

ENS Themes

CTG interpretation

The impacted fetal head

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Early Notification Scheme

In 2018/2019 obstetric claims totaled 10% of all claims but were 50% of value

The estimated cost for obstetric claims in 2019/2020 is £718.7 million

From 1st April 2017 all hospitals were required to report within 30 days all maternity incidents of potentially severe brain injury according to Each Baby Counts criteria

Term baby >37 weeks following labour with a severe brain injury diagnosed in the first seven days of life.

Early Notification scheme
Reporting criteria

NHS Resolution

Step one

To establish whether a maternity incident should be reported to the Early Notification (EN) scheme please answer the following questions:

a) Does the incident involve a baby born at 37 weeks gestation or more?
b) Did delivery of the baby follow labour (as per the [Each Baby Counts definition of labour](#))?
c) Did the baby survive to day seven?

YES NO

If the answer to **ALL** of the questions above is 'yes' please go to step two

If the answer to any of the above is 'no' the incident is not reportable under the EN scheme.
Please note that babies that die within the first week of life (0-6 days) fall outside of the EN scheme

Step two

Has the baby had one or more of the following?

a) Diagnosis of Grade III hypoxic ischaemic encephalopathy (HIE); or
b) Active cooling; or
c) Decreased central tone AND a loss of consciousness AND seizures of any kind.

YES NO

If the answer is 'yes' to a, b or c the incident is reportable to EN. Please go to step three.

If the answer to all of the above is 'no' the incident is not reportable to the EN scheme.

Step three

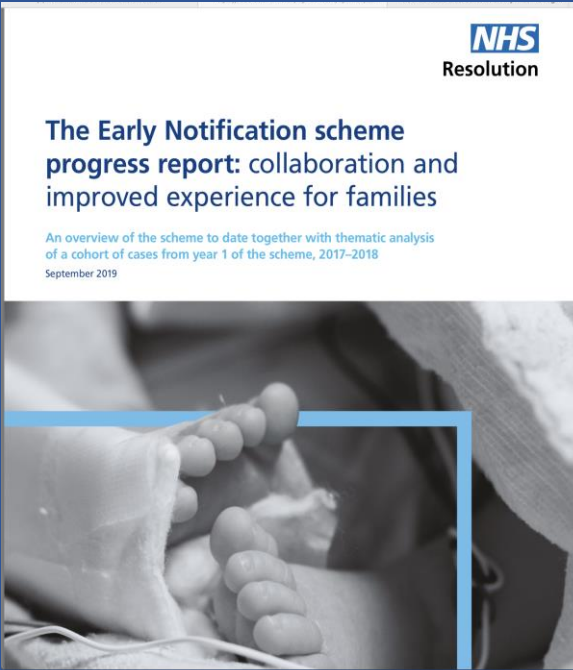
Please report the case to NHS Resolution using our Claims Reporting Wizard ensuring that the case is identified as an EN incident.

Where possible please upload the following items at the time the case is reported to the EN scheme:

- A fully completed EN report form including:
 - the trust's preliminary assessment of risk;
 - the notification criteria that has been met; and
 - Whether the family has been told of our involvement.
- The relevant pregnancy, delivery and neonatal records and a copy of the cardiocirculatory (CTG) trace and magnetic resonance imaging (MRI) reports.
- Copies of all trust investigations reports (i.e. - serious incident report / 72 hour report / Data incident report etc.).
- The Healthcare Safety Investigation Branch (HSIB) reference number.

Where it is not possible to upload the items at the time of reporting, please provide these within **30 days** of reporting the incident to the EN scheme.

- Trust legal team informed by clinical team within 14 days of the incident
- Trust legal team to report to NHS resolution within 30 days
- Aims to reduced the time between incident and resolution with an associated reduction in costs
- Identifies those babies who have suffered an injury as a result of substandard care
- Families can receive a written apology, offered financial support and practical advice in accessing ongoing care.
- Identify learning and share at national regional and local levels



NHS
Resolution

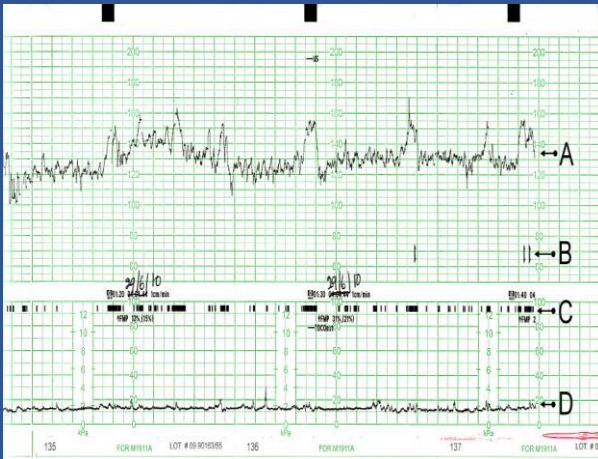
**The Early Notification scheme
progress report: collaboration and
improved experience for families**

An overview of the scheme to date together with thematic analysis
of a cohort of cases from year 1 of the scheme, 2017-2018
September 2019

Key themes

- Limited support for staff, insufficient input from families and confusion over duty of candour
- Issues with fetal monitoring in 70% of cases
- Impacted fetal head in 9%
- Concurrent medical emergencies in 6% including maternal hyponatraemia
- Immediate neonatal care and resuscitation

Fetal monitoring



- 96 cases
- 70% (67/96) showed complications with fetal monitoring
- 84% (56/67) of complications were linked to poor outcome

Method of fetal monitoring in the 96 cases of the ENS cohort

Method of fetal heart monitoring		
CTG alone	65	(67.7%)
Intermittent auscultation followed by CTG at some point in labour	20	(20.8%)
Intermittent auscultation alone throughout	6	(6.3%)
No fetal heart monitoring	2	(2.1%)
Unknown method	3	(3.1%)
Total	96	

History of EFM

- EFM began in the 1970s to prevent the consequence of hypoxia such as CP and HIE despite poor supportive data.
- Although the rates of CP and HIE have declined there is very little evidence that this is to do with EFM
- A Cochrane review showed no difference in perinatal death and CP rates when comparing EFM to IA
- Reduced rate of neonatal seizures in EFM group
- Increased rate of surgical intervention in EFM
- Surgical delivery increase both short and long term maternal risks

Rationale for CTG monitoring

- Well established method of confirming fetal wellbeing and screening for fetal hypoxia
- In high risk labour where continuous monitoring is required it is the best clinical tool
- CTG interpretation is a high-level skill and susceptible to variation in judgement between clinicians and by the same clinician over time.

Saving babies lives version 2 2019



It's not a perfect system, but it's the best we've got!

RCOG Each baby counts (2017)

- Fetal monitoring identified in 74% of babies as a critical contributory factor where improvement in care may have prevented outcome
- Failure to initiate a CTG
- Failure to obtain good quality monitoring
- Poor CTG interpretation
- Failure to escalate to senior staff in a timely manner

Themes from fetal monitoring ENS

- Rarely occurred as a single factor
- 63% (42/67) had two or more adverse factors
 - Delay in acting on an abnormal/pathological CTG or abnormal FH rate on intermittent auscultation (51.7%)
 - Delay in escalation (44.6%)
 - Incorrect classification (42.8%)

Issues highlighted

- Human factors such as communication, escalation and timely decision making

are as important as

- CTG interpretation

RCOG Each Baby Counts



Human factors

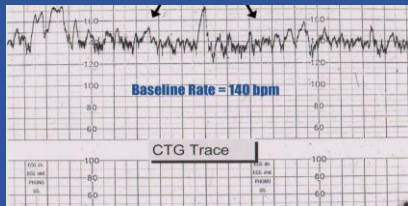
“Enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities and application of that knowledge in clinical settings”.

Catchpole (2010), cited in Department of Health Human Factors Reference Group Interim Report, 1 March 2012, National Quality Board, March 2012.

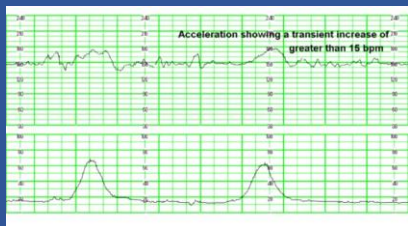
Problems with fetal monitoring persist

- Initiatives to improve interpretation, classification and documentation
- Current approaches to CTG interpretation, training and competency are heterogeneous





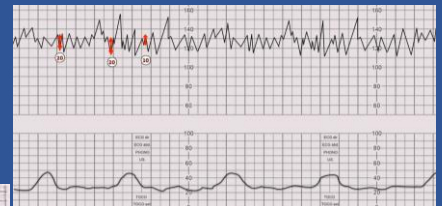
Baseline



Accelerations



Contractions



Variability



Decelerations

Helpful approach to interpretation DR C BRAVADO

- Dr - define risk
- C - contractions
- BR - baseline rate
- A - accelerations
- VA - variability
- D - decelerations
- O - Overall assessment

CTG interpretation

- Interpreting and reacting to a CTG is a complex socio-technical process
- Multiple individuals from multiple professions and disciplines
- Takes place over several stages
- Usually in a highly pressurised context
- Purely technical interventions and individual based training have not fully addressed the challenges

Initiatives to improve CTG interpretation

- Classification system – NICE or FIGO
- CTG training packages – Baby lifeline/K2
- Mandatory training
- CTG updates
- CTG review meetings
- Feedback and continued learning
- CTG Stickers
- Buddy systems

NICE CTG interpretation CG190 February 2017

Description	Feature		Decelerations
	Baseline (beats/minute)	Baseline variability (beats/minute)	
Reassuring	110 to 160	5 to 25	None or early Variable decelerations with no concerning characteristics* for less than 90 minutes
Non-reassuring	100 to 109† OR 161 to 180	Less than 5 for 30 to 50 minutes OR More than 25 for 15 to 25 minutes	Variable decelerations with no concerning characteristics* for 90 minutes or more OR Variable decelerations with any concerning characteristics* in up to 50% of contractions for 30 minutes or more OR Variable decelerations with any concerning characteristics* in over 50% of contractions for less than 30 minutes OR Late decelerations in over 50% of contractions for less than 30 minutes, with no maternal or fetal clinical risk factors such as vaginal bleeding or significant meconium
Abnormal	Below 100 OR Above 180	Less than 5 for more than 50 minutes OR More than 25 for more than 25 minutes OR Sinusoidal	Variable decelerations with any concerning characteristics* in over 50% of contractions for 30 minutes (or less if any maternal or fetal clinical risk factors (see above)) OR Late decelerations for 30 minutes (or less if any maternal or fetal clinical risk factors) OR Acute bradycardia, or a single prolonged deceleration lasting 3 minutes or more

Abbreviation: CTG, cardiotocography.

* Regard the following as concerning characteristics of variable decelerations: lasting more than 60 seconds; reduced baseline variability within the deceleration; failure to return to baseline; biphasic (W) shape; no shouldering.

† Although a baseline fetal heart rate between 100 and 109 beats/minute is a non-reassuring feature, continue usual care if there is normal baseline variability and no variable or late decelerations.



CTG classification

2015 revised FIGO guidelines on intrapartum fetal monitoring

	Normal	Suspicious	Pathological
Baseline	110-160 bpm	Lacking at least one characteristic of normality, but with no pathological features	<100 bpm
Variability	5-25 bpm		Reduced variability. Increased variability. Sinusoidal pattern.
Decelerations	No repetitive* decelerations		Repetitive* late or prolonged decelerations for >30 min (or >20 min if reduced variability). Deceleration >5 min
Interpretation	No hypoxia/acidosis	Low probability of hypoxia/acidosis	High probability of hypoxia/acidosis
Clinical management	No intervention necessary to improve fetal oxygenation state	Action to correct reversible causes if identified, close monitoring or adjunctive methods	Immediate action to correct reversible causes, adjunctive methods, or if this is not possible expedite delivery. In acute situations immediate delivery should be accomplished

* Decelerations are repetitive when associated with >50% contractions.
Absence of accelerations in labour is of uncertain significance.

Element description

Effective fetal monitoring during labour.

Interventions

- 4.1 All staff who care for women in labour are required to undertake annual training and competency assessment on cardiotocograph (CTG) interpretation and use of auscultation. Training should be multidisciplinary and include training in situational awareness and human factors. The training and competency assessment should be agreed with local commissioners (CCG) based on the advice of the Clinical Network. No member of staff should care for women in a birth setting without evidence of training and competence within the last year.
- 4.2 There is a system agreed with local commissioners (CCG) based on the advice of the Clinical Network to assess risk at the onset of labour which complies with NICE guidance⁴⁷, irrespective of place of birth. The assessment should be used to determine the most appropriate fetal monitoring method.
- 4.3 Regular (at least hourly) review of fetal wellbeing to include: CTG (or intermittent auscultation (IA)), reassessment of fetal risk factors, use of a Buddy system to provide 'Fresh Eyes (or Ears)', a clear guideline for escalation if concerns are raised through the use of a structured process. All staff to be trained in the review system and escalation protocol.
- 4.4 Identify a Fetal Monitoring Lead for a minimum of 0.4 WTE per consultant led unit during which time their responsibility is to improve the standard of intrapartum risk assessment and fetal monitoring.

Continuous learning

- 4.5 Maternity care providers must examine their outcomes in relation to the interventions, trends and themes within their own incidents where fetal monitoring was likely to have been a contributory factor.
- 4.6 Individual Trusts must examine their outcomes in relation to similar Trusts to understand variation and inform potential improvements.
- 4.7 Maternity providers are encouraged to focus improvement in the following areas:
 - a. Risk assessment of the mother/fetus at the beginning and during labour.
 - b. Interpretation and escalation of concerns over fetal wellbeing in labour.

NHS England

Saving babies lives
version 2

A care bundle for
reducing perinatal
mortality

March 2019

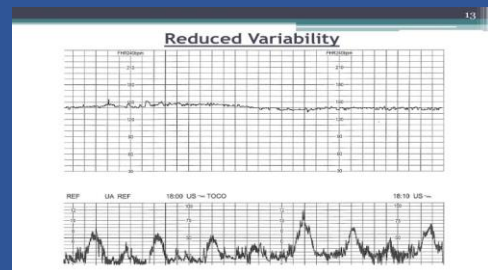
INTRAPARTUM CTG		Hospital N°	Date and Time	
Risk Factors		Liquor colour		Dilatation
Maternal pulse	Contractions in 10min	Oxytocin rate		Initial baseline rate
Baseline rate	110-160bpm No increase >20bpm	100-109 or 160 - 180		<100bpm >180bpm Unable to determine
Variability	5-25bpm <5bpm for <50min	< 5 for 30-50 mins > 25 for 15-25 mins		<5bpm for ≥50 mins Increased variability > 30min Sinusoidal pattern >30min
Decelerations	<ul style="list-style-type: none"> None Early (RARE) Variable with no concerning characteristics ≤ 90 minutes 	Variable <ul style="list-style-type: none"> No concerning characteristics for ≥ 90 mins Concerning characteristics ≤ 50% of contractions for ≥ 30 mins Concerning characteristics in > 50% of contractions for ≤ 30 mins Late decelerations in > 50% of contractions for <30 mins		<ul style="list-style-type: none"> Variable with any concerning characteristics in > 50% of contractions for ≥ 30 minutes Late for ≥ 30 minutes Acute bradycardia Single deceleration lasting ≥ 3 minutes
Impression	Normal	Suspicious	Pathological	
Clinical management	No intervention needed	Take action to correct reversible cause if identified		Treat reversible causes Consider FBS or delivery
Positive features Accelerations Cycling Scalp stimulation	Plan:			Interpretation and action agreed with colleague <input type="checkbox"/> Senior review required <input type="checkbox"/>
Concerning characteristics of decelerations Last > 60 seconds, reduced variability within the deceleration, failure to return to baseline, biphasic (W) shape, no shouldering				
Sign, print name and designation				

CTG interpretation sticker

An aide memoir to look at all the relevant risk factors and interpret the full clinical picture
Sheffield Teaching Hospitals

A CTG is not always what it seems

- CTG interpretation will depend on the whole clinical picture
- Gestational age
- Previous history
- Medical history
- Fetal growth
- Maternal factors
- Labour
- Rupture of membranes



Sleep/wake cycle
 Opiates
 Fetal hypoxia
 Fetal tachycardia
 Prematurity
 Congenital fetal heart disease

What do we do with a non reassuring CTG?

- Exclude an acute event such as abruption or cord prolapse
- Correct reversible causes hypotension, tachysystole
- Encourage change of position
- IV fluids
- Stop syntocinon
- Consider terbutaline
- Consider fetal blood sampling

Fetal blood sampling

- Do not perform if there has been an acute event or delivery should be expedited.

- Contraindications:

Maternal infections - HIV, hepatitis

Pyrexia >37.9 degrees Celsius

Fetal bleeding disorders – haemophilia

Prematurity < 34 weeks

Face presentation

Breech presentation

FBS(pH)	Interpretation	Action
7.25 or above	Normal	<p>FBS should be repeated in an hour if the CTG remains abnormal</p> <p>If there was no acceleration in response to fetal scalp stimulation consider taking a second sample in no more than 1hr later if still indicated by the CTG trace</p> <p><i>Remember, in second stage results are only valid for 30minutes</i></p> <p>Consider sooner if CTG deteriorates.</p>
7.21-7.24	Borderline	<p>Repeat FBS within 30 minutes if CTG abnormal, or sooner if fetal reserves are likely to be compromised (IUGR/abnormal dopplers) or CTG deteriorates.</p> <p>If there were no accelerations in response to fetal scalp stimulation Consider taking a FBS no more than 30mins later if still indicated by the CTG</p>
7.20 or below	Abnormal	<ol style="list-style-type: none"> 1. Discuss case with consultant on call. 2. Inform the neonatal team 3. Expedite delivery

Why do we get it wrong?

- A patient should be managed as a whole and not on a CTG – look at the whole clinical picture
- Most CTGs are managed by junior doctors
- There is no consensus on CTG interpretation, guidelines will change from Trust to trust and from clinician to clinician
- Doctors will rarely be looking after one CTG
- CTG interpretation can occur in a very highly pressurised situation

ENS antenatal CTG

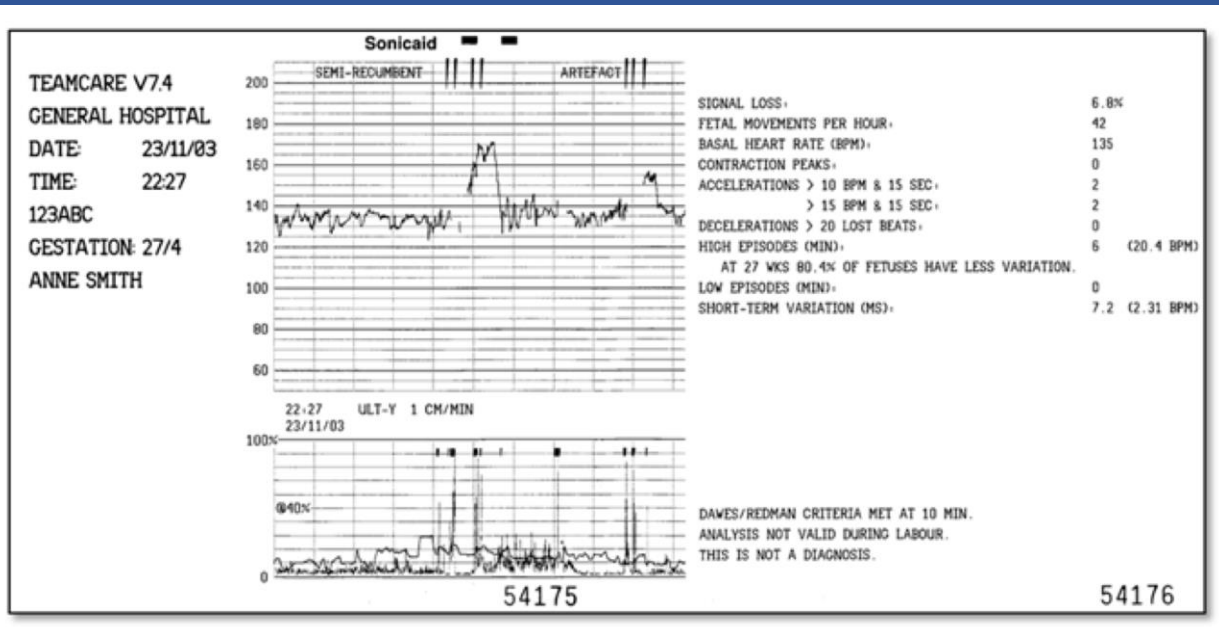
- In addition to fetal monitoring in labour there were a small number of cases where the interpretation, escalation and management of the antenatal CTG showed failings in care
- Cochrane review recommended the use of computerised CTGs in antenatal patients conferring a five-fold reduction in perinatal mortality compared to traditional CTG
- Saving babies lives version 2 also advocates computerised CTG use in antenatal women

Computerised CTG – Dawes Redman criteria

- A unique software tool providing a numeric analysis of the CTG
- Clinicians do not agree with each other or even themselves
- Particularly a problem in "The Grey Zone" in between CTGs which are clearly normal or clearly abnormal.
- Based on an archive of 100,000 CTG traces
- It does not take over; relies on clinician to look at the whole clinical picture
- Increases efficiency as the criteria can be met within 10 minutes thus freeing up a monitor for another patient

Dawes-Redman CTG interpretation pathway		
Analysis Outcome	What does this mean?	What do I do?
Criteria met	Normal reactive CTG	Continue routine management
Criteria not met at <60 mins	Record too short to classify as normal features not yet identified	Continue trace until criteria met
Criteria not met at 60 mins	Non-reassuring or pathological outcome	Review full clinical scenario - manage according to local protocols for pathological trace

The analysis is for use prior to the onset of labour as an adjunct to, and not a replacement for, clinical expertise & judgement. It must be used within the context of the full clinical scenario, including visual CTG assessment. If any concern arises from visual trace assessment before 60 minutes, take appropriate action in accordance with local guidelines & protocols.



Computerised CTG in labour?

INFANT TRIAL

Prospective RCT investigating a decision support system to reduce the incidence of suboptimal care and poor perinatal outcomes.

Hypothesis alerts from computer analysis of FHR would improve recognition and response to abnormal patterns

Results

Computerised CTG completely valid in only 33.8%
39.4% of traces had a score of 0-6
Computerised CTG failed to detect decelerations,
reduced variability and tachysystole



Conclusion

A significant proportion of abnormal FHR patterns were not identified accurately by computer analysis and its use did not reduce substandard care

Recommendations – CTG monitoring

3

There is an urgent need for an evidence-based, standardised approach to fetal monitoring in England.

Effective improvement strategies for fetal monitoring require in-depth understanding of the social mechanisms underpinning the process, not just the technical issues. Research in this area should be prioritised urgently.

For more detail see page 47

How can this be achieved?

National

- Collaboration between policy makers, academics and NHS to commission research to understand the social and technical mechanisms of EFM
- Maternity transformation programme (MTP) to develop a national standardized core curriculum
- Saving babies lives 2 strengthen the requirement for CTG training, competency assessment, buddying and introduction of fetal monitoring leads
- NICE intrapartum care guideline update

How can this be achieved?

Local

- Local maternity systems to support uptake of SBLV2 including computerised CTG for antenatal patients
- Fetal monitoring lead to improve local implementation.
- Maternity service champions should monitor safety and outcome data from national reports as well as from local incidents
- Trust boards should encourage and support an open culture including publication of local indicators including neonatal outcomes.

The impacted fetal head

- Difficult delivery of the fetal head and/or an impacted fetal head at caesarean section is an emerging problem
- NIHR are now awarding funding for research in this area
- UK obstetric surveillance system (UKOSS) has announced this as a subject for surveillance and are collecting data from 1st March 2019 for six months

Incidence in ENS

- Occurred in 9% (9/96) of cases
- (Shoulder dystocia occurred in 12% of cases)
- Established National training standards for SD leading to improved care
- No such protocols for impacted fetal head
- RCOG commissioned scientific impact paper to address

Demographics in ENS group

- No positive correlations with birthweight or maternal BMI
- All 9 babies were <3700 grams
- Maximum maternal BMI at booking was 28
- 44% had a failed forceps
- No cases of ventouse or multiple instrumentation
- 56% labour was induced
- 67% had syntocinon

Fully dilated C/S

- C/S accounts for 26% of all UK deliveries
- At least 5% occur at full dilatation
- C/S in the second stage increases risks for mother and baby over 1st stage C/S or elective C/S
- Complicated by deep impaction of the fetal head in the pelvis
- Moulding of the head makes it more difficult for surgeon to reach below the head increasing delivery time
- The uterus is stretched and thinned in the 2nd stage resulting in increased incidence of uterine tears

Basic technique

- Delivery compounded by uterine contractions
- Stop syntocinon prior to C/S
- Consider uterine relaxants – terbutaline, GTN
- Uterine relaxants increase the risk of postpartum uterine atony and this postpartum haemorrhage
- Consider head down tilt
- Lower operating table
- Use of a stool for operator



The Push Method

Patient placed in semi-lithotomy
Fetal head pushed up from the vagina
by an assistant while the operating
surgeon applies upward traction on
the baby

Spread equal pressure over the fetal
head

Pressure points most likely to cause
fetal trauma

The head should be flexed to narrow
its diameter to aid delivery

Increased trauma to uterine segment,
introduction of infection, fetal scalp
trauma



The Pull Method

Grasp one or both fetal feet at the fundus of the uterus and applying steady traction in a downward direction

Buttocks then follow with flexion of the spine in the thoracolumbar region allowing more space to deliver the fetal head

Risk of extension of uterine incision and neonatal trauma due to traction on limbs

Patwardhan's method

- Less commonly described
- Delivery of fetal shoulder through the incision
- Followed by trunk, buttocks
- Finally lift the head out of the pelvis



Fetal disimpacting system (Fetal Pillow)

Silicone balloon inserted through the vagina to rest under the fetal head

Estimated to raise the fetal head by 3 cms to aid delivery

Fetal C Snorkel



Impacted fetal head release device
Curved tube with multiple ventilation ports
Inserted between the vaginal wall and the fetal head
Aeration through the ports can reduce the vacuum
Thereby reducing the amount of force required to disimpact the fetal head



Simulation devices are known to be successful
Improving practical skills in a safe environment
Particularly successful with shoulder dystocia
Improves manoeuvres techniques
Timeline of interventions
Overall performance

Desperate Debra

The model can be used to simulate varying degrees of flexion, rotation and impaction into the pelvis

Routinely taught on the RCOG franchised ROBUST course to ST2 junior doctors

Factors affecting incidence of full dilatation C/S

- Increasing rates of C/S
- Increasing rates of failed operative delivery
- Reduced attempts at operative delivery
- EWTD – junior doctors work less hours
- Trainees required extensions to meet their competencies
- Reduced working time and training time may result in less exposure to complicated vaginal deliveries and thus less confidence in performing them
- Consultant should be present at delivery but not always possible

Recommendations – impacted fetal head

4

Increase awareness of impacted fetal head and difficult delivery of the fetal head at caesarean section, including the techniques required for care.

Research to understand the prevalence, causes and management of impacted fetal head is a priority, along with effective training in the management techniques.

For more detail see page 49

How can this be achieved?

National

- Continue to work on research into this area
- Develop evidence-based guidance on management protocols and skills and drills training for fetal head disimpaction
- Add to the core curriculum for trainees

Local

- Service managers, trainers and practice development teams to consider the guidance and supervision in place to train obstetricians to release the fetal head
- Consider scenario in multi professional simulation training for difficult delivery of the fetal head at C/S

Conclusions

- The EN scheme is an innovative scheme in this complex area of legal practice
- It focuses on safer , kinder and more personalised maternity care
- It addresses the need to reduce the cost of preventable harm to families and society
- It brings all the functions of NHS resolution to provide expert advice, fair resolution and to share learning from harm
- Highlighting themes will inform national, regional and local guidance and reduce rates of substandard care and harm



Thank you