HSIB

HEALTHCARE SAFETY INVESTIGATION BRANCH

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East Kent Hospitals University NHS Foundation Trust

HSIB summary report

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Executive summary

The Healthcare Safety Investigation Branch (HSIB) conducts independent investigations of patient safety concerns in NHS-funded care across England. Since April 2018, under Directions from the Secretary of State for Health and Social Care, HSIB has been responsible for conducting all maternity investigations in the NHS for cases that meet the Royal College of Obstetrics and Gynaecologist's Each Baby Counts (EBC) programme criteria and maternal deaths (excluding suicides). For these cases, the HSIB investigation replaces the local trust investigation.

HSIB's maternity investigators commenced working with East Kent Hospitals University NHS Foundation Trust ('EKHUFT, 'the Trust') in early July 2018 at the Trust's two sites providing maternity services – William Harvey Hospital in Ashford and the Queen Elizabeth the Queen Mother Hospital in Margate. In the 18 months since, 24 maternity investigations were commenced, of which 16 have been completed. The remaining eight are at varied stages of completion.

These investigations have enabled HSIB to identify recurrent safety risks around several key themes of clinical care in the Trust's maternity services, which include:

- CTG interpretation
- Neonatal resuscitation
- Recognition of deterioration
- Escalation of concerns and responses

From December 2018, HSIB engaged frequently with the Trust to present evidence of recurrent patient safety concerns in its maternity services. Despite repeatedly raising these concerns with the Trust, HSIB investigators continued to see the same themes reoccurring and in August 2019, asked the Trust to self-refer themselves to their CCG and the CQC. The Trust has since responded to HSIB safety recommendations by making changes to their maternity services.

Introduction

The Healthcare Safety Investigation Branch (HSIB) conducts independent investigations of patient safety concerns in NHS-funded care across England. HSIB's role is not to apportion blame or liability, but to identify learning from our investigations to reduce patient safety risks. HSIB's investigations also provide patients and families with clarity and insight about what happened during their care.

Since April 2018, under Directions from the Secretary of State for Health and Social Care, HSIB has been responsible for conducting all NHS maternity investigations for cases that meet the RCOG's Each Baby Counts (EBC) programme criteria and maternal deaths (excluding suicides). For these cases, the HSIB investigation replaces the local trust investigation. A phased implementation of the programme across England commenced in 2018 and was operational in all Trusts providing NHS maternity services by April 2019.

This report provides an overview of the referrals caseload under the maternity investigations programme for East Kent Hospitals University NHS Foundation Trust (EKHUFT), the themes which were repeatedly identified as indicative of patient safety risk to mothers and babies, and the engagement and escalation process that HSIB undertook with the Trust and then the wider system in response.

Overview of HSIB maternity investigations at EKHUFT

HSIB's maternity investigations programme became operational at EKHUFT on 11 June 2018. The first referral from the Trust for a case which met the criteria for HSIB maternity investigations was received on 6 July 2018. Since then, HSIB has received 31 referrals from the Trust through to 31 January 2020. Seven cases have been rejected due to duplicate reporting by the trust (four cases); for not meeting the HSIB criteria upon review (one case); or for not having the consent of the family to investigate (two cases).

At 31 January 2020, there were 24 cases that had progressed to an investigation, of which 16 investigations had been completed. Of the remaining eight cases still active, five investigations have reached draft final report stage and are being assessed through HSIB's internal quality assurance process. The remaining three

investigations are underway. A breakdown of the maternity investigations by category and status is provided in Table 1.

Table 1: HSIB maternity investigations caseload at EKHUFT at 31 January 2020

Category	**Status**				
	Investigation underway	HSIB QA	Report with family or trust	Complete	**TOTAL**
Cooled baby	2	1	2	14	**19**
Neonatal death	0	0	2	1	**3**
Stillbirth	0	0	0	0	**0**
Maternal death	1	0	0	1	**2**
TOTAL:	**3**	**1**	**4**	**16**	**24**

Prior to the commencement of the maternity investigations programme, HSIB also conducted a scoping investigation into a neonatal death at EKHUFT. Although this did not proceed to a full national investigation, the findings provided early insight into the themes that would emerge at the Trust through the maternity investigations programme.

Since April 2019, when the maternity investigations programme was live in all trusts, the referral caseload from EKHUFT has been similar to that reported by other Trusts of comparable maternity unit size and birth rate across the country. However, it should be emphasised that the volume of reporting is not a useful indicator of safety risk. HSIB's approach is focussed on identifying the facts of the cases reported by Trusts. From these, HSIB identify clinical practice issues and recurrent themes that indicate the presence of unrecognised and unaddressed patient safety risks. These are raised with the Trust through regular engagement meetings. Additional escalation processes are used if warranted by the urgency of the concern or its repeated occurrence despite having been presented as a safety risk.

Themes identified from HSIB investigations

The 16 completed investigations identified a broad range of contributory factors relevant to the safety of maternity care. They are not unique to EKHUFT and have

been observed by other HSIB maternity investigations in Trusts throughout England. The investigations also identified some examples of effective patient safety practices used by the Trust's maternity staff in responding to these incidents. However, there are findings of recurrent patient safety risks from the HSIB maternity investigations at EKHUFT which are spread across four specific themes: interpretation of cardiotocograph (CTG) monitoring, neonatal resuscitation, recognition of deterioration, and escalation of concerns.

Interpretation of CTG monitoring

The investigations identified concerns related to the unavailability of staff with suitable skills in reading and interpreting CTG results. They also indicate there were issues, specifically around consistency, with categorisation tools and guidance which were available to staff to enable them to recognise results that are of concern or require escalation.

Neonatal resuscitation

Effective and timely neonatal resuscitation was an area of concern across many of the investigation reports. Specifically, the reports highlighted the physical environment as a barrier to effective and timely resuscitation. The location of resuscitation equipment added delay, risk and distress to critical situations and staff responsible for resuscitation were often under supported by appropriately skilled colleagues.

Recognition of deterioration

Deterioration in the condition of mothers and babies had occurred in several cases because staff had not recognised the signs and symptoms that indicate deterioration. As a consequence, clinical interventions that could have prevented further deterioration were missed.

Escalation of concerns

Processes and procedures for escalation were not consistently applied. This appeared to be due to multiple factors that undermined their practical application in the working environment. These factors included site-based team alliances, professional team alliances, skill gaps across specialisms and across community

and hospital-based teams. Staff interviewed repeatedly conveyed a reluctance of midwifery staff to escalate concerns to obstetric and neonatal colleagues.

Escalation with the Trust and other organisations

The evidence of recurrent and unaddressed safety risks progressively emerged during investigations for the first 10 referred cases. HSIB first raised these particular concerns with the Trust in December 2018, six months after the maternity investigation programme commenced. HSIB asked the Trust to consider these concerns, respond and escalate to their Board, regional and national channels as appropriate. HSIB's investigators continued to observe the same risks occurring with subsequent investigations. Consequently, HSIB applied its own escalation process with the Trust and then externally to ensure the appropriate authorities were aware of these safety concerns. A summary of HSIB's escalation of the EKHUFT maternity services safety risks is provided in Table 2, below.

Table 2: Escalation of HSIB concerns to EKHUFT.

Date	Purpose of engagement and key issues raised
12 December 2018	The first roundtable review with the Trust. HSIB outlined the themes which were identified from the first 10 cases to enable the Trust to identify actions to prevent or mitigate against reoccurrence. The themes raised from HSIB's investigations included: • The location of resuscitaires away from the labour ward creating a safety risk in relation to transportation of babies and timely resuscitation. • Poor documentation of Apgar score assessment and timings during resuscitation due to no official scribe allocated to record timings of events. • Clarity of communication and processes for escalation for neonatal attendance prior to the birth of a baby when there is an awareness of a suboptimal condition of the baby at birth, which had reduced the support available for resuscitation.
27 March 2019	HSIB's Chief Investigator wrote to the Trust's Chief Executive to express concerns that HSIB had not received any formal feedback or reassurance that the themes identified following the roundtable discussion in December 2018

	had been shared within the Trust or actions taken to rectify the concerns raised. The Trust responded by letter on 2 April 2019 to confirm a robust action plan was in place. Supporting information was provided but no agreed action plan was shared with HSIB.
26 April 2019	A second roundtable discussion held with the Trust where a further six cases were discussed. The safety concerns shared at the December roundtable were raised again as consistent across cases that had been reported to the HSIB. The Trust's Head of Midwifery was unable to attend on this occasion. HSIB sent a letter to the Medical Director requesting a meeting to review current cases, findings and recommendations. HSIB requested attendance from Head of Midwifery (HoM), Clinical Director, Interim Director of Nursing and additional staff the Trust would like to be in attendance. The HSIB team leader implemented monthly meetings with the HoM.
21 June 2019	A third roundtable held at the Trust where the HSIB representatives presented all current cases and ongoing concerns. At this meeting the Trust's Head of Midwifery, Medical Director and Chief Executive were present.
17 July 2019	Letter sent from HSIB's Maternity Director to the Trust Chief Executive, asking the Trust to share information from the June roundtable with their local NHS Clinical Commissioning Group (CCG) and Care Quality Commission (CQC) representatives.
25 July 2019	Email received from the Trust Chief Executive confirming that NHSE/I, the CQC and CCG had been informed of HSIB's investigation findings and safety concerns.
12 August 2019	HSIB wrote to the Deputy Chief Inspector of Hospitals CQC to confirm the Trust had made them aware of HSIB's concerns.
16 October 2019	A Quarterly Review Meeting where HSIB and the Trust representatives discussed interventions the Trust had put in place in response to HSIB's ongoing concerns. There was Trust representation from obstetric and neonatology consultants, along with the Head of Midwifery, midwifery team and the Medical Director. Interventions put in place included: • Escalation training for staff • Evening safety huddle with the multi-professional team

	• In situ training simulations • Intrapartum teaching sessions focusing on leadership and escalation for obstetric registrars
25 November 2019	HSIB attended a meeting with the NHS England south east regional Medical Director to discuss ongoing concerns at East Kent Hospitals. As a result, HSIB presented factual information to an intelligence gathering meeting the following week chaired by the NHSE/I south east regional Director of Nursing.
12 December 2019	HSIB attended an NHSE/I single item quality surveillance group meeting for the Trust to present factual information relating to themes identified at East Kent Hospitals, the actions taken by the Trust and the response from the Trust. This meeting was chaired by the NHSE/I south east regional Chief Nurse.
6 January 2020	A Quarterly Review Meeting where the HSIB presented an overview of ongoing investigations and anticipated findings and recommendations. There was also a discussion of previously identified themes.

Conclusion

This report summarises HSIB's maternity investigations with EKHUFT, the recurrent patient safety risks identified through these investigations, and the timeline of escalation with the Trust and relevant external bodies regarding the continued presence of these risks. HSIB considers the Trust's early response was inappropriately slow given the evidence of ongoing patient safety risks and the safety recommendations made. Involvement of the Trust's senior clinical team has led to stronger engagement with the HSIB and the implementation of interventions to resolve issues identified by HSIB safety recommendations.

HSIB's maternity investigations are a new approach for Trusts and NHS regulators, which need to be incorporated into existing patient safety governance and assurance mechanisms. The efficacy of these processes at EKHUFT and the national regulatory system is unclear, based on information and experience that HSIB has accumulated from the maternity investigations undertaken to date.

Appendix

The following is a sample of recommendations made to EKHUFT from the HSIB reports.

Recommendation	Theme
The Trust should ensure that CTG interpretation is carried out in line with NICE or FIGO guidance.	CTG interpretation
The Trust should ensure that staff follow the guidelines for fetal blood sampling in labour especially when there are ongoing concerns with the CTG	CTG interpretation
The trust should ensure that all staff who interpret and categorise CTGs have an understanding of the assessment of the fetal heart rate, its classification and escalation.	CTG interpretation
The Trust review and update local guidance to reflect current recommendations for the assessment and interpretation of cardiotocograph traces. Such assessments must be clearly documented in the medical records and on the CTG recording, and any concerns regarding fetal wellbeing must be appropriately escalated to the on-call obstetric team.	CTG interpretation, recognition of deterioration, escalation
The Trust must ensure that prior to starting electronic fetal monitoring, the fetal heart rate is differentiated from the mother's heart rate using a Pinards stethoscope, and where electronic fetal monitoring indicates that the maternal and fetal heart rates are similar or the same, the fetal heart rate should be assessed and confirmed via ultrasound scan.	CTG interpretation
The Trust to ensure attendance of the on-call manager when acuity is high to facilitate implementation of the escalation policy and to ensure the required level care for women is provided.	Escalation
The Trust undertakes a review of the current escalation process for obstetrics and maternity and seeks assurance regarding its effectiveness for frontline staff.	Escalation
The Trust to ensure that there is a method for staff in the MLU to call for the help from the labour ward coordinator on the delivery suite in an emergency.	Escalation
To ensure during handovers there is an alternative available point of contact to escalate concerns.	Escalation
The Trust should ensure that MEOW scores are correctly calculated and documented. High scores should be escalated and responded to in accordance with Trust policy.	Escalation
The Trust should ensure that any doubts over the quality or interpretation of continuous fetal monitoring are escalated for obstetric review.	Escalation
The Trust reviews their emergency calls process systemwide, ensuring clarity and consistency for all staff involved. This should be reflected in the unit's training programme.	Escalation
The Trust to provide resuscitation equipment within or adjacent to the delivery room.	Neonatal resuscitation

The Trust to ensure that contemporaneous records of neonatal resuscitation is undertaken by an appropriately trained staff member on a designated proforma.	Neonatal resuscitation
The Trust must undertake a full review of the processes and procedures they have in place in the event a baby is born in poor condition and requires resuscitation. This should include reviewing any potential delay in resuscitation, separation of baby from parents, transferring of the baby, communication with the multidisciplinary team and risk assessments relating to health and safety.	Neonatal resuscitation, Recognition of deterioration, Escalation of concerns
The Trust undertakes a review of its emergency procedures for neonatal resuscitation to include the allocation of a scribe to take detailed notes of the events taking place so that there is a clearly documented record of events.	Neonatal resuscitation
Documentation of a Neonatal resuscitation should be undertaken on a designated proforma by an appropriately trained member of staff.	Neonatal resuscitation
The Trust undertakes a review of its emergency procedures for neonatal resuscitation. The procedure should include allocation of a scribe and ensure that documentation is available to record events.	Neonatal resuscitation
The Trust undertake a health and safety risk assessment for the transfer of babies outside of the birthing room for emergency treatment, and re-assess the birth environment, to make sure all birthing rooms are equipped with essential equipment required for managing neonatal clinical emergencies and resuscitation.	Neonatal resuscitation
The Trust should consider a clearly identified clinician who has ownership of the case in order to question, review and monitor when a mother is not responding to treatment, and to question what is occurring in the management pathway to ensure coordinated care is provided in a timely manner.	Recognition of deterioration
The Trust should ensure that if a CTG is pathological, preparation should be made to commence immediate resuscitation at birth. This should include escalation to the paediatric team.	Recognition of deterioration, Escalation
The Trust ensure all clinicians maintain a high index of suspicion when assessing vaginal bleeding at term and ensure compliance with national and local guidance.	Recognition of deterioration