

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)	A Systematic Review of Medical Literature for Medico-legal Claims and Complaints Involving Neonates
AUTHORS	Aiyengar, Apoorva; Morris, Tom; Bagshaw, Kaye; Aladangady, Narendra

VERSION 1 – REVIEW

REVIEWER	Reviewer name: Hawdon, Jane M Institution and Country: Royal Free London NHS Foundation Trust Competing interests: I was first author of a paper quotes
REVIEW RETURNED	08-Jun-2021

GENERAL COMMENTS	<p>This is an important topic and an thoughtful and family centred review. In addition impact upon staff is appropriately covered in discussion, although there is no evidence from the papers reviewed. The work could have been enhanced by working collaboratively with NHS Resolution, Hospital Safety Investigation Branch and Health Service Ombudsman departments.</p> <p>I am sure the authors share this reviewer's experience that many maternity service investigations of incidents "skate over" neonatal care, so it is important to highlight the impact of such care. There is a little confusion as to the subject matter because many claims and complaints arise from issues outside of the neonatal unit. Rephrase to ... complaints and (and/or not needed and looks strange in a title) litigation relating to care and outcomes of newborn babies.</p> <p>Many complaints and claims are not received by neonatal units, replace with received by organisations providing neonatal care. Whilst the paper in many places states that litigation is not the focus of the paper, many references are to litigation, and the themes are not that different, so the authors should just be clear, and not apologetic, that it is about complaints and litigation. The similar themes is a point that could be brought out. In any event complaints and litigation are a continuum depending on the level of harm caused and the distress of the family. "Complaints and litigation" should be used when general comments are being made eg in the discussion.</p> <p>The discussion is slightly unstructured and duplicates much of the results section. It should be reviewed eg group according to most common, or in a chronological sequence relating to birth and subsequent care of the baby.</p> <p>There should be a much more focused conclusion about recommended actions, what would the authors like to see change as a result of the paper?</p> <p>Specific points:</p> <p>What is the logic for the sequence in table 1? if no logic, order alphabetically by author or country.</p> <p>Country of origin should have a column of its own, as it gets lost</p> <p>Change payouts to financial settlements</p> <p>Change sugar to glucose</p>
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	<p>Because there were papers from many countries, various terms are used for staff, for example in UK we would not use the term physician. Use a general term eg clinician because non-medical staff are sometimes implicated.</p> <p>Was there any variation between countries? Were the majority/all of the papers from developed nations? There should be a comment about this.</p> <p>An explanation should be given as to what is a grey literature search and for the methodology of thematic analysis, was an author trained in thematic analysis (this was a question I was asked by a reviewer and required me to rephrase the methodology)?</p> <p>It is a missed opportunity that families and public were not involved, the authors should consider this for future work.</p> <p>As an aside, the late and respected Marvin Cornblath had 2 slides - "Helen of Troy, the face that launched a thousand ships" followed by a picture of his first paper on neonatal hypoglycaemia "The paper that launched a thousand lawsuits". He permitted me to use them, I still do.</p>
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REVIEWER	<p>Reviewer name: Muniraman, Hemananda Institution and Country: None Competing interests: A couple of my studies have been referenced in the manuscript.</p>
REVIEW RETURNED	26-Jun-2021

GENERAL COMMENTS	<p>The authors present findings of their systematic review of medico-legal claims and complaints involving neonates and report their findings under 3 categories, clinical problems, complaints and factors implicated and identify delayed/incorrect diagnosis and treatment as the major category of complaint and list factors implicated in some of the studies.</p> <p>Overall the manuscript reads well. The authors seemed to have deliberately used simple language in their introduction, seemingly meant for a larger audience, not limiting to only medical professionals (one that I am not opposed to). The methodology is sound and presented well, adhering to PRISMA guidelines, and meets the objectives. The results are presented well with appropriate tables listing the included studies and listing the categories of the complaint and factors implicated. The discussion section is well written stating pertinent findings of the study and mentioning strengths and weakness of the study.</p> <p>I would recommend the manuscript for publication with suggestions for minor revisions that may be considered by the authors if appropriate.</p> <p>Title: Reviewing the included studies, it appears that not all the infants were admitted to the neonatal units, some of them may have died in the labor ward (Muniraman et al) or may have been discharged from newborn nursery (Hawdon et al) and hence not all complaints may be received by the neonatal units. The authors may consider changing the title to "A systematic review of medico-legal claims and complaints involving neonates".</p> <p>2. Abstract : Page 3, line 6 Suggest using families in place of family to ensure consistency throughout the manuscript Page 3, line 32, Conclusions: Would suggest authors state conclusions based on results of the study such as the main category</p>
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	<p>of compliant and factors implicated, similar to the conclusion at the end of the manuscript.</p> <p>3, Results: Page 8, Table 1. What are the superscript numbers next to the included studies for? as the number in the parenthesis is the reference number.</p> <p>4. Discussion: It appears that only 3 studies in the included studies explored and reported factors (human or systems) contributing to the complaints and litigations, suggest authors mention this in the discussion section emphasizing on the need for studies to identify factors contributing to patient harm.</p> <p>Suggests authors mention about organizations and institutions adopting quality improvement and assurance initiatives to develop a 'culture of patient safety and 'just culture' as most errors that result in patient harm are not due to isolated provider failure but likely following series of systematic errors or breaches in defense system meant to prevent these errors.</p> <p>Page 23: Line 16: The first sentence in the conclusion: 'Complaints and litigation about patient care are received by neonatal units' seem redundant, suggest removing the sentence.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1 (Dr. Jane M Hawdon, Royal Free London NHS Foundation Trust)

This is an important topic and an thoughtful and family centred review. In addition impact upon staff is appropriately covered in discussion, although there is no evidence from the papers reviewed.

The work could have been enhanced by working collaboratively with NHS Resolution, Hospital Safety Investigation Branch and Health Service Ombudsman departments.

I am sure the authors share this reviewer's experience that many maternity service investigations of incidents "skate over" neonatal care, so it is important to highlight the impact of such care.

There is a little confusion as to the subject matter because many claims and complaints arise from issues outside of the neonatal unit. Rephrase to ... complaints and (and/or not needed and looks strange in a title) litigation relating to care and outcomes of newborn babies.

Many complaints and claims are not received by neonatal units, replace with received by organisations providing neonatal care.

Thank you for your encouraging positive comments. Thank you for your comment on involving NHS Resolution and HSIB. However, our main objective was to was to review published reports of complaints by family on the care of their babies in the neonatal units.

As per the Editor in Chief's recommendation, the title is now changed to 'A Systematic Review of Medical Literature for Medico-legal Claims and Complaints Involving Neonates'.

We have accepted and amended phrasing in manuscript of complaints received by 'organisations providing neonatal care' rather than 'by neonatal units' in various areas of the manuscript.

Whilst the paper in many places states that litigation is not the focus of the paper, many references are to litigation, and the themes are not that different, so the authors should just be clear, and not apologetic, that it is about complaints and litigation. The similar themes is a point that could be brought out. In any event complaints and litigation are a continuum depending on the level of harm caused and the distress of the family. "Complaints and litigation" should be used when general comments are being made eg in the discussion.

We agree with this point and have removed the line suggesting that litigation is not the focus. We have now used 'complaints and litigation' when using general comments are being made throughout the manuscript.

The discussion is slightly unstructured and duplicates much of the results section. It should be reviewed eg group according to most common, or in a chronological sequence relating to birth and subsequent care of the baby.

There should be a much more focused conclusion about recommended actions, what would the authors like to see change as a result of the paper?

We hope that we have now rephrased the conclusion to make a clearer recommendation with regards to units analysing and sharing complaints data. This is to pick out similar themes and focus on the underlying cause and also human factor causes at play (See page no 17 titled 'Conclusions') .

Specific points:

What is the logic for the sequence in table 1? if no logic, order alphabetically by author or country.

This is now ordered alphabetically by the name of the author, with a general order of listing studies reporting on data from national databases first, then regional data and finally studies reporting on data collected within a single centre last as recommended by the Editor in Chief (See Table 1 in page nos 5-10).

Country of origin should have a column of its own, as it gets lost

Accepted and amended

Change payouts to financial settlements

Accepted and amended

Change sugar to glucose

Accepted and amende

Because there were papers from many countries, various terms are used for staff, for example in UK we would not use the term physician. Use a general term eg clinician because non-medical staff are sometimes implicated.

Accepted and amended within the manuscript

Was there any variation between countries? Were the majority/all of the papers from developed nations? There should be a comment about this.

Thank you for this comment and added this into strengths and limitations section (See paragraph 2 Line 3 onwards in page no 16).

An explanation should be given as to what is a grey literature search and for the methodology of thematic analysis, was an author trained in thematic analysis (this was a question I was asked by a reviewer and required me to rephrase the methodology)?

Grey literature search was performed by using Google and Google Scholar. This was added to method section (See Line 6, 2nd paragraph in page no 4).

Thematic analysis was initially performed by AA and finalised in discussion with clinical researchers with previous experience in thematic analysis (TM and NA). See Lines 3-4, 3rd paragraph in page no 4).

It is a missed opportunity that families and public were not involved, the authors should consider this for future work.

We agree that opinions from family and public would be valuable. This is added into limitations of the study as a suggestion for further study (See Lines 8-10, 2nd paragraph in page no 16).

Reviewer: 2 (Dr. Hemananda Muniraman)

The authors present findings of their systematic review of medico-legal claims and complaints involving neonates and report their findings under 3 categories, clinical problems, complaints and factors implicated and identify delayed/incorrect diagnosis and treatment as the major category of complaint and list factors implicated in some of the studies.

Overall the manuscript reads well. The authors seemed to have deliberately used simple language in their introduction, seemingly meant for a larger audience, not limiting to only medical professionals (one that I am not opposed to). The methodology is sound and presented well, adhering to PRISMA guidelines, and meets the objectives. The results are presented well with appropriate tables listing the included studies and listing the categories of the complaint and factors implicated. The discussion section is well written stating pertinent findings of the study and mentioning strengths and weakness of the study.

Thank you for your encouraging comments

I would recommend the manuscript for publication with suggestions for minor revisions that may be considered by the authors If appropriate.

Title: Reviewing the included studies, it appears that not all the infants were admitted to the neonatal units, some of them may have died in the labor ward (Muniraman et al) or may have been discharged from newborn nursery (Hawdon et al) and hence not all complaints may be received by the neonatal units. The authors may consider changing the title to “ A systematic review of medico-legal claims and complaints involving neonates”.

Accepted and Amended as the new title in the revised manuscript (See Title in page no 1).

2. Abstract : Page 3,line 6 Suggest using families in place of family to ensure consistency throughout the manuscript

We have now used 'families' to keep the consistency throughout the manuscript.

Page 3, line 32, Conclusions: Would suggest authors state conclusions based on results of the study such as the main category of compliant and factors implicated, similar to the conclusion at the end of the manuscript.

We have now rephrased the conclusion of the abstract to make it similar to the conclusion at the end of the manuscript to emphasize the human factors aspect too (within the word count permitted) (See conclusion in page 2).

3, Results: Page 8, Table 1. What are the superscript numbers next to the included studies for? as the number in the parenthesis is the reference number.

Apologies this was an error (use of the different referencing system on an older draft). This has been removed and updated accordingly in our revised manuscript.

4. Discussion: It appears that only 3 studies in the included studies explored and reported factors (human or systems) contributing to the complaints and litigations, suggest authors mention this in the discussion section emphasizing on the need for studies to identify factors contributing to patient harm.

We agree, only some of the articles have explored the factors that may be underlying the complaints. We have put a line in the discussion emphasizing this (See 3rd paragraph pages 15).

Suggests authors mention about organizations and institutions adopting quality improvement and assurance initiatives to develop a 'culture of patient safety and 'just culture' as most errors that result in patient harm are not due to isolated provider failure but likely following series of systematic errors or breaches in defense system meant to prevent these errors.

This was raised in one of the papers by Fanaroff and goldsmith so have emphasizaized this point with a reference in the discussion section (See 3rd paragraph Page 15).

Page 23: Line 16: The first sentence in the conclusion: 'Complaints and litigation about patient care are received by neonatal units' seem redundant, suggest removing the sentence.

Accepted and Amended

We hope we have answered to all comments of the Editor in Chief and Reviewers and that the revised manuscript is acceptable for publication in BMJ Paediatrics Ope

Yours sincerely,

Apoorva Aiyengar