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Neonatal hypoglycaemia: learning from claims

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ABSTRACT

Objectives Neonatal hypoglycaemia is a potential cause of neonatal morbidity, and on rare but tragic occasions causes long-term neurodevelopmental harm with consequent emotional and practical costs for the family. The organisational cost to the NHS includes the cost of successful litigation claims. The purpose of the review was to identify themes that could alert clinicians to common pitfalls and thus improve patient safety.

Design The NHS Litigation Authority (NHS LA) Claims Management System was reviewed to identify and review 30 claims for injury secondary to neonatal hypoglycaemia, which were notified to the NHS LA between 2002 and 2011.

Setting NHS LA.

Patients Anonymised documentation relating to 30 neonates for whom claims were made relating to neonatal hypoglycaemia. Dates of birth were between 1995 and 2010.

Interventions Review of documentation held on the NHS LA database.

Main outcome measures Identifiable risk factors for hypoglycaemia, presenting clinical signs, possible deficits in care, financial costs of litigation.

Results All claims related to babies of at least 36 weeks' gestation. The most common risk factor for hypoglycaemia was low birth weight or borderline low birth weight, and the most common reported presenting sign was abnormal feeding behaviour. A number of likely deficits in care were reported, all of which were avoidable. In this 10-year reporting period, there were 25 claims for which damages were paid, with a total financial cost of claims to the NHS of £162 166 677.

Conclusions Acknowledging that these are likely to be the most rare but most seriously affected cases, the clinical themes arising from these cases should be used for further development of training and guidance to reduce harm and redirect NHS funds from litigation to direct care.

INTRODUCTION

Neonatal hypoglycaemia continues to be a source of clinical concern and of some controversy. In the absence of a robust evidence base, recent guidance has by necessity been pragmatic and based upon clinical experience.^{1 2} Clinicians seek to avoid the harm which results from unrecognised and untreated neonatal hypoglycaemia, while adopting practices which avoid unnecessary separation of mother and baby. This is a focus of the Neonatal Hypoglycaemia Working Group, chaired by JMH and DS, which is contributing to the NHS Improvement Patient Safety Programme to reduce admissions of full-term and near-term babies to neonatal units (<https://www.england.nhs.uk/patientsafety/re-act/red-term-ad>).

What is already known on this topic?

- ▶ The majority of babies make successful metabolic adaptation to postnatal nutrition without developing clinically significant hypoglycaemia.
- ▶ When there are risk factors for impaired metabolic adaptation, there must be monitoring and management to prevent progression to clinically significant hypoglycaemia.
- ▶ Treatment of neonatal hypoglycaemia associated with abnormal clinical signs is a clinical emergency.

What this study adds?

- ▶ Cases of neonatal hypoglycaemia sufficiently severe to cause brain injury and resulting in litigation are rare.
- ▶ In these rare cases, in addition to human costs to the family, there are enormous financial costs to the NHS in terms of payments against claims.
- ▶ Despite standard texts and guidelines, deficits in clinical care result in delayed diagnosis and management of neonatal hypoglycaemia.

Despite the described controversy, it is well recognised that neonatal hypoglycaemia on rare but tragic occasions causes long-term neurodevelopmental harm to the baby with consequent human cost for the family. The organisational cost to the NHS of potentially avoidable harm has not been quantified but includes the cost of successful litigation claims.

The NHS Litigation Authority (NHS LA) was established in 1995 as a special health authority. It is a not-for-profit arm of the NHS providing indemnity cover for legal claims against the NHS, assisting the NHS with risk management, sharing lessons from claims and providing other legal and professional services for its members. When managing claims, the NHS LA acts on behalf of its members to ensure justified claims are settled fairly and quickly and to defend unjustified claims robustly to protect NHS resources. Ninety-six per cent of justified claims are resolved out of court to minimise legal costs.

An important aspect of the work of the NHS LA is to share information on the learning from claims



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with individual trusts and across the NHS to support learning and improvements in safety. This is accomplished by sharing with NHS organisations examples of avoidable harm in order to improve patient safety, which brings both human and organisational benefits.

The NHS LA has to manage two competing interests to minimise the overall costs of clinical negligence to the NHS—settling justified claims efficiently and defending unjustified actions robustly. The appropriate balance is sought to ensure individual patients (and staff where applicable) are properly compensated while protecting the public purse.

The numerical volume of claims related to obstetrics/maternal (including potential neonatal harm) received by the NHS LA represents 10% of the total volume of claims received by the NHS LA. However, the monetary value associated with these claims at £479 530 652 is 41% of the total £1 169 586 958, and is significantly greater than that for any other specialty.³ The goal of providing safer care is to minimise harm, but these figures indicate that, in addition, safer care would release money which can in turn be invested to provide better care.

METHODS

Research Ethics Committee approval was not required, as this was a retrospective anonymised study using routinely collected anonymised data from NHS LA database.

Claims notified to NHS LA between 2002 and 2011 (inclusive) alleging that neonatal hypoglycaemia caused harm were identified from the NHS LA Claims Management System. Anonymised documentation, with no patient identifiers, relating to the claims was reviewed by a consultant neonatologist (JMH) and the NHS LA Safety and Learning Lead (Obstetrics) (JB) to identify themes in terms of risk factors and clinical management which were likely to have caused or contributed to harm. Potential deficits in care were taken from letters of claim, letters of response, expert reports or equivalent documentation, and corroborated where necessary by reference to documents containing factual, non-identifiable information, for example, the baby's birth weight.

The NHS LA's Claims Management Database (CMS) interacts with a number of reporting tools to allow NHS trusts to examine claims relating to their own organisation. CMS is primarily designed for claims management, and holds patient-sensitive and legally privileged data. However, the data held on CMS is also used for financial forecasting, the pricing of the indemnity schemes managed by NHS LA, the management of internal performance, informing policy and responding to requests from the public and parliament for information in accordance with the procedures for Freedom of Information, Data Protection Act and Parliamentary questions. The database was searched for keywords, for example, neonatal and hypoglycaemia, and then manually checked by JB and JMH for the relevance of claims to each enquiry.

The following data were extracted where available from documentation held on the database for each case, and the clinical experience of JMH was applied where necessary in interpretation of data:

- ▶ Source of admission
- ▶ Healthcare professional making assessment of the baby, hospital versus community
- ▶ Risk factor for hypoglycaemia (eg, low birth weight) identifiable at the time of birth
- ▶ Feeding method
- ▶ Likely aetiology of hypoglycaemia
- ▶ Reported clinical signs before or at diagnosis

- ▶ If identifiable risk factors were present, was blood glucose monitoring instituted?
 - ▶ Method of blood glucose measurement
- Possible deficits of care extracted from documents were grouped as follows, based on the expected chronology of postnatal care and according to clinical experience of JMH:
- ▶ Failure to commence blood glucose monitoring when identifiable risk factors present
 - ▶ Early discharge of baby with risk factors without assurance that feeding was sufficient to maintain blood glucose, or without assessment of abnormal neurological signs
 - ▶ Insufficient advice to mother on discharge
 - ▶ Not paying heed to maternal concerns
 - ▶ Failure to recognise and document abnormal clinical signs, including abnormal feeding behaviour, and assessment of baby for cause of signs
 - ▶ Delayed testing for blood glucose level and/or to obtain result after clinical signs identified
 - ▶ Delayed appropriate action for low blood glucose result
 - ▶ Delayed referral for medical review
 - ▶ Delayed medical review after referral
 - ▶ Delayed admission to neonatal unit
 - ▶ Delayed administration of intravenous glucose
 - ▶ Insufficient intravenous glucose delivery

RESULTS

Forty-one potential claims were initially identified during the search period. Of these, 30 were suitable for thematic review. Reasons for excluding the other 11 cases were as follows:

- 5—No letter of claim/allegations
- 2—Not hypoglycaemia claims
- 2—Papers archived
- 1—No claim made
- 1—Not a neonatal case

The babies were born between 1995 and 2010, inclusive. All babies were >36 weeks' gestation.

The average time elapsed between date of alleged incident and notification of the claim to the NHS LA was 4.8 years, range 3–72 months. The reasons why some claims took longer to be submitted to the NHS LA are as follows:

- ▶ Some claims were submitted following an internal complaints process at the trust
- ▶ Some parents were not aware of the extent of the damage to their babies until some of the early milestones were missed
- ▶ A claimant solicitor firm may ask the trust for copies of the hospital records and seek their own expert evidence before submitting a formal letter of claim

For one baby, there were claims against two provider trusts regarding the same alleged injury. Details of these were merged into one case for review.

For one claim, no care issues were identified, and the baby had not been documented as experiencing neonatal hypoglycaemia; therefore, there were no identifiable themes.

Data were therefore extracted from claims relating to 28 babies, and those relating to provision of care grouped in themes.

While clinical outcomes were not in the scope of the review, the following quotes from documentation reviewed demonstrate the extent of injury in some cases:

The child is severely disabled and requires 24 hour care support. It has not been established whether the brain injury will have any impact upon life expectancy although limited mobility and cognitive deficits would contribute to a loss of life expectancy and her medical needs for the rest of her life are likely to be complex.

She is mobile indoors but cannot walk properly on uneven ground or on even ground for more than 200 metres. She requires assistance with dressing, cleaning after toileting and has to have food cut up. She has no sense of danger to herself or others, acts in a dangerous and destructive way and requires constant close supervision.

Documentation

The quantity and nature of documentation available on NHS LA database varied according to how far the litigation process had progressed before the claim was settled. For example, where NHS LA advised early settlement, data were taken from limited documents, for example, letter of claim and letter of response. For others that progressed to trial, there were more documents, for example, expert reports.

Source of referral

Fifteen babies presented with neonatal hypoglycaemia on a postnatal ward, 11 developed clinical signs at home, one baby was in a midwifery-led unit and one baby initially presented on a postnatal ward and was treated on a neonatal unit but had recurrence of neonatal hypoglycaemia on discharge home.

Risk factors and aetiology for neonatal hypoglycaemia

The most common risk factor for development of hypoglycaemia identified by the authors was low birth weight or borderline low birth weight (birth weight around or below 2.5 kg) (table 1). This was the case for 16/28 (57%) babies, some of whom were above 40 weeks' gestation. In 14 of these 16 babies,

Table 1 Likely aetiology of hypoglycaemia

Case number	LBW	Poor feeding	Cold	Infection	IDM	Hyper insulinism
1		x				
2		x				
3	x					
4					x	
5						x
6	x	x				
7	x	x				
8				x		
9	x	x				
10	x	x	x			
11	x	x				
12	x	x				
13	x		x			
14	x	x				
15		x			x	
16	x	x				
17		x	x			
18	x	x	x			
19	x					
20	x	x				
21		x	x			
22		x	x			
23		x				
24		x				
25		x				
26	x		x			
27	x	x				
28	x	x	x			x

IDM, infant of diabetic mother; LBW, low birth weight for gestational age (around or below 2.5 kg). x, likely aetiology for each baby.

there was documentation that, in addition, the babies developed abnormal feeding behaviour or hypothermia prior to diagnosis of hypoglycaemia. It is acknowledged that some clinical signs, for example, poor feeding may be the cause of hypoglycaemia, or the consequence of hypoglycaemia, or both.

Two (7%) babies were born after maternal diabetes in pregnancy.

Ten out of 28 (36%) babies had no clear risk factors that would have been detectable at the time of birth. One of these babies had subsequent diagnosis of neonatal hyperinsulinism, and one baby had subsequent diagnosis of gram-negative septicaemia. Both of these babies presented with abnormal clinical signs before the diagnosis of hypoglycaemia and underlying pathologies were made. The remaining eight babies with no risk factors had no identified underlying cause for becoming hypoglycaemic, but all presented with abnormal feeding behaviour (including not waking for feeds, not latching at the breast, not sucking effectively, appearing unsettled and demanding very frequent feeds). The majority of babies in the cohort were initially breast fed, but some of these were subsequently offered formula feeds.

Presenting clinical signs

For 21/28 (75%) babies, it was the abnormal feeding behaviour (see Risk Factors and Aetiology) which caused clinical concern. Of these 21 babies, 2 were also described as hypotonic, 5 also as cold, 1 also as irritable and 1 also as sleepy.

Eight out of 28 (29%) babies were described as hypothermic, either in isolation or in combination with poor feeding or being sleepy.

One baby was described as being hypotonic in isolation, and one baby presented with cardiorespiratory collapse.

For two babies presenting clinical signs were not documented.

Likely deficits in care

The following likely deficits in care were identified; for most babies, there was more than one likely deficit of care:

- ▶ For 27 babies (96%):
 - The initial method of blood glucose estimation was a near-patient testing device.
 - For the remaining baby, there was no near-patient test result, as the unit policy was to use laboratory methods only. However, the adherence to this policy resulted in excessive delay in diagnosis and treatment, as the sample was analysed in a distant laboratory.
- ▶ For 20 babies (71%):
 - Failure to make an adequate and documented assessment of risk factors (including birth weight) or clinical signs and history (including feeding history)
 - Failure to recognise the significance of abnormal clinical signs (including abnormal feeding behaviour)
 - Failure to assess the underlying cause of clinical signs
 - For 16 babies, this was by staff in hospital maternity or emergency departments, for 3 by staff in the community and for 1 by staff in both settings.
- ▶ For 10 babies (36%):
 - Failure to take into account maternal concerns (box 1)
- ▶ For 9 babies (32%):
 - Failure to commence blood glucose monitoring for a baby with identifiable risk factors
- ▶ For 9 babies (32%):
 - Discharge from postnatal ward to community of baby with risk factors or abnormal clinical signs without assurance that feeding was sufficient to prevent hypoglycaemia

- ▶ For 4 babies (14%):
Delay in acting upon blood glucose result once available
- ▶ For 3 babies (11%):
Delayed referral to paediatrician after concerns identified
- ▶ For 3 babies (11%):
Delayed admission to neonatal unit following diagnosis of clinically significant hypoglycaemia
- ▶ For 2 babies (7%):
Delayed administration of intravenous glucose after admission to neonatal unit
- ▶ For 2 babies (7%):
Insufficient intravenous glucose to correct hypoglycaemia; one baby was born after maternal diabetes, and one had unexpected neonatal hyperinsulinism
- ▶ For 1 baby:
Delayed attendance by a paediatrician after midwife's request
- ▶ For 1 baby:
Delay in obtaining blood glucose result after taking sample (see method of blood glucose estimation)
- ▶ For 1 baby:
Failure to provide appropriate advice to the mother on discharge

Financial settlements

Of the 30 cases reviewed, damages were paid in 25 cases. For one case, no legal costs or damages were paid by NHS LA, and for four, defence costs only (total £135 772) were paid.

The total value (value of all claims whether open/closed or subject to periodic payments) of the 25 claims where damages + legal costs were paid is £162 166 677. The allocation of these costs, in terms of proportion paid to the claimant and proportion allocated to legal costs, is demonstrated in [figure 1](#). To date,

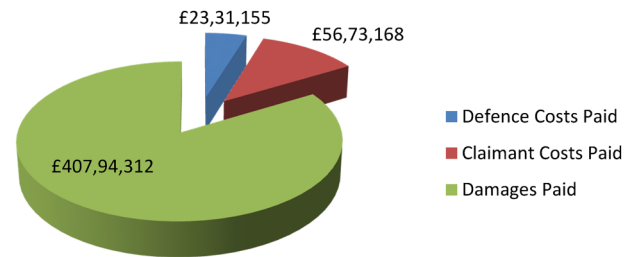


Figure 1 Allocation of total costs in 25 claims in which damages were awarded (as of December 2015).

£48 798 635 has been paid in legal costs and damages. The remaining £118 474 042 will be paid out over time as either part of a Periodic Payment Order or once the case is closed and final costs and damages agreed.

Range for individual claims, inclusive of costs, was £2 465 000–£12 640 000, median £6 300 000.

DISCUSSION

The immense personal impact on the child and family when harm occurs in the neonatal period cannot be quantified financially and cannot be ignored. This paper highlights the additional financial costs to the NHS of potentially avoidable harm. Added to these costs are the costs of acute neonatal care and the ongoing costs of healthcare, education and social care. The rationale for including the financial data in this paper is to highlight that prevention of even these few cases of injury would release immense NHS resource to improve patient care. Despite the costs involved in litigation, it is to an extent reassuring that the vast majority is passed to the claimants who have suffered harm, and the minority is legal costs.

It is recognised that the babies in this cohort are not typical of the population of babies at risk for or presenting with neonatal hypoglycaemia. They are likely to be babies with severe and prolonged hypoglycaemia such that harm was sustained and whose parents identified potential deficits in care. It is likely that a small number of babies who have come to harm have not been reported to NHS LA through the litigation process, or were not detected in the database search. However, the total of 25 cases over a 10-year period should be viewed in the context of the UK birth rate of around 800 000/year.

The authors acknowledge that the variable nature of documentation held on the NHS LA database has prevented full ascertainment of clinical details, as would be the case if medical records were studied. Consideration should be given to seeking approval to applying 'confidential enquiry' methodology to such a cohort.

The severity and duration of hypoglycaemia and the likely consequent neurological deficit are outside the scope of this paper, as there were insufficient details in documents reviewed to determine this.

While not all of the above possible deficits of care have been forensically proven, there are themes which reinforce standard published guidance and introduce new areas for consideration. While individual trust guidelines for management of the infant at risk of neonatal hypoglycaemia were not included in the documentation reviewed, one author (JMH) has experience of reviewing a large number of such guidelines and considers that, had guidelines in common use been applied, a number of cases would have been prevented. However, it is possible that

Box 1 Examples of concerns raised by mothers of babies in the review cohort as expressed in documents reviewed

'By the third day he was sleepy and disinterested in feeding. His mother asked for assistance to latch him onto the breast and voiced concerns that he was not feeding. His mother continued to alert staff to her problems in getting the baby to feed and the fact that he was sleepy.'

'The mother informed the midwifery staff on the ward on a number of occasions on this and subsequent days following the baby's birth, that she was concerned the baby was not sucking when feeding was attempted and she was concerned he was not feeding properly. These concerns were not heeded, resulting in the baby not being fed adequately and ultimately causing his collapse due to hypoglycaemia.'

'The mother felt she had expressed concerns on multiple occasions about baby's feeding technique both on delivery unit and on the ward but she felt she had not received adequate support. These concerns were not listened to.'

'The parents brought the baby to the accident & emergency department with feeding problems and episodes of rolling his eyes. Seen by the paediatric team. After giving advice on feeding to the parents, baby was discharged home. The parents continued to be concerned and brought baby back to accident & emergency 3 days later. Blood glucose levels were not measured and parents told they could take him home.'

recognition of early abnormal clinical signs, abnormal feeding behaviour and maternal concerns are not sufficiently emphasised in guidelines or in education of maternity health professionals. The Neonatal Hypoglycaemia Working Group of the NHS Improvement Patient Safety Programme, 'Reducing Term Admissions to Neonatal Units', is reviewing current guidance and practice. Findings of this review and the current paper will inform the Framework for Practice (see below).

There were insufficient details in documents available of feeding patterns, feed frequency, mode of feeding at each feed and measures to monitor feeding at each feed, to draw conclusions as to how feeding support and monitoring contributed to clinical harm. However, the findings of this review indicate that future guidance should include greater emphasis on support and monitoring of feeding and well-being, even in the baby without apparent risk factors. It is recommended that maternity services adopt the UNICEF UK Baby Friendly standards⁴ to inform training in assessment and monitoring of infant feeding. It is anticipated that the Framework for Practice expert group will consider the use of a feeding assessment tool, such as that recommended by UNICEF UK Baby Friendly⁴ for babies in the first week after birth. This tool provides a professional assessment of the effectiveness of feeding and early identification of feeding problems, which can then be addressed by individualised feeding plans and referral for paediatric advice where necessary.

All babies should be assessed at birth for risk of hypoglycaemia. For those with risk factors, the BAPM NEWTT chart is likely to be a useful adjunct.⁵

In almost all cases, near-patient blood glucose measurement devices were used, which are acknowledged to be an insufficiently accurate method to monitor for and diagnose neonatal hypoglycaemia.¹ There was insufficient information available to determine whether inaccuracy of measurement contributed to harm in these cases. In one case, perversely, a policy of not using such a device and relying on distant laboratory measurement is likely to have caused harm.

Unlike NHS trust reporting systems for incidents, which for the most part are contemporaneous, there is time delay from the incident occurring and a claim being made. Therefore, there may have been changes in practice since the time of the incident. However, the authors' experience is that the themes identified are likely to remain pertinent and informative of practice.

The authors propose the following learning points drawn from the analysis of the cases described:

1. A small number of babies with no identifiable risk factors develop clinically significant neonatal hypoglycaemia.
2. Although a birth weight of below 2.5 kg is often used as a threshold for initiation of blood glucose monitoring, a number of babies born after 40 weeks' gestation with this birth weight, and a number with birth weight slightly above 2.5 kg may have experienced intrauterine growth restriction and are at risk of developing hypoglycaemia if there is insufficient milk intake. Clinicians should make a clinical assessment of the adequacy of intrauterine nutrition when examining a newborn baby, for example, 'clinically wasted' appearance. The BAPM NEWTT chart includes a table of second centile birth weights at gestational ages of 37–42 weeks.⁵ Consideration should also be given to recently developed customised growth charts to determine whether these may more accurately predict the risk of neonatal hypoglycaemia. These considerations will be covered by the Framework for Practice expert group (see below).
3. Babies presenting with abnormal clinical signs, including abnormal feeding behaviour and hypothermia, must undergo detailed and documented assessment including measurement of blood glucose levels and investigations for underlying cause, for example, infection, inborn error of metabolism and endocrine disorder. If it is not possible to differentiate between 'the reluctant feeder' and the baby with abnormal clinical signs, experienced assistance should be sought.
4. Maternal concerns, especially with regards to feeding, should not be discounted and should be followed by a detailed and documented history and assessment of the baby's condition.
5. In the presence of clinical signs, once a diagnosis of hypoglycaemia is suspected or made, this constitutes a clinical emergency.
6. Babies with risk factors for neonatal hypoglycaemia or abnormal feeding behaviour should not be discharged from postnatal ward to the community without assurance that the milk intake is sufficient to prevent hypoglycaemia.
7. Emergency department staff should include neonatal hypoglycaemia as a differential diagnosis when an unwell newborn baby presents from home.
8. All clinical areas should have access to rapid and accurate blood glucose measurement.
9. If blood glucose level does not rapidly recover with initial treatment, neonatal hyperinsulinism and the requirement for a higher glucose delivery rate should be considered.

These learning points are covered in the training of maternity and paediatric health professionals (as relevant to their discipline) and feature in many standard texts, but these claims indicate that they are not always sufficiently well communicated or followed. The authors acknowledge the continuing controversy as to which babies should undergo blood glucose monitoring.^{1 2} However, all health professionals in maternity and neonatal services should be aware that the apparently 'normal' infant may have a latent disorder such as infection or hypoglycaemia, and assessing for and acting upon abnormal clinical signs in the broader population of babies is a more rational approach than 'blanket' screening.

The Neonatal Hypoglycaemia Working Group contributing to the NHS Improvement Patient Safety Programme has commissioned an expert group to develop a national Framework for Practice. This framework will be informed by a prospective audit of factors which result in admission of babies to neonatal units with a diagnosis of hypoglycaemia, existing published guidance and the learning from claims. It is anticipated that the Framework for Practice will provide a single document to inform effective and safe care of mothers and babies, to reduce admissions of babies to neonatal units and to prevent harm secondary to neonatal hypoglycaemia, but at the same time ensuring that feeding outcomes and the experience of families are optimised.

Correction notice This paper has been amended since it was published Online First. One correction submitted by the author was not implemented by the production office. In the section 'Likely deficits in care', in the first bullet point it should be 27 babies and not 24.

Contributors JMH and JB devised and carried out the review of documents and drafted the paper. MU and DS made subsequent comments and amendments.

Competing interests JMH receives occasional expenses and honoraria for invited articles and chapters and speaking at conferences on the subject of neonatal hypoglycaemia, and receives fees for expert reporting on litigation claims, some of which relate to neonatal hypoglycaemia, the latter being carried out outside of NHS hours. JMH is a member of the board of trustees of the charity Bliss and a member of the NICE guideline development committee, 'Intrapartum care for high-risk pregnancy'.

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