it is impossible to make any conclusions about differences in approach between the two units, nor the impact of pandemic impacts, society-wide policies in the UK and Spain and specific unit protocols for the management of COVID-19. Plus, as the authors explain, there are significant differences in the delivery of routine care between the two units, making comparison even more difficult.</p> <p>The collection of data prospectively makes reporting of care difficult, as parents may be less likely to make significant concerns known while their infants are still in hospital.</p> <p>It is not clear in the Methods whether the questionnaires were anonymised after completion, or completed anonymously.</p> <p>How were parents made aware of the survey?</p> <p>How were the participating centres identified? Was this a pragmatic approach?</p>
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	<p>What was the App that was used for data collection (manufacturer)?  Were participants provided with an information sheet about the study?  How was consent gained?  Parent involvement: could parents or the public have been involved in the peer review of the paper and advice on its dissemination? It is impossible to assess whether the Mann Whitney U test was appropriate for all statistical comparisons. What was the level of statistical significance?</p> <p>Results</p> <p>How many responses were from mothers, fathers or others? Is any data available on other characteristics, e.g., the gestation of their infant or duration of care on the NICU?  Numbers should be given alongside percentages. Did all parents complete all questions?  What proportion of parents chose not to complete the questionnaires? The number of admissions during the study collection periods are not given, meaning the denominator is not known. Based on admissions data, there should have been around 80 admissions over the KCH data collection period (although the authors mention admissions dropped significantly during the first wave). For BCN, there should have been around 230 admissions during that time. If 38 were collected in 6 weeks, why were only 36 collected over 5 months in Barcelona?  On a similar point, it would have been interesting to conduct the same survey and data collection process in the same units over different time periods so that like could be compared with like. Can these groups be comparable if less restrictive visiting practices were used in Spain compared to the UK NICU?  Sample comments should be given to support each statement / theme from the free text comments.</p> <p>Discussion</p> <p>In the discussion, parents are described as not reporting a significant reduction in time spent breastfeeding or providing kangaroo care. What is this comparable against? The same with parental satisfaction – compared to what?  “It is crucial that health professionals remain vigilant in identifying parents who require additional emotional support and sign posting them to appropriate organisations.” Was there no on-unit psychological support for parents?  It is unclear how the findings support the use of video technology, where greater involvement with care was reported in the group that had also visiting facilitated by both parents. While digital innovations have a place where parental absence is unavoidable, maintaining family centred care with parents viewed not as visitors but integral to the care of the infant has a significantly stronger evidence base.  “Overall, parents were very happy and thankful for the clinical care and continuous support provided, despite the challenges of the pandemic.” How is this conclusion supported?  The figures are not provided for review.  The survey and answer options are not provided for review.</p> <p>What this study adds</p> <ul style="list-style-type: none"> <li>• Despite the restrictive visiting policies implemented satisfaction with the care that infants received and with medical updates remained positive</li> </ul> <p>I am not clear how this conclusion is reached, given the problems outlined above with data collection.  Overall time spent in breastfeeding and in Kangaroo Care was affected by the pandemic but there were no significant differences between different visiting policies  Can this conclusion be made when the baseline level of care pre-pandemic is not described?</p>
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<b>REVIEWER</b>	Reviewer name: Prof. ELizabeth M Molyneux Institution and Country: Paediatrics College of Medicine, Malawi Competing interests: None
<b>REVIEW RETURNED</b>	25-Jan-2022

<b>GENERAL COMMENTS</b>	<p>In this paper the authors present the results of a questionnaire used in 2 urban, tertiary care neonatal intensive care units in 2 high income countries to evaluate the impact of COVID-19 on the experience of parents whose infant were admitted during the pandemic. Two time periods are covered; in the London NICU parents were approached prospectively over a 6 week period in the first wave. In Spain the parents filled in the questionnaire retrospectively to cover a 5 month period in the second and third wave.</p> <p>The London NICU is larger with a greater number of admissions than the Spanish NICU (700 v 550); though the number requiring intensive care were a higher proportion in the Spanish unit (46.7% v 33.7%). The premature babies were also a greater proportion in Spain - 35.4% v 76.7%.</p> <p>The physical set up was similar in both units except that the Spanish unit seemed to have more cameras for parents to view their infants when not physically able to be present.</p> <p>Both units altered visiting rules according to national, professional and international guidelines when COVID infections became widespread. But rules about visiting were less ridged during the second and third wave.</p> <p>Parents found visiting restrictions difficult, limiting visitors to one at a time, and only to parents, wearing a facemask was especially restrictive and some felt that breastfeeding was more difficult or not possible. All felt well-informed and that care was good. General societal problems with transport also made any visits difficult. Overall COVID had significant impact on parental feelings of how they bonded with their baby and their level of anxiety. The Spanish parents were very glad of the 24 hour ability to watch the unit and their baby on camera. In the second and third wave visiting was a little more open and the parent room was also open – all of which helped.</p> <p>Comments:</p> <p>It is really quite hard to compare 2 different units of different sizes, in different countries at 2 different times in the COVID -19 epidemic. Also one unit provided the questionnaires prospectively when the babies were still inpatients. In Spain questionnaires were filled retrospectively, I do not know how long after discharge, when parents views may have been changed with time and distance.</p> <p>How did staffing compare between the two units?</p> <p>The questionnaire was short – 6 questions, but with permission could more be gained from the notes?</p> <p>Were the parents most affected those with a very ill infant, or very premature, or first time parents?</p> <p>Did all the infants survive? I imagine they did in the retrospectively questioned cohort, but is this also true of the prospective group? If not was there any bias in selecting who received a questionnaire?</p> <p>In the conclusion, what has been learnt to be able to improve in a future pandemic?</p> <p>Should something different have occurred in the first wave (when so little is known about the virus, about infant related morbidity and mortality)?</p> <p>Have the units learnt from each other?</p> <p>Are changes anticipated in either unit of physical space/isolation, communications, or policy?</p>
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<b>REVIEWER</b>	Reviewer name: Dr. nicole r van veenendaal Institution and Country: AmsterdamUMC, United Kingdom of Great Britain and Northern Ireland Competing interests: None
<b>REVIEW RETURNED</b>	14-Jan-2022

<b>GENERAL COMMENTS</b>	Comments to the author. Thank you for giving me the opportunity to review this manuscript.
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My expertise is within family integrated care, and I'm trained as an epidemiologist and statistician. Above, I'm a semi-native English speaker. Overall, I have some methodological concerns. I used the STROBE guidelines to make my review. (von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol [Internet]. 2008 Apr [cited 2018 May 13];61(4):344–9. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/18313558>)

I do fully support the research in that it is important to study the effect of the current pandemic on outcomes in parents, as this is a very important subject to study.

This study reports on the effect of the impact of the pandemic on the experience of parents with newborns admitted to two tertiary neonatal intensive care units.

In this study parents of infants admitted to each neonatal unit were asked to complete a questionnaire regarding their experience during the Covid-19 pandemic. At one unit, UK (KCH) data were collected prospectively between June 2020 and August 2020 (first wave). At the other unit (BCN) data were collected retrospectively from parents whose infants were admitted between September 2020 and February 2021 (second and third wave).

Major concerns:

The main question of this study was: "to assess the effect of the pandemic on parental experience within two neonatal intensive care units in Europe. Specifically, we wanted to explore common themes experienced by families with infants admitted to intensive care during the pandemic in two healthcare settings in Europe."

The objective of this study is to assess the impact of an exposure (the pandemic) on outcomes (parental experience), for which questionnaires are appropriate to collect the data. However, I do have some concerns considering the methodology of this study, as it is not set up to address above question, but more answers the differences in outcomes between the units during the pandemic. I'm therefore unsure how this study exactly addresses the main research question as several comparisons are made, and precisely comparing different time windows and different units with each other. To study the effect of the pandemic on outcomes, preferably a control group that did not experience the pandemic would have been included to answer the main question of this study, or otherwise can the authors elaborate on how they addressed this objective?

For example, the question considering the quality time spent with infants during the pandemic was more negatively affected at KCH compared to BCN, which is not an answer to the effect of the pandemic on outcomes, but the difference in time spent with infants during the pandemic between the KCH and BCN which is tested. Possibly other exposures are affecting this outcome, which could be multifactorial and is very prone to bias, namely: country where the unit is situated, no. of wave of pandemic, mode of data collection (prospectively versus retrospectively) etc. I think the authors should address this issue thoroughly throughout the manuscript. For now it seems they should adjust their research question and underline that this study studies the difference between two units during the pandemic and not the influence of the pandemic itself.

Throughout the manuscript, parents are suggested to be visitors, and the authors describe "visiting policies". From a family integrated care perspective, parents are not visitors to their infants (they are their parents!) and therefore this should be rewritten throughout the manuscript.

No (or very very brief) statistical methods are mentioned. No qualitative analyses methods are mentioned, whereas the authors claim that they have searched for common themes.

I wonder if all the figures are appropriate, as I think this data is potentially more fit to be presented in tables.

The following STROBE items are missing and are recommended to add:

- "Present key elements of study design early in the paper". Is this a qualitative paper? Or did the authors use mixed-methods? Or did they use matched-controls? Please clarify.
- "Give the eligibility criteria, and the sources and methods of selection of participants." How many parents were asked to participate? What were the inclusion criteria? Please consider to include a flow-diagram for this study. What was the response rate of this study?
- "Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers."
- "Describe any efforts to address potential sources of bias"
- "Explain how the study size was arrived at", or present why no sample size calculation was performed.
- "Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why"
- (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
- (b) Give reasons for non-participation at each stage
- (c) Consider use of a flow diagram: A flow diagram is missing on how many parents were asked to participate and how many were eligible with reasons for non-participation, is selection bias therefore present?
- (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
- (b) Indicate number of participants with missing data for each variable of interest
- a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included

**Minor concerns**

The authors state that "it was not appropriate or possible to involve patients...". I think it is always appropriate to include patients, I think the authors mean "not possible"?

Just from a curiosity point of view: how did the authors test that the pandemic did not affect the time breastfeeding? Did parents simultaneously first experience the non-pandemic era and then the pandemic era, and therefore could compare those different periods? I think, if parents did not experience the pre-pandemic period, it is for them very difficult to tell what the influence is of the pandemic, and if this has a negative influence or not (I have the same concern for the other outcomes that were tested (please see my above comment on the study design)).

L. 45: "difficulties were expressed balancing home life with frequent visits to the hospital, especially with twins or siblings at home": I wonder if this is the influence of the pandemic or not, as from my clinical experience, this is a difficulty often reported by parents also in times without a pandemic. How can the authors verify that this is the influence of the pandemic?

Also, maybe co-interventions were different in the different time periods and within the different units (for instance availability/use of psychological help, use of depressive medication or other follow-up and support after hospital discharge) and were not measured/presented in this report, and were not used to adjust for in the main analyses.

**Detailed concerns:**

I. 22-26: "The universal responses by most healthcare organisations in imposing restrictions particularly in the early stages, however, often did not consider the unique situation that arises with the newborn mother-baby dyad." Do the authors mean "with the mother-baby dyad"?

Please consider to use information and results from the following publication to strengthen your objective and discussion throughout

	the manuscript: Kostenzer J, Hoffmann J, von Rosenstiel-Pulver C, Walsh A, Zimmermann LJI, Mader S. Neonatal care during the COVID-19 pandemic - a global survey of parents' experiences regarding infant and family-centred developmental care. EClinicalMedicine [Internet]. 2021 [cited 2021 Aug 22];39:101056. Available from: <a href="https://doi.org/10.1016/j.eclinm.2021.101056">https://doi.org/10.1016/j.eclinm.2021.101056</a>
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## VERSION 1 – AUTHOR RESPONSE

Dear Professor Choonara and Dr Allegaert Re: bmjpo-2021-001396 - "Assessing the impact of the Covid-19 pandemic on parental satisfaction in two European neonatal intensive care units" Thank you for inviting us to submit a major revision. We have now submitted a manuscript modified to meet all the peer review comments and a point-by-point response to explain any changes we have made to the original article. **RESPONSE TO EDITOR AND REVIEWERS** Editor in Chief Comments to Author: Please confirm ethical approval for your study in both centres. **RESPONSE:** Ethical approval was not sought for the study, as this survey was performed as a service evaluation/improvement project. All answers, including single comments were anonymised and all the patient identifiable information removed to preserve confidentiality and privacy. Add the questionnaire as an appendix. **RESPONSE:** We have added the English and Spanish version of the questionnaire as an appendix. The questionnaire in Spanish has one extra question (question 1) which ask about the length of stay in NICU, to determine eligibility for inclusion, otherwise the two questionnaires were identical Avoid statistical comparison between the two centres -it is not appropriate to compare data collected prospectively with that collected retrospectively **AND** during different time periods in the pandemic. **RESPONSE:** We have removed the p-values from the paper as suggested. Use numbers not % **RESPONSE:** We have included both percentages and numbers as requested by your and another reviewer. Respond in full to the reviewers Be cautious in your interpretation as your numbers are small **RESPONSE:** We have modified our interpretation as suggested. 2 Associate Editor Comments to the Author: (There are no comments.) Reviewer: 1 Prof. ELizabeth Molyneux In this paper the authors present the results of a questionnaire used in 2 urban, tertiary care neonatal intensive care units in 2 high income countries to evaluate the impact of COVID-19 on the experience of parents whose infant were admitted during the pandemic. Two time periods are covered; in the London NICU parents were approached prospectively over a 6 week period in the first wave. In Spain the parents filled in the questionnaire retrospectively to cover a 5 month period in the second and third wave. The London NICU is larger with a greater number of admissions than the Spanish NICU (700 v 550); though the number requiring intensive care were a higher proportion in the Spanish unit (46.7% v 33.7%). The premature babies were also a greater proportion in Spain - 35.4% v 76.7%. The physical set up was similar in both units except that the Spanish unit seemed to have more cameras for parents to view their infants when not physically able to be present. Both units altered visiting rules according to national, professional and international guidelines when COVID infections became widespread. But rules about visiting were less rigid during the second and third wave. Parents found visiting restrictions difficult, limiting visitors to one at a time, and only to parents, wearing a facemask was especially restrictive and some felt that breastfeeding was more difficult or not possible. All felt well-informed and that care was good. General societal problems with transport also made any visits difficult. Overall COVID had significant impact on parental feelings of how they bonded with their baby and their level of anxiety. The Spanish parents were very glad of the 24 hour ability to watch the unit and their baby on camera. In the second and third wave visiting was a little more open and the parent room was also open – all of which helped. Comments: It is really quite hard to compare 2 different units of different

sizes, in different countries at 2 different times in the COVID -19 epidemic. Also one unit provided the questionnaires prospectively when the babies were still inpatients. In Spain questionnaires were filled retrospectively, I do not know how long after discharge, when parents views may have been changed with time and distance. RESPONSE: The questionnaires in Spain were sent in April and May 2021 to all the families whose babies were admitted to ITU between 22nd September 2020 and 28th February 2021. As the responses were anonymous, it is not possible to determine exactly how long after discharge these were filled in and how would this impact on parents' views. We have now further commented in the discussion a limitation of this study was the retrospective nature of the Spanish data How did staffing compare between the two units? RESPONSE: Nursing ratio is 1:1 or 1:2 in ITU, 1:2 in HDU and 1:4 in SCBU in both units. Medical staffing ratio at KCH is 1:4 per weekday shift and in Barcelona is 1:4 to 1:4.6 including middle grade doctors and consultants. 3 The questionnaire was short – 6 questions, but with permission could more be gained from the notes? RESPONSE: As responses from Spain were completely anonymous, no more information can be obtained. The questionnaire was short so it would be rapid and burden free for the parents to complete. Were the parents most affected those with a very ill infant, or very premature, or first time parents? RESPONSE: Parents of babies receiving palliative care or extremely unwell on the end-of-life pathway were not included in this survey (one patient at KCH). Information on whether they were first time parents was not collected. As responses from Spain were anonymous, this information is not available but all babies survived to discharge. At KCH, 12 babies were in ITU, 10 in HDU and 16 in SCBU at the time of completing the survey. Did all the infants survive? I imagine they did in the retrospectively questioned cohort, but is this also true of the prospective group? If not was there any bias in selecting who received a questionnaire? RESPONSE: All infants survived in both cohorts, this is now included in the results. In the conclusion, what has been learnt to be able to improve in a future pandemic? Should something different have occurred in the first wave (when so little is known about the virus, about infant related morbidity and mortality)? RESPONSE: Separation between parents and babies affect parental experience and bonding and neonatal units need to mitigate this impact and try to avoid restrictive policies as much as possible. Have the units learnt from each other? RESPONSE: Results have been shared amongst both units and actions taken to improve parental experience and service development. Are changes anticipated in either unit of physical space/isolation, communications, or policy? RESPONSE: At KCH, there is an ongoing project to expand the neonatal unit and also increase the number of isolation rooms. The limited space and the challenges to facilitate family integrated care were even more evident during the pandemic. In Spain, the onsite parent accommodation room was refurbished and now has an ensuite bathroom. A new “welcoming plan” includes a QR code by which they can download a video explaining how the unit works, the organisation and the facilities. This is to avoid written information and to have the information available at any time. 4 Visiting policies are constantly reviewed in both units based on the dynamic situation of the pandemic. At present, there are no restrictions for the parents, but visiting restrictions are still in place for siblings and extended family We have now included this in the discussion Reviewer: 2 Dr. Natalie Shenker, Imperial College of Science Technology and Medicine This original research uses a simple survey to examine the experiences of parents of infants cared for on two neonatal units, in the UK and Spain, at two different time periods during the first year of the COVID-19 pandemic. Thank you for the opportunity to review this paper, I have the following comments in its current form: Major comments Methods There is no statement of ethical approval. Was this waived as a service evaluation? Given the scope of questions and the free text fields, plus the prospective nature of the KCH data collection with surveys completed on the unit and therefore difficult to anonymise, this would need assessing by an ethics board.

Where single comments have been referenced, this makes individuals potentially identifiable. RESPONSE: Ethical approval was not sought for the study as this study was performed as a service evaluation/ improvement project. All answers, including single comments were anonymised and all the patient identifiable information removed to preserve confidentiality and privacy. The lack of baseline assessment is a significant problem, particularly as the authors note the differences in data collection between the two sites (prospective vs. retrospective). Without a comparator, it is impossible to make any conclusions about differences in approach between the two units, nor the impact of pandemic impacts, society-wide policies in the UK and Spain and specific unit protocols for the management of COVID-19. Plus, as the authors explain, there are significant differences in the delivery of routine care between the two units, making comparison even more difficult. RESPONSE: We have now acknowledged this as a limitation to our study and this is included in the manuscript. We have now removed any statistical comparison as requested by another reviewer, and commented on observations of parental satisfaction during the pandemic in the two countries. The collection of data prospectively makes reporting of care difficult, as parents may be less likely to make significant concerns known while their infants are still in hospital. RESPONSE: Surveys were anonymised and participation on the survey was voluntary. Questions were directed to understand the overall parental experience during the pandemic rather than quality of care. This is now included in the manuscript. It is not clear in the Methods whether the questionnaires were anonymised after completion, or completed anonymously. 5 RESPONSE: At KCH, questionnaires were anonymised after completion. In Spain, questionnaires were completed anonymously via the application “Lyme Survey”, which sends the questionnaire to a list of email addresses. Families answer those questionnaires and Lyme Survey provides the answers with no identification at all. This is now included in the manuscript. How were parents made aware of the survey? RESPONSE: In the UK, parents of all babies who met the inclusion criteria were approached by the doctor leading the survey, she explained the aim of it, obtained verbal consent and gave the questionnaires. In Spain, parents received an email explaining the survey and they decided whether to complete it or not. This is now included in the manuscript. How were the participating centres identified? Was this a pragmatic approach? RESPONSE: The survey was designed by one of the doctors at KCH. A similar neonatal unit in Spain was identified, with the aim to have a broader view of the parental experience during the pandemic, What was the App that was used for data collection (manufacturer)? RESPONSE: In Spain, the on-line statistical survey web app “LimeSurvey” which meets their legal requirements of confidentiality. In the UK, an Excel spreadsheet was created for data collection and analysis. Were participants provided with an information sheet about the study? RESPONSE: Information about the survey was given to the parents by the doctor leading it in UK and by email for the parents in Spain. How was consent gained? RESPONSE: In the UK, verbal consent was obtained after information given by the doctor leading the survey. In Spain, families of babies admitted in the unit are asked to provide contact details and an email address at the beginning of the admission. When they provided it, they consent to be contacted via email. HCM has a quality and safety management program (“ISO 9001” and “UNE179003) by which questionnaires to assess parental satisfaction are regularly sent to the families. All parents receive these questionnaires via email and by completing them, they consent to its final use. This is now included in the manuscript. Parent involvement: could parents or the public have been involved in the peer review of the paper and advice on its dissemination? It is impossible to assess whether the Mann Whitney U test was appropriate for all statistical comparisons. What was the level of statistical significance? RESPONSE: As above we have now taken out the statistical comparison 6 It was not possible to involve patients or the public due to the Covid pandemic and associated restrictions. Results How



many responses were from mothers, fathers or others? Is any data available on other characteristics, e.g., the gestation of their infant or duration of care on the NICU?

RESPONSE: This information is not available for the Spanish cohort as the questionnaire was completed anonymously and those questions were not asked. In the UK, one questionnaire was given per household and mainly mothers completed the survey (33 mothers, 2 fathers, 2 both parents and 1 non specified) this is now included. Numbers should be given alongside percentages. Did all parents complete all questions? What proportion of parents chose not to complete the questionnaires? RESPONSE: As requested we have now included numbers alongside percentages. Missing data: 1 for effect on length/quality of time, 3 for time spent giving kangaroo care, 3 for time spent breastfeeding, 1 for visiting This is now included in the table. The number of admissions during the study collection periods are not given, meaning the denominator is not known. Based on admissions data, there should have been around 80 admissions over the KCH data collection period (although the authors mention admissions dropped significantly during the first wave). For BCN, there should have been around 230 admissions during that time. If 38 were collected in 6 weeks, why were only 36 collected over 5 months in Barcelona? RESPONSE: We have now included the denominators. On a similar point, it would have been interesting to conduct the same survey and data collection process in the same units over different time periods so that like could be compared with like. Can these groups be comparable if less restrictive visiting practices were used in Spain compared to the UK NICU? RESPONSE: We have included in our discussion this would be an interesting point to explore. Sample comments should be given to support each statement / theme from the free text comments. RESPONSE: As requested, we have included sample comments Discussion In the discussion, parents are described as not reporting a significant reduction in time spent breastfeeding or providing kangaroo care. What is this comparable against? The same with parental satisfaction – compared to what? RESPONSE: Parents felt that the pandemic did not have a significant impact in reduction in time spent breastfeeding, providing kangaroo care or satisfaction in receiving medical 7 updates. This is comparable against their own expectations of time to spend breastfeeding or providing Kangaroo care or quality of medical updates “It is crucial that health professionals remain vigilant in identifying parents who require additional emotional support and sign posting them to appropriate organisations.” Was there no on-unit psychological support for parents? RESPONSE: There was psychological support on site for the parents in Spain. At KCH regular psychological support in the neonatal unit started in September 2021 It is unclear how the findings support the use of video technology, where greater involvement with care was reported in the group that had also visiting facilitated by both parents. While digital innovations have a place where parental absence is unavoidable, maintaining family centred care with parents viewed not as visitors but integral to the care of the infant has a significantly stronger evidence base. RESPONSE: Family integrated care is the gold standard, however, when it is not possible for the parents to be with their babies (for example because of self isolation or restrictions during the pandemic), the use of video technology was well received by the parents in both units, as described in the sample comments, these have now been included “Overall, parents were very happy and thankful for the clinical care and continuous support provided, despite the challenges of the pandemic.” How is this conclusion supported? RESPONSE: This conclusion is supported in the free text comments sent by the parents. Sample comments have now been included as you suggested The figures are not provided for review. RESPONSE: Apologies – we have now removed the figures and included a table as requested by another reviewer. The survey and answer options are not provided for review. RESPONSE: Apologies – we have now included the survey and answer options, both in English and Spanish, as requested by you and by the Editor in Chief What this study adds •Despite the restrictive visiting policies implemented satisfaction with the

care that infants received and with medical updates remained positive I am not clear how this conclusion is reached, given the problems outlined above with data collection. RESPONSE: This conclusion was reached based on question 4 which asked about satisfaction with medical updates as well as free comments, which are now included 8 Overall time spent in breastfeeding and in Kangaroo Care was affected by the pandemic but there were no significant differences between different visiting policies Can this conclusion be made when the baseline level of care pre-pandemic is not described? RESPONSE: The questions on Kangaroo Care and breastfeeding are not comparing to pre pandemic level but ascertaining if there are aspects of the pandemic, as well as the unit policies (in response to the pandemic) which has affected breastfeeding and KMC. We have included as a limitation of this study that we do not have a precovid baseline Reviewer: 3 Dr. nicole r van veenendaal, AmsterdamUMC . Thank you for giving me the opportunity to review this manuscript. My expertise is within family integrated care, and I'm trained as an epidemiologist and statistician. Above, I'm a semi-native English speaker. Overall, I have some methodological concerns. I used the STROBE guidelines to make my review. (von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol [Internet]. 2008 Apr [cited 2018 May 13];61(4):344–9. Available from: <https://eur03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.ncbi.nlm.nih.gov%2Fpubmed%2F18313558&data=04%7C01%7Cdeirdre.gibbons%40kcl.ac.uk%7Cfd41036aff14549b29508d9efb93443%7C8370cf1416f34c16b83c724071654356%7C0%7C0%7C637804400995456176%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ikl1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=mLUiLwnLJBBOOK bxRIXBYL1QRnNP6jRO8hJEBhPfqSA%3D&reserved=0>) I do fully support the research in that it is important to study the effect of the current pandemic on outcomes in parents, as this is a very important subject to study. This study reports on the effect of the impact of the pandemic on the experience of parents with newborns admitted to two tertiary neonatal intensive care units. In this study parents of infants admitted to each neonatal unit were asked to complete a questionnaire regarding their experience during the Covid-19 pandemic. At one unit, UK (KCH) data were collected prospectively between June 2020 and August 2020 (first wave). At the other unit (BCN) data were collected retrospectively from parents whose infants were admitted between September 2020 and February 2021 (second and third wave). Major concerns: The main question of this study was: “to assess the effect of the pandemic on parental experience within two neonatal intensive care units in Europe. Specifically, we wanted to explore common themes experienced by families with infants admitted to intensive care during the pandemic in two healthcare settings in Europe.” The objective of this study is to assess the impact of an exposure (the pandemic) on outcomes (parental experience), for which questionnaires are appropriate to collect the data. However, I do have some concerns considering the methodology of this study, as it is not set up to address above question, but more answers the differences in outcomes between the units during the pandemic. I'm therefore unsure how this study exactly addresses the main research question as several comparisons are made, and precisely comparing different time windows and different units with each other. To study the effect of the pandemic on outcomes, preferably a control group that did not experience the pandemic would have been included to answer the main question of this study, or otherwise can the authors elaborate on how they addressed this objective? 9 RESPONSE: We have now included this as a limitation of our study in that no control group pre pandemic was included. We have now clarified that this is an observational study on parental experiences during the pandemic, rather than comparing parental experiences pre

and post pandemic. For example, the question considering the quality time spent with infants during the pandemic was more negatively affected at KCH compared to BCN, which is not an answer to the effect of the pandemic on outcomes, but the difference in time spent with infants during the pandemic between the KCH and BCN which is tested. Possibly other exposures are affecting this outcome, which could be multifactorial and is very prone to bias, namely: country where the unit is situated, no. of wave of pandemic, mode of data collection (prospectively versus retrospectively) etc. I think the authors should address this issue thoroughly throughout the manuscript. For now it seems they should adjust their research question and underline that this study studies the difference between two units during the pandemic and not the influence of the pandemic itself. RESPONSE: We have modified our research question accordingly and stated that this observational study demonstrates the difference between how two European neonatal units changed their parental policies during the pandemic, and to describe parental satisfaction during this time. Throughout the manuscript, parents are suggested to be visitors, and the authors describe “visiting policies”. From a family integrated care perspective, parents are not visitors to their infants (they are their parents!) and therefore this should be rewritten throughout the manuscript. RESPONSE: We have amended this in the manuscript as we completely agree that parents are not visitors and we advocate for a Family integrated care approach in both units. No (or very very brief) statistical methods are mentioned. RESPONSE: As requested by other reviewers we have removed any statistical comparison between the two countries. No qualitative analyses methods are mentioned, whereas the authors claim that they have searched for common themes. RESPONSE: Common themes in the free text responses were those primarily relating to bonding with their baby, together with those of wearing a face mask and how this would influence bonding and development. We have removed any statistical analysis as requested by another reviewer and commented on the observational nature of the study together with common arising themes. I wonder if all the figures are appropriate, as I think this data is potentially more fit to be presented in tables. RESPONSE: We have removed some of the figures and encompassed the remaining data in table format. 10 The following STROBE items are missing and are recommended to add: - “Present key elements of study design early in the paper”. Is this a qualitative paper? Or did the authors use mixed-methods? Or did they used matched-controls? Please clarify. RESPONSE: We have removed statistical analyses as requested by other reviewers; hence this study is now observational in nature. - “Give the eligibility criteria, and the sources and methods of selection of participants.” How many parents were asked to participate? What were the inclusion criteria? Please consider to include a flow-diagram for this study. What was the response rate of this study? RESPONSE: We have specified eligibility criteria and methods for selection of participants. We also included a flow diagram (figure 1) as suggested - “Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers.” RESPONSE: The exposures were having an infant nursed in neonatal intensive care during the study time period, with outcomes as outline in the study questionnaire. As this was an observational study no potential confounders and effect modifiers were included. - “Describe any efforts to address potential sources of bias” RESPONSE: Parents of all infants were approached to avoid selection bias. - All parents eligible were approached during the study time and all responses were included. As no statistical analysis was subsequently undertaken, we felt it appropriate to include all comments and answers received. - “Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why” RESPONSE: As requested by another reviewer we have removed statistical analysis to overcome these challenges. - - Consider use of a flow diagram: A flowdiagram is missing on how many parents were asked to participate and how many were eligible with reasons for non-participation, is selection bias therefore present? RESPONSE: We have included a flow

diagram (figure 1) as suggested - Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. RESPONSE: As the questionnaire was completed anonymously in Spain and these questions were not asked, these information in not available - Indicate number of participants with missing data for each variable of interest RESPONSE: Missing data: 1 for affect on length/quality of time, 3 for time spent giving kangaroo care, 3 for time spent breastfeeding, 1 for visiting 11 Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included RESPONSE: This is no longer appropriate as we have removed statistical analyses as requested by another reviewer. Minor concerns The authors state that "it was not appropriate or possible to involve patients...". I think it is always appropriate to include patients, I think the authors mean "not possible"? Just from a curiosity point of view: how did the authors test that the pandemic did not affect the time breastfeeding? Did parents simultaneously first experience the non-pandemic era and then the pandemic era, and therefore could compare those different periods? I think, if parents did not experience the pre-pandemic period, it is for them very difficult to tell what the influence is of the pandemic, and if this has a negative influence or not (I have the same concern for the other outcomes that were tested (please see my above comment on the study design)). RESPONSE: Yes, we meant it was "not possible" to involve patients and have corrected this in the manuscript. With regards the impact of the pandemic on Kangaroo Care and breastfeeding the aim was not to compare to pre pandemic level but to ascertain if there are aspects of the pandemic as well as the unit policies (in response to the pandemic) which has affected breastfeeding and KMC. This is comparable against their own expectations of time to spend breastfeeding or providing Kangaroo care. L. 45: "difficulties were expressed balancing home life with frequent visits to the hospital, especially with twins or siblings at home": I wonder if this is the influence of the pandemic or not, as from my clinical experience, this is a difficulty often reported by parents also in times without a pandemic. How can the authors verify that this is the influence of the pandemic? Also, maybe co-interventions were different in the different time periods and within the different units (for instance availability/use of psychological help, use of depressive medication or other follow-up and support after hospital discharge) and were not measured/presented in this report and were not used to adjust for in the main analyses. RESPONSE: Before the pandemic, parents with other children used to come with them to the unit so they could visit the baby or wait with other relatives in the family room. However, restrictive policy meant that siblings and other relatives were not allowed in the unit and the family facilities were closed. Detailed concerns: l. 22-26: "The universal responses by most healthcare organisations in imposing restrictions particularly in the early stages, however, often did not consider the unique situation that arises with the newborn mother-baby dyad." Do the authors mean "with the mother-baby dyad?". RESPONSE: We have now corrected it. 12 Please consider to use information and results from the following publication to strengthen your objective and discussion throughout the manuscript: Kostenzer J, Hoffmann J, von Rosenstiel-Pulver C, Walsh A, Zimmermann LJI, Mader S. Neonatal care during the COVID19 pandemic - a global survey of parents' experiences regarding infant and family-centred developmental care. *EClinicalMedicine* [Internet]. 2021 [cited 2021 Aug 22];39:101056. Available from: <https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fdoi.org%2F10.1016%2Fj.eclinm.2021.101056&data=04%7C01%7Cdeirdre.gibbons%40kcl.ac.uk%7Cfcd41036aff14549b29508d9efb93443%7C8370cf1416f34c16b83c724071654356%7C0%7C0%7C637804400995456176%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ikl1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=YnxtH3Ed2SrAgBB8>

xERNF%2B4Vesnq2ch3F2sy4zM7NEo%3D&reserved=0 RESPONSE: We have now referenced this article within our manuscript.

### VERSION 2 – REVIEW

<b>REVIEWER</b>	Reviewer name: Prof. ELizabeth M Molyneux Institution and Country: Paediatrics College of Medicine, Malawi Competing interests: None
<b>REVIEW RETURNED</b>	20-Mar-2022
<b>GENERAL COMMENTS</b>	The authors have addressed adequately my previous review comments.

### VERSION 2 – AUTHOR RESPONSE

Dear Professor Choonara and Dr Allegaert Re: bmjpo-2021-001396.R1 - "Assessing the impact of the Covid-19 pandemic on parental satisfaction in two European neonatal intensive care units" Thank you for inviting us to submit a minor revision. Editor(s)' Comments to Author (if any): Please add the text to the Methods re exemption from seeking ethical approval that is within your rebuttal We added the text to the Methods re exemption from seeking ethical approval. We attach an amended version of our revised manuscript which states that: "The study is registered as a service evaluation with the Clinical Governance Department of King's College Hospital NHS Foundation Trust, London, UK. The Health Research Authority Toolkit of the Medical Research Council, United Kingdom confirmed that the study would not be considered as research and would not require regulatory approval by a research ethics committee." Reviewer: 1 Prof. Elizabeth Molyneux **Comments to the Author** The authors have addressed adequately my previous review comments. Thank you With kind regards Dr Carolina Zorro Consultant Neonatologist

### VERSION 3 – AUTHOR RESPONSE

Dear Dr Allegaert and Professor Choonara

Re: Assessing the impact of the Covid 19 pandemic on parental satisfaction in two European neonatal intensive care units

Thank you for your email requesting revision of our manuscript.

Response to Editor's Comments

We note the approval from Kings college Hospital as a service evaluation. However, we still need confirmation of a similar evaluation in Barcelona. This needs adding to the Methods, if such approval was given prior to the study

RESPONSE: We have now added in the methods section that the study was registered as a service evaluation with the Clinical Governance Department of King's College Hospital NHS Foundation Trust, London, UK and the Legal Department of Hospital Clínic Barcelona, Barcelona, Spain.

Yours sincerely  
Dr Carolina Zorro  
Consultant Neonatologist

