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# Systematic review of medical literature for medicolegal claims and complaints involving neonates

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## ABSTRACT

**Importance** Complaints and malpractice claims by families on the care of their babies are pertinent issue. Beyond just the financial implications, it involves harm to babies and distress to parents.

**Objective** The aim was to review published reports of complaints by families on the care of their babies in the neonatal units in order to understand the nature of these complaints and the areas of care that they relate to.

**Methods** We considered articles in English, which report on complaints made by families to organisations providing neonatal care. We performed our structured search on AMED, CINAHL, EMBASE, EMCARE, SCOPUS and MEDLINE from January 2000 to December 2020. A total of 378 articles were appraised using eligibility criteria.

**Results** A total of 12 articles were included. The most common category of complaint was delayed/incorrect diagnosis. Communication issues were highlighted as a significant category of complaints. The majority of such claims were between the physicians and families. Factors implicated for clinician's errors that resulted in complaints were lack of clinical and communication training, inadequate supervision of junior clinicians, work culture and hierarchy, not listening to families' concerns and system failure.

**Conclusions** The most frequent categories of complaint reported in our systematic review were delayed/incorrect diagnosis and delayed/incorrect treatment. Organisations should be encouraged to share complaints data as it can facilitate shared learning. An understanding of human factor principles and its role in patient safety is also emphasised in this report in order to optimise patient outcomes and improve experience for families requiring neonatal care.

### What is known about the subject?

- In 2019/2020, maternity claims (including neonatal cases) made up 9% of the number of clinical negligence claims received by the National Health Service litigation authority but represented 50% of the total claim value.
- Analysis of successful litigation claims in childhood fatalities over a 7-year period in England (in the paediatric population) showed that the top reasons included delay in diagnosis followed by delay in treatment.
- In America, 60% of Neonatal Intensive Care Unit (NICU) physicians who had been in practice for over 15 years had experienced a case of malpractice litigation.

### What this study adds?

- Communication-related allegations are a significant cause of complaints. This includes communication during preterm counselling, resuscitation, during an NICU admission as well as in situations on the postnatal ward.
- Factors implicated for clinician's errors that resulted in parental complaint were inadequate supervision of junior staff, work culture and hierarchy, resulting in a fear of asking for help, not listening to families' concerns and system failure.

## INTRODUCTION

In the UK, approximately one in seven newborn babies (105 000) require specialist attention from neonatal units.[1] The advancement of neonatal medicine over the past 25 years has meant that smaller and more fragile babies are admitted to the Neonatal Intensive Care Unit (NICU) at earlier gestational ages.[2] Care is provided by specialist staff using highly developed equipment, and babies may undergo multiple medical or surgical procedures during a prolonged admission. Parents of babies on the neonatal unit describe an emotional and stressful journey during this period[3 4] and also afterwards, when some babies progress to experience long-term complications of their prematurity.[5] During this time, when the health and well-being of the baby hangs in the balance[6] and the trust that parents place in those taking care of their baby could not be more fragile, it stands to reason that medicolegal claims and complaints are commonly received by organisations that provide neonatal care.

A survey of American NICU physicians in practice for over 15 years showed that around 60% of physicians had faced at least one malpractice allegation.[7] However, there was no systematic review study published

regarding complaints received at neonatal units. The aim of this systematic review was to evaluate such complaints. We have outlined the common themes across complaints received at different units and identified potential underlying causes for them. We have also addressed non-clinical aspects of care that make up complaints, which hold an equal value in improving the quality of patient care on NICU.

## METHODS/LITERATURE SEARCH

This systematic review was conducted according to Preferred Reporting Items for Systematic Review and Meta-Analysis guidelines.[8] The project protocol was registered with PROSPERO database.[9]

The literature search was performed by authors (KB and AA). Searches were performed on AMED, CINAHL, EMBASE, EMCARE, SCOPUS, MEDLINE and grey literature from January 2000 to December 2020. The strategy used to search the Medline database was as follows:

("Neonatal unit" **OR** NICU **OR** "neonatal intensive care" **OR** SCBU **OR** "special care baby unit" **OR** Newborn **OR** Baby **OR** Babies **OR** Neonate **OR** Infant) **AND** (Complaint **OR** complaints **OR** litigation **OR** claim **OR** claims **OR** liability **OR** malpractice)

These terms were subsequently used in an equivalent way when searching the other databases. We restricted articles to a study population of infants and those reported in English. The initial list of articles obtained was screened using a title and abstract search by the first author (AA) and then full texts were reviewed by two independent reviewers (AA and TM) to ensure that they met the eligibility criteria. Any disagreement or discrepancies were resolved with joint article review and discussion in meetings with the clinical members of research group (AA, TM and NA). In addition, a grey literature search was performed using Google and Google scholar search engines. We have excluded articles that reported complaints based on a single patient.

The articles included in our systematic review were collated and summarised in an excel spreadsheet. The number of neonatal cases, clinical category and category of complaints were extracted. A descriptive thematic analysis was undertaken initially by AA and then finalised in discussion with clinical researchers with previous experience in thematic analysis (TM and NA).

## PATIENT AND PUBLIC INVOLVEMENT STATEMENT

Patients or the public were not involved in the design, or conduct, or reporting or dissemination plans of our research.

## RESULTS

Following our structured search, a total of 374 articles were obtained, with an additional four articles from a bibliography and grey literature search (figure 1).

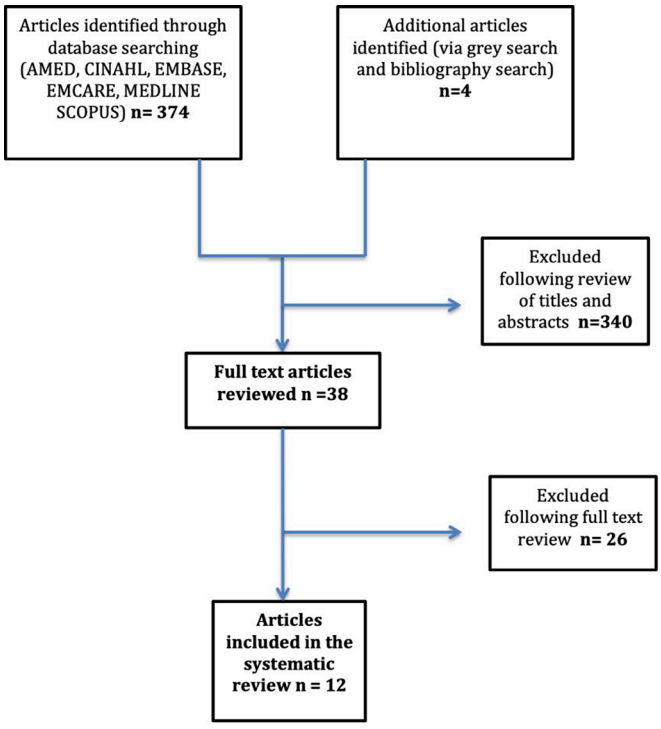


**Figure 1** Preferred Reporting Items for Systematic Review and Meta-Analysis diagram[8] depicting the stages of our systematic review.

Following the initial screening process of title and abstract review, 38 full-text articles were examined for eligibility. A total of 12 studies were included in our systematic review and analysed. See table 1 for a summary of the studies included. Please review online supplemental table 1B for full details.

The articles included in this systematic review reported on data collected in many different countries. Most of the articles reported data of neonatal complaints obtained from national databases (reflecting data from multiple centres), however, two[10 11] studies reported data from single centres. Donn and Fanaroff[12] presented two separate legal cases involving the decision around providing therapeutic hypothermia as a treatment for hypoxic ischaemic injury in neonates.

### Category of clinical problems

The complaints received by neonatal units related to neonates with diagnoses spanning a wide range of clinical problems, including respiratory (eg, meconium aspiration, pneumonia, pneumothorax), cardiac, metabolic (eg, hypoglycaemia), haematological (eg, jaundice) and neurological (hypoxic ischaemic injury, intraventricular haemorrhage and cerebral palsy). The details of clinical problems are listed in the online supplemental table 1B. In some cases, the infants often had more than one diagnosis as reported by Mangurten *et al*[11]

Nguyen *et al*[13] reported complaints relating to a procedural complication, which occurred in 13 (24%) cases, and this was also reported in six cases (5.4%) of malpractice by Fallahi *et al*.[14] Examples of procedural

**Table 1** Studies included in the systematic review

| Authors (reference number) | Country of origin of the study | Study methodology |
|---|---|---|
| Berglund *et al*[15] | Sweden | ▶ Retrospective review of malpractice claims (1990–2005 nationwide insurance database)<br>▶ Reviewed the immediate postdelivery management in medical case notes (obstetric and neonatal) of severely asphyxiated infants following presumed malpractice in labour<br>▶ Authors highlighted failure events in conjunction with neonatal resuscitation specifically based on their neonatal resus guidelines |
| Fallahi *et al*[14] | Tehran | ▶ Retrospective review of malpractice cases in Tehran 2012–2014<br>▶ Data from the Medical Commissions office (National database) |
| Fanos *et al*[18] | Italy | ▶ Retrospective review of malpractice claims (2005–2010) from a nationwide database in Italy<br>▶ Studied neonatal claims specifically in the labour room, nursery and NICU |
| Hawdon *et al*[19] | UK | ▶ Retrospective review of cases from NHS Litigation Authority Claims Management database (2002–2011)<br>▶ Data extracted from the national database, letters of complaints and responses |
| Muniraman *et al*[16] | USA | ▶ Retrospective review of cases from Westlaw database (1980–2016)<br>▶ National legal database<br>▶ Review of medical and legal notes |
| Nguyen *et al*[13] | USA | ▶ Retrospective review of cases from Westlaw database (January 1975– August 2016)<br>▶ National legal database<br>▶ Review of medical and legal notes |
| Rennie *et al*[20] | UK | ▶ Retrospective review of cases from NHS resolution database (2001–2011)<br>▶ Data extracted from the national database, letters of claim and response |
| Zhou *et al*[21] | China | ▶ Retrospective analysis of cerebral palsy malpractice claims collected from 1999 to 2017<br>▶ National database |
| Ashcroft[17] | UK | ▶ Retrospective review of babies that had been admitted to the Neonatal unit with severe birth asphyxia<br>▶ Collected over a set time period (February 2001–March 2002) from seven maternity units (regional data)<br>▶ Cognitive interviewing technique of staff involved, the data from the interviews and case notes were presented to an expert panel who applied the Bolam test to identify acceptable standard of care |
| Kaempf *et al*[10] | USA | ▶ Retrospective review of live births in single centre (April 1996–December 2013) of infants born at 22+0–26+6 to identify resuscitation and outcome<br>▶ Highlight any cases with parental complaints or dissatisfaction expressed during counselling or formally via legal department |
| Mangurten *et al*[11] | USA | ▶ Retrospective review of cases (1972–1992)<br>▶ Single centre—tertiary NICU<br>▶ Review of medical and legal notes |
| Donn and Fanaroff[12] | USA | ▶ Review article with two actual legal cases presented highlighting medicolegal issues around offering neuroprotective hypothermia |

NHS, National Health Service; NICU, Neonatal Intensive Care Unit.

complications included issues with intravenous line placement, resulting in ischaemia to digit, and also acquired laceration during the delivery and resuscitation period.[14] Several studies[10 13 15–17] reported complaints relating to neonatal resuscitation.

## Category of complaints

Table 2 summarises the main categories of complaints received by the neonatal units. The most frequently reported categories of complaints are of incorrect/delayed diagnosis[11 12 14 18–21] and incorrect/delayed treatment.[11 12 14 19–21] As different studies reported complaints variably, and on occasion more than one category was cited to each complaint, it is difficult to quantify this and directly compare these categories across all the cases in the systematic review. Delay in initiation of resuscitation, including delay in administration of emergency drugs, was reported in 5 of the 12 studies.[10 15–17 21] Inappropriate resuscitation against parental directive was reported in three studies.[10 15 16] Communication issues were cited in five studies.[10 13 16 17 19] Medication errors featured in three studies[15 18 21] and general improper care of infants were reported in four studies.[11 18 19 21]

## Factors implicated

Some of the studies included did investigate contributing factors to errors resulting in complaints (see table 3). Ashcroft[17] undertook a cognitive interview of clinicians, exploring various factors implicated in serious incidents and outstanding claims on the Labour ward. This paper

**Table 2** Categories of complaints received by neonatal units

| Category of complaint | Studies that have reported such claims |
|---|---|
| Delay or incorrect diagnosis | Mangurten *et al*[11]<br>Hawdon *et al*[19]<br>Rennie *et al*[20]<br>Fallahi *et al*[14]<br>Fanos *et al*[18]<br>Donn and Fanaroff[12]<br>Zhou *et al*[21] |
| Delay in or incorrect treatment (not including resuscitation) | Mangurten *et al*[11]<br>Hawdon *et al*[19]<br>Rennie *et al*[20]<br>Fallahi *et al*[14]<br>Donn and Fanaroff[12]<br>Zhou *et al*[21] |
| Delay in resuscitation/emergency drugs | Muniraman *et al*[16]<br>Ashcroft[17]<br>Kaempf *et al*[10]<br>Berglund *et al*[15]<br>Zhou *et al*[21] |
| Inappropriate initiation/continuation of resuscitation | Muniraman *et al*[16]<br>Kaempf *et al*[10]<br>Berglund *et al*[15] |
| Communication issue | Muniraman *et al*[16]<br>Hawdon *et al*[19]<br>Ashcroft[17]<br>Nguyen *et al*[13]<br>Kaempf *et al*[10] |
| Medication error | Fanos *et al*[18]<br>Berglund *et al*[15]<br>Zhou *et al*[21] |
| General improper care | Mangurten *et al*[11]<br>Hawdon *et al*[19]<br>Fanos *et al*[18]<br>Zhou *et al*[21] |
| Equipment issue | Mangurten *et al*[11]<br>Hawdon *et al*[19]<br>Rennie *et al*[20] |
| Service issue (includes data/medical records loss) | Rennie *et al*[20]<br>Zhou *et al*[21] |
| Procedural complications | Nguyen *et al*[13]<br>Fallahi *et al*[14] |

**Table 3** Factors implicated for complaint against neonatal units

| Factors implicated in cause of errors | Study |
|---|---|
| Inadequate supervision of junior colleagues in resuscitation setting—delay in senior arriving | Ashcroft[17] |
| Lack of training of junior doctors in resuscitation | Ashcroft[17] |
| Culture of work and hierarchy resulting in a fear of asking for help | Ashcroft[17] |
| Errors due to lack of adequate on site expert medical assistance (generally on shifts after 5 pm or over the night the shift) | Ashcroft[17] |
| Not adequately listening to maternal or family concerns | Hawdon *et al*[19] |
| Reduced access to proper equipment in a timely fashion for example, lab testing of glucose versus near patient testing devices | Hawdon *et al*[19] |
| System failures for example, lack of cots in neonatal unit or on the ward contributing to delays in initiating time critical treatment (phototherapy) | Rennie *et al*[20] |
| Lack of training in communication | Nguyen *et al*[13] |
| Staff shortage and high workload | Ashcroft[17] |
| Human factors—for example, tiredness | Ashcroft[17] |

reported that failing to take action, making the wrong decision or a delayed decision were implicated as human errors in all the cases of malpractice they presented. Interestingly, they reported that the most dangerous time for errors to happen was during the night shift (51% n=19 cases), where there was reduced availability of onsite expert medical support. Moreover, the author suggests that there is a host of systemic and cultural factors that propagate errors of decision-making with individual doctors and nurses in maternity. One such cause was poor staffing of labour wards and forcing inexperienced clinicians to work without adequate supervision and support. In particular, this paper highlighted how junior paediatricians received little training in infant resuscitation; nevertheless, in 46% of cases (n=17), they were the first to be called, performing unsupervised resuscitation, including on severely asphyxiated infants. They identified that in 78% of the cases, senior clinicians did not provide assistance to inexperienced clinicians (including junior paediatricians), and that the juniors often felt unable to ask for help for fear of being labelled as 'unable to cope'.[17]

Issues relating to suboptimal communication were highlighted as a significant category of complaints, as noted above and in tables 1 and 2. However, we could also consider poor communication as contributary to errors resulting in malpractice claims. Nguyen *et al*[13] reported that 74% of communication-related claims are against neonatologists related to the communication between the doctors and family. This mostly occurred during prenatal counselling and resuscitation, when parents felt unable to give informed consent (57% of cases) having received no anticipatory guidance (21%) due to suboptimal communication by the neonatologist.

Communication-related allegations between doctors and within medical teams were also reported, and though there is little detail given about this in the article, miscommunication between team members could directly impact on patient safety and be a potential cause for errors. Kaemf *et al*[10] also included cases of parents reporting lack of informed consent through miscommunication during prenatal counselling discussions.

## DISCUSSION

The most frequent category of complaint seen was *delayed/incorrect diagnosis*, followed closely by *delayed/incorrect treatment*. Though our systematic review focused on complaints and litigation received by organisations providing neonatal care, we are able to draw parallels with research in the field of paediatrics. Sen *et al*[22]

analysed the causes and nature of successful litigation claims involving childhood fatalities over a 7-year period in the UK received by the National Health Service litigation authority (NHS LA). The most common cause for error (45% of cases) identified was delayed or failed diagnosis, followed by delayed or failed treatment in 15% of cases. Communication errors were highlighted in 4% of their cases; however, poor communication plays a role in other categories, including *inappropriate medical advice resulting in delayed presentation*, which was noted to be the cause of error in 5% of cases.[22] Communication issues were highlighted as a significant category of complaints and litigation in our study. Neonatologists and paediatricians should be trained to provide accurate and understandable *safety-netting* advice to parents and caregivers, including when to seek help should their child unexpectedly deteriorate. This is not only relevant in accident and emergency departments when discharging a child but also on the postnatal ward, as highlighted by Hawdon *et al*,[19] for example, counselling parents about poor feeding is vital in picking up serious medical problems such as hypoglycaemia, sepsis and jaundice. Effective safety-netting not only helps parents and caregivers feel supported and reassured, strengthening the relationship between doctor and family, but also can be lifesaving if a child deteriorates acutely.

In some of the studies included in the systematic review, the exact costs incurred for financial settlement were not always reported. In 2019/2020, maternity claims (including potential neonatal cases) made up 9% of the number of clinical negligence claims received by the UK NHS LA, but represented 50% of the £4.8 billion total claim value.[23] A medical error that results in harm to a neonate is a tragedy itself and, though money received as part of a claim, can be put forward to caring for the additional needs and support of the child, it is difficult to put a price on the emotional distress incurred by the family. The distress experienced by the medical professional involved is also not to be underestimated: there is little data available on this subject, however, facing a medical malpractice suit can be a stressful and isolating experience for the medical professional implicated.[24]

From our review, only four studies[13 17 19 20] reported on factors implicated in the errors resulting in complaints, there is a need for further research and reporting of factors that result in patient harm particularly in the neonatal population. Errors leading to patient harm in neonatal medicine are very rare due to the mistakes of a single person. As quoted by Reason,[25] it is often due to a 'systems failure', where a series of errors occur and align together, much like the *holes* in a *Swiss cheese* model of system failure, resulting in patient harm. Adopting quality improvement and listening to staff feedback when they report underlying systems failures to create a 'culture of safety' is crucial.[24] Identifying breakdowns in the usual defence systems and using clear protocols to minimise such organisational errors will also help prevent them.[24] An awareness of human factor principles and how this influence patient safety is vital.

As mentioned by Fanaroff and Goldsmith,[24] 'to borrow shamelessly' from mistakes made in other units, learning from these and implementing safety measures in our units is one way to enhance patient safety. Another area to consider is staff training with an emphasis on evidence-based guidelines. Simulation training is a relatively new learning tool that has gained popularity in the paediatric training curriculum in the UK.[26] With the aid of equipment and mannikins, scenarios are staged allowing doctors and nurses to practice working together in simulated situations. This was incorporated into the neonatal teaching programme at one UK neonatal unit,[27] addressing neonatal-specific training issues, for example, endotracheal tube fixation and received unanimously positive feedback from attending staff.

## Strength and limitations

From our broad-based searches of different databases, we have captured data from units across the world. However, by restricting searches to articles in English, we may have missed reports from neonatal units that have not published their data in English. Due to restrictions in language, it follows then that majority of the papers included originate from developed nations. The categories of complaints between nations showed recurring themes of 'failure or error in diagnosis or treatment'. However, complaints and litigation relating to communication issues do not appear to be reported in units from less developed countries. It is likely that this is under-reported as we have not captured data from non-English-speaking countries. Perhaps an area for further study includes collecting data from both English and non-English-speaking units and exploring trends and characteristics of the complaints themselves. Furthermore, we did not include the public or patients in this systematic review, however, a study investigating nature of complaints and litigation would benefit from the views and input of families who have received care from such organisations.

Given the immense progression of neonatal medicine over the last few decades, we were keen to restrict our searches to articles published from the year 2000 as we believe the lessons to be learnt before this may not necessarily be relevant to our current practice. We excluded single case reports from this study, which inevitably has impacted the total number of articles we have reviewed. By only including papers reporting complaints *indiscriminately* from whole centres or groups of organisations, we have been able to consider our data with a lower risk of selection bias.

Two of the papers[13 16] included reported on complaint data collected through the Westlaw database, which is a national legal database in America. It is possible that there may be some reporting duplications as the data were collected during overlapping years 1980–2016. Muniraman *et al*[16] focused on complaints relating to peripartum or immediate postdelivery management of extreme preterm infants (study population included only 22–26 weeks of gestation) primarily concerning neonatal

resuscitation. Nguyen *et al*[13] studied all communication-related allegations in infants born from 22 weeks to 36 weeks of gestation. This not only included complaints relating to resuscitation but also reported on complaints relating to other clinical categories including procedural complications, infection and retinopathy of prematurity. We made the decision to include both papers as complaints relating to several different clinical areas, which would be more reflective of complaints received by all neonatal units.

## CONCLUSIONS

The most frequent categories of complaint reported in our systematic review were delay in/incorrect diagnosis and delay in/incorrect treatment. We would recommend that it is valuable for individual organisations to analyse and publish their complaints data. The aim is to pick up similar or recurring themes for complaints, and this could contribute to a shared learning and appreciation of human factors.

**Contributors** AA was involved in planning of this systematic review, extracted the data from the studies and performed thematic analysis (together with NA and TM who have previous experience doing thematic analysis). AA prepared the manuscript and edited it. TM was involved in the planning of the systematic review and edited the manuscript. NA was the supervisor of this project and produced the idea for this systematic review. NA was involved in the planning of the project, analysis of data (thematic analysis) and editing the manuscript. KB performed the structured searches on the various databases in order to obtain data for the systematic review.

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