

Understanding Maternity and Newborn Safety Investigations (MNSI)

This guide is aimed at mothers and families whose baby was born at an NHS hospital after 1st April 2018 and who may be concerned that their baby sustained a brain injury at birth.

Contents

Overview of investigation processes	2
What is Action against Medical Accidents (AvMA)?	2
Definition of a severe brain injury	2
Frequently Asked Questions (FAQs).	3
What is the MNSI and what do they do?	3
How are maternity investigations carried out?	4
How do MNSI know that an incident meeting their criteria has occurred?	4
The MNSI Process	5
How long does the MNSI Investigation take?.	5
What can I do while the MNSI investigation is carried out?	5
Is there a connection between MNSI and the Early Notification Scheme (ENS) process?	5
How can AvMA help me?	6



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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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The days immediately after the birth of a baby can be difficult, they may be even more difficult if you are concerned that you and/or your baby has experienced an injury as a result of the birth.

There are investigation processes which may take place if there are concerns about the care given. This guide has been produced to help families understand more about the MNSI investigation and to let you know that AvMA can support you through this process.

Overview of investigation processes

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. This is understandable as there are at least two possible investigations which might take place in these circumstances, some families may go through both investigations.

The first investigation which might occur is the Maternity and Newborn Safety investigation (MNSI). The other investigation process is NHS Resolution's Early Notification Scheme (ENS), AvMA have prepared a separate leaflet on the ENS process which can be found here:

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

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, it is separate from the NHS. Please see below paragraph, 'What is the MNSI and what do they do?'

MNSI will investigate if the definition of a brain injury meets the Royal College of Obstetricians and Gynaecologists (RCOG) Each Baby Counts guidelines. The RCOG definition of severe brain injury is set out below.

MNSI will also investigate other areas of obstetric and neonatal injury and some deaths, not just where a potential brain injury has been identified. For more information, see the section below, 'How are maternity investigations carried out?'

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 convenient time for you to make initial telephone contact with you.

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 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

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 and still showing signs of neurological injury
- Had all three of the following signs: decreased central tone AND comatose AND seizures

Since 2020 MNSI will 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 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 the MNSI and what do they do?

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 hosted by the Care Quality Commission but is an independent, investigative body within that.

MNSI investigations do not look at establishing criminal or civil liability or carry out investigations from a legal or litigation perspective. They do not seek to place blame or investigate individual members of NHS staff. They do not investigate under Safe Space principles, which means that information from investigations can be shared.

How are maternity investigations carried out?

MNSI have a specific investigation programme for maternity related issues which include potential severe brain injuries in babies that meet the definition of a serious brain injury (see above). MNSI also investigates intrapartum stillbirths, neonatal deaths and maternal deaths which meet their criteria, details can be found here: <https://www.mnsi.org.uk/our-investigations/what-we-investigate/>

The MNSI criteria for investigation into potential brain injuries at birth are:

- Baby must have been born following labour
- Baby must have been born at least 37 complete weeks of gestation
- Baby experienced a potential severe brain injury at birth. The brain injury must meet the RCOG definition which is set out above.

The MNSI criteria for investigation into intrapartum stillbirth are:

- Baby must have been born following labour
- Baby must have been born at least 37 complete weeks of gestation
- Baby was an intrapartum stillbirth, that is when baby was believed to be alive at the start of labour but was born with no signs of life.

The MNSI criteria for investigation into neonatal deaths are:

- Baby must have been born following labour
- Baby must have been born at least 37 complete weeks of gestation
- Baby died in the early neonatal period, that is where the baby died within the first week of life (0–6 days old) of any cause.

The MNSI criteria for investigation into maternal deaths are:

- Maternal deaths of women while pregnant or within 42 days of the end of pregnancy.
- DIRECT DEATHS: The death may be a direct death where it arose as a result of obstetric complications of pregnancy or labour, or after the birth.
- The direct death must be related to surgical interventions, omissions in medical care, incorrect treatment or from events which arise from any of these things.
- INDIRECT Deaths: These are deaths which occur due to previous existing disease or as a result of disease that develops during pregnancy.
- The indirect death will have been brought on by the physiological effects of pregnancy in the perinatal period, that is in the period of time between the pregnancy and giving birth and up to 42 days after the end of the pregnancy.

MNSI will NOT carry out investigations where:

- Baby was born before 37 weeks of gestation.
- Baby was not born following labour, for example where a caesarian section was performed before the mother started having contractions or ruptured her membranes.
- Baby was cooled at birth and does not show signs of neurological injury.
- Baby is thought to have died before labour started or was induced.
- A maternal death was caused by suicide.
- The incident occurred before 2018.

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

How do MNSI know that an incident meeting their criteria has occurred?

Where an NHS trust considers that a potentially severe brain injury which meets the RCOG Every Baby Counts criteria has occurred (see definition of severe brain injury above) and any other maternity incidents which meet the MNSI criteria have occurred the trust is:

- (i) Required to report this to MNSI. NHS trusts have a designated electronic portal called HMS to help with this reporting process.
- (ii) Expected to inform the family that a referral has been made to MNSI and provide information about MNSI
- (iii) Expected to ask the family to give their consent for MNSI to contact them. The trust will then confirm to MNSI whether that consent has been given.

The MNSI Process

Once MNSI receives notification from an NHS hospital trust that a baby meets the RCOG definition of a severe brain injury and that the family has consented to the MNSI investigation process, they will contact you within five days. MNSI will then introduce you to their named investigator who will keep you updated on the investigation.

MNSI will:

- Explain the process
- Ask you for permission to seek mothers' and babies' medical records
- Discuss how and to what extent you wish to be involved in the investigation
- Ask you to tell them what happened and your experience
- Ask you questions to understand your individual needs and how they can support you and where you can go for support
- Involve you in the investigation
- Discuss the terms of reference of the investigation.
- With your agreement arrange an initial meeting between you and the investigators

Understanding Maternity and Newborn Safety Investigations (MNSI)

- Interview both the hospital staff involved in providing the maternity care and the family. Interviews can be in person or by video but if you prefer to engage on the telephone or in writing please let them know. Please note that a lawyer cannot usually attend such meetings.
- Seek expert medical advice from a panel of experienced clinicians.

How long does the MNSI Investigation take?

An MNSI investigation takes about 6 months to complete although it can be longer than this. MNSI will discuss this with you and should update you on when you can expect their investigation to be completed.

Although MNSI may make safety recommendations the responsibility for putting them into action rests with the trust.

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

What can I do while the MNSI investigation is being carried out?

Where MNSI agrees to carry out an investigation, the hospital **DOES NOT** need to carry out its own internal investigations as well.

If MNSI does not investigate then the patient safety incident must be considered under the Patient Safety Incident Response Framework (PSIRF) which 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:

<https://www.avma.org.uk/wp-content/uploads/Complaints-England.pdf>

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

Please do contact AvMA so a designated case worker can be appointed, and all of your options discussed. AvMA can explain the pros and cons of using other avenues of redress while the MNSI or ENS investigation processes are 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/

Is there a connection between MNSI and the Early Notification Scheme (ENS) process?

The short answer is no, there is no connection between MNSI and ENS which is run by NHS Resolution. The MNSI investigation is completely separate from the ENS investigation process. They are two separate investigation processes, run by separate organisations, with separate aims.

MNSI investigations are independent of the NHS and aim to identify where safety improvements should be made.

The ENS investigation is designed by NHS Resolution, primarily to establish whether the trust will be liable in a legal claim for birth injuries arising because of negligent treatment.

However, NHS Resolution will not consider whether a case is to be investigated until the MNSI report is available to them.

Under the ENS investigation process you will not be entitled to see any of the medical reports, statements or other documents prepared as part of the ENS investigation.

Please see our separate leaflet on the ENS process for more information:

If you would like to discuss your case in confidence and free of charge with AvMA please complete the MNSI/ENS New Client Form and one of our caseworkers will be assigned to you and get back to you:

www.avma.org.uk/help-advice/brain-injuries/ens-mnsi-new-client-form/

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.
- 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 MNSI 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.

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better patient safety and justice

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