Health Services Safety Investigations Body

Investigation report

Investigation report: Severe brain injury, early neonatal death and intrapartum stillbirth associated with larger babies and shoulder dystocia

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Communication and decision making, Maternity

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1 About this report

This report is intended for trusts, healthcare leaders, policymakers and the public to help improve patient safety in relation to shoulder dystocia associated with larger babies. For readers less familiar with this area of healthcare, medical terms are briefly explained within the report and abbreviations are listed at the end of the document.

This report is based on the analysis of 31 HSIB maternity investigation reports. As HSIB maternity investigations are individual to a specific family and trust we have used extracts, example findings and safety recommendations from a number of investigation reports to illustrate the main areas of learning that we have identified from this analysis.

Where we have identified an opportunity for learning we have indicated this as an option for what trusts could do. Where we consider this requires national change, we have noted this as an HSIB national safety recommendation.

2 Maternity investigations – emerging learning 2019/2020

In March 2020, HSIB published a national learning report that summarised eight themes arising from its early maternity investigations. One of these themes was babies that are significantly larger than average being at increased risk of a birth injury, brain damage or very rarely death because their shoulders get stuck during birth (known as shoulder dystocia). This was identified as an area where further analysis could benefit system-wide learning.

As defined by the Royal College of Obstetricians and Gynaecologists (RCOG), shoulder dystocia is where additional manoeuvres are required to complete the birth of a baby, after routine traction has failed to release the shoulders during a vaginal birth (Royal College of Obstetricians and Gynaecologists, 2012). The reported incidence of shoulder dystocia varies between 0.58% and 0.70% of births (Royal College of Obstetricians and Gynaecologists, 2012).

The majority of cases of shoulder dystocia occur when the uppermost shoulder of a baby impacts behind a mother’s pelvic bone after the birth of the head, preventing the birth of the body. It is a time-critical obstetric emergency that can result in severe brain injury or death and other injuries such as brachial plexus injuries (nerve injuries affecting the arm) or fractures to

the arm or collar bone of a baby. Shoulder dystocia may also cause increased injury to the mother including bleeding and perineal trauma. The majority of babies born with the complication of shoulder dystocia do not sustain injuries or long-term complications.

The condition (health) of a baby at birth following a shoulder dystocia depends on the time interval between the delivery of the head and the body (known as the head to body interval) and the condition of the baby at the start of the shoulder dystocia. It has been reported that there is a very low rate of brain injury if the head to body interval is less than five minutes (Leung, 2011).

While shoulder dystocia can occur during any birth, regardless of the baby's birthweight, babies that are larger than average are at an increased risk of a birth injury, brain damage or, very rarely, death, because their shoulders get stuck during birth (National Institute for Health and Care Excellence, 2019).

The RCOG (2012) has produced guidance on shoulder dystocia. Several antenatal (pregnancy) and intrapartum (labour and birth) characteristics have been reported to be associated with shoulder dystocia. Each of the characteristics is recognised as being poorly predictive of a shoulder dystocia occurring. These include:

- previous shoulder dystocia
- the baby being large for gestational age (LGA), defined as being greater than 4,500g
- the mother having gestational diabetes mellitus (GDM) (diabetes that develops during pregnancy)
- the mother having a body mass index (BMI) greater than 30kg/m2
- induction of labour (the process of artificially starting labour using a variety of medications and techniques)
- prolonged first stage of labour (slower progress than expected before the mother's cervix is fully dilated)
- prolonged second stage of labour (slower progress than expected after the mother's cervix is fully dilated)
- oxytocin augmentation (where the mother is given synthetic hormones to increase the frequency, duration and intensity of contractions)
- assisted vaginal birth (using forceps or vacuum).

This HSIB national learning report considers the impact of larger baby size in relation to shoulder dystocia. It uses the definition of greater than 4,000g when discussing the larger (LGA) baby.

3 Method

All maternity investigations reports are reviewed, and themes identified by a Healthcare Safety Investigation Branch (HSIB) multi- professional panel which includes neonatologists, midwives and obstetricians. HSIB identified that a review of cases where shoulder dystocia was identified as a factor that contributed to a severe brain injury or death, would generate potential learning for maternity care. The cases where this was identified have been included in this national learning report.

Selection criteria

The HSIB database of completed reports, excluding reports related to maternal deaths, was searched on 28 January 2020 using the key phrase ‘shoulder dystocia’.

Analysis

Of the 326 completed reports at the time, the search identified 31 cases where babies were born following a shoulder dystocia, accounting for 9.5% of the completed reports or 11% of the babies with hypoxic ischaemic encephalopathy (HIE) reported to HSIB. HIE is a term used to describe a lack of oxygen and damage to cells within the baby’s brain.

It is recognised that approximately 3,770 to 4,550 cases of shoulder dystocia occur in England per year (based on the incidence of shoulder dystocia and births in England), the majority of which do not result in birth injuries.

The reports identified were reviewed by a multi-professional panel using a quantitative analysis tool and the findings were categorised into themes. The team did not have access to the case notes or individual interviews and based their findings on the completed reports.

Outcomes

In 3 of the 31 cases the baby died: 2 were intrapartum stillbirths related to the shoulder dystocia and 1 was a neonatal (newborn) death which was not attributed to the shoulder dystocia as there were other health concerns present. The other 28 babies were treated in neonatal intensive care units with therapeutic cooling (a procedure where a baby is cooled to between 33C and 34C with the aim of preventing further brain injury following a hypoxic (lack of oxygen) injury and were diagnosed with HIE.

In the majority of the babies with HIE, shoulder dystocia was the main contributory factor to the hypoxic brain injury.

4 Current clinical practice in England

National guidance by the National Institute for Health and Care Excellence (NICE) (2019) recognises that LGA babies are at increased risk of a birth injury, brain injury or in rare cases, death, because their shoulders get stuck during birth. There is no standardised definition of an LGA baby. Centile charts are used to assess baby size and growth. LGA is often considered to mean a baby weighing more than the 90th birthweight centile. In other definitions it refers to a birthweight more than the 95th centile or a birthweight above 4,000g (Boulvain et al, 2016) or more than 4,500g (Royal College of Obstetricians and Gynaecologists, 2012; National Institute for Health and Care Excellence, 2019).

For the purposes of this national learning report, we have defined LGA as more than 4,000g. This is due to the Cochrane review (Boulvain et al, 2016) which concluded that earlier induction of labour may reduce the incidence of shoulder dystocia in babies estimated to weigh more than 4,000g.

Current practice for the management of suspected LGA babies in England is varied. All maternity services monitor babies' growth by symphysis fundal height (SFH) measurements (measurements of the size of the uterus which are used to assess a baby's growth during pregnancy) using a customised or population- based centile chart. These charts were designed to identify small for gestational age (SGA) babies or babies with suspected growth restriction. Mothers may also undergo ultrasound scans (USS) to monitor their baby's growth if risk factors are identified or if there is a concern about SFH measurements.

USS is the most accurate way of estimating fetal weight. An error rate of 15% is commonly accepted when estimating fetal weight based on USS (Grunebaum, 2018). This error rate may increase in mothers with LGA babies (Barel et al, 2013). When considering this a 15% margin of error in a baby that is LGA is significant. For example, for an estimated fetal weight (EFW) of 4,200g based on USS, 15% less would mean a birthweight of 3,570g, or 15% more would mean a birthweight of 4,830g.

There is no specific national guidance that provides recommendations for the management of pregnancies where the baby is LGA. There are multiple national guidelines that refer to some aspects of management for an LGA baby many of which are contradictory:

- The NICE (2008a) antenatal care for uncomplicated pregnancies guideline recommends that USS estimation of a baby's size for suspected LGA babies should not be undertaken in a low-risk population.
- The NICE (2008b) induction of labour guideline in the absence of any other indications recommends that induction of labour (IOL) should not be carried out simply because the health professional suspects a baby is larger.

- The RCOG (2012) shoulder dystocia guideline determines that IOL does not prevent shoulder dystocia in non-diabetic mothers with a suspected LGA baby. It suggests IOL can reduce the incidence of shoulder dystocia in mothers with diabetes and recommends that a caesarean section (CS) should be considered for mothers with diabetes and a baby with a suspected EFW larger than 4,500g. It is acknowledged that this guideline is currently being updated.
- The NICE (2014) intrapartum care for healthy women and babies guidance recommends transfer to obstetric-led care (care overseen by an obstetrician rather than a midwife) when a baby is suspected to be LGA during labour, and that mothers should be given a choice between continuing labour, including augmented labour (the process of stimulating the uterus to increase the frequency, duration and intensity of contractions after the onset of spontaneous labour), and CS.
- The NICE (2015) diabetes in pregnancy guidance recommends that mothers with pre-existing type 1 or type 2 diabetes should be offered IOL or CS between 37 weeks and 0 days' gestation (37+0 weeks) and 38+6 weeks and that the risks and benefits of vaginal birth, IOL and CS for mothers should be discussed with those mothers with an LGA baby confirmed by USS.
- A Cochrane review (Boulvain et al, 2016) found that IOL in mothers with LGA babies reduced the number of babies who had a shoulder dystocia, when compared with expectant management (allowing the pregnancy and labour to progress without specific intervention). This is because the babies were born earlier and thus had a lower birthweight. The review did not find a clear difference between the two groups for low Apgar scores or low arterial cord blood pH (signs of the baby not receiving enough oxygen during birth). The review also found an unexpected observation of increased perineal damage in the IOL group.
- The RCOG (2018) care of mothers with obesity in pregnancy guideline recommends that where an LGA baby is suspected, IOL may be considered. The options of IOL and expectant management should be discussed with the parents.
- The NICE (2020) intrapartum care for women with obstetric complications guideline recommends mothers in labour should be informed of the higher chance of shoulder dystocia and brachial plexus injury with vaginal birth. This guideline relates to mothers already in labour rather than those during the antenatal period.

The array of varying national guidance reflects the lack of robust evidence regarding the diagnosis and management of LGA babies, and how best to share this information with mothers to support them to make an informed choice about their birth preference.

A recent large literature review (Moraitis et al, 2020) found that third trimester USS screening reliably predicted delivery of an LGA baby. However, a larger EFW was not strongly associated with a risk of shoulder dystocia with low-risk and medium-risk pregnancies and the authors

conclusion recommended caution prior to introducing universal third trimester screening for LGA as it would increase the rate of intervention with the potential of iatrogenic harm (harm caused by the process of medical treatment) without reducing neonatal morbidity.

The Big Baby Trial (Warwick Clinical Trials Unit, 2020) is a trial being led by a partnership between the University of Warwick, University Hospitals Coventry and Warwickshire NHS Trust and the Perinatal Institute. Its aim is to establish whether a policy of inducing labour at 38 weeks in mothers with a baby considered LGA (more than the 90th customised EFW centile) will reduce the incidence of shoulder dystocia. The trial aims to collect data from 4,000 mothers identified as having LGA pregnancies confirmed by USS to be recruited and randomised to either IOL at 38 weeks or for the mother to await the natural onset of labour. The primary outcome measure is the incidence (frequency) of shoulder dystocia in each group. The trial aims to be completed in 2022.

5 HSIB investigation themes

As HSIB maternity investigations are individual to a specific family and trust we have used extracts from investigation reports, example findings and recommendations from a number of investigations to illustrate the main areas of learning that we have identified from the analysis of the 31 investigation reports.

Where we have identified an opportunity for learning, we have indicated this as an option for what trusts could do.

Where we consider this requires national change, we have suggested a HSIB safety recommendation.

This section is in two parts, covering relevant issues relating to pregnancy (antenatal) and labour/birth (intrapartum).

Antenatal

1 Identification and management of large for gestational age (LGA) babies during pregnancy

During pregnancy, a mother’s symphysis fundal height (SFH) is measured on a two to three weekly basis commencing from 24 to 26 weeks to screen for small for gestational (SGA) babies. Mothers who have a higher chance of being pregnant with an SGA baby are often on a serial growth ultrasound scan (USS) pathway or a combination of SFH and indicated growth USS (NHS England, 2019).

Some trusts use customised growth charts to assess a baby's growth, and others use population-based centile charts. There is no clear evidence to support which chart should be used in practice. The rationale supporting the use of customised charts compared to population- based centile charts (which show national average size) is that individual factors relating to a mother, for example her weight, height, ethnicity, and parity (number of previous births) are taken into consideration.

In the absence of robust evidence and subsequent dearth of specific national guidance, there is little consistency across maternity services as to how to identify LGA babies, whether identifying them is necessary, and how to manage the care of mothers with LGA babies. HSIB has found variation in the way trusts monitor the growth of babies, with a lack of consistency observed in how LGA babies are identified. In the same context what is considered a 'large' baby differs for individual mothers, depending on the mother's height, weight and number of previous births. The guidance supporting customised growth charts
does not recommend a growth USS for an SFH measurement greater than the 90th centile alone; it does recommend a growth USS for an acceleration in the growth trajectory from one measurement to the next. The guidance accompanying the customised growth charts suggests the management of suspected LGA babies is at the discretion of trusts.

HSIB investigations found that there was a wide variation in what action trusts take when there is a suspected LGA baby identified by increased SFH measurement; some trusts do not refer the mother for a growth USS whereas others do. If they do undertake a USS, some trusts carry out further investigations and then discuss with the mother her options for birth while other trusts do not do anything further.

The RCOG (2012) shoulder dystocia guideline suggests that IOL does not reduce the incidence of shoulder dystocia in the absence of diabetes. The Cochrane review (Boulvain et al, 2016) found that offering IOL as opposed to awaiting spontaneous labour reduced the number of babies who had a shoulder dystocia. The Cochrane review recommends that further trials of IOL for LGA babies are needed in order to determine what the possible management options might be to reduce harm such as fractures and hypoxic injury (signs of babies not receiving enough oxygen during birth).

The NICE intrapartum care guideline (2014) is clear that mothers who are suspected to have an LGA baby should be under obstetric-led care and transferred to an obstetric-led unit for birth. The NICE (2020) guideline on intrapartum care for women with existing medical conditions or obstetric complication and their babies explains that these mothers are at increased risk of complications during labour such as shoulder dystocia, brachial plexus injury, assisted birth (where instruments such as forceps or a vacuum suction cup are used to help deliver the baby) or CS. If LGA is suspected in labour NICE advises that mothers in labour should be offered the option to continue, to augment (speed up) the labour, or to have a CS.

Within the 31 investigation reports analysed, HSIB found that the birthweights of the babies ranged from 3,565g to 5,177g. The NHS maternity statistics for England showed that 10% of babies were born with a birthweight of more than 4,000g during 2019/20. HSIB found that in the incidents it reviewed, 22 of the 31 babies (71%) weighed more than 4,000g at birth (see table 1).

Table 1 Birthweight of babies in HSIB investigations reporting shoulder dystocia

Table 1 Birthweight of babies in HSIB investigations reporting shoulder dystocia

Birthweight	**Less than 4,000g**	**4,001g to 4,500g**	**4,501g to 5,000g**	**Greater than 5,001g**
Number of babies	9 (29%)	14 (45%)	3 (10%)	5 (16%)

Eight of the 22 mothers with babies weighing more than 4,000g at birth were not identified as having an LGA baby by USS prior to birth. In some of these mothers there was an opportunity to offer a growth USS as the SFH was above the expected range.

Extract from HSIB maternity investigation report

> ‘A baby was born weighing over 5kg in the pool in a birth centre with a shoulder dystocia. During pregnancy it was noted that the SFH was measuring very large, this was plotted on a population based SFH chart. The SFH chart did not include a centile line for the 90th centile. This did not enable staff to recognise the importance of the accelerating SFH growth trajectory and a growth USS or testing for GDM were not undertaken. There was no discussion with the Mother regarding birth choices.’

Examples of findings from HSIB maternity investigation reports

- Once accelerated growth was identified at 40 weeks by USS the mother did not have review by an obstetrician. This may have led to a different plan of care.
- The mother was not referred for a growth USS when accelerated SFH growth was identified from 37 weeks onwards.

2 Screening for gestational diabetes mellitus (GDM)

Diabetes can pre-exist a pregnancy or develop during a mother's pregnancy. Diabetes that develops during pregnancy is known as gestational diabetes mellitus (GDM) and usually starts in the middle or towards the end of pregnancy. GDM may affect up to 18% of mothers during pregnancy. Diabetes can also cause a baby to grow bigger and extra growth surveillance is recommended during the pregnancy (National Institute for Health and Care Excellence, 2015).

Diabetes is an independent risk factor for shoulder dystocia. Babies of mothers with diabetes have a two to four times increased risk of shoulder dystocia compared with babies of the same birthweight born to mothers without diabetes (Royal College of Obstetricians and Gynaecologists, 2012). This means that a 4,000g baby of a mother with diabetes is more likely to have shoulder dystocia than a 4,000g baby of a mother without diabetes. In England, national guidance recommends GDM screening on a risk assessment basis; this non-universal screening has the potential to exclude some at risk mothers.

GDM screening takes place at 24 to 28 weeks (or earlier if a mother had GDM in a previous pregnancy) and mothers with the following risk factors are tested with an oral glucose tolerance test (OGTT) (National Institute for Health and Care Excellence, 2015):

- a BMI above 30 kg/m2
- previous LGA baby weighing 4,500g or above
- previous gestational diabetes
- first-degree relative with diabetes
- black, asian, or minority ethnic family origin with a high prevalence of diabetes (South Asian, Chinese, African-Caribbean or Middle Eastern).

Limited screening will exclude some at risk mothers. NICE (2015) guidance only uses one definition of LGA and will miss other mothers who would be considered to have had an LGA baby; for example, a mother who gives birth at 36 weeks' gestation with a baby weighing 4,300g (more than 90th centile) would not fulfil the NICE screening criteria for testing. NICE (2015) also does not offer guidance for maternal GDM testing if a baby is suspected to be LGA in the current pregnancy.

An individualised discussion about risks, benefits, and choices to enable mothers to make decisions is enabled by the identification of an LGA baby, particularly when combined with other factors such as GDM.

RCOG guidelines (2012) suggest that CS should be offered to mothers with diabetes where the weight of their baby is estimated as greater than 4,500g. RCOG guidelines (2012) also suggest that IOL may be indicated in mothers with diabetes to reduce the incidence of shoulder dystocia.

In the investigation reports reviewed, HSIB found that 18 of the 31 mothers had an antenatal risk factor as defined by NICE and all underwent screening for GDM. Twelve of the 18 mothers screened had a raised BMI as the risk factor for screening. Of all the mothers screened, 4 had confirmed GDM.

There were three babies in the cohort suspected to be LGA based on USS where GDM screening had not already taken place. It is recognised that a USS diagnosis of LGA is commonly made late in pregnancy and there is no national guidance on how to screen mothers for GDM in the third trimester. The OGTT may not be accurate late in the third trimester and other methods are required such as home blood sugar monitoring, which is more time consuming and invasive for a mother.

HSIB found that in the absence of national guidance, some trusts have developed their own pathways for managing pregnancies where there is a suspected LGA baby. The pathways include guidance on the frequency of growth USS, testing for GDM in late pregnancy (using home blood sugar monitoring) and sharing information with mothers regarding their options for timing and mode of delivery.

Examples of findings from HSIB maternity investigation reports

- There is no guidance in the antenatal period locally or nationally for the management of babies who are suspected to be LGA in the absence of diabetes.
- When the USS found the baby's EFW to be above the 90th centile the Mother was screened for GDM to enable a full discussion with the Mother about birth choices.

3 Information sharing

Mothers with a suspected LGA baby are more likely to have an assisted vaginal birth or CS. The baby is also at increased risk of shoulder dystocia and birth trauma, in particular fractures of the arms, collar bone or a brachial plexus injury.

In the investigation reports reviewed, HSIB identified that 14 of the 31 babies were suspected to have a predicted birthweight of more than 4,000g after a growth USS. In the cases of 10 of the 14 mothers who had a suspected LGA baby based on USS there was no evidence of a discussion with the mother regarding the increased risk of shoulder dystocia or what this may mean for the labour and birth.

There were several mothers with a greater than expected SFH (greater than 90th centile) who did not have a growth USS with EFW calculation before birth. These mothers did not have the opportunity to discuss what a raised SFH might mean for labour and birth.

The Montgomery ruling makes it clear that all healthcare professionals must inform a mother of the risks and benefits of different birth options in all pregnancies, not exclusive to LGA or shoulder dystocia, so that she can make an informed choice about her care.

RCOG (2016)

The Montgomery vs NHS Lanarkshire case

‘In this case, a Lanarkshire woman (Mrs Nadine Montgomery) whose baby suffered brain damage during birth was awarded £5.25m compensation. This decision followed a 16-year legal fight which concluded with Mrs Montgomery’s claim being upheld by the Supreme Court.

Mrs Montgomery has Type 1 diabetes, which increases the risk of having a larger than average baby, a risk compounded by Mrs Montgomery’s small stature. This increases the risk of complications from vaginal births, including shoulder dystocia. In Mrs Montgomery’s case her baby’s shoulder got stuck, and during the subsequent procedures, her baby suffered oxygen deprivation resulting in brain damage leading to cerebral palsy.

Mrs Montgomery had expressed concerns about her ability to deliver her baby safely and indicated that, had she been advised of the risks, she would have chosen a caesarean section. Her obstetrician made the decision not to discuss the risks of shoulder dystocia with Mrs Montgomery or to discuss a caesarean.

The ruling makes it clear that any intervention must be based on a robust decision-making process, ensuring the patient is aware of all options and supported to make an informed choice by their healthcare professional.’

As well as a predicted LGA baby, a mother may have other factors that are associated with shoulder dystocia, such as a raised BMI or GDM. Individualised discussions with a mother are required, exploring her personal risk factors and preferences, with the aim of facilitating safe, personalised care.

Extract from HSIB maternity investigation report

‘A mother had concerns during the pregnancy that her baby was too big for a vaginal birth. Following a growth USS the EFW was >95th centile and predicted to be greater than 4,000g at birth. It was agreed for the mother to have a CS at 40+2 weeks due to the LGA. There was no documented antenatal counselling regarding risks of shoulder dystocia or what should occur should she go into labour prior to the date of the CS. The mother went into spontaneous labour at 39 +3 weeks and had a vaginal birth of a 4,400g baby with a shoulder dystocia.’

Examples of safety recommendations from HSIB maternity investigation reports

- The Trust to ensure all risks to both mothers and babies are discussed for those identified to be at increased risk of shoulder dystocia.

This discussion should be in line with the Montgomery ruling.

- The Trust to ensure all mothers with an identified characteristic associated with shoulder dystocia receive counselling regarding the risks and benefits associated with a vaginal birth and alternative options for care. Details of this discussion should be documented in the mother’s healthcare records.
- The Trust to ensure that the information provided to mothers informs them of birth options and associated advantages and risks to support decision making and informed consent during childbirth.

What trusts could do

The General Medical Council (2020) has published new guidance on decision making and consent. This guidance explains that the exchange of information between the doctor and the mother is essential and that shared decision making and consent are fundamental to good practice.

HSIB has considered the Cochrane review (Boulvain et al, 2016) regarding IOL at or near term for suspected fetal macrosomia (another term for a larger baby) and considers this a useful tool for trusts to adopt to inform discussions with mothers to enable shared decision making.**See Appendix A.**

HSIB has reviewed two further tools that may be of benefit for trusts to support discussions with mothers.

IDECIDE (Birthrights, 2020) is a new digital tool being developed by NHS England and NHS Improvement, with input from RCOG and a wide range of organisations and service user representatives, to help frontline staff with communication, decision-making and consent processes, when obstetric interventions are recommended. The first iteration is due to be formally piloted during 2021.

The IDECIDE tool

I – Identify urgency
D – Details of the current situation
E – Exchange objective and subjective information (history, organisational context, mother's perspective, healthcare professionals' expertise)
C – Choices available (evidence- based information will be on the tool – generic at first but in time individualised)
I – I (the mother) confirm my understanding and seek any further clarification needed
D – Decision is made (by mothers) and recorded on the tool
E – Evaluation takes place a few days/weeks later using a recorded experience measure

The BRAIN acronym is a mnemonic that healthcare professionals can use to engage antenatal and intrapartum discussions. This may be a useful tool for health professionals to use when having discussions with mothers about their options for birth.

The BRAIN acronym

B – What are the **benefits** of this course of action?
R – What are the **risks**?
A – Are there any **alternatives**?
I – What are the **implications** of following this course of action? What does **intuition** tell you?
N – What happens if we do **nothing**?

Intrapartum

1 Place and mode of birth

Shoulder dystocia is associated with prolonged first and second stages of labour and assisted vaginal birth. National guidance recommends intrapartum care should be transferred to obstetric-led care if an LGA baby is suspected during pregnancy or on assessment in labour.

In the investigation reports reviewed, the majority of mothers gave birth in an obstetric-led unit with 20 of the 31 mothers undergoing IOL. There were a variety of reasons for the decisions to induce labour. All of the mothers with GDM were offered IOL in line with national guidance, three of the four mothers within the cohort were offered IOL for a suspected LGA baby and the majority were offered IOL for prolonged pregnancy, defined by NICE as greater than 41 weeks.

Six of the 31 mothers gave birth in a midwife-led unit. Two of these mothers were suspected as having an LGA baby, one following a growth USS and the other on SFH measurement. Both mothers remained in a midwife-led setting without any counselling or discussion about complications. Transfer to obstetric-led care was indicated for these mothers in line with NICE guidance.

Extract from HSIB maternity investigation report

> ‘The mother had an USS with an EFW of greater than 90th centile. The size of the Baby was not discussed during an antenatal appointment. A decision was made that the mother could use the midwifery led birth centre during labour. There was an opportunity on admission to the birth centre to review the holistic risk assessment and consider transfer to obstetric led care as there was a suspicion that the Baby may be large for gestational age (LGA). The baby was born after a shoulder dystocia and was noted to be LGA.’

Examples of safety recommendations from HSIB maternity investigation reports

- The Trust to review and update their planning place of birth risk assessment tool so that a holistic approach is taken ensuring that ongoing risk assessment is thorough.
- The Trust to ensure that a birth plan is developed as early as possible, and that this includes place of birth, mode and timing of birth and staff who need to be present, as well as any specific care requirements. This plan is to be made available to the maternity team and to the family.
- If a mother chooses to use the birth centre in labour and has risk factors which would indicate a recommendation to use the obstetric unit, the Trust should ensure that multidisciplinary input and review is gained during labour so that the plan of care and decision making is not carried out in isolation.

HSIB is aware of a new intrapartum risk assessment tool for all birth settings which is being developed by the RCOG and Royal College of Midwives that would support initial and ongoing risk assessment throughout labour. This is expected to be piloted in 2021 and will be supported by a training package.

2 Recognition of shoulder dystocia

In the 31 investigation reports reviewed, there were a number of occasions where there was a delay in recognition of a potential shoulder dystocia. Signs of a potential shoulder dystocia include slow or difficult delivery of the baby's head. As this was not recognised additional help, such as neonatal or obstetric support, was not summoned prior to the birth of the babies.

When a shoulder dystocia was recognised there was not always an emergency response using the national emergency 2222 call system. In four of the 31 cases the neonatal team was not present for the birth of the baby.

Extract from HSIB maternity investigation report

> 'During birth there was very slow delivery of the head observed and the body delivered more than 10 minutes after the eyes were visible, during this time the fetal heart rate could not be heard. This was not recognised as a potential shoulder dystocia and help was not summoned. The neonatal team were not present for the birth of the baby, who required extensive resuscitation.'

Delay in calling the neonatal team has previously been recognised as a common difficulty in training drills (PROMPT, 2012) and should be a focus of multi-professional training. Trusts should ensure that their annual multiprofessional training includes a focus on anticipation of shoulder dystocia and earlier neonatal team involvement.

Examples of safety recommendations from HSIB maternity investigation reports

- The Trust to ensure that staff are supported to follow the escalation process to alert the neonatal team to attend so that skilled staff are present at a baby's resuscitation.
- The Trust to ensure that neonatal clinicians are called as an emergency to attend a birth when a shoulder dystocia occurs. Scenario training may improve team working at resuscitations.

3 Management of shoulder dystocia

Once shoulder dystocia was recognised in the majority of cases it was managed according to the RCOG (2012) shoulder dystocia algorithm. Multiprofessional training for shoulder dystocia using recognised algorithms was commonplace and well embedded in all trusts and staff were able to undertake recognised manoeuvres. Investigations identified a number of excellent examples of team working and exemplary execution of manoeuvres (hands-on manipulation techniques used to aid delivery).

Shoulder dystocia training and manoeuvres aim to deliver a baby as quickly and as safely as possible without sustaining injury to the baby, particularly a permanent brachial plexus injury. One hospital has shown a 100% reduction in brachial plexus injuries and a 50% reduction in HIE since introducing shoulder dystocia training (Crofts et al, 2016).

Extract from HSIB maternity investigation report

> ‘A mother was admitted to a co-located birth centre in spontaneous labour at 39+5 weeks. During the birth it was noted that the head was slow to deliver and help was called for as a shoulder dystocia was anticipated. A shoulder dystocia was declared and a 2222 emergency call was placed to the obstetric and neonatal teams. The manoeuvres used were well documented and showed a clear order of events in line with the RCOG shoulder dystocia algorithm, helped by use of a scribe. There was evidence of good teamwork and communication, with staff regularly swapping roles as they recognised, they would tire easily and others may be more effective. The clinicians adopted a confirmatory strategy to deal with the issues of time focus and perception. There was evidence that staff knew each other well and had often trained together on obstetric emergencies. The head to body interval was 13 minutes. The mother and father praised the staff involved in the emergency and felt well communicated with throughout and they felt reassured that everyone was working together to deliver their baby safely.’

Examples of safety recommendations from HSIB maternity investigation reports

- The Trust to continue to provide local multi-professional training in emergency drills as recommended by NHS Resolution.
- The Trust to develop joint skills and drills training for obstetric and neonatal emergencies that involves all teams across the perinatal service [clinical teams that provide care through pregnancy and up to a year after giving birth].

4 Injuries to babies following shoulder dystocia

In the 31 cases reviewed, the head to body interval (HBI) time ranged from 2 to 25 minutes with a median of 7 minutes. The development of hypoxia (low oxygen) has been explained by compression of the umbilical cord between a baby's body and the mother's pelvis, compression of the baby's neck and carotid vessels (which supply blood to the head and neck) by the mother's perineum and premature separation of the placenta during a prolonged shoulder dystocia.

HSIB found in the majority of cases the babies' umbilical cord blood gas results were within an expected range (even witha prolonged HBI of over five minutes). These babies were born in poor condition requiring resuscitation, which suggests there had been compression of the umbilical cord vessels allowing no transfer of oxygen to occur between the baby and the placenta or premature separation of the placenta during the shoulder dystocia.

Extract from HSIB maternity investigation report

> 'A severe shoulder dystocia with a HBI of 12 minutes occurred. The baby was born with Apgar scores of 1 at 1 minute, 6 at 5 minutes and 9 at 10 minutes. The cord blood gas results were within the expected range.'

In a few cases, the babies' umbilical cord blood gases showed a profound and prolonged hypoxia with a short HBI and in these babies it was likely that there was pre- existing hypoxia before the shoulder dystocia occurred. The shoulder dystocia was one of the contributory factors to the baby's condition.

Extract from HSIB maternity investigation report

> 'A shoulder dystocia with a HBI of three minutes occurred. The baby was born with Apgar scores of 2 at 1 minute, 6 at 5 minutes, 8 at 10 minutes of age. The umbilical cord blood gases showed severe hypoxia. It is likely that this baby was compromised before the shoulder dystocia as demonstrated by fetal heart rate abnormalities during labour and the 3 minute HBI was only a contributory factor to the HIE.'

HSIB found that in the majority of cases the condition of the baby following the shoulder dystocia could be explained by the shoulder dystocia alone. In some babies it was found that there were multiple contributory factors. If a baby is in good condition (not hypoxic) entering the shoulder dystocia, then they are more likely to be able to withstand a longer HBI.

Six of the 31 babies sustained a further birth injury: three babies sustained brachial plexus injuries and three had a fractured humerus (the long bone of the upper arm). All but one of the cases involved a shoulder dystocia of more than 6 minutes (durations ranged from 2 to 14 minutes).

HSIB makes the following safety recommendation

Safety recommendation R/2021/114:

It is recommended that the Royal College of Obstetricians and Gynaecologists (RCOG) takes into consideration the findings of this HSIB review when updating the RCOG Green Top shoulder dystocia guideline (No.42)

6 Summary of findings, safety recommendation and what trusts can do

Findings from the review of HSIB maternity investigation reports

Analysis of the 31 reports related to shoulder dystocia identified the following main findings:

- Risk factor screening for GDM appears to be in line with national guidance which does not always take into consideration previous births of an LGA baby.
- When mothers are identified as having a suspected LGA baby some trusts test for GDM to support their information sharing with mothers. There is no national guidance regarding this.
- There was a wide variation in how trusts act when there is a suspected LGA baby based on an increased SFH measurement trajectory. There is no national guidance regarding this.
- There is no clear national guidance to support mothers and clinicians with regard to the mode of birth when a baby is identified as LGA. This leads to a wide variation in practice with some mothers having a discussion about the mode of birth and a small number of mothers being offered earlier IOL when a LGA baby is suspected on USS.
- There was varied information shared with mothers regarding the risks and benefits of having a vaginal birth or CS when an LGA baby was suspected. The majority of mothers were not counselled regarding the risk of a shoulder dystocia.
- Mothers in labour with a suspected LGA baby should be advised to give birth in an obstetric-led unit. Some cases of shoulder dystocia occurred outside of an obstetric-led unit when an LGA baby had been suspected in the antenatal period.

- The signs of imminent shoulder dystocia were not always recognised during birth and this led to delays in escalation for obstetric and neonatal support.
- When a shoulder dystocia was recognised there was not always an emergency call made. In a small number of cases this meant that the neonatal team was not present for the birth.
- In the majority of cases, when a shoulder dystocia was diagnosed it was managed using recognised manoeuvres in a structured way with examples of excellent teamwork in line with national guidance.
- Multi-professional training for shoulder dystocia appears to be well embedded in practice.
- In most babies with HIE following a shoulder dystocia this can be explained by the shoulder dystocia alone; in some babies HIE is the result of multiple factors. If a baby is in good condition (not hypoxic) entering the shoulder dystocia, they may be more likely to be able to withstand a longer HBI.

Examples of safety • recommendations from HSIB maternity investigation reports

- The Trust to ensure all risks to both mothers and babies are discussed for those identified to be at increased risk of shoulder dystocia. This discussion should be in line with the Montgomery ruling.
- The Trust to ensure all mothers with an identified increased risk of shoulder dystocia receive counselling regarding the risks and benefits associated with a vaginal birth and alternative options for care. Details of this discussion should be documented in the mother's healthcare records.
- The Trust needs to ensure that the information which is provided to mothers informs them of birth options and associated advantages and risks to support decision making and informed consent during childbirth.
- The Trust to review and update its place of birth risk assessment tool so that a holistic approach is taken ensuring that ongoing risk assessment is thorough.
- The Trust to ensure that a birth plan is developed as early as possible and that this includes place of birth, mode and timing of birth and staff who need to be present, as well as any specific care requirements. This plan is to be made available to the maternity team and to the family.
- If a mother chooses to use the birth centre in labour and has risk factors which would indicate a recommendation to use the obstetric unit, the Trust should ensure that multidisciplinary input and review is gained during labour so that the plan of care and decision making is not carried out in isolation.
- The Trust to ensure mothers are advised of the risks and offered all available options when a baby is suspected of being LGA.

- The Trust to ensure that staff are supported to follow the escalation process to alert the neonatal team to attend so that skilled staff are present at a baby's resuscitation.
- The Trust to ensure that neonatal clinicians are called as an emergency to attend a birth when a shoulder dystocia occurs. Scenario training may improve team working at resuscitations.
- The Trust to continue to provide local multi-professional training in emergency drills as recommended by NHS Resolution.
- The Trust to develop joint skills and drills training for obstetric and neonatal emergencies that involves all teams across the perinatal service.

HSIB makes the following safety recommendation

Safety recommendation R/2021/114:
It is recommended that the Royal College of Obstetricians and Gynaecologists (RCOG) takes into consideration the findings of this HSIB review when updating the RCOG Green Top shoulder dystocia guideline (No.42).

What could trusts do?

HSIB has reviewed three tools that may be of benefit for trusts to adopt:

- **Cochrane review** (Boulvain et al, 2016) regarding IOL at or near term for suspected fetal macrosomia: HSIB considers this a useful tool for trusts to adopt to inform discussions with mothers to enable shared decision making.
- **IDECIDE**: a new digital tool being developed by NHS England and NHS Improvement, with input from RCOG, to help frontline staff with communication, decisionmaking and consent processes, when obstetric interventions are recommended. The first iteration is due to be formally piloted during 2021.
- The **BRAIN** acronym: a useful mnemonic to engage antenatal and intrapartum discussions which may be a useful tool for trusts to use when having discussions with mothers about their options for birth.

Trusts should continue to provide annual multi-professional skills and drills training on the management of a shoulder dystocia, using mannikins, documentation, scenarios, practising calling for help using 2222 and emergency buzzers, and hands-on manoeuvres.

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8 Abbreviations

Abbreviations used in this report

CS caesarean section

BMI body mass index

EFW estimated fetal weight

GDM gestational diabetes mellitus

HBI head to body interval

HIE hypoxic ischaemic encephalopathy

HSIB Healthcare Safety Investigation Branch

IOL induction of labour

LGA large for gestational age

NICE National Institute for Health and Care Excellence

OGTT oral glucose tolerance test

RCOG Royal College of Obstetricians and Gynaecologists

SFH symphysis fundal height

SGA small for gestational age

USS ultrasound scan

9 Appendix A

Induction of labour for big babies

Cochrane Pregnancy and Childbirth

Trusted evidence. Informed decisions. Better health.

What is this review about?

Big babies (over 4000g or 9lb) can be injured at birth. Inducing labour early, before the baby grows too big, may reduce this trauma.

However, if done too early, induction can lead to babies being born prematurely and with immature organs. Also, estimating a baby's weight before birth is not very accurate, so induction will sometimes be unnecessary.

What evidence did we find?

We found four studies (randomised trials), involving 1190 non-diabetic pregnant women with suspected large babies.

This infographic shows some of the results of the review comparing pregnant women who were induced at 37 to 40 weeks with women who waited for labour to start naturally.

What's best for babies?

Big babies have a higher chance of being injured during birth.

Does inducing labour make a difference to the number of babies who are injured?

Any fracture

The baby may fracture a bone during birth, e.g. the collarbone.

4 out of 1000 babies	Induction
20 out of 1000 babies	Waiting

Induction of labour decreased fracture by about 16 babies per 1000.

Shoulder dystocia

When the baby's shoulder becomes stuck during birth.

41 out of 1000 babies	Induction
68 out of 1000 babies	Waiting

Induction of labour decreased shoulder dystocia by about 27 babies per 1000.

Brachial plexus injury

Damage to the network of nerves that send signals to the baby's shoulder, arm and hand.

1 out of 1000 babies	Induction
3 out of 1000 babies	Waiting

There was no clear difference between induction of labour and waiting.

Birthweight



On average, babies weighed 178g less when labour was induced compared with waiting.

Low Apgar score

This assesses the baby's health. A low score shows that the baby may need medical attention.

7 out of 1000 babies	Induction
5 out of 1000 babies	Waiting

There was no clear difference between induction of labour and waiting.

Low arterial cord pH

This shows that the baby hasn't had enough oxygen during birth.

29 out of 1000 babies	Induction
29 out of 1000 babies	Waiting

There was no difference between induction of labour and waiting.

Induction of labour reduced the number of babies who had shoulder dystocia or any fracture.

There were no clear differences between groups for brachial plexus injury, low Apgar score, or low arterial cord blood pH.

UNIVERSITY OF LIVERPOOL

NHS National Institute for Health Research

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Induction of labour at or near term for suspected fetal macrosomia

Boulvain M, Irion O, Dowswell T, Thornton JG

Full review: http://ow.ly/9Kbd300ts9W

How good is the evidence?

In all trials women and health professionals knew in advance whether induction was happening or not, which may have affected the results.

The quality of the evidence was **high** for any fracture, **moderate** for caesarean section & cord pH, and **low** for instrumental delivery, brachial plexus injury, & Apgar score.



What's best for women?

A big baby is more likely to need delivering by caesarean section or instrumental delivery (using ventouse or forceps).

Caesarean section carries risks such as infection for the mother and breathing difficulties for the baby. The mother may take longer to recover from a caesarean section than from a vaginal birth.

An instrumental delivery increases the chance of the mother having a vaginal tear, blood clot, or incontinence.

Does inducing labour make a difference to the number of women needing a caesarean section or instrumental delivery?

Caesarean section

267 out of 1000 women	Induction
293 out of 1000 women	Waiting

Induction of labour made no clear difference to caesarean section.

Instrumental delivery

130 out of 1000 women	Induction
152 out of 1000 women	Waiting

Induction of labour made no clear difference to instrumental delivery.

Perineal damage

26 out of 1000 women	Induction
7 out of 1000 women	Waiting

Induction of labour may increase the number of women with severe perineal tears.

Induction of labour made no clear difference to the number of women who needed a caesarean section or an instrumental delivery.

There is limited evidence that more women in the induction of labour group had severe perineal damage.

What does this mean?

There appear to be benefits from induction, but there may also be some disadvantages. The option should be discussed with parents when their baby is suspected to be big.

We need more trials to find out the best time to induce labour towards the end of pregnancy, and how to identify big babies more accurately.

Infographic by Helen West, Research Associate, Cochrane Pregnancy and Childbirth
E h.west@liverpool.ac.uk T @CochranePCG pregnancy.cochrane.org

Providing feedback and comment on reports

We welcome feedback on our investigation reports. Please complete our online feedback form or email enquiries@hssib.org.uk.

We aim to provide a response to all correspondence within five working days.

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