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SM/CR-07

3 May 2016

PRIVATE AND CONFIDENTIAL
The Coroners Service
Middlesbrough Town Hall
Albert Road
MIDDLESBROUGH TS1 2QJ

For the attention of Miss C Bailey, Acting Senior Coroner for Teesside

Dear Miss Bailey

INQUEST INTO THE DEATH OF BABY LINCOLN JAMES BRADY

This is a response to the Regulation 28 Report sent to the Chief Executive of South Tees NHS Foundation Trust (the Trust) on 23 March 2016.

The background to this report is that the inquest into the death of Lincoln Brady was concluded after one day upon hearing compelling independent evidence that Lincoln was a stillbirth. In advance of the inquest, the Trust had been asked to provide a witness to address the issues as identified in the Trust's internal investigation. [redacted], Consultant Obstetrician and the Obstetric lead on risk management within the Trust, provided written evidence for this purpose. [redacted] had also been included in the inquest witness list to address the Coroner on these issues orally.

The Trust is disappointed that, in spite of this evidence being readily available and in spite of a specific request for evidence to be heard; the Trust was denied the opportunity of having this evidence entered onto the formal record of the inquest. The Trust would have welcomed the opportunity to provide assurances to the Coroner, the family, and the wider public that Lincoln's death was carefully investigated and significant changes were made as a result.

Had this opportunity been given, in addition to the documentary evidence, you would have heard oral evidence from [redacted] around the significant steps taken to improve practices and procedures in maternity care as a result of this incident. This response sets out only those measures taken to address the areas of concern highlighted in the Regulation 28 report, namely that:

1 The findings of the abdominal and vaginal examinations did not correlate
2 No further investigations, including an ultra sound scan were carried out
3 This prevented appropriate planning including discussion around preferred method of delivery

For the avoidance of doubt, the measures set out below were in place in advance of the inquest commencing and are not steps that have been taken as a result of the Regulation 28 report having been issued.

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Learning and reflection

With regard to the concern that the findings of the abdominal and vaginal examinations did not correlate, this was a significant learning point for the unit at the time of the incident. Evidence was heard at the inquest from [redacted] that she now understood why her clinical findings should have triggered further investigation and input from a senior midwife or obstetrician. She went on to say that, if faced with that situation again, she would now seek input from a senior clinician and would request a scan to confirm presentation.

As you will see from the information set out below, determination of presentation will no longer be confirmed without the use of scanners in any event. Nevertheless, important lessons were learned by the Trust on this point. Had the inquest heard [redacted] evidence, it would be known that this incident was explored in detail in the department's risk management meetings, which are open to all members of clinical staff. Specifically, the obstetric and midwifery risk management leads and unit managers regularly attend along with representatives from the neonatal and anaesthetic disciplines. The minutes from each meeting are disseminated to all clinical staff along with a 'risky business' monthly bulletin that reinforces key points of learning.

Through this medium, in September 2014, staff were reminded of the importance of seeking input from senior clinicians at an early stage where there are clinical concerns. This was followed in October 2014 with a further bulletin regarding the importance of alerting senior clinicians where there are concerns about clinical findings. Specifically in January 2015, 'Lincoln's Rule' was implemented, urging staff to adopt a low threshold when considering the use of a presentation scan where there is any doubt about clinical findings. Lincoln's Rule also highlighted 4 red flags that should prompt further investigation, specifically drawing from the issues that were noted in this case. These were:

- Tooth paste meconium
- A soft presenting part
- On abdominal palpation presenting part feels deeply engaged, but on vaginal examination the presenting part is high
- Location of the fetal heart is higher than you expect on auscultation

In addition to local learning, the inquest would also have heard that the Trust is taking an integral part in the newly-developed Regional Maternity Patient Safety Network. The principles behind this are set out in the statement of [redacted] at paragraph 48. Had oral evidence been heard, she would have added that the Network is now established, the first meeting having taken place in November 2015. This case is on the agenda for discussion on the forthcoming Network meeting on 24 May, where lessons learned will be disseminated on a regional level.

Additional training

In respect of the concerns around appropriate planning for dealing with breech presentation, the Trust has taken various measures to enhance that training and skills base around breech deliveries, all of which would have been outlined by [redacted]

An upright breech study day took place on 21 November 2014 (as referred to at paragraph 30 of [redacted] statement), which was open to all doctors and midwives within the Trust. It was operated by [redacted] along with two external trainers, both of whom have expert knowledge within the field of breech deliveries. The study day covered the following topics:

- Mechanism of normal upright breech birth including hands on techniques
- Counselling for informed consent
- Training on when and how to assist delivery if labour does not progress normally

An amended training programme to enhance vaginal breech delivery simulation sessions was also implemented in November 2014. The session was updated to teach the practice of upright breech deliveries. The session continues to run once every two weeks and there is a requirement for all clinical staff to attend the session on an annual basis, compliance with which is subject to audit.

Policies and guidelines

In order to underpin and support the learning and training around appropriate planning and management of breech presentations, the Trust substantially updated its policies and guidance on this issue. The first amendment was implemented in October 2014 to include consultant attendance at breech deliveries and to highlight the 'red flags' that may indicate a breech (as outlined above in 'Lincoln's rule'). Had the inquest permitted evidence from [redacted] it would have been clear that the policy was further updated in January 2015. A number of the changes to the policy are directly relevant to the concerns noted in the Regulation 28 report and these are summarised below.

Lincoln's rule (as set out above) is included at the commencement of the new policy to highlight factors that would prompt suspicion that there is a breech presentation. It goes on to highlight the importance of informed consent, noting that choices should be put to the woman, so that she can decide which risk factors are most acceptable to her. The policy sets out common risks and benefits to the mother and the baby associated with vaginal breech delivery and caesarean section, including situations where the breech is undiagnosed. The purpose of this addition to the policy is to aid clinicians in their consent discussions with patients.

The 'management in labour' section has been updated to note that any doubt in presentation of the baby will result in an ultra sound scan to confirm presentation. It goes on to mandate that the consultant obstetrician, ST3 (or above) in obstetrics, the theatre team and the on-call anaesthetist are contacted. Once the woman is fully dilated, the policy dictates that the consultant should be requested to attend the labour ward and be present for delivery, unless delivery is too rapid for them to arrive. The Trust again reiterates that this policy, which has been in place for 16 months, goes over and above the requirements set out in the College guidance.

The 'delivery' section of the policy has been updated to reflect the additional training that was delivered on methods/positions for delivery, as referred to in [redacted] statement at paragraphs 28 to 30. It reminds practitioners that the CTG will not be reliable after the baby is delivered to the umbilicus and says that, instead the movement, tone, colour and cord should be assessed continually. The manoeuvres for assisting/extracting a breech and the circumstances in which they should be used are set out in detail in the new guidance, with visual diagrams to assist. There have been amendments to other policies to take account of the new procedures around scanning, details of which are set out below.

Scanning

As you would have heard from [redacted] nationally, 30% of breech presentations are undiagnosed when the mother arrives at hospital in labour. This is because a breech presentation is inherently difficult to diagnose on palpation. As referred to at paragraph 4 of [redacted] statement, scanning of women on admission to maternity units is not within national guidelines. There are not enough resources on a national level to implement such a policy. Resource issues not only include the availability of equipment but also the training and competency maintenance of staff to carry out and interpret the imaging. The Trust position remains that any changes on a

national level in the policies around the scanning of women on arrival at maternity units would need to be considered and addressed by NICE or the Department of Health due to the resource implications that it would have for the NHS as a whole. For the avoidance of doubt, the steps taken by the Trust far in advance of the Regulation 28 report, which go beyond national practice and expected standards, has only been possible because of significant funding secured from the Department of Health's capital fund for the prevention of avoidable harm in maternity care.

Given the concerns set out in the Regulation 28 report, it is vital to bear in mind that adopting this policy will not eliminate situations whereby unplanned vaginal breech deliveries occur as this depends on how advanced the labour is when the mother first presents and receives her scan on arrival at hospital. If, for example, a women presents at hospital fully dilated with the baby at the perineum, regardless of the availability of a scan, the only safe way to deliver the baby would be vaginally.
Although the policies around scanning at South Tees were in accordance with NICE guidelines, the Trust could see the benefit of introducing scanning in the early stages of labour. Many months in advance of this inquest, the Trust set out a framework for introducing this practice. Had [redacted] statement been admitted into the record, the inquest would have heard details of this implementation programme as set out in paragraphs 5 and 6. Had the Trust been permitted to take oral evidence from [redacted], the inquest would have heard how far this implementation plan has developed to date. Details of the progress of this plan are set out below.

The aim of the programme, as set out in September 2015, was to ensure that all midwives have the ability to perform abdominal scans to determine the presentation of the baby at the onset of labour or on induction of labour, with a view to reducing the risk of undiagnosed breech presentations. For this purpose, 8 hand-held ultra sound scanners were purchased and distributed to the maternity wards across the Trust in April 2016.

All midwives working in areas where there is induction of labour or admissions of women suspected to be in labour are to be trained in the technique of scanning for presentation by June 2016. Approximately 50 midwives have commenced and in fact almost completed their training, which commenced in September 2015. Midwives have been trained in the skill of carrying out and interpreting the results of a presentation scan using the equipment that was already available on the unit. Now that the additional handheld machines are available, staff are being trained in the practical use of the scanner, although skill in clinical interpretation of the scan is transferrable to the new machines.

The inquest would have heard that a Standard Operating Procedure (SOP) for presentation scanning was implemented in March 2016, the details of which are set out below. Currently, all high and low risk women who are admitted for induction of labour have a presentation scan. This has been the case since September 2015. By June 2016, when all training will be completed, the SOP will apply to all women who are admitted in labour or who are suspected to be in labour. The SOP sets out the following:

- All women admitted will have an abdominal examination to determine the presenting part.
- All women who are admitted for induction of labour are to have a presentation scan prior to the first dose of prostin or artificial rupture of membranes. The scan is to be repeated if a second cycle of medication is required.
- All women who are admitted in labour or suspected to be in labour are to have a presentation scan, ideally prior to, or if not, following vaginal examination.
- All midwives are to be trained in presentation scanning using the following programme
  - Witness one presentation scan
  - Manage 10 cases under the direct supervision
  - Final scan to be signed off for certification

- The skills maintenance programme is as follows:
  - Evidence of 10 scans every 12 months are to be presented at the Supervisor of Midwives and Staff Development Review
  - If skills are not maintained over a 12 month period, 5 further scans with supervision are required prior to further certification

Currently, the findings from the scan results are documented in the patient's notes. From June 2016, the partogram (a composite graphical record of key maternal and fetal data during labour) will have a specific section for documenting presentation scan results.

The relevant guidelines to accompany Trust policy on the first stage of labour and induction of labour were updated in March 2016 to reflect the requirement for presentation scanning. Furthermore, the information around presentation scanning available to women via the Trust website will be updated to reflect the new policy on this issue.

Conclusion

All of the above actions are subject to continued audit and review, the Trust being committed to continued learning and development of practices and procedures. We trust that the actions outlined above, which we reiterate were in place prior to the hearing, are not only sufficient to alleviate the concerns set out in the Regulation 28 report, but also demonstrate that the steps taken to improve patient safety outcomes as a result of this case go beyond national clinical practice guidelines and standards.

Yours sincerely

Siobhan McArdle
Chief Executive