

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

TITLE (PROVISIONAL)	Developing a method to capture parental experience in a neonatal surgical centre in the context of COVID-19
AUTHORS	Mernenko, Rebecca Kate Littlejohns, Anna Latchford, Gary Lakshminarayanan, Bhanumathi Metcalf, Fiona Crouzen, Emile McElwaine, John G Sagoo, Gurdeep Singh Lawson, Elizabeth McConachie, Douglas Moni-Nwinia, Waaka Chauhan, Hemma McKechnie, Liz Sutcliffe, Jonathan

VERSION 1 – REVIEW

REVIEWER	Reviewer name: Dr. James Webbe Institution and Country: Imperial College London, United Kingdom of Great Britain and Northern Ireland Competing interests: None
REVIEW RETURNED	18-Mar-2022

GENERAL COMMENTS	<p>A clear account of a commendable project completed under difficult circumstances with a clear focus on improving the patient experience. The information presented will doubtless be useful to others attempting similar work in the future.</p> <p>Minor comment: Page 8, Line 5: Typo in the sentence "Reassurance was to be given to families that any data would be stored anonymously, in a way that was consistent with data protection rules, that participation (or non-participation) would not affect their care and that withdrawal from the study at any time was acceptable." I think it should read data would be stored anonymously.</p>
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REVIEWER	Reviewer name: Dr. Richard Wood Institution and Country: Nationwide Children's Hospital, United States Competing interests: None
REVIEW RETURNED	08-Mar-2022

GENERAL COMMENTS	<p>Thank you for this contribution.</p> <p>I have several questions. Firstly, do you have any information of how you will implement this testing process within the context of a very different environment now that many COVID restrictions have been ended. Secondly, there is some evidence that outcomes have a</p>
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	big influence on patients experience, do you have a way to match patient outcomes to the results of the survey? Are there any balancing measures proposed to assess the experience results with clinical outcomes and results. Please describes steps to be taken to ensure a diverse group of patient family volunteers.
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REVIEWER	Reviewer name: Ms. Mandy Daly Institution and Country: Irish Neonatal Health Alliance Director of Advocacy and Policymaking, Ireland Competing interests: None
REVIEW RETURNED	17-Mar-2022

GENERAL COMMENTS	<p>I commend the authors for recognising and addressing this important and topical subject and for engaging with families as PPI partners from outset.</p> <p>In terms of the study design, it should be borne in mind that the families involved in the development of this study do not have the benefit of comparison and the perspective offered by them, is directly linked to their experience during the pandemic. They do not a pre-pandemic NICU experience and the process of developing the interview questions would have been richer had families with pre-pandemic experience and a relevant patient organisation with both pre and post pandemic experience been included in the stakeholder group. I note the omission of any reference/questions to breastfeeding and expressing, and skin-to-skin care; interventions whose benefits are well supported by scientific evidence and all of which were badly affected by NICU access restrictions during the pandemic.</p> <p>I would liked to have seen a statement in the paper from the PPI partners about their experience of being involved with the design of the study.</p> <p>I also note the absence of representation from Allied Health Professionals (Lactation Cons, OT, SLT, Physio, Dietician) and no mention of the European Standards of Care For Newborn Health (www.newborn-health-standards.org) which have specific topics related to parental access, nutrition and infant and family centred developmentally supportive care and who spearheaded the global survey of parental experience in the NICU during COVID-19 (Lancet publication).</p> <p>The domain of "discharge" has been omitted from the abstract but appears as one of the five main topics described later in the paper.</p> <p>It is unclear from the paper how consent will be obtained i.e. will families be provided with written patient information brochures/material relating to the the process and once a family has expressed an interest in participating, how long after the initial discussion will they be approached to provide written consent to participate.</p> <p>In this study, the "Closed Parent Facebook" group was selected as a forum to advertise the project but it is worth mentioning that it would be necessary to ensure that the rules governing such groups allows for this type of "recruitment" as oftentimes such closed groups are deemed safe spaces for families with infants in the NICU and using this platform to recruit to a study may contravene group rules.</p>
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	<p>I note that copies of the questions will be provided to families in advance of the interviews; does this include P15, 16 & 17 and if so, some of the language on P15 is not written for the lay-person i.e. GI, co-morbidities. Can the authors confirm at which stage of the process families will be provided with copies of the questions i.e. prior to or post consent. P17 Line 7- An alternative question might be "Do you have a physical, intellectual or mental health disability?"</p> <p>I would recommend that the authors consider presenting their findings at national Neonatal and Paediatric conferences to support the dissemination of the work and also to engage with the national patient organisation supporting families with infants in the Neonatal Unit during the dissemination process. Collaborative efforts may help to accelerate some of the more challenging recommendations for change.</p> <p>The project team plan to provide participants with a list of changes that have been made following data collection but I would question why is this feedback restricted to the changes that have been made v's the complete list of recommended changes. The plan to engage with families during the change process is encouraging but is unclear how this will look and I would also recommend that the national patient organisation, local NICU Support Group and NICU Patient Liaison Person be included at this stage of the process.</p> <p>Can the authors clarify what they mean by peer support P9 Line 45/46. It was unclear to me in what context this is intended.</p> <p>Can the authors clarify what "other outcomes" they are referring to in P9 Line 49.</p> <p>P19 Question 8. The authors may need to reconsider the choice of words or be more specific in their use of words; when they refer to "the rules about COVID-19" it is unclear whether this question relates to changes in practices within the NICU setting as a result of COVID-19 or COVID-19 rules in general as applied to the public.</p> <p>P19 Line 30, Question 2 of, Thinking about COVID-19, the word regulation is used so for consistency and clarity it would be preferable if the authors used the same word throughout. It was unclear to me whether this question related to restrictions in the NICU that may have impacted bonding or whether the question was much broader and was asking about bonding post discharge which might have been affected by the inability of "important" people travelling to be with and bond with baby. If the question relates to post discharge, I would recommend that the authors consider asking a specific question about bonding in the section of the interview titled "Thinking About The Neonatal Unit".</p> <p>The objective of the study is well intentioned and lessons need to be learned from decisions taken during COVID-19 however in order to ensure widespread dissemination and implementation of the findings, the authors may wish to consider strengthening the study through engaging with a broader field of stakeholders and refining the interview questions.</p>
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VERSION 1 – AUTHOR RESPONSE

Thank you for your helpful comments on our paper. Our responses to each point are listed below in italics.

Editor in Chief Comments:

Title add " a qualitative study"

Thank you, we have added this

Abstract Discussion delete the first sentence, which is just praising your own work! You will need to amend the second sentence.

We have changed this

Add a What is already known and What this study adds sections.

We have added this:

What is known?

Improved parental experience is significantly related to better outcomes for the infant but systematic methods for assessing parental experience are currently lacking, particularly in a neonatal surgical setting.

What does this add?

We have created a systematic tool to assess parental experience and with the methodology we have shared this can be adapted and used in different settings.

Reviewer: 1

Thank you for this contribution.

Thank you for this

Firstly, do you have any information of how you will implement this testing process within the context of a very different environment now that many COVID restrictions have been ended.

Good point! In fact, we carried out a further study implementing this protocol during the COVID restrictions that we are currently writing up. Many of the results from the current study and our subsequent use of this protocol are generic rather than related to COVID restrictions. We also feel that the protocol is suitable for use outside of a pandemic. We have a doctoral student hopefully joining us soon to continue the qualitative work on parental experience.

Secondly, there is some evidence that outcomes have a big influence on patients experience, do you have a way to match patient outcomes to the results of the survey?

A very good point. Although the stakeholders in phase 1 did not suggest recording clinical outcome we can see that this would be extremely useful. In fact, clinical outcome did emerge when we implemented the protocol in terms of it being discussed by the parent. Having it recorded and triangulated with the qualitative data would be very useful and we will do this in future work where possible.

Are there any balancing measures proposed to assess the experience results with clinical outcomes and results.

If we could prospectively record the clinical outcomes for patients, it would be interesting to map this to the parental experience results to determine if there is a relationship – which is likely. Interestingly, one of the striking findings in our later implementation of the protocol was positive feedback from a parent who sadly lost a child, a reminder that even with the worst clinical outcome parental experience can be improved through good care.

It would be very useful to know if any measures designed to improve experience also improve outcomes – something for us to consider going forward.

Please describes steps to be taken to ensure a diverse group of patient family volunteers.

We felt that this was extremely important. We asked service users, providers, managers and funders what the characteristics of family volunteers should be to ensure the group was diverse and representative of all service users. We recorded these characteristics (see table) and ensured these were all covered when recruiting when we implemented the protocol.

Reviewer: 2

I commend the authors for recognising and addressing this important and topical subject and for engaging with families as PPI partners from outset.

Many thanks for this comment

In terms of the study design, it should be borne in mind that the families involved in the development of this study do not have the benefit of comparison and the perspective offered by them, is directly linked to their experience during the pandemic. They do not a pre-pandemic NICU experience and the process of developing the interview questions would have been richer had families with pre-pandemic experience and a relevant patient organisation with both pre and post pandemic experience been included in the stakeholder group.

This is an excellent point, and has been added as a limitation in the discussion:

One other issue to be considered when eliciting parent perspectives on the impact of pandemic restrictions is that they may have no other experience with which to compare, and in hindsight we might have sought the views of parents who did have this experience.

I note the omission of any reference/questions to breastfeeding and expressing, and skin-to-skin care; interventions whose benefits are well supported by scientific evidence and all of which were badly affected by NICU access restrictions during the pandemic.

Thank you for these important comments. We have now implemented the protocol in a study undertaken during the COVID restrictions that we are currently writing up. In this, parents made a number of comments in relation to breastfeeding and expressing (for example around privacy and comfort) and skin-to-skin care, particularly with the use of

plastic. We are reassured that the protocol allows for parents to describe anything important to them, including issues that we had emerged from the stakeholder discussions described in this paper.

I would liked to have seen a statement in the paper from the PPI partners about their experience of being involved with the design of the study.

This is a good point. We are actually planning a small study to gather feedback from the healthcare professionals involved in the study to learn lessons for the future, but hadn't in truth considered broadening the scope to approach PPI partners. We'd like to do that, and will be checking ethical approval.

I also note the absence of representation from Allied Health Professionals (Lactation Cons, OT, SLT, Physio, Dietician) and no mention of the European Standards of Care For Newborn Health (www.newborn-health-standards.org) which have specific topics related to parental access, nutrition and infant and family centred developmentally supportive care and who spearheaded the global survey of parental experience in the NICU during COVID-19 (Lancet publication).

You are correct that there was limited representation from AHP groups. The study evolved in spring 2020 at the hight of the early phase of the pandemic. The focus was on representative families and other staff groups. Whilst OT have very infrequent input on our surgical newborn unit, the other groups mentioned do, and if we were to repeat this in a less time- and resource-limited way, we would actively involve a broader range of AHPs. The European Standards of Care For Newborn Health were not mentioned by stakeholders but we actively collaborated with the Picker Institute throughout our project who kindly provided a sense check on our work.

The domain of "discharge" has been omitted from the abstract but appears as one of the five main topics described later in the paper.

Thank you – a slip from a previous draft! We have corrected this.

It is unclear from the paper how consent will be obtained i.e. will families be provided with written patient information brochures/material relating to the process and once a family has expressed an interest in participating, how long after the initial discussion will they be approached to provide written consent to participate.

Sorry – the need for brevity in the paper meant we couldn't give a full account of what we planned, and later carried out:

1. *The study will be advertised on posters throughout the children's hospital. A QR code linked to further information, and for families who preferred discussion (including those with limited electronic access, reading ability or non-English speaking), a ward nurse will be trained and able to give information about the project in person.*
2. *Once people show an interest, they will contact us either through the ward staff or via an email address for the project. Permission for their contact details to be stored was obtained and recorded.*

3. *We will record initial information about characteristics, and set up the interview when appropriate. Study information sheets will be available in 5 languages. Consent will be obtained but we do not state a minimum time after provision of information. Typically, for the work we have now carried out, it was over 24 hours. Participants were offered a choice of interview modality (telephone, video, MS teams, face to face). Face to face was often preferred, especially if language was an issue.*
4. *Before the interview started, parents are again asked verbally if they were happy to continue and this will be recorded*

In this study, the "Closed Parent Facebook" group was selected as a forum to advertise the project but it is worth mentioning that it would be necessary to ensure that the rules governing such groups allows for this type of "recruitment" as oftentimes such closed groups are deemed safe spaces for families with infants in the NICU and using this platform to recruit to a study may contravene group rules.

Yes, good point – we have added ‘if allowed’ to this stakeholder suggestion.

I note that copies of the questions will be provided to families in advance of the interviews; does this include P15, 16 & 17 and if so, some of the language on P15 is not written for the lay-person i.e. GI, co-morbidities.

Table 4 sets out the final list of questions. These had been through two rounds of pilot testing and a round of cognitive testing – to establish how parents understood them. The items contained in table 3 were collected by the study team from electronic patient records, and by asking respondents about any data items not recorded electronically. This was done when families had said they wished to be considered. They did not form part of the questions to be asked at interview

Can the authors confirm at which stage of the process families will be provided with copies of the questions i.e. prior to or post consent?

Prior to consent

P17 Line 7- An alternative question might be "Do you have a physical, intellectual or mental health disability?"

This is a good suggestion. In fact, we recognised that all of the women who had given birth likely had physical or potentially psychological considerations in play, especially in the first few days post-partum.

I would recommend that the authors consider presenting their findings at national Neonatal and Paediatric conferences to support the dissemination of the work and also to engage with the national patient organisation supporting families with infants in the Neonatal Unit during the dissemination process. Collaborative efforts may help to accelerate some of the more challenging recommendations for change.

Thank you for this. We have presented our thoughts on stakeholder analysis, cognitive diversity and what we learned from this project to a national group of neonatal surgical nurses, a national neonatal conference and to a national group of paediatric colorectal

surgeons. Any other specific recommendations are welcomed and the suggestion to collaborate with patient organisations is well-taken. The end point for this project is improvement of parental experience for local families and potentially those in other centres, and we have seen submission for peer-reviewed publication as an important part of this process.

The project team plan to provide participants with a list of changes that have been made following data collection but I would question why is this feedback restricted to the changes that have been made v's the complete list of recommended changes.

Thank you for this suggestion – we will do this, and have completed our results tables for the second phase in a way that allows this

The plan to engage with families during the change process is encouraging but is unclear how this will look and I would also recommend that the national patient organisation, local NICU Support Group and NICU Patient Liaison Person be included at this stage of the process.

Thank you very much for this suggestion. We agree that co-design is appropriate and would be most likely to work

Can the authors clarify what they mean by peer support P9 Line 45/46. It was unclear to me in what context this is intended.

I think our phrasing here is unclear. This was meant to refer to our desire to facilitate further involvement of the parents. We've re-written this:

It was suggested that we provide a way for families to stay involved in supporting change in the long term.

Can the authors clarify what "other outcomes" they are referring to in P9 Line 49.

We had hoped that the interviews in the next stage would lead to suggestions about how to improve parent experience. We also hoped that it would highlight potential improvements relating to other aspects of the baby's stay – for example timing of ward rounds, discharge information etc. These wider outcomes were considered "other outcomes". I think our phrasing here is unclear and we've re-written this:

Re-audit or re-survey following intervention was suggested and a recommendation was made to obtain data to evaluate the link between the parent feedback and subsequent changes to parent experience and other aspects of care.

P19 Question 8. The authors may need to reconsider the choice of words or be more specific in their use of words; when they refer to "the rules about COVID-19" it is unclear whether this question relates to changes in practices within the NICU setting as a result of COVID-19 or COVID-19 rules in general as applied to the public.

Good point; we used the question after cognitive testing to check the meaning - the intent was 'NICU setting as a result of COVID-19'; we've clarified this in the paper.

P19 Line 30, Question 2 of, Thinking about COVID-19, the word regulation is used so for consistency and clarity it would be preferable if the authors used the same word throughout.

Good point; we've reviewed this and think that covid rules would be a better fit, and have changed this.

It was unclear to me whether this question related to restrictions in the NICU that may have impacted bonding or whether the question was much broader and was asking about bonding post discharge which might have been affected by the inability of "important" people travelling to be with and bond with baby. If the question relates to post discharge, I would recommend that the authors consider asking a specific question about bonding in the section of the interview titled "Thinking About The Neonatal Unit".

This relates to restrictions on the neonatal unit; bonding post discharge sometimes came up during the questions focussed on leaving the unit.

The objective of the study is well intentioned and lessons need to be learned from decisions taken during COVID-19 however in order to ensure widespread dissemination and implementation of the findings, the authors may wish to consider strengthening the study through engaging with a broader field of stakeholders and refining the interview questions.

Thankyou. We have now completed the second phase using the protocol from this phase.

Reviewer: 3

A clear account of a commendable project completed under difficult circumstances with a clear focus on improving the patient experience. The information presented will doubtless be useful to others attempting similar work in the future.

Many thanks for this comment

Minor comment:

Page 8, Line 5: Typo in the sentence "Reassurance was to be given to families that any data would being stored anonymously, in a way that was consistent with data protection rules, that participation (or non-participation) would not affect their care and that withdrawal from the study at any time was acceptable." I think it should read data would be stored anonymously.

Yes, we've changed this typo! We felt the reassurance was important as members of the research team were the treating clinicians or at least had the potential to meet the families on the unit. We thought this might be useful for any other groups should they chose to use similar methodology.

VERSION 2 – REVIEW

REVIEWER	Reviewer name: Ms. Mandy Daly Institution and Country: Irish Neonatal Health Alliance Director of Advocacy and Policymaking, Ireland Competing interests: None
REVIEW RETURNED	10-May-2022

GENERAL COMMENTS	Thank you for addressing the various questions posed after the first review. Your amendments have provided the clarity required and I am pleased to accept your paper. This tool will be very useful for others going forward.
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REVIEWER	Reviewer name: Dr. James Webbe Institution and Country: Imperial College London, United Kingdom of Great Britain and Northern Ireland Competing interests: None
REVIEW RETURNED	11-May-2022

GENERAL COMMENTS	A commendable project to improve neonatal surgical care during a difficult period. All previous issues addressed, I have no further suggestions.
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