HEALTHCARE SAFETY
INVESTIGATION BRANCH

Maternity Formative Evaluation

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Terms of Reference

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- **TOR 1 Quality and efficiency of the maternity investigation process:** To what extent is the HSIB maternity investigation methodology and approach capable of gathering sufficient and relevant evidence from which to develop analysis and recommendations in the required timeframe?

- **TOR 2 Quality of report and reporting:** To what extent do the HSIB investigations produce and communicate recommendations that have traction and legitimacy within NHS Maternity Services?

- **TOR 3 Quality of evidence and analysis:** To what extent do the HSIB investigations produce evidence and analysis that is sufficient to develop recommendations that have legitimacy within the care system?

- **TOR 4 Training and Development:** To what extent does the existing training and ongoing development equip maternity investigators to conduct their role?

Methodology: Qualitative & quantitative – progressive focussing approach

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Methods:

- observation
- interviews
- focus groups
- emails & letters
- data sets
- reports
- training materials
- informal interactions
- official documents and survey responses

Sample:

- team meetings
- panel & SMART meetings
- maternity investigators
- team leads
- regional leads
- national teams
- heads of north and south
- intelligence unit
- corporate team
- clinical advisors
- subject matter advisors
- Trust medical directors
- Trust heads of nursing
- Trust heads of midwifery
- family feedback

Analysis:

- thematic and cross cutting framework of High-Reliability Organising

1. Quality and efficiency of the maternity investigation process:

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To what extent is the HSIB maternity investigation methodology and approach capable of gathering sufficient and relevant evidence from which to develop analysis and recommendations in the required timeframe?

Specific areas for consideration:

1. What changes to the structure of maternity investigation teams might improve the HSIB method for generating safety improvements through investigation?
2. What changes to the process would further improve the balance between quality and timeliness of investigation?
3. How realistic is the current target timeframe for Maternity Investigations? Are there subgroups of investigations that should have different time targets?
4. How can delays be tracked and recorded and understood more accurately and formally?
5. How can the current mix of SMA and in-house expertise be improved to produce the best value for money investigations?
6. In what ways do investigation teams reflect and learn from experience?
7. What are the thresholds for quality in the teams
8. How could the remit of HSIB be better articulated to patients, families, staff and organisations?

2. Quality of reports and reporting:

To what extent do the HSIB investigations produce and communicate recommendations that have traction and legitimacy within NHS Maternity Services

Specific areas for consideration:

1. To what extent do recommendations rehearse familiar issues or offer innovative challenge to service providers?
2. To what extent do the recommendations logically follow the analysis?
3. To what extent do recommendations recognise human factors, workforce and resource constraints in the system?

3. Quality of evidence and analysis:

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To what extent do the HSIB investigations produce evidence and analysis that is sufficient to develop recommendations that have legitimacy within the care system?

Specific areas for consideration:

1. What evidence gathering and analysis methodologies inform the investigation process?
2. To what extent are these methods employed in maternity investigations;
3. How effective is the application of these methods in ensuring timely and relevant recommendations?
4. How do investigations engage service providers to acquire sufficient evidence, particularly of work systems?

4. Training and Development:

To what extent does the existing training and ongoing development equip maternity investigators to conduct their role?

Specific areas for consideration:

1. A financial analysis of training spends to date and the effectiveness of the training and any identified gaps.
2. What benefits are there in developing a ‘train the trainer’ approach to improve quality/consistency and reduce costs and what might this look like?
3. What changes to the current homeworking approach would improve the efficiency and effectiveness of the programme?

Commitment to the programme

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- There could be no doubt that across the maternity programme individuals and teams are working very hard to do investigations, complete reports, work inclusively with families and Trusts and develop a sustainable programme.
- Right across the programme there is a strong commitment to the principles of providing independent, family-centred investigations.
- The senior team take personal and professional ownership of the programme.
- The investigation workforce, including those who no longer work for HSIB, who offered their perspectives and reflections, believe in the need for independent, family-centred investigations. They are passionate about the ambition of HSIB to provide investigations that put the family at the centre and are clinically supported.

Structure

- The programme is organised with a tall (hierarchical, top down) structure. Managers have a long chain of command and a narrow span of control.
- Many investigators, team leaders and HSIB staff outside of the maternity programme commented to the evaluation team that the structure resembles that of a maternity department. This was generally not perceived to be positive, rather something that stifles critical refection on investigation processes and governance.

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Demography

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- All of the maternity senior team are qualified clinicians and identify more as clinicians rather than as investigators.

- 85% of the investigation workforce are clinically qualified:
  - 11 investigators came to HSIB from other professional investigation jobs such as regulators, police, solicitors etc.
  - Many of the workforce report having attended some form of human factors training prior to joining HSIB.

- None of the 158 staff (not including SMAs) who work in the maternity programme hold an academic qualification in safety science or human factors.

Culture

The structure, purpose and challenges of the maternity programme have driven a cultural identity which fosters pride in the combined aim to improve maternity services in England. The 14 regional teams provide individual investigators with a secure base from which they derive operational and emotional support and resilience.

Investigators reported:

- The programme structure and a *'[Redacted]'* attitude cultivates a sense of oppression and control.
- Significant numbers (>20) of investigators openly reported either feeling bullied themselves or having knowledge of other people who had been bullied by staff more senior to themselves.
- Others (>30) recognised pressure which at times resembled bullying.
- They largely attributed this to the pressure being placed upon their direct line managers to, *'[Redacted]'* of reports.
- Many investigators (>30) talked about feeling they could not challenge what was described as *'Redacted'*, which encouraged *'Redacted'* attitudes towards investigations contrasting with the just culture they had been trained (at Cranfield) to adopt.
- Job satisfaction is significantly affected by this and recent messages from the senior team that unless the backlog is cleared by November 2020 *'[Redacted]'.*
- HSIB staff from across the whole organisations raised concerns that the *''[Redacted]'.*

Quality and Outputs

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The question of “what is a high-quality maternity report” was explored throughout the evaluation, showing inconsistent opinion. This is exemplified by the varying quality of maternity report outputs and the potential effectiveness of the associated recommendations.

Feedback explored in this evaluation highlighted:

- Feelings that quality is driven by ensuring that the investigations have input and direction from clinical professionals.
- A limited quality assurance review process against standards for reports before they are released. There is evidence of poor formatting, grammar and spelling in reports.
- Evidence that the process does not fully take account of factual accuracy challenges with inclusion of changes or clarification to those challenging the report as to why changes have not been made.
- Recommendations are generally lower in the hierarchy of effectiveness of recommendations and do not commonly focus on system improvements, rather guidance and policy. Trusts reported concerns that some recommendations were not linked to evidence or causality.
- A repeated concern was the delay to receipt of actions from reports. This meant that trusts were not able to put in place early learning to help prevent similar invents and instead had to wait till the final report which may be a year later.
- The review team also heard of individual cases that undermined the intention for HSIB to provide no-blame investigations via the way local staff have been interviewed.

Improvement Opportunities

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IO 1. Define roles so that individuals are responsible for functions within their expertise.

IO 2. Design and implement an investigation framework.

IO 3. Define the methodological approach taken, and methods to be used to investigate events.

IO 4. Empower maternity investigators to lead their investigations.

IO 5. Review the expertise of the investigation team and consider introducing investigation scientists.

IO 6. Review the process of obtaining clinical opinion in the programme.

IO 7. Reassure the workforce.

IO 8. Explore leadership development and coaching to foster a culture of support and where staff feel safe to challenge.

IO 9. Evaluate and reflect upon the training programme.

IO 10. Explore ways the senior team can develop their own understanding of safety/ investigation/ human factors science.

IO 11. Focus on quality.

IO 12. Taking the opportunity to learn.

IO 1. Define roles so that individuals are responsible for functions within their expertise.

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- The rapid growth of the programme did not allow the organisation to best plan and arrange an inclusive cross-organisational support function. The original structure separated the function and day to day management of the maternity programme from the national programme. This left the maternity management team to establish all aspects of the business function.
- The management team, who initially set up the maternity investigation programme, brought significant knowledge and experience of clinical practice and healthcare systems. However, they did not have operational management, information governance, business management or investigation science experience or qualification to match the task. The rapid growth of the programme has led to those individuals filling roles they were not equipped for and there have been no actions to address gaps in skill, knowledge or responsibility.
- This has affected the integrity of the programme and left the HSIB vulnerable in terms of information governance because it lacks defined processes, deference to expertise, and knowledge and appreciation of governance. Not reaching out to expertise across the corporate function of the organisation is common both within the senior management and across individual teams. At a team level this was demonstrated when adopting their own systems of data storage. This practice threatens corporate function and makes HSIB vulnerable to security and information governance breaches.

There is an opportunity to define the roles of the existing individuals/roles, and to foster support from those who have responsibility/ expertise across the branch in governance, procurement etc.

IO 2. Design and implement an investigation framework

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- There is little evidence in either the investigation process or reports, of the appreciation of systems factors which may have contributed to events.
- The programme does not have the methodological framework to enable delivery against the directions to 'identify all contributory factors that led to the outcome'. The investigation process lacks a basic methodological structure which means there is no analytical framework to guide investigations.
- Findings are reached by clinicians who, where possible, evaluate what was done against what national and local guidance suggests should have been done. Where there is no such guidance, they review evidence, and influence and shape the recommendations, through their own clinical, and in some cases medico-legal experience. This often leads to reports which suggest responsibility for outcomes lie with the clinical practice of individuals and teams and fail to consider the systems of work which contribute to the outcome.

There is an opportunity to develop and introduce a framework for investigation planning, evidence collection and analysis, which supports investigators to identify all the contributory factors that led to outcomes.

IO 3. Define the methodological approach taken to investigate events

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- Reports demonstrate a fundamental confusion between a method and methodology.
- Reports do not clearly define the methodological approach to the investigation, which is strongly rooted in clinically reviewing the event. Rather they list the methods used to collect evidence.
- Reports suggest a human factors approach is taken, but that in itself is not a methodology.

There is an opportunity to define the methodology and distinguish between methods and methodological approaches (this links to IO 2)

IO 4. Empower the maternity investigators to lead investigations

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- There is a strong hierarchical system influenced by the culture of front-line maternity services. This takes investigation decision making and planning out of the control of the investigator and places it with the clinical advisors (internal and external).
- This also results in investigations heavily weighted toward clinical opinions as oppose to analysis based on safety science.

There is an opportunity to empower investigators and, in doing so, balance specialist opinion on clinical treatment, decisions and actions with understanding of the systems of work which drive them.

IO 5. Review the expertise of the investigation team to consider introducing investigation scientists

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- There are two safety/ investigation science subject matter advisors who are occasionally invited to contribute; although that is generally on an informal basis or through the monthly HF clinic.
- The investigators report not having enough knowledge or confidence to apply human factors to their investigations. When investigators do attempt to analyse events using 'human factors', the trained safety/ investigation scientist can ably recognise the novice understanding. This is largely because the safety/ investigation/ human factors knowledge is confused and focussed upon the behaviour science elements and excludes systems' understanding.
- The HSIB maternity investigations can never be anything other than good quality clinical reviews without the involvement of safety/ investigation/ human factors scientists. To be an investigation which is capable of identifying all contributory factors there must be significant input from experienced safety/ investigation/ human factors scientists.

There is an opportunity to review the expertise to include safety/ investigation/ human factors scientists.

IO 6. Review the process for obtaining clinical opinion

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- Each investigation usually goes through 3-5 panel meetings with clinical advisors to plan the direction of the investigation, identify findings and write and approve recommendations. Each meeting is allocated a specific amount of time, usually between 20 minutes to 2 hours.
- It is possible that different advisors will attend each meeting. Investigators report that this adds confusion and diminishes cohesion of the report and the quality of the investigation. Investigators have narrow windows of opportunity to gain opinion, direction, and approval to progress, from clinical advisors which adds significant delay to the investigation process. At the time of writing, investigators are waiting 6 weeks to take an investigation to a SMART 1 meeting.
- There is an imbalance between gaining specialist opinion about clinical treatment and decision making, with understanding the systems of work that drive clinical decisions and practice.
- Investigators and some SMAs report that a number of SMAs are unprepared for meetings and contribute little or rely upon personal anecdotal evidence to compensate for a lack of preparation or information.
- 1 in 4 SMART and panel meetings are cancelled at the last minute, or the cancellation is not communicated, meaning the SMA gets paid for not attending a meeting. This cost the HSIB is estimated to be Approx. £80k/Annum.

There is an opportunity to review the system of obtaining clinical opinion to improve on efficiency, quality and cost.

IO 7. Reassure the workforce

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- Investigators feel insecure in their jobs and a significant number report they are considering or actively looking to leave HSIB because they feel their job is not secure.
- This is something which has intensified over the period of the evaluation largely because of the pressure to reduce the backlog of reports.

[Redacted]

There is an opportunity to improve the wellbeing of the workforce and retention by offering reassurance about the methods being taken to reduce the backlog of reports.

IO 8. Explore leadership development and coaching to foster a culture of support where staff feel safe to challenge.

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- [Redacted]

There is an opportunity for improving the culture within the programme and the retention of the workforce. Exploring leadership coaching.

IO 9. Evaluate and reflect upon the training programme

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- General feedback was positive in relation to initial training particularly Cranfield based. Some felt that a stronger Healthcare focus would of prepared them better to perform their roles. The week in Bristol, at points, conflicted with the principles they had learned around investigation science whilst at Cranfield.
- There are gaps in the training particularly around general induction, information governance, data storage systems, accessing technology, practical application of safety science theory, evidence collection, analysis and report writing.
- Subject matter advisors in particular reported a gap in basic induction to HSIB, but praised the uniqueness of the crash site training at Cranfield. They reflected that it may not have helped prepare them for the job.
- As the training has evolved to take account of the fast pace of the developing programme, early cohorts of investigators have not been updated so there are inconsistencies across the workforce. Investigators from early cohorts have expressed concern that they may have been disadvantaged and even prejudiced because they have not had their training updated.

There is an opportunity to reflect and improve the training for new staff and update it for existing staff.

IO 10. Explore ways the senior team can take time to develop their own understanding of safety/ investigation/ human factors science so they can model their curiosity

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- The workforce will follow the example of the senior team.
- To enable them to set an example of engaging with and showing an inquisitive investigatory approach to contributory factors, they will need time to engage in learning and set the standard of learning across their team.

There is an opportunity for the senior team to explore ways they could upskill to improve their own and the programme knowledge and approach to investigating safety incidents in maternity services.

IO 11. Focus on quality

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- Quality was explored recurrently through the evaluation with questions around quality of reports, analysis and recommendations.
- There is a need to balance quality with efficiency, with early learning shared with trusts to help bring about changes.
- There is no defined standard of *'[Redacted]'* resulting in poorly written reports and recommendations that might not offer more than a standard, local, serious incident investigation. *'[Redacted]'*
- Quality should include listening and responding appropriately to Trust challenges to findings and factual accuracy.

There is an opportunity for the maternity programme to define standards for quality throughout their investigations, including report writing, report content and recommendation writing.

IO 12. Taking the opportunity to learn

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- There are limited opportunities for maternity investigators to debrief and explore the impact of their reports.
- This includes how they utilise knowledge and evidence that does not reach the final report, yet may offer themes for learning and triangulation to support future investigation foci and thematic reviews.
- The impact of recommendations has not yet been explored, which would provide an opportunity to understand the impact of maternity reports on the healthcare system.

- **There is an opportunity for the maternity programme to consider implementing a system of reflection and develop a process to enable further insight from wider intelligence not included within their reports.**