

Understanding NHS Resolution's Early Notification Scheme (ENS) Investigation

*Investigation
processes
following
possible serious
brain injury at
birth*

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.

Contents

What is Action against Medical Accidents (AvMA)?	2
Definition of a severe brain injury	2
Frequently Asked Questions (FAQs).	3
What is the Early Notification Scheme (ENS) process?	4
How are ENS investigations carried out?	4
Things you should understand about the ENS process	6
How can AvMA help me?	7



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)*

0345 123 2352



82 Tanner Street
London SE1 3GN



www.facebook.com/AvMAuk



www.instagram.com/AvMAuk



@AvMAuk



bit.ly/AvMAYouTube

Registered charity in England & Wales
(299123) and Scotland (SCO39683)

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. This guide has been produced to help families understand more about NHS Resolution's Early Notification Scheme (ENS).

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 Maternity and Newborn Safety Investigations (MNSI). MNSI is an independent organisation. Please see our separate leaflet on MNSI.

A brain injury will be considered severe if it meets the MNSI criteria for a severe brain injury. The working definition of severe brain injury used in the Early Notification Scheme (ENS) is set out below.

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. AvMA's public facing services are made up of our [helpline](#), [written advice and information service](#), and our [Inquest Service](#), we provide advice and information free of charge.

AvMA note:

- If, after reading this leaflet you are still unsure about the process then please complete our ENS/MNSI New Client Form and ask us for help: avma.org.uk/help-advice/brain-injuries/ens-mnsi-new-client-form/
- Our advice is given free of charge, without obligation and in complete confidence. Once you have completed the ENS/MNSI new client form one of our caseworkers will email you within two days to offer an appointment at a time convenient to you for an initial telephone conversation.

AvMA does not receive government or NHS funding – we raise our own funds. AvMA is 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

Early Notification Scheme Criteria for investigation

NHS Resolution's Early Notification Scheme will only investigate cases which meet the definition of a severe brain injury. NHS Resolution does not investigate anything other than babies with potential brain injuries which meet these criteria. Please see below for definition of severe brain injury. NHS Resolution will no longer routinely investigate cases involving therapeutically cooled babies where there is **NO** ongoing neurological injury. However, they will investigate these cases if it can be shown that baby was therapeutically cooled **AND** there is still evidence of damage, for example – "Babies who have an abnormal MRI scan where there is evidence of changes in relation to intrapartum hypoxic ischaemic encephalopathy (HIE)".

It is important to stress that babies who meet the ENS 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.

Definition of a severe brain injury

To meet this definition a baby must have been born at 37 weeks gestation or beyond and within the first 7 days following their birth they had one or more of the following:

- been diagnosed with a moderate to severe encephalopathy (see FAQ below for more information) and/or
- was actively therapeutically cooled and is still showing signs of neurological injury
- had an altered state of consciousness with seizures, weak muscle tone, abnormal reflexes or abnormal suck.

Frequently Asked Questions (FAQs)

What is a moderate to severe encephalopathy?

An encephalopathy is damage or disease which affects the brain. The type of encephalopathy likely to be found in babies within the first seven days of life 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.

Who are NHS Resolution and what do they do?

NHS Resolution stands for National Health Service Resolution. It is a body which acts as the insurer for all NHS hospital trusts. If something has gone wrong with the care provided by a hospital, then, like most insurers, NHS Resolution want to know about this as soon as possible. NHS Resolution also try to ensure that lessons are learned when mistakes in care are made.

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 a multi- million-pound compensation claim, you should not attempt to value these claims yourself. AvMA can put you in touch with a solicitor.

What is the difference between MNSI and ENS investigations?

MNSI came into being in October 2023, it was previously known as Health Safety Investigation Branch (HSIB) maternity investigations. MNSI is funded by the Department of Health and Social Care and is hosted by the Care Quality Commission but is an independent, investigative body.

MNSI investigations aim to identify where safety improvements can and should be made. They do not look at establishing criminal or civil liability or carry out investigations from a legal or litigation perspective. They also do not seek to place blame on individual members of staff or investigate individual members of NHS staff.

The Early Notification Scheme (ENS) investigates primarily to establish whether the NHS trust providing the maternity care will be subject to a legal claim in clinical negligence. They do not need your consent to investigate, and they do not share their investigation with you although they will tell you whether they accept liability or not.

What can I do while NHS Resolution carry out their ENS investigation?

If NHS Resolution does not investigate under ENS then an investigation under the Patient Safety Incident Response Framework (PSIRF) must be considered. PSIRF has taken over from serious incident reporting (SIR) investigations. Please see our leaflet on PSIRF for more information:

<https://www.avma.org.uk/wp-content/uploads/PSIRF-investigations.pdf>

The trust remains responsible for complying with the Duty of Candour.

More information on the duty of candour can be found in our website:

<https://www.avma.org.uk/wp-content/uploads/Duty-of-candour.pdf>

See also the section on Duty of Candour in our PSIRF guide.

You are still entitled to use the NHS Complaints process, details of which can be found here: www.avma.org.uk/wp-content/uploads/Complaints-England.pdf

How will I know if I meet the criteria for the Early Notification Scheme (ENS) process?

Once the MNSI has completed its investigation a copy of their report will be sent to you and to the trust who provided the care when your baby was born. The trust is obliged to share a copy of the MNSI report with NHS Resolution.

NHS Resolution will read the MNSI report and look at the report of the MRI scan of your baby's brain. NHS Resolution will consider all of the evidence and discuss it with relevant members of the Early Notification Scheme team which may include obstetricians to decide if the case meets their criteria for investigation. NHS Resolution will write to you to let you know whether an investigation under ENS will be carried out or not.

What happens if I am told I meet the ENS criteria?

If NHS Resolution confirms that an investigation can be carried out under the ENS scheme **they will not start the full investigation until you have consented to the legal investigation**. You will also need to give permission for NHS Resolution to access additional medical records. NHS Resolution only decided in October 2023 that families need to consent to the legal investigation, prior to October 2023 NHS Resolution would conduct the legal investigation in any event.

How long do I have to consider whether to consent to the ENS investigation?

You will have 3 months to decide whether to consent to the ENS process or not. The 3 months begin to run from the date of the letter advising you that you meet the ENS criteria is sent. However, if you do need more time to consider your position then you can explore this with NHS Resolution's Early Notification Family Liaison and Mediation Lead who will be identified in the letter.

What happens if I do not give my consent?

Nothing will happen. NHS resolution will not investigate, and you remain entitled to seek your own legal advice at any point provided you are within the legal time limits for making a claim. However, the earlier you seek independent legal advice and representation, the sooner an investigation begins on your behalf, the better and more cogent the evidence will be. The likelihood of key medical staff and witnesses going missing or moving hospital trusts is reduced, the risk of medical notes being lost or accidentally destroyed is also far less likely if the investigation is carried out early on than if the investigation starts many years after the birth.

In the case of a child, the relevant time limits for issuing proceedings depend on whether they have capacity or not.

Limitation Advice (the following is guidance only): As a guide, if you consider that your child does have a brain injury but the brain injury is not so severe that the child's mental capacity has been affected then the time limit is three years from their eighteenth (18th birthday), that is until they are twenty-one (21 years of age). If your child does not have capacity because their brain damage at birth is so severe then there is no time limit.

Limitation time limits can be complicated and if you are considering bringing a claim we urge you seek independent legal advice from a solicitor specialising in this type of work. AvMA can help you find the right lawyer.

What happens if I do give my consent?

If you do give your consent, then NHS Resolution will obtain the rest of the medical records and start a full legal investigation to identify whether the care you received during the birth of your baby was negligent or not. The investigation will take at least 18 months. For more information please see the section below headed: "How ENS Investigations are Carried Out". If you do give your consent to the ENS investigation there are three important things you need to understand:

(i) That you will not be able to see any of the reports, documents, or other information obtained by NHS Resolution as part of the ENS investigation. Even though the investigation is about the care provided to you and your baby during your labour the information is protected under legal privilege.

(ii) You can seek your own legal representation at any time. AvMA can help you find a solicitor who has expertise and experience in this complex area of law and medicine. We recommend that you only instruct a lawyer who has been accredited as a specialist clinical negligence lawyer.

(iii) The ENS investigation only looks for cases where the NHS is fully liable (100% liability basis) for the care they provided. However, birth injury cases are very complicated and will often settle on a compromise basis, that is at less than 100% liability basis, for example 80% liability basis. Even if your case is investigated under ENS and they subsequently tell you they are not liable you may still have a case. If you think this might apply to you, please contact AvMA so one of our caseworkers can advise you further.

You are entitled to seek independent legal advice at any point, you do not have to wait for NHS Resolution to complete their ENS investigation.

Please do contact AvMA so a designated case worker can be appointed, and all your options discussed, AvMA can explain the pros and cons of using other avenues of redress while the ENS investigation process is underway. Please contact us by completing the ENS/MNSI New Client Form: www.avma.org.uk/help-advice/brain-injuries/ens-mnsi-new-client-form/

What is the Early Notification Scheme (ENS) process?

The MNSI investigation is completely separate from the ENS investigation process, details can be found here:

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

They are two separate investigation processes, run by separate organisations, with separate aims.

NHS Resolution designed the ENS so it could identify the likelihood of a legal claim in clinical negligence being brought against one of its NHS trusts as soon as possible. NHS Resolution is responsible for how the ENS process is run and managed.

Any information, reports, statements, or other information which NHS Resolution gathers as part of its ENS process are 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 a full explanation and an apology for the care that mother and baby received.

How are ENS investigations carried out?

Since the 1st April 2020, NHS Resolution will wait until MNSI 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 MNSI report, NHS Resolution will then decide whether the case meets the ENS criteria for investigation.

The ENS criteria for investigation follows the definition of severe brain injury found at page 2 of this leaflet. The ENS investigation only looks at brain injured babies meeting this criteria, it does not investigate any other type of injury such as neonatal death, whereas MNSI criteria for investigation is much broader. If NHS Resolution considers their criteria has NOT been met, they will not carry out an investigation under ENS. NHS Resolution will send a letter to the family and the trust confirming their decision.

Where NHS Resolution considers the MNSI report and believe the criteria for their own ENS investigation has been met they will start the investigation by conducting a Clinical Review. If the clinical review process finds that substandard care was NOT identified and the care provided was acceptable, the investigation will stop at this point. NHS Resolution will write to the family and the trust where the incident occurred to let them know they will not be continuing with their investigations.

If the clinical review does consider there to be substandard care the investigation will proceed and the family will be advised of this in writing.

The ENS investigation from this point will consist of putting together a panel of experts to consider the case. As part of this process, NHS Resolution can be expected to send instructions to independent medical experts, appoint lawyers including counsel (a barrister) to discuss the evidence and the issues with the medical experts and advise on the prospects of a legal claim succeeding.

The NHS trust, the panel of experts (put together as part of the ENS investigation) and NHS Resolution will consider the advice and evidence. At this point they will decide whether the evidence leads them to either:

- Deny liability altogether.
- Admit that the care provided was substandard and therefore negligent and that injury was caused by that substandard care. (A full admission of liability).
- Admit that the care provided was substandard but there is no evidence to suggest that baby has experienced any long term consequences or brain injury as a result of the failings in care.
- Admit that the care provided was substandard but they are unable to determine at that stage what injury or the extent of the injury caused by negligent care. In these cases, the baby is usually carefully monitored to identify whether they are meeting their milestones and if there is developmental delay, the extent of the delay and whether they can and do catch up – this can take several years to fully establish.

NHS Resolution will then write to the family to advise on the outcome of the investigation.

NHS Resolution will expect the trust to consider the learning from the investigation and to make any necessary changes.

How long does the ENS investigation take?

Typically, an ENS investigation can take up to 18 months to complete although it can be longer than this, depending on the complexities in the case. You should note, the ENS investigation does not commence until MNSI have completed their investigation and reported. The MNSI investigation typically takes 6 months.

The total time taken to complete the MNSI investigation and the ENS investigation is about 2 years, it could be longer.

What can I do if NHS Resolution says they are not negligent?

The ENS investigation process is thorough and independent expert evidence is obtained which should provide NHS Resolution with robust and impartial advice upon which to make a fair and reasoned decision.

However, birth injury claims are extremely complex it is quite common for different leading independent experts to have different views on the standard of care provided and the injury caused by the breach (causation). The complex nature of these cases is such that it is quite usual for these types of claims to be compromised, for example, that lawyers reach an agreement the claim should be settled at 85% liability, not 100% liability. If the full value of the claim were worth say £10 million, a settlement at 85% would mean that compensation would be agreed at £8.5 million.

AvMA can help to guide you on the next steps to be taken, consider the evidence and if necessary, put you in touch with an AvMA accredited clinical negligence solicitor who has experience of these specialist claims. You will need to complete our MNSI/ENS new client form: avma.org.uk/help-advice/brain-injuries/ens-mnsi-new-client-form/

AvMA's caseworkers are highly experienced and our public facing services are free.

What should I do if NHS Resolution admit they were negligent?

AvMA urges you to urgently obtain your own independent legal advice from an AvMA accredited clinical negligence solicitor. Please complete our [MNSI/ENS new client form](https://avma.org.uk/help-advice/brain-injuries/ens-mnsi-new-client-form/) so a designated caseworker can help introduce you to a specialist solicitor who will support you through the rest of the process.

Valuing claims like this is expensive, time consuming but important. Regardless of whether you own your own home or if you rent, you may need a report from an architect to advise on the cost of adapting your home or finding alternative accommodation suited to your child's needs as they grow up. While local authorities are expected to provide care to people who qualify for it, they often struggle to employ enough carers to meet the need, in practice the solution is to calculate the cost of private carers, a care report will be required which will also look at equipment needed such as a hoist.

Other reports are likely to be required from speech and language specialists, physiotherapists, and many others besides. An AvMA accredited clinical negligence solicitor will be able to help you with this. AvMA strongly advises you NOT to settle the claim on your own or to attend any sort of mediation without representation or at the very least without having first sought legal advice.

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 litigation is contemplated or anticipated, and as such they attract litigation privilege.
- NHS Resolution will need to review all medical records relating to your pregnancy, labour and birth as well as baby's records. NHS Resolution will have access to the medical records kept by the hospital trust where baby was born.
- NHS Resolution will need your consent to review medical records held by other providers such as neonatal records held by another hospital trust if baby was transferred to a specialist unit after their birth; any GP records for baby or other services such as physiotherapy and/or occupational therapy. NHS Resolution may ask for your consent to access these records when they contact you to advise of the investigation under ENS.
- Even though you are going through the 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 complete the MNSI /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 highly recommended by us: www.avma.org.uk/find-a-solicitor
- If NHS Resolution accepts liability, then obtain your own independent legal advice from a specialist solicitor without delay.
- NHS Resolution should attempt to resolve concerns fairly and ensure that any compensation is paid. They may contact you with an offer or invite you to mediation. If they do, we strongly advise that you should take independent legal advice on the suitability of that offer and/or mediation appointment.

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 is possible that your solicitors' own investigations will form a different view on liability.

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, the following guides may also help you:

www.avma.org.uk/wp-content/uploads/Approaching-a-lawyer.pdf

www.avma.org.uk/wp-content/uploads/Funding-options.pdf

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 MNSI process 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 ENS investigation by explaining the process and setting out your options.
- 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.

Be part of the movement for better
patient safety and justice

Support
AvMA's work
today



You can help make healthcare safer and fairer for all

Our vision is a simple: **People who suffer avoidable medical harm get the support and the outcomes they need.**

This vision is underpinned by four objectives, we believe, will transform trust in the NHS and healthcare generally and significantly cut the cost – financial and human – which is incurred annually in settling legal claims as well as dealing with the human costs associated with traumatic medical injuries and death. Our four key objectives are:

- To expand the range of communities we serve and so enabling more people experiencing avoidable harm to access services from us that meet their needs
- To empower more people to secure the outcomes they need following an incident of medical harm, whilst providing caring and compassionate support
- To eliminate compounded harm following avoidable medical harm
- To have the necessary diversity of sustainable resources and capacities to deliver

Ongoing donation from as little as £5 a month could go a long way:

£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

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

Please donate today at www.avma.org.uk/donate

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)

0345 123 2352



82 Tanner Street
London SE1 3GN



www.facebook.com/AvMAuk



www.instagram.com/AvMAuk



@AvMAuk



bit.ly/AvMAYouTube

Registered charity in England & Wales
(299123) and Scotland (SCO39683)