

Understanding HSIB and ENS birth investigations

Investigation processes following possible serious brain injury at birth

Health Safety Investigation Branch (HSIB) maternity investigations and NHS Resolution's Early Notification Scheme (ENS)

This guide is aimed at mothers and families whose baby was born at an NHS hospital after 1st April 2017 and who may be concerned that their baby sustained a brain injury at birth.

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The **charity** for **patient safety** and **justice**

AvMA is the charity for patient safety and justice. We provide specialist advice and support to people when things go wrong in healthcare and campaign to improve patient safety and justice.

For advice and information visit **www.avma.org.uk**

Or call our helpline
For further advice please complete our ENS/HSIB new client form
www.avma.org.uk/ens-form

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Mothers and families whose baby was born at an NHS hospital after 1st April 2017 and who may be concerned that their baby sustained a brain injury at birth may be going through an investigation process. You may feel confused about why an investigation is taking place and what is being investigated. You may feel unsure of what is going on and what, if anything, you should be doing and what should happen next.

It is important to remember that thankfully, most women who have their babies on the NHS have good, safe outcomes. Sometimes, an NHS hospital may suspect or be concerned that the medical care provided to a mother during her labour was not as it should have been and as a result baby may have experienced a severe brain injury. If the NHS hospital concerned think the care they provided caused this injury, then it must report this to another organisation called the Health Safety Investigation Branch (HSIB). HSIB is an independent organisation and is not affiliated with the NHS. Prior to 1st April 2020, the hospital trust had to report their concerns to NHS Resolution (this is the NHS body responsible for investigating clinical negligence claims, see FAQ below for more information). HSIB will carry out its own investigation. Following the HSIB investigation, NHS Resolution might also carry out a further, separate investigation, their investigation is called the Early Notification Scheme (ENS).

A brain injury will be considered severe if it meets the Royal College of Obstetricians and Gynaecologists (RCOG) Each Baby Counts guidelines – the RCOG definition of severe brain injury is set out below.

The days immediately after the birth of a baby can be difficult. This guide has been produced to help families understand more about the Health Safety (HSIB) investigation and NHS Resolutions Early Notification Scheme (ENS).

AvMA note:

- If, after reading this leaflet you are still unsure about the process then please complete our ENS HSIB New Client Form and ask us for help: www.avma.org.uk/ens-form
- One of our specialist caseworkers will contact you within two working days to support you with your concerns. Our advice is given free of charge, without obligation and in complete confidence.

What is Action against Medical Accidents (AvMA)?

We are a well-established, independent charity which specialises in offering help, information and advice on the legal process and options for redress to members of the public who may have suffered harm as a result of a medical accident. We do not receive any government or NHS funding – we raise our own funds. We are not associated with any government or medical agency or college and the advice and information we provide is completely impartial. Our highly skilled team of caseworkers are medically and/or legally qualified, they are here to help you find the right solution for your concern. That might be providing you with general advice and information, or it may be putting you in touch with one of our specialist clinical negligence solicitors. We also have a range of advice leaflets which you may find useful and which can be found at www.avma.org.uk/guides.

Definition of a severe brain injury

The Royal College Obstetricians and Gynaecologists (RCOG), "Each baby counts" definition: The RCOG definition is that baby must have been born at 37 weeks gestation or beyond and that within 7 days following their birth they had one or more of the following:

- A diagnosis of a grade III hypoxic ischaemic encephalopathy (HIE)
- Actively therapeutically cooled but still showing signs of neurological injury
- Had all three of the following signs: decreased central tone AND comatose AND seizures.

HSIB and NHS Resolution both use the RCOG definition of a severe brain injury to consider eligibility for their investigation processes.

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From time to time the RCOG may tweak their definition of severe brain injury. For example, an earlier definition required that babies who had been therapeutically cooled would be considered to have a severe brain injury. Since April 2020, the definition requires that only babies who have been therapeutically cooled **and** who show signs of neurological injury will meet the definition.

It is important to stress that babies who meet the RCOG definition of severe brain injury may not go on to have a significant long-term disability although it is often not possible to know the severity of the injury until the child is of school age.

Frequently Asked Questions (FAQs)

What is hypoxic ischaemic encephalopathy (HIE)?

HIE is a term doctors use to refer to a brain injury caused by not enough oxygen reaching a baby's brain when it is being born. It can also be referred to as intrapartum asphyxia.

What is therapeutic cooling?

This involves taking a baby as soon as possible after birth (but in any event usually within 6 hours of birth) and putting them in a controlled environment which will bring their body temperature down to as low as 33.5 °C. The baby may be kept in these conditions for about 72 hours before a gradual re warming process is started. This process has been shown to reduce the risk of serious brain injury. Since 1st April 2020, you have to show that not only was your baby therapeutically cooled but that despite cooling baby shows signs of neurological injury.

My baby was therapeutically cooled after their birth, what sort of signs might indicate neurological injury?

If your baby has undergone an MRI scan of their brain and the scan shows signs of actual or possible damage to the brain, this may indicate neurological injury. If your baby has not had an MRI scan, he or she might have other signs such as not meeting their usual milestones when they are expected to, for example your baby may not be holding their head up when they are supposed to. Other signs might include abnormal body movement, not walking or crawling when they ought to be; baby may be having long-term feeding difficulties and/or decreased levels of consciousness.

These are just examples; it is not an exhaustive list. Just because you think your baby might be showing one or more of these signs does not mean your baby does have a neurological injury, if you have concerns then we urge you to discuss these with your GP as soon as possible.

What is NHS Resolution and what do they do?

NHS Resolution stands for National Health Service Resolution. It is a body which acts like an insurer for all NHS hospital trusts. If something has gone wrong with the care provided by a hospital, then like most insurers, NHS Resolution wants to know about this as soon as possible. NHS Resolution also seeks to ensure that lessons are learnt when mistakes are made to make things safer for all mothers and babies.

NHS Resolution is responsible for funding any award of compensation a patient may be entitled to because of negligent care and treatment. Substandard obstetric care which results in severe brain injury to a baby may result in multi-million-pound compensation claims.

What is the Health Safety Investigation Branch (HSIB) and what do they do?

You may also find our HSIB leaflet helpful:

www.avma.org.uk/wp-content/uploads/HSIB-investigations.pdf

HSIB is funded by the Department of Health and Social Care and hosted by NHS England and NHS Improvement but is an independent, investigative body within that.

HSIB carries out two types of investigations, general national investigations, and maternity related investigations. Both types of investigation are focused on identifying the clinical and medical aspects of care, including the working environment and culture at the hospital. HSIB investigations look at whether the medical care and treatment provided raises any patient safety issues or concerns.

HSIB investigations do not look at establishing criminal or civil liability.

This leaflet will refer to HSIB's maternity investigations into potentially severely brain injured babies only.

How are HSIB maternity investigations carried out?

HSIB have a specific investigation programme for maternity related issues. They will investigate cases that meet the RCOG Each baby counts definition of severe brain injury. They will also look at some other aspects of maternity care such as certain types of intrapartum stillbirths; neonatal and maternal deaths (see AvMA leaflet on HSIB for more information on other HSIB investigations: www.avma.org.uk/wp-content/uploads/HSIB-investigations.pdf).

Trusts must report any case which meets the RCOG Every Baby Counts criterion to HSIB.

HSIB cannot carry out their investigation without the family giving their consent to the investigation process. Most families do consent to the process.

Once HSIB receives notification from an NHS hospital trust that a baby meets the RCOG severe brain injury criteria and that the family has consented to the HSIB investigation process, they will first arrange to meet the family to discuss the circumstances of the birth. Since the coronavirus pandemic, HSIB endeavour to introduce themselves to the family using remote technology such as Zoom or Teams although they recognise this may not be possible in every case.

HSIB aims to

- i. Contact the family within 5 working days of being notified by the hospital that the family have consented to HSIB investigating. HSIB will explain the process and offer a time to meet and endeavour to answer any questions you may have.
- ii. Interview both the hospital staff involved in providing the maternity care and the family. HSIB may not offer face to face meetings, increasingly meetings are being held remotely by Teams or Zoom but they will discuss the options with you when they first make contact
- iii. Ask the family to describe what happened so they can understand what went wrong from their perspective.
- iv. Start the investigation process as soon as possible, preferably within 4 weeks of the incident
- v. Avoid naming individual staff members in their report or give information like the staff grade unless it is considered relevant to the circumstances of the incident.
- vi. Produce a report which identifies the factors that contributed towards any harm that has been done to your baby.

- vii. Advise you of the approximate length of time it will take to investigate and report
- viii. Use evidenced based accounts to establish what happened during your labour and immediately afterwards and to establish why it happened.
- ix. Make safety recommendations to improve maternity care locally and nationally.

HSIB initially prepares a draft report which they will share with you and the trust, they will invite your feedback on the report (which is anonymised) and the process more generally. The report will include safety recommendations where appropriate.

Although HSIB may make safety recommendations the responsibility for putting them in action rests with the trust.

Other than the report HSIB does not volunteer any additional information it may have gathered as part of its investigation. NHS Resolution will also receive a copy of the HSIB report. The report belongs to the family and the trust.

Where HSIB carries out a maternity investigation, this replaces the need for the hospital to carry out its own internal investigations as well.

HSIB aims to carry out about 1,000 maternity investigations each year.

What is the Early Notification Scheme (ENS) process?

NHS Resolution designed the Early Notification Scheme so it could identify the likelihood of litigation as soon as possible. NHS Resolution is responsible for how the ENS process is run and managed.

The ENS process is about enabling NHS Resolution to identify whether the care they provided to mother and baby during labour fell below an acceptable standard and if you can bring a clinical negligence action against the hospital trust that provided the care.

Any information, reports, statements, or other information which NHS Resolution gathers as part of its ENS process is confidential and covered by litigation privilege. This means that you are not entitled to see this information even though the investigation is about the care provided to mother and baby during labour. However, the NHS trust where the birth took place should provide you with full explanations and apologies where appropriate about the care that mother and baby received. You should be invited to take part in the internal investigation into what happened if there is one.

How are ENS investigations carried out?

- i. Since the 1st April 2020, NHS Resolution will wait until HSIB has carried out its maternity investigation and shared its report with them before deciding whether they need to investigate under the ENS process. Having received the HSIB report, NHS Resolution will then decide whether they should proceed with their own ENS investigation. It is possible that NHS Resolution will consider it appropriate to admit liability following HSIB's report, but it is not yet clear how NHS Resolution will respond.
- ii. If NHS Resolution decides to proceed with their own ENS investigation they will obtain copies of your maternity medical records and your baby's neonatal records. They do not need your permission to do this, although they may as a matter of courtesy ask you to agree to this.
- iii. The hospital trust that delivered your baby should tell you that NHS Resolution is conducting a review into the care you received, they may even provide you with a leaflet. The ENS process is that review. You may also find it helpful to read our leaflet on the Duty of Candour: www.avma.org.uk/policy-campaigns/duty-of-candour.
- iv. NHS Resolution has an internal triage team who will consider the HSIB final report and your medical records. Where they think that it was at least "likely" you received substandard care they will instruct one of their specialist clinical negligence solicitors to explore their risk of litigation more carefully.
- v. NHS Resolution's solicitors may instruct either internal or independent medical experts to give their opinion on the care provided. Those experts may give NHS Resolution verbal or written advice or both.
- vi. NHS lawyers may go to a barrister (counsel) for an opinion on liability once they have received the medical expert opinion.
- vii. Once the ENS investigation is complete NHS Resolution should write to you and inform you of the outcome of their investigation. This means you will usually be advised of one of the two following situations:
 - The investigation confirms that whilst things might have been done better and/or differently the care provided was not substandard. That is, legal liability is not admitted.

OR

 - The investigation shows that there were "shortcomings" in the care provided. This sort of wording can indicate that NHS Resolution accepts

that the care provided fell below an acceptable standard. However, this is not the same as saying they admit liability. This letter will often go on to explain that NHS Resolution need to investigate further to identify whether your baby's injuries would have been avoided if those "shortcomings" had not occurred. Lawyers refer to this as causation. If you receive this type of letter NHS Resolution will also ask you to consent to them accessing your baby's more recent medical records.

Things you should understand about the ENS process

NHS Resolution is not obliged to give you copies of any medical reports or barrister's opinions which they may have obtained as part of their ENS investigation. These documents were obtained by NHS Resolution in circumstances where they believe litigation is reasonably contemplated or anticipated whether or not you have any intention of taking legal action, and as such they attract litigation privilege.

NHS Resolution does not need your consent to carry out their ENS investigation or to get hold of copies of your medical records or your baby's neo natal records. By contrast HSIB does need your consent to investigate.

Even though you are going through either the HSIB and/or ENS process you can seek independent information, advice and assistance and legal representation at any stage if you want to. AvMA can help you with this if you completed the HSIB/ENS New client Form.

If you are going to obtain your own independent legal advice, we urge you to appoint a clinical negligence accredited solicitor who has expertise and experience in bringing these types of complex claims. An AvMA accredited panel solicitor is a good place to start: www.avma.org.uk/find-a-solicitor. However we would encourage you to complete our ENS/HSIB New client form at www.avma.org.uk/ens-form so one of our specialist caseworkers can get back to you and talk through your options.

If NHS Resolution accepts liability, then NHS Resolution should attempt to resolve concerns fairly and ensure that any compensation is paid. They may contact you with an offer. If they do, we strongly advise that you should seek independent legal advice on the suitability of that offer.

If NHS Resolution does not accept that it is liable you should still receive a letter confirming this and advising you of your right to seek independent legal advice or to contact AvMA. It may be that your / your solicitors' own investigations will form a different view on liability.

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You may be able to obtain legal aid to investigate your claim, or your claim may be pursued under a conditional fee ('no-win no-fee') agreement. Your solicitor will advise you.

It may take a long time to identify whether a baby has experienced a brain injury and if so, the extent of the injury and the effect on the child's life and that of their family. For this reason, it can take a long time for these investigations to be concluded you may have to wait until your child reaches school age before this happens. That can be the case whether you go through the ENS process or not.

How can AvMA help me?

Now you have read our guide you may feel that you would like to speak to one of our specialist advisors

AvMA can:

- Provide advice and assistance on a wide range of issues relating to concerns you may have about your labour and your baby/child's development.
- Explain the Early Notification Scheme and HSIB to you in more detail.
- Explain letters and any offers made to you by NHS Resolution following their ENS investigation.
- Advise you on other routes for investigation such as the NHS complaints process, and health professional fitness to practise procedures if you feel that a doctor or midwife is unfit to practise.
- Help you understand an HSIB investigation, what questions to ask, support you through the investigation and help formulate any additional questions you may have because of the report.
- Put you in touch with a specialist AvMA accredited solicitor who has the experience and expertise to assist you in this highly complex area of medicine and law.

AvMA's advice and information services are available to the public without charge or obligation although if you telephone us you will be liable to pay your telephone providers tariffs.

How to contact us

For the ENS process & HSIB severe brain injury maternity investigations:

If you would like an AvMA caseworker to talk to you about your options, then **please complete the ENS/HSIB new client form at www.avma.org.uk/ens-form**

Once we have received your completed ENS/HSIB new client form, one of our caseworkers will aim to make **initial telephone contact with you within two working days of receipt of your form.**

AvMA's working days are Monday – Friday.

It may take longer than two working days to signpost you or support your next course of action.

Be part of the movement for
better patient safety and justice

Become a
Friend of AvMA
today



You can help make healthcare safer and fairer for all

AvMA wants to build on the support we enjoy from people all round the country who share our passion for making healthcare safer and fairer for those who do suffer harm.

By signing up to be a Friend of AvMA you will belong to a growing movement for change. Join injured patients and their families, healthcare professionals, lawyers and many more who share our goals.

Becoming a Friend of AvMA costs from as little as £5 a month.

£5/month could provide vital advice to patients and families via our helpline

£10/month could help train a volunteer helpline advisor

£50/month could help support a family through an inquest hearing

Benefits of membership

- Regular newsletter keeping you up-to-date with our work
- Invitations to special events
- Share your thoughts on our work and policy issues

Your help could make a real difference to patient safety in the UK

Please sign up today at www.avma.org.uk/friends

avma
action *against* medical accidents

The **charity** for
patient safety and justice

AvMA is the charity for patient safety and justice. We provide specialist advice and support to people when things go wrong in healthcare and campaign to improve patient safety and justice.

For advice and information visit
www.avma.org.uk

Or call our helpline
10am-3.30pm Monday-Friday
(03 calls cost no more than calls to geographic numbers (01 or 02) and must be included in inclusive minutes or there can be a cost per minute)

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