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.

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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 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 seperate 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?'.

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 harmas 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

MNSI has largely adopted The Royal College Obstetricians and Gynaecologists (RCOG), "Each baby counts" definition: The MNSI working 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:

- Has been diagnosed with moderate to severe encephalopathy consisting of an altered state of consciousness such as lethargy, stupor or coma (see Q&A below for more information on encephalopathy). As well as being diagnosed with a moderate to severe encephalopathy baby must also be showing one of the followings signs (i) hypotonia (decreased muscle tone) and/or (ii) abnormal reflexes and/or (iii) absent or weak suck reflex and/or (iv) clinical seizures.
- Actively therapeutically cooled and still showing signs of neurological injury

Since 2020 MNSI will not 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 injury, 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 definition of severe brain injury may not go on to have a significant long-term disability although it is often not possible to know until the child is of school age.

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.

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 for example their ability to suck may be absent or weak; they may have decreased levels of consciousness and/or clinical seizures.

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 labour?

The MNSI consider that labour has commenced when 37 weeks gestation has been completed and one of the following has occurred:

- Labour has been diagnosed by a health professional this includes at the start of labour when cervical dilation is less than 4 cm
- When the mother calls the maternity unit reporting abdominal pains, contractions or her waters have broken. These are just examples of concerns which might be reported which suggest labour has commenced.
- Where labour has been started artificially such as induction of labour
- Where the baby is thought to have been alive after suspected or confirmed rupture of membranes (waters breaking).

Am I allowed to see the MNSI investigation records?

In principle the answer to that question is yes. The MNSI investigations are carried out under the principle of duty of candour which is about being open with families, there are some other investigations which are carried out under the principle of safe space which does restrict the investigating body's ability to share information but safe space does not apply to MNSI. However, in practice MNSI is very protective of the NHS staff interviews and any investigation reports it has access to as part of its MNSI investigations, it may not voluntarily disclose this information.

This can be a very difficult area for families to navigate on their own and we recommend that if you do want to see documents other than the MNSI report which is produced and shared with families and trusts alike that you complete an ENS/MNSI <u>new client form</u>. AvMA will then allocate you a designated caseworker so this can be explored in more detail.

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 in England
- 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 which is diagnosed within the first 7 days of life. (Please see frequently asked questions section above for the definition of a potential severe brain injury).

The MNSI criteria for investigation into intrapartum stillbirth are:

- Baby must have been born in England
- 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 early neonatal deaths are:

- Baby must have been born in England
- 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 between 0-6 days old
- Baby's death can be due to 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 outside of England
- Baby was born before 37 complete 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 death or injury to baby or mother occurred before 2018.

Do families have to consent to an investigation?

If you want the investigation to proceed then you should consent to MNSI accessing mother and baby's relevant medical records.

It is unlikely that MNSI could investigate and produce a report where a family does not give their consent for MNSI to access the medical records. 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 has occurred (see definition of severe brain injury above) and any other maternity incidents which meet the MNSI criteria have occurred (including where a baby has been therapeutically cooled and there is no evidence of ongoing neurological injury) the Trust is:

- (i) Required to report this to MNSI. NHS trusts have a designated electronic portal called HIMS 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.
- (iv) 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 definition of a severe brain injury 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 mother and baby's medical records (it is unlikely that the investigation will take place without consent)
- 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
- 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://hww.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, ENS does also look to support a learning culture within the NHS with a view to delivering safer maternity care.

NHS Resolution will not consider whether a case is to be investigated under ENS 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:

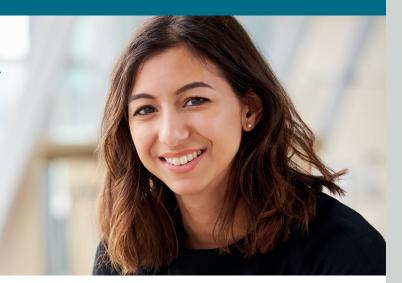
- Provide advice and assistance on a wide range of issues relating to concerns you may have about your labour and your baby/child's development.
- Explain the Early Notification Scheme and MNSI process to you in more detail.
- Advise you on other routes for investigation such as the NHS complaints process, 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; help you with 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.

www.avma.org.uk/donate

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



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